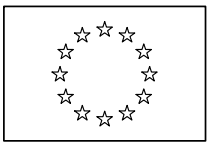

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1. ENTERPRISE AND INDUSTRY

1.1. General introduction

Responsibility for ensuring the free movement of goods within the Single Market is entrusted to the Directorate-General for Enterprise and Industry which manages a large part of the European Union (EU) *acquis* consisting of Articles 34 to 36 TFEU in the non-harmonised area and a large quantity of subordinate EU legislation (regulations, directives and decisions) in the harmonised area. The *acquis* of the EU under the management of Directorate-General for Enterprise and Industry" (the latest version of the "Pink Book") is listed on the internet at the following address:

http://ec.europa.eu/enterprise/policies/single-market-goods/files/pink-book_en.pdf

As 'harmonising' rules are adopted in more and more sectors of the Single Market, the non-harmonised area is gradually shrinking. But some 25% of the market is still not subject to harmonised rules and, here, Articles 34-36 TFEU ensure the easy cross-border exchange of goods.

Generally speaking, the EU *acquis* governing the free movement of goods is stable and effective, although the highly technical nature of much of the legislation means that there is always considerable activity adapting it to technological progress.

The Commission's legislative activity in the "Enterprise and Industry" sector is fully in accordance with Better Regulation principles with preference being given to regulations which require less effort in relation to their transposition. This sector also regards the simplification and codification of existing legislation as important tools in achieving better implementation of EU law.

The New Legislative Framework (NLF) adopted in 2008 consists of two complementary instruments, Regulation (EC) No 765/2008 on accreditation and market surveillance relating to the marketing of products and Decision 768/2008/EC on a common framework for the marketing of products. The Regulation has been in force since 1 January 2010. It sets out the provisions for the European policy on accreditation (control of the competence of laboratories and certification/inspection bodies for the mutual recognition of certificates in the EU) and for the policy in the field of market surveillance and controls of products from third countries (for safe products whatever their origin)

The Decision contains elements of product legislation which are commonly used throughout directives and provides a horizontal harmonised framework for that legislation. The systematic use of the Decision will make the regulatory framework more coherent and user-friendly for economic operators and national authorities. It is a tool of the Commission's Better Regulation policy, eliminating unnecessary disparities in product legislation.

Existing legislation is being aligned with the NLF both as when it comes up for revision (e.g. the **toys** directive, the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (RoHS) Directive and the Radio and telecommunications terminal

equipment (R&TTE) Directive) and as part of an alignment package involving ten new approach directives[1].

Alignment with the NLF Decision concerns the following elements of the directives:

- Horizontal definitions (e.g. placing on the market)
- Obligations of economic operators and traceability requirements
- Conformity assessment and CE marking
- Rules on notified bodies and notification process
- Safeguard mechanisms (Common procedures to deal with non-compliant products)

The NLF also strengthens market surveillance to protect consumers from unsafe products, and shelter businesses from unfair competition (from operators not complying with EU law). A multi-annual action plan on market surveillance, forming part of both the Single Market Act and the Commission's industrial policy, is under preparation.

Directive 2009/43/EC of the Council and the European Parliament simplifying intra-EU transfers of defence-related products is the first internal market instrument on these products and will enable operators to benefit from smoother and more predictable supply chains while improving security of supply for EU armed forces relying on cross-border deliveries. The transposition deadline was set for 30 June 2011 and will fully apply from 30 June 2012.

The Directorate-General for Enterprise and Industry also manages EU regulation under the Common agricultural policy and the common commercial policy (Articles 43 and 207 TFEU) in relation to trade in certain goods resulting from the processing of agricultural products.

The Commission provides guidance and other assistance to help Member States transposing and implementing new directives on time. Assistance is given using a variety of different tools (e.g. interpretative documents, bilateral meetings and Committee meetings).

A very valuable tool for dealing *in advance* with possible technical barriers to the free movement of goods in the non-harmonised area is Directive 98/34/EC, which requires the 27 Member States, the EFTA countries and Turkey to notify all national technical regulations

[1] The 10 directives are:

1. **Low Voltage Directive**: Directive 2006/95/EEC on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits;
2. **Simple Pressure Vessels Directive:** Council Directive 2009//105/EC on the harmonisation of the laws of the Member States relating to simple pressure vessels;
3. **Non-automatic Weighing Instruments Directive:** Council Directive 90/384/EEC on the harmonisation of the laws of the Member States relating to non-automatic weighing instruments;
4. **Civil Explosives Directive**: Council Directive 93/15/EEC on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses;
5. **ATEX Directive:** Directive 94/9/EC of the European Parliament and the Council on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres;
6. **Lifts Directive** European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts;
7. **Pressure Equipment Directive:** Directive 97/23/EC of the European Parliament and of the Council on the approximation of the laws of the Member States concerning pressure equipment;
8. **Measuring Instruments Directive**: Directive 2004/22/EC of the European Parliament and of the Council on measuring instruments;
9. **Electromagnetic Compatibility Directive**: Directive 2004/108/EC on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC;
10. **Pyrotechnic articles** Directive 2007/23/EC on the placing on the market of pyrotechnic articles.

concerning products and Information Society Services *at the draft stage*. The steady high number of notifications (843 in 2010) and reactions from the Commission (124) and the Member States (220) underlines the importance of Directive 98/34/EC in preventing barriers to intra-EU trade - and also in promoting better regulation since it provides a forum for making suggestions to improve the quality of national legislation. It often means that infringement procedures can be avoided.

The Directorate-General for Enterprise and Industry monitors the correct application of the *acquis* under its responsibility and opens infringement procedures against Member States if necessary. However, great importance is attached to resolving problems as quickly as possible using methods other than infringement proceedings. The most significant of these is the EU Pilot project, designed to clarify and solve problems concerning the application of EU law in cooperation with the participating Member States. It has significantly contributed to reducing the number of formal infringement proceedings for those Member States which participate in the project.

Other methods include "package meetings" and bilateral meetings with the Member States to provide advice to national authorities to help ensure the correct application of EU law.

In the context of infringement proceedings, non-communication cases and article 260 TFEU cases are dealt with as quickly as possible, given their priority status under the 2007 Communication. In accordance with the other criteria set out in the Communication, since 2009 priority status in this sector has been given to the following cases:

Non-harmonised area

• The failure by a Member State to notify national technical rules in draft form under Directive 98/34/EC. Such failure renders the rules liable to be declared null and void.

• Breaches of Articles 34-36 TFEU raising horizontal questions about the functioning of the market (e.g. the registration of vehicles).

Harmonised area

Breaches of key directives, in particular new legislation, which is adopted in response to a clearly identified need to correct/enhance market performance and should be enforced in a manner commensurate with the risk of failing to achieve that aim.

The significant part of the EU *acquis* dealt with by the Commission services responsible for the "Enterprise and Industry" sector covers a wide variety of product domains, in relation to each of which are set out below:

- a description of the current state of the legislation in force;

- an evaluation of the effectiveness of regulatory framework in the domain concerned; and

- an indication of plans for the future.

Information is also provided about infringement proceedings pursued in each product domain.

1.2. Automotive Industry

Current position

General introduction

The harmonised legislative framework in the automotive sector covers three categories of vehicles: motor vehicles and their trailers, motorcycles (two and three-wheelers as well as certain quadricycles), and agricultural or forestry tractors. This legislation lays down common requirements designed to achieve environmental and safety objectives. It is based on a system of whole-vehicle type-approval which allows manufacturers to have a vehicle "type" approved in one EU Member State and then to market vehicles of that type in all other EU Member States without further tests. It deals with a multitude of detailed technical specifications for different vehicle systems and components which are frequently modified to adapt them to technical progress while reducing the regulatory burden on industry.

There are three main framework instruments in relation to type-approval of new vehicles:

- Directive 2007/46/EC establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles;
- Directive 2002/24/EC relating to the type-approval of two-or three-wheel motor vehicles; (to be replaced by a Regulation on the approval and market surveillance of two- or three-wheel vehicles and quadricycles which is currently being discussed in the Council and the European Parliament); and
- Directive 2003/37/EC relating to the type-approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units (to be replaced by a Regulation on the approval of agricultural or forestry vehicles which is also currently under discussion in the Council and the European Parliament).

The above legislation provides for the obligatory EU whole vehicle type-approval but, in certain cases, a national approval system for certain vehicle categories remains in parallel. In addition to these framework instruments, separate legislative acts lay down harmonised technical requirements for the type-approval of individual parts and characteristics of a vehicle.

In line with better regulation and simplification policies and to increase the competitiveness of EU industry on the global market, as a result of the CARS 21 exercise the regulatory framework in the automotive sector has been and continues to be reformed along the following lines: (i) the introduction of the split-level approach: (a "framework" act adopted under the ordinary legislative procedure lays down fundamental provisions while technical specifications are set out using the comitology procedure); (ii) the adoption of Regulations instead of Directives; and (iii) international harmonisation (whenever possible, EU acts are replaced by UNECE Regulations compliance with which is made mandatory).[2]

Work done in 2010

[2] UNECE Regulations are harmonized technical regulations regarding new motor vehicles and motor vehicle equipment that are adopted pursuant to the 1958 Agreement under the auspices of the United Nations Economic Commission for Europe (www.unece.org). As a contracting party to the 1958 UNECE Agreement, the European Union can decide to apply a Regulation.

Various steps were taken in 2010 to implement, simplify and update the technical legislation in the sector.

A proposal for a Regulation revising the regulatory framework on the approval of agricultural or forestry vehicles was adopted by the Commission on 23 July 2010[3] and a proposal for a Regulation revising the regulatory framework for the approval of two and three-wheel vehicles and quadricycles was adopted on 4 October 2010[4]. These proposals were subsequently discussed - under the ordinary legislative procedure - with the European Parliament and the Council.

The first half of 2010 also saw the adoption of a Directive on spray-suppression systems of certain categories of motor vehicles[5] and two Regulations, one amending several Annexes to Framework Directive 2007/46/EC[6] and the other on type-approval of hydrogen-powered motor vehicles[7]. This was followed in July by the first measure implementing Regulation (EC) No 661/2009 on the general safety of motor vehicles ("the GSR")[8], namely a Regulation on windscreen defrosting and demisting systems[9]. Then, in November, the Commission adopted four more regulations implementing the GSR, concerning rear registration plates[10], towing devices[11], windscreen washers and wipers[12] and wheel guards[13]. Later, two

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3 Proposal for a Regulation (EU) No …/… of the European Parliament and of the Council on the approval of agricultural or forestry vehicles - http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0395:FIN:EN:PDF

4 Proposal for a Regulation (EU) No .../2010 of the European Parliament and of the Council on the approval and market surveillance of two- or three-wheel vehicles and quadricycles http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0542:FIN:EN:PDF

5 Directive 2010/19/EU of 9 march 2010 amending, for the purposes of adaptation to technical progress in the field of spray-suppression systems of certain categories of motor vehicles and their trailers, Council Directive 91/226/EEC, and Directive 2007/46/EC of the European Parliament and of the Council (OJEU L72, 20.3.2010, p. 17).

6 Regulation (EC) 371/2010 of 16 April 2010 replacing Annexes V, X, XV and XVI to Directive 2007/46/EC establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) – (OJEU L 110, 1.5.2010, p. 1).

7 Regulation (EC) No 406/2010 of 26 April 2010 implementing Regulation (EC) No 79/2009 on type-approval of hydrogen-powered vehicles (OJEU L 122, 18.5.2010, p. 1).

8 Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor (OJEU L 200, 31.7.2009, p.1).

9 Regulation (EU) No 672/2010 of 27 July 2010 concerning type-approval requirements for windscreen defrosting and demisting systems of certain motor vehicles and implementing Regulation (EC) No 661/2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor (OJEU L 196, 28.7.2010, p. 5).

10 Regulation (EU) No 1003/2010 of 8 November 2010 concerning type-approval requirements for the space for mounting and the fixing of rear registration plates on motor vehicles and their trailers and implementing Regulation (EC) No 661/2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor (OJEU L 291, 9.11.2010, p.22).

11 Regulation (EU) No 1005/2010 of 8 November 2010 concerning type-approval requirements for motor vehicle towing devices and implementing Regulation (EC) No 661/2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor (OJEU L 291, 9.11.2010, p.36).

Regulations on spray suppression systems and statutory plates were adopted by the Technical Committee – Motor Vehicles.

By virtue of the GSR, UNECE Regulations adopted in accordance with the 1958 UNECE Agreement will become compulsory for the majority of items currently subject to EU type-approval requirements, thereby contributing significantly to the simplification of the EU regulatory system. Against this background, preparatory work began on a Regulation implementing the GSR and listing 62 compulsory UNECE Regulations[14] – among them, UNECE Regulation No 100 on electrical safety - particularly important in view of the development of electric vehicles. This required very careful translation of numerous UNECE regulations into all EU languages with the aim of publishing them all in the OJ. Work on other measures implementing the GSR (tyre installation, gear shift indicators, masses and dimensions, lane warning departure systems and advanced emergency braking systems) was also carried out.

A Regulation on Individual Vehicle Approval was endorsed by the Technical Committee – Motor Vehicles on 17 September 2010[15]. The impact assessment for a new proposal replacing Directive 70/157/EEC on motor vehicle noise was finalised in December 2010. Finally, a proposal for a Directive amending Directive 2000/25/EC as regards provisions for tractors placed on the market under the flexibility scheme was adopted by the Commission on 27 October 2010[16] and a proposal for a Directive on emission from narrow tractors was finalised at the end of 2010[17].

The TAAEG (Type-Approval Authorities Expert Group) – established by the Commission services in October 2009 in the form of a consultative body composed of representatives of all national type-approval authorities[18] – met on 12 April 2010 and discussed the enhancement of market surveillance in the automotive sector, the application of Directive 2006/40/EC relating to emissions from air-conditioning systems in motor vehicles and the delivery of certificates

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12 Regulation (EU) No 1008/2010 of 9 November 2010 concerning type-approval requirements for windscreen wiper and washer systems of certain motor vehicles and implementing Regulation (EC) No 661/2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor (OJEU L 292, 10.11.2010, p. 2).

13 Regulation (EU) No 1009/2010 of 9 November 2010 concerning type-approval requirements for wheel guards of certain motor vehicles and implementing Regulation (EC) No 661/2009 of the European Parliament and of the Council concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor Text with EEA relevance (OJEU L 292, 10.11.2010, p. 21).

14 http://ec.europa.eu/enterprise/sectors/automotive/files/application-unece-regulations_en.pdf

15 http://ec.europa.eu/enterprise/sectors/automotive/files/directives/draft_regulation_iva_en.pdf

16 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0607:FIN:EN:PDF

17 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0001:FIN:EN:PDF

18 Bearing in mind that EU whole vehicle type-approval will gradually become mandatory by October 2012 for new types of all categories of motor vehicles, the aim of the TAAEG is to ensure uniform application of the relevant technical requirements within the EU type-approval system. Several tasks are envisaged, including the monitoring of the enforcement of EU legislation by national authorities and solving the issue of the diverging views concerning type-approval in order to ensure mutual recognition.

of conformity of EU type-approved vehicles (enforcement of Article 18 of Framework Directive 2007/46/EC).

As regards clean and energy efficient vehicles, the Commission organised a public hearing on 11 March 2010 and adopted a Communication on 28 April 2010[19]. This document sets out a comprehensive strategy for encouraging the development and uptake of clean and energy efficient ("green") heavy-duty (buses and trucks) and light-duty vehicles (cars and vans) as well as two- and three-wheelers and quadricycles.

In October 2010 the CARS 21 process (Competitive Automotive Regulatory System for the 21st century) – initially launched in 2005 - was re-launched. The re-launch was effected more formally than the original launch, through a Commission Decision adopted on 14 October 2010[20]. CARS 21 aims to make recommendations for the short-, medium-, and long-term public policy and regulatory framework of the European automotive industry. This framework enhances global competitiveness and employment, while sustaining further progress in safety and environmental performance at a price affordable to the consumer. The CARS 21 High Level Group met for the first time on 10 November 2010. Further meetings are planned throughout 2011.

Seven infringement cases were opened during 2010 in relation to EU legislation in this sector (compared to 32 cases in 2009) and 25 cases were closed. All of these cases were opened as a result of late communication of national measures transposing EU Directives which generally contained technical updates of the *acquis*. The Member States concerned by these non-communication cases were Austria, Bulgaria (two proceedings), the Czech Republic, Hungary, Ireland and Portugal. Most of these cases were closed after national transposition measures were communicated by the Member States concerned (but one 2009 case remains open and is currently before the Court of Justice). In around 70% of cases opened in 2010 and subsequently closed in the same year, national measures were communicated before the reasoned opinion stage. However, in only 40% of all open cases that were closed in 2010 did communication take place before that stage.

During 2010 the Commission services continued to deal with a steady number of questions, complaints and queries in relation to legislation in the automotive sector. Complaints or requests for information were also periodically sent via the petition procedure. Most inquiries were submitted by individuals or SMEs. In many cases, the issues raised could be dealt with by giving guidance on the Commission service's interpretation of the relevant EU legislation. Where the complaint turned out to be unsubstantiated, the matter was closed and the reasons for doing so were explained.

Evaluation

The current situation regarding compliance by Member States with the EU *acquis* in the automotive sector is generally satisfactory. Nevertheless, there are delays in the timely

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19 http://ec.europa.eu/enterprise/sectors/automotive/competitiveness-cars21/energy-efficient/communication_en.htm

20 Commission Decision of 14 October 2010 re-launching of the CARS 21 High Level Group on the Competitiveness and Sustainable Growth of the Automotive Industry in the European Union, OJEU C280 of 16.10.2010, p.32. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:280:0032:0034:en:PDF

transposition of certain Directives (for example, in the context of amendments to framework Directive 2007/46/EC, where only 15 EU Member States communicated national transposition measures prior to the expiry of the deadline – one case was brought before the Court of Justice in 2010). In this regard, the constant evolution of the technical legislation means that it is important to pay close attention to timely transposition and effective enforcement to ensure that policy objectives are met.

Through the CARS 21 process, the Commission has developed a medium to long-term, coordinated and predictable policy framework for the automotive industry based on continuous dialogue and consultation with all main stakeholders. In this regard, in the preparation of legislative proposals and policy initiatives, the Commission is assisted by two types of advisory bodies: comitology committees and working groups. In the case of technical amendments to legislation, the Commission acts in close cooperation with EU Member States on implementation issues under the comitology procedure. Likewise, the informal working groups, which may consist not only of national experts but also experts or stakeholders from business, NGOs, trade unions, academia, etc., provide expert advice to the Commission.

There is close cooperation between the Commission and EU Member States, notably through the TAAM (Type-Approval Authorities Meeting) forum, which met at the beginning of June 2010 in Sofia, Bulgaria and discusses questions regarding the interpretation of EU directives in the automotive sector as well as the equivalent UNECE Regulations with a view to ensuring their common and harmonised application. As a result of this, significant problems regarding conformity or incorrect application are relatively rare. Nevertheless, the complexity of the legislation in this sector and the constant development of new technologies, for example on hybrid and electric vehicles (and the corresponding adaption of legislation), means that problems of interpretation are ever-present. On occasion, the Commission has set out its interpretation of the legislation in order to maintain a harmonised approach. It may still be that Member States take measures which could potentially compromise the harmonised approach.

In many cases, due to the technical nature of the legislation, EU Member States transpose technical amendments by reference to EU acts. Where this is not the case, the use of correlation tables is very helpful.

Finally, the approach taken regarding legislation harmonising vehicle standards under the ordinary legislative procedure now tends towards the adoption of regulations rather than directives (e.g. a proposal for framework Regulations on two and three wheel vehicles and on tractors). One exception to this is framework Directive 2007/46/EC on type-approval of motor vehicles. No transposition of regulations is required and this should increase overall efficiency by significantly lowering the number of infringement cases based on non-communication of national transposition measures.

Evaluation results

(1) Priorities

The main priority in the automotive sector remains the proper implementation, management and enforcement of legislation. In particular, there has to be long-term regulatory clarity as well as an accurate quantification of the costs and benefits of legislative activity, notably by recourse to impact assessments where appropriate. Given the impact of the economic crisis, the Commission will continue to weigh up the costs and benefits of new legislative initiatives

and seek, as far as possible, to avoid creating new economic burdens.

(2) Planned action (2011 and beyond)

A significant proportion of the work in the automotive sector in 2011 and beyond will focus on the recasting of the legislative framework (and its subsequent completion) and the implementation of new technical legislation.

In particular, the revised regulatory framework for type-approval legislation in relation to two and three-wheeled vehicles and tractors will progress under the ordinary legislative procedure (this revised legislation will update and replace the present framework Directives on two and three-wheeled vehicles and on tractors and separate completing directives). Delegated and implementing acts for the revised regulatory frameworks regarding two and three-wheeled vehicles and tractors will be prepared.

The Commission will also work on various proposals to complete framework Directive 2007/46/EC (e.g. notably to take into account UNECE Regulations replacing EU Directives) as well as implementing measures on type-approval of hydrogen vehicles, Euro VI, the GSR, the Strategy of 2007 on CO2 and the strategy on clean and energy efficient vehicles. A proposal replacing Directive 70/157/EEC on noise of motor vehicles is to be adopted by the Commission in 2011 and submitted to the European Parliament and Council under the ordinary legislative procedure. Finally, the Commission will participate actively in activities relating to the ITS (Intelligent Transport Systems) action plan including eCall.

1.3. Chemicals

1.3.1. **REACH**

Current position

General introduction

Regulation No 1907/2006 (REACH), most parts of which began to apply in June 2008, constitutes the horizontal framework and cornerstone of the EU's new chemicals legislation. REACH includes four main processes - registration, evaluation, authorisation and restriction of chemical substances. Registration of chemicals with the European Chemicals Agency ("ECHA") is designed to generate information on manufactured and imported substances in order to ensure that industry implements adequate measures to ensure their safe use. Subsequent evaluation by ECHA includes compliance checks on registration dossiers and examination of testing proposals. Certain substances may undergo 'substance evaluation', where national authorities can request further information from industry about a given substance on a risk basis and further regulatory measures may be considered. Substances giving rise to very high concern may be required to obtain Commission authorisation before being placed on the market or used under stipulated conditions. Finally, the manufacture, import and use of substances that pose unacceptable risks to human health or the environment may be partially or totally restricted.

Work done in 2010

The main goal of the Commission in 2010 was to contribute to the successful registration by industry of the highest volume and most hazardous substances by 30 November 2010. To this end, in January 2010, a dedicated high-level Directors' Contact Group (DCG) was established, composed of the representatives of the Commission, ECHA and several industry associations. The objectives of the DCG are to monitor the overall preparedness of companies and to identify and resolve issues of priority concern in relation to meeting registration obligations. Special attention is also paid to securing the supply of high volume substances to downstream users. By the 30 November 2010 deadline, ECHA had received nearly 25.000 registration files covering around 3.400 substances. Overall, the results are satisfactory.

Commission Regulation (EU) No 453/2010 was adopted with a view to adapting Annex II to REACH, which contains a guide to the compilation of safety data sheets, to the new criteria for classification and other relevant provisions laid down in Regulation (EC) No 1272/2008 and to the rules for safety data sheets of the United Nations Globally Harmonised System (GHS).

The Test Methods Regulation (Commission Regulation (EU) No 1152/2010) was also adapted to technical progress by including two new in-vitro test methods to reduce the number of animals used for experimental purposes.

The Commission prepared amendments to Annex XIII to REACH (criteria for the identification of persistent, bio-accumulative and toxic substances and very persistent and very bio-accumulative substances) and to Annex XIV (the first list of substances to be subject to Commission authorisation).

The Commission adopted an amendment to REACH to introduce into Annex XVII all restrictions adopted under the previous legislation (Commission Regulation (EU) No 276/2010). The Commission also prepared two new amendments to Annex XVII relating to transitional provisions. These concern the use of acrylamide in grouting applications and the use of cadmium in plastics, jewellery and brazing fillers. The Commission further requested ECHA to prepare a file in accordance with Annex XV to restrict the use of mercury in some measuring devices and to analyse whether, in the light of new scientific information, the existing restrictions in Annex XVII concerning phthalates need to be revised.

The REACH Regulation is complemented by a comprehensive package of technical guidance published by ECHA to ensure its uniform and consistent interpretation. Most of the guidance was already in place by mid 2008. However, the existing guidance is constantly being updated to address implementation needs. Throughout 2010, the Commission assisted ECHA in developing new guidance (e.g. Guidance on authorisation applications) and updating the existing guidance documents (notably those necessary to facilitate compliance with the 2010 registration deadline).

Many implementation problems faced by industry were resolved in collaboration with ECHA, which has developed various tools to help operators to fulfil their REACH obligations (guidance package, Navigator tool, helpdesk, FAQs etc.). National REACH helpdesks are also functioning satisfactorily. The Commission actively participated in numerous meetings of ECHA committees and in workshops.

The Commission called for a study, which analysed and compared penalties for

infringement of REACH in all Member States with a view to assessing their effectiveness, proportionality and dissuasiveness. As the study did not address how the penalties are implemented in practice, it provides only an overview. As a follow-up to the study results, the Commission held a workshop on national penalties for REACH enforcement. Later in 2010, the Commission received reports from Member States under Article 117 on the operation of REACH containing information on enforcement, which is currently under consideration.

The Commission actively participated in, and contributed to the work of, the ECHA Forum for the Exchange of Information on Enforcement which coordinates a network of national authorities responsible for enforcement. The Forum evaluated the first EU coordinated enforcement project (REACH-EN-FORCE 1) and extended it for the rest of 2010 and beyond. The project is an important step towards the harmonisation of enforcement practices.

The Commission continued to hold regular dialogues on various implementation issues with Member States' competent authorities and other stakeholders via three meetings of its expert group "Competent Authorities for the REACH and CLP Regulations (CARACAL)" and its subgroups, notably the subgroup on nanomaterials.

In addition, the Commission worked to clarify and smooth the transition of materials between different EU regulatory regimes (e.g. the development of end-of-waste criteria and the implications of REACH for these materials and the involvement of customs authorities in REACH enforcement).

In 2010, the Commission received two complaints regarding REACH compliance by Member States' authorities in the area of restrictions, which are currently under investigation.

Evaluation

REACH being a Regulation, directly applicable in the Member States with no need for transposition, the role of the Commission is limited to monitoring its consistent application and ensuring that the Member States enforce it through a system of official controls and other appropriate activities.

Given the early stages of its implementation, the objectives of REACH will be realised in successive stages by 2020. Different obligations will be phased-in successively during this period. This is relevant mainly for registration (where deadlines are set for 2010, 2013 and 2018). Authorisation requirements apply in accordance with transitional arrangements specifically provided for each substance listed in Annex XIV (the first "sunset date" is scheduled for the second half of 2014). Authorisation is a gradual process, whereby additional substances of very high concern will be included in Annex XIV over time, in accordance with the procedures laid down in Articles 58 and 59 of REACH.

As the first deadline for registration expired as recently as 1 December 2010, enforcement of this obligation will begin in earnest in 2011. The Commission has not yet received any complaints regarding the enforcement of the registration obligation.

Obligations on the provision of information in the supply chain and to consumers already apply and should be enforced by Member States. The Commission has not yet received any complaints in this respect.

The enforcement of restriction obligations came under the umbrella of REACH in the second half of 2009. The change from Directive 76/769/EEC to REACH allows more coherent implementation of the restrictions in the Member States.

The Commission will study the information received in the Member State reports mid 2010 in order to prepare its own report in mid 2012 and any necessary follow-up on penalties.

Evaluation results

(1) Priorities

The priorities indicated in the 2009 Annual Report largely remain. The Commission monitors the effective and consistent application of the obligations that are already applicable. The highest priorities are the enforcement of registration and restriction obligations. Launching the first review of certain aspects of REACH is a new priority.

(2) Planned action (2011 and beyond)

The Commission will begin its first review of various aspects of REACH. The results of this review are due by mid 2012. REACH specifically requires three reviews: a review of ECHA, a review of the requirements for low tonnage substances and a review to assess whether to amend the scope of REACH to avoid overlaps with other EU legislation. In addition, the Commission will start the preparatory work for the first general report on experience acquired with the operation of REACH, due in mid 2012. The Commission has decided to carry out a larger review exercise covering some additional elements of REACH (a report on the first lessons learned, paying particular attention to costs, administrative burdens and other impacts on innovation). The various reviews and reports will be presented as a package by June 2012.

The Commission will continue to prepare for one of its main tasks under REACH – granting authorisations for the placing on the market and the use of substances of very high concern, listed in Annex XIV. The first applications may be received by ECHA as soon as 2011. The Commission will also prepare a new draft regulation with a view to adding more substances to Annex XIV.

On the basis of opinions from ECHA committees (the Committee for Risk Assessment and the Committee for Socio-economic analysis) expected in 2011, the Commission will prepare amendments to Annex XVII relating to restrictions of the following substances: dimethylfumarate, mercury in measuring devices, phenylmercury compounds and lead in jewellery.

The Commission will continue to monitor how Member States enforce REACH in order to ensure transparency, impartiality and consistency in enforcement throughout the EU. To this end, the Commission will in particular continue to work closely with the ECHA Forum for the Exchange of Information on Enforcement. The Commission will also review the Member States reports and later on, the ECHA report on the operation of REACH due by mid 2011.

The Commission will continue other activities, including enhancing cooperation, coordination and exchange of information with national authorities and ECHA, extending the mandate of the existing DCG group, holding meetings with industry stakeholders, providing assistance

with interpretation problems and participating in workshops to ensure timely implementation.

Summary

As the new horizontal regulatory framework for chemicals, REACH has the long-term objectives of providing a high level of protection of human health and the environment while ensuring the free circulation of substances on the internal market and enhancing competitiveness and innovation. The objectives of the *acquis* should be largely attained by 2020. The correct implementation of REACH obligations will be critical for the chemical industry sector in the coming years. It will only be possible to evaluate to what extent these objectives are being met over time, whereupon corrective action will be taken if necessary.

Links to legislation

REACH and its implementing legislation are available through the following link:
http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/index_en.htm

REACH and its links to previous legislation on restriction is available here:
http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/market-restrictions/index_en.htm

1.3.2. Other chemicals legislation

1.3.2.1. Classification, labelling and packaging

Current position

General introduction

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation) aligns previous EU legislation on this topic with the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Its main objectives are to facilitate international trade in chemicals and to maintain existing levels of protection of human health and the environment. The GHS is a United Nations system designed to identify hazardous chemicals and to inform users about these hazards through standard symbols and phrases on packaging labels and through safety data sheets.

The CLP Regulation entered into force on 20 January 2009. According to the Regulation, substances and mixtures must be classified, packaged and labelled according to its provisions. After a transitional period, the CLP Regulation will replace current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and mixtures (Directive 1999/45/EC). From 1 December 2010 substance classification and labelling have to comply with the new rules, whilst for mixtures the transitional period will end on 1 June 2015.

The 1st Adaptation to Technical Progress (ATP) of the CLP Regulation came into force on 25 September 2009, inserting the harmonised classifications adopted in the 30th and 31st ATPs of Directive 67/548/EEC into Annex VI to the CLP Regulation.

Report of work done in 2010

The main priority in 2010 was to contribute to the proper implementation of the legislation, in particular the application by industry of the new rules regarding the classification, labelling and packaging of dangerous substances. For that purpose, the Commission has used the communication structures already created under REACH to ensure constructive dialogue with ECHA, national authorities and industry associations. The main goal was to provide support to solve concerns related to meeting classification and labelling obligations, and also notification obligations. All manufacturers and importers of substances (whether as such or in mixtures) had to notify the classification and labelling applicable from 1 December to the European Chemicals Agency (ECHA) by 3 January 2011. ECHA has received 3.114.835 notifications for 107.067 substances.

To facilitate correct and uniform implementation of the CLP Regulation, several technical guidance documents were published by ECHA. In 2010, the Commission assisted ECHA in revising existing guidance documents and developing new ones, providing information to reply to Frequently Asked Questions and participating in ECHA committees and workshops related to the CLP Regulation, including in particular meetings of the Risk Assessment Committee (RAC) when proposals for the harmonised classification and labelling of dangerous substances were discussed.

The Commission prepared the draft 2nd ATP, which will incorporate into the CLP Regulation the changes introduced by the 3rd revision of the GHS.

The Commission has also received information from Member States regarding the penalties adopted at national level for non compliance with the obligations of the Regulation. Although most Member States have implemented national provisions, some notifications of the national measures are still missing.

The Commission has continued to contribute to work done in the framework of the United Nations to further revise the GHS.

In addition, Commission Regulation (EU) No 440/2010 on the fees payable to the European Chemicals Agency pursuant to the CLP Regulation (Articles 24(1) and 37(3)) entered into force on 25 May 2010.

Evaluation

Since the deadlines for applying the new classification and labelling provisions to substances and for notification in the C&L Inventory only expired on 1 December 2010 and 3 January 2011 respectively, it is premature to conduct an evaluation. However, the fact that more than 3 million notifications for over 107.000 substances have been submitted is an indication that industry can successfully cope with the new requirements.

Evaluation results

(1) Priorities

The Commission will monitor enforcement and official controls reported by Member States. It will also support the work of the national authorities responsible for market surveillance in the framework of the Enforcement Forum coordinated by ECHA and will follow-up information on the C&L Inventory managed by ECHA. The Commission will assess the need to initiate infringement procedures for non communication of national measures concerning

penalties for those Member States who have not yet notified their measures.

(2) Planned action (2011 and beyond)

The Commission will proceed with the final adoption and publication of the 2nd ATP to the CLP Regulation and will continue to support ECHA, national authorities and industry in various fora and in the development of information and guidance documents that will be required by industry to ensure that mixtures comply with the provisions of the CLP Regulation by June 2015.

The Commission will also assess the opinions on the proposals for the harmonised classification and labelling of certain substances submitted by ECHA to assess whether to include them in the list of harmonised classification and labelling in Annex VI of the CLP Regulation.

Discussions will start with national experts and stakeholders on incorporating the 4th revision of the GHS at EU level in a future ATP of the CLP Regulation.

Summary

Given that the obligations of the legislation related to substances became compulsory on 1 December 2010 and the provisions for mixtures will only become compulsory in 2015 the CLP Regulation is in a very early stage of implementation. A great deal of work in support of correct implementation has been accomplished. Compliance with the deadline for submitting notifications of classification and labelling information to ECHA by 3 January 2011 seems to have been satisfactory. A more detailed analysis will take place in 2011.

Links to legislation

http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/index_en.htm

1.3.2.2. ***Pyrotechnic Articles and Explosives***

Current position

General introduction

Directive 2007/23/EC protects consumers by requiring that pyrotechnic articles meet essential safety requirements. It also creates an internal market for those articles that meet these requirements. The Member States had to transpose the Directive by early 2010. Directive 93/15/EEC regulates the placing on the market and the supervision of intra-EU transfers of explosives for civil uses and has been applied since January 1995.

Report of work done in 2010

On 19 June 2010, the Commission adopted Decision 2010/347/EU amending Commission Decision 2004/388/EC of 15 April 2004 on an intra-EU transfer of explosives document. The new Decision allows Member States to use an electronic system, which will significantly reduce the time taken to grant transfer approvals to companies manufacturing or trading

explosives.

The Commission continued to follow up the transposition of Directive 2008/43/EC, setting up a system for the unique identification and full traceability of explosives for civil use from manufacturing/import to final use in order to protect the general public from illicit use. Of 10 infringement procedures launched at the tail end of 2009, 9 were closed during 2010 after communication of the required national transposition measures.

CEN has delivered the necessary standards for the correct implementation of Directive 2007/23/EC. However, objections to a few very specific parts of the standard have been raised by two Member States, which have been dealt with and appropriate solutions have been found.

Evaluation

Overall, the situation is satisfactory with regard to the Explosives Directive. However, the industry sector concerned has signalled that more time will be required to fully implement Directive 2008/43/EC due to the need to develop complicated IT systems and because an exemption for certain small articles will be necessary. The implementation of Directive 2007/23/EC is still at an early stage.

Evaluation results

(1) Priorities

Finding solutions to the request to postpone the taking effect of Directive 2008/34/EC and defining articles for which an exemption could be acceptable. Updating certain parts of the standards for pyrotechnic articles to overcome the objections raised by some Member States.

(2) Planned action

At the end of 2010 the Commission launched a study to assess whether Directive 2007/23/EC on pyrotechnic articles has been correctly transposed by all Member States and the outcome will be evaluated by the Commission in 2011.

Summary

Overall, the situation with regard to the Directive on explosives is satisfactory; the Directive does not require major modifications. The Directive on pyrotechnic articles is at an early stage of implementation and finalising all required standards as well as monitoring its correct implementation by the Member States will be important in the near future.

Links to legislation

http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/index_en.htm

1.3.2.3. ***Drug precursors***

Current position

General introduction

Drug precursors are chemicals with wide and varied legitimate uses, for example in the production of plastics, pharmaceuticals, cosmetics, perfumes, detergents or aromas. However, these chemicals may be diverted from legal trade for use in the illicit manufacture of drugs such as cocaine, heroin, ecstasy or methamphetamines. European drug precursor legislation establishes measures to monitor trade in drug precursors, aiming at striking a balance between preventing their diversion into drug manufacture and allowing their legitimate trade without creating unnecessary administrative burdens.

Report of work done in 2010

The Commission has continued to support better implementation of drug precursor legislation, for instance by organising a best practice workshop with Member States and stakeholders in June 2010. The Commission also presented a paper setting out possible changes to the existing legal framework and collected information to prepare an impact assessment on options for legislative amendments.

Work also continued on infringement procedures against Member States for non-communication of national implementing measures. Of 8 infringement cases begun in 2007, only one remained open. In that case, the European Court of Justice ruled that the Member State in question had not met its obligations under drug precursor legislation by failing to communicate national transposition measures.

Evaluation

On 7 January 2010, the European Commission adopted a Report on the implementation and functioning of the EU legislation on monitoring and controlling trade in drug precursors[21]. The report concludes that the legislation has functioned well overall, but also identifies some weaknesses in the current system and sets out recommendations for further improvement.

In reaction to the Commission's Report, the Council adopted conclusions which recognise the importance of continuing active co-operation between authorities and industry and improving the implementation of existing legislation. The Council invited the Commission to set up a work programme to address weaknesses identified in the legislation in co-operation with Member States and to propose legislative amendments before the end of 2011 after carefully assessing their potential impact on national authorities and economic operators.

Evaluation results

(1) Priorities

The Commission services are giving priority to addressing the weaknesses identified in the above mentioned report, with the aim of preventing diversion of drug precursors from legal trade to the production of illicit drugs. This includes the exchange of best practices among Member States and the preparation of a review of the existing legislation.

(2) Planned action

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One action the Commission services will take to address these weaknesses is the preparation of an impact assessment in relation to different options for the amendment of existing legislation with a view to presenting a legislative proposal, if justified, by the end of 2011. In parallel, efforts to support a better implementation of the existing legislation will continue.

Summary

Whilst the *acquis* with regard to drug precursors overall functions rather well, an evaluation has identified certain weaknesses, which might lead to some legislative modifications if justified following an impact assessment on various options.

Links to legislation

http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/index_en.htm

1.3.2.4. ***Detergents***

Current position

General introduction

Regulation (EC) No 648/2004 on detergents ensures that only detergents with surfactants that are fully biodegradable are placed on the market and that detergents are appropriately labelled to protect the health of consumers, especially against allergies.

Report of work done in 2010

In accordance with the requirements of Article 16(1) of the Regulation, the Commission submitted a report to the Parliament and the Council on the use of phosphates in detergents in 2007. Subsequently, a study was done to gather more scientific evidence on the contribution of detergents to the eutrophication of EU waters. The study was completed in 2009 and reviewed by the Scientific Committee of Health and Environmental Risks (SCHER). In the course of 2010, the Commission prepared an impact assessment for a range of policy options regarding the use of phosphates in detergents. Based on the impact assessment, a legislative proposal to restrict the use of phosphates and phosphate-containing compounds in laundry detergents was adopted by the Commission on 4 November 2010 (COM(2010) 597 final) and was forwarded to the European Parliament and the Council for adoption under the ordinary legislative procedure.

In accordance with Article 15(1) (safeguard clause) of Regulation (EC) No 648/2004, the German Competent Authorities for Detergents notified a national measure prohibiting the placing on the German market of a specific lime-scale and rust remover containing up to 25% nitric acid due to the risk to human health. Shortly thereafter, the Belgian authorities notified a similar measure. The Commission consulted all Member States and other stakeholders and will prepare a Commission Decision in accordance with Article 15(2).

An infringement proceeding opened against Luxembourg for the non-implementation of Regulation (EC) No 648/2004 on detergents was closed in 2010 after Luxembourg adopted penalties for non-compliance with the Regulation.

Evaluation

The situation with regard to the Detergents Regulation and its implementation is satisfactory.

Evaluation results

(1) Priorities

Following delivery of all required reports in earlier years, the main priority will be the effective and consistent application of the Regulation.

(2) Planned action

A Commission Decision under Article 15(2) is planned for the first quarter of 2011 in response to the use of the safeguard clause by Germany.

Summary

The *acquis* with regard to detergents is effective and does not require significant modifications, except for additional measures to restrict the use of phosphates and phosphate-containing compounds in laundry detergents.

Links to legislation

http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/index_en.htm

1.3.2.5. ***Fertilisers***

Current position

General introduction

The purpose of Regulation (EC) No 2003/2003 on mineral fertilisers is to allow the free circulation within the internal market of 'EC fertilisers'.

Report of work done in 2010

In 2010, the Commission prepared the 5th adaptation to technical progress (ATP) to include new types of fertilisers that can be marketed as 'EC fertilisers' and to introduce new CEN test methods that will facilitate compliance with the provisions of the Regulation. The draft Commission Regulation received a favourable opinion from the relevant regulatory committee.

As recommended in the Risk Reduction Strategy on cadmium established under Regulation (EC) No 793/93, the Commission continued to assess the possibility of reducing the content of cadmium in phosphate fertilisers. Meetings were organised with stakeholders and Competent Authorities to understand the impact of potential measures and gather information for the Impact Assessment required prior to action at EU level. Work on the impact assessment progressed well throughout 2010.

Evaluation

An ex-post evaluation of Regulation (EC) No 2003/2003 was carried out by an external consultant to analyse the strengths and weaknesses of the current legislation and its potential

for improvement. The evaluation concluded that that Regulation represents an important step towards the harmonisation of mineral fertilisers, but that an important and growing part of the market is not covered. Mutual recognition of 'national fertilisers' is perceived as problematic. For most stakeholders, EU legislation needs to be broader in scope.

Evaluation results

(1) Priorities

No change compared to earlier years: activity will continue to adapt the Regulation to technical progress, notably to include new fertiliser types in Annex I and simplify analytical methods in Annex IV. In parallel, the necessary preparatory work for a fundamental review of the Regulation will begin to extend its scope and achieve full harmonisation of the sector.

(2) Planned action (2011 and beyond)

After adoption of the 5th ATP, work on a 6th ATP will continue to include additional types of fertilisers and to replace some national standards by common EU-wide standards. The aim is full harmonisation of the fertiliser market.

In preparation for full harmonisation of the fertiliser market, a study has been commissioned by the Directorate-General for Enterprise and Industry to collect information about national regulatory frameworks on fertilisers. Some policy options for the revision of fertilisers legislation will be proposed having regard to their impact on the environment, human health and the economy as a whole. The results of the study will feed into an impact assessment report accompanying the future legislative proposal.

Summary

The current fertiliser Regulation has been effective in achieving its main objective, namely to simplify and harmonise the regulatory framework in relation to mineral fertilisers. The Regulation appears to be less effective in meeting two other objectives such as the protection of the environment and the promotion of innovation. Mutual recognition of national fertilisers is not well perceived by a majority of Member States as industry is either unaware of it, or very sceptical about its use. These legal uncertainties should be overcome in the future revision of the fertiliser Regulation, which should significantly extend its scope to cover a broader range of fertilising materials and related products (such as soil improvers and growing media) and reduce administrative burdens for companies and authorities.

Links to legislation

http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/index_en.htm

1.4. The Transparency Directive

Current position

In accordance with the Treaty, pharmaceutical pricing and reimbursement policies fall within the responsibility of the Member States. However, Directive 89/105/EEC, commonly referred to as the "Transparency Directive", lays down a series of procedural requirements to ensure the transparency of national pricing and reimbursement measures. Its provisions do not affect the capacity of Member States to determine the organisation and financing of their healthcare

systems. In particular, each Member State is free to set the prices of medicines and to decide on their reimbursement status in the framework of national or regional health insurance schemes.

Report of work done in 2010

In 2010, three infringement proceedings related to the incompatibility of national legislation with the requirements of the Directive were closed.

Discussions with the Member States on the application and interpretation of the Directive were also pursued in the framework of the Transparency Committee which was held in March 2010.

Evaluation

Directive 89/105/EEC is a peculiar instrument under EU law because it lies at the interface between EU competences (free movement of goods within the internal market) and national responsibilities (organisation of social security systems). The directive only provides for partial harmonisation, based on the underlying principle of minimum interference in the organisation by Member States of their domestic social security policies. In other words, Member States are free to establish their own regulatory framework, provided that the rules and procedures chosen include certain guarantees of transparency. This has consequences for the management of infringement proceedings: the investigations always require a case-by-case analysis of complex national systems and the exercise is often complicated by regular reforms or adjustments of social security schemes introduced by many Member States to curb rising public health expenditure. Where compliance issues arise, Member States must implement their own solutions because they remain responsible for the organisation of their social security system. In addition, pharmaceutical pricing and reimbursement is a politically sensitive area in all Member States due to the impact of national measures on healthcare budgets. Consequently, the resolution of problems always requires dialogue and a sustained cooperation with the competent national authorities.

The Commission has significantly stepped-up its efforts to ensure the enforcement of the Directive in recent years. Indeed, after enlargement, it became apparent that several Member States had adopted pricing and reimbursement measures at odds with the principles of the Transparency Directive. Different issues relating to compliance with the time-limits and other procedural obligations were identified by the Commission on the basis of complaints from economic operators. A majority of these issues were resolved through constructive dialogue with the competent national authorities. This enabled the Commission to put an end to infringement proceedings in a dozen cases between 2005 and 2009.

Evaluation results

An impact assessment for the review of Directive 89/105/EEC is currently being carried out. A review is included in the Commission Legislative Work Programme 2011.

(http://ec.europa.eu/atwork/programmes/docs/cwp2011_annex_en.pdf).

One of the aims of the review is to update the text of the Directive so as to incorporate the case-law of the Court of Justice and tackle some ambiguous or out-of-date wording in the Directive. This would provide a solution to various interpretation and implementation issues

which regularly arise.

Summary

Given the rapid evolution of health insurance systems and the recent multiplication of cost-containment measures in many Member States, the compatibility of national measures with Directive 89/105/EEC continues to require constant scrutiny. The Commission will therefore continue to investigate complaints indicating potential incompatibilities of national measures with the Directive. Priority will be given to solve problems of insufficient or incorrect implementation of the procedural requirements of the directive into national law which could entail significant barriers to trade in medicinal products.

1.5. Mechanical, electrical and telecommunications equipment

Current position

General introduction

The Machinery Directive 2006/42/EC, published on 9th June 2006, began to apply on 29 December 2009, replacing Directive 98/37/EC. The new Directive aims to consolidate previous achievements in terms of free circulation and safety, while improving the application of the legislation. The scope of the new Directive is wider, since construction-site hoists and cartridge-operated fixing and other impact machinery are no longer excluded. The new Directive has already been amended to introduce environmental protection requirements for new machinery placed on the market for use in the application of pesticides.

Report of work done in 2010

An infringement case brought under Directive 98/37/EC had been referred to the Court in 2009. Following amendment of the legislation by the Member State concerned to comply with the requirements of the Directive, the case was closed in 2010. By the end of 2010, all infringement proceedings for non-communication of national measures implementing Directive 2006/42/EC were closed following receipt of the national transposition measures.

In 2010, Commission Directive 2010/26/EC was adopted, amending Directive 97/68/EC on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery. The amendment is an adaptation to technical progress relating to type approval testing procedures for certain larger diesel engines.

Finally, as concerns the lifts Directive (95/16/EC), one infringement case was closed when the Member State introduced required changes to national legislation following a reasoned opinion sent by the Commission.

Evaluation

The existing *acquis* is well established and is not expected to require substantial development. Compliance by Member States with the law in this sector is satisfactory. The situation is stable, manageable and acceptable. The volume of problems arising is limited and no specific corrective action is required.

Evaluation results

(1) Priorities

As in 2009, priorities were the non-communication cases. In 2010, Directive 2006/42/EC was fully transposed and no other non-communication cases remain open.

(2) Planned action

Following adoption of Decision No 768/2008/EC on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, some existing directives must be revised, in particular Directive 2006/95 relating to electrical equipment designed for use within certain voltage limits, Directive 2004/108/EC on the approximation of the laws of the Member States relating to electromagnetic compatibility, Directive 94/9/EC regarding equipment intended for use in potentially explosive atmospheres and Directive 95/16/CE on lifts. This revision process began in 2010.

An increase in work on the amendment of existing legislation is therefore expected.

A Commission proposal for a Directive of the European Parliament and Council amending Directive 97/68/EC on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, as regards the provisions for engines placed on the market under the "flexibility scheme" was adopted in 2010. Negotiations with the European Parliament and the Council are underway.

Summary

Future work will include the revision of some directives, to align them with Decision No 768/2008/EC on a common framework for the marketing of products. However, the *acquis* is relatively well established and the situation is stable. The mechanical, electrical and telecommunications equipment sectors all function smoothly.

1.6. Gas appliances, pressure equipment and legal metrology

Gas appliances, pressure equipment, and metrology are technically complex sectors that are regulated by EU harmonisation legislation to a certain extent.

1.6.1. Gas appliances

Current position

General introduction

The gas appliances sector is mainly regulated by Directive 2009/142/EC relating to appliances burning gaseous fuels (a codified version of Directive 90/396/EEC). It aims to ensure the free movement of gas appliances through technical harmonisation with regard to hazards due to gas and to ensure a high level of safety and health protection by imposing mandatory essential safety requirements and conformity assessment procedures.

Other EU harmonisation legislation, covering other aspects, may also apply to gas appliances (or their parts).

Report of work done in 2010

Infringement proceedings and issues relating to the correct implementation of the Directive 2009/142/EC were priority issues for the Commission services in 2010. A case against Greece for incorrect implementation of the Directive with regard to gas appliances was resolved following clarification by the Greek authorities.

Most inquires and complaints in the sector related to problems with the installation and putting into service of gas appliances due to their incompatibility with the gas supply conditions at the place of installation (a non-harmonised aspect). The Commission intervened where incorrect implementation of the Directive (harmonised aspects) was detected. Another group of problems concerned the simultaneous application of other directives, in particular Directive 89/105/EC on construction products, to exhaust gas facilities placed on the market as integral parts of a gas appliance operating as a complete system.

Concerns have also been raised about measures taken by some Member States in relation to energy efficiency which have the effect of restricting the free movement of certain types of gas appliances. As this involves the application of other pieces of EU legislation, in particular legislation on the promotion of renewable energies, the matter is being examined by the Commission services involved.

Evaluation

Directive 2009/142/EC has been operational and functioning satisfactorily for more than fifteen years. However, experience with its implementation, together with technical progress and innovation, have made it necessary to revise the Directive. Currently, the Commission services together with the Member States Working Group on Gas Appliances and the sub working group on Revision, are examining the different options for revision and will prepare a working document with a proposal. The Gas Appliances Expert Group met once this year mainly to discuss progress made on preparation for the revision and the outcome of the work of the Working Group GAD Revision, which met seven times.

The revision of the Directive was also the main topic in the meetings of the Gas Appliances Directive Advisory Committee (GADAC) and the Notified Bodies Gas Appliances (NBGA), both composed of representatives of notified bodies.

Discussion centred on the possible extension of the scope of the Directive to cover not appliances “burning gaseous fuels” but appliances “using gaseous fuels” and to cover some components for gas installations. The limitations of the harmonisation of the gas appliances themselves are recognised, since gas types and supply pressures (which are very important for the safe functioning of appliances) are not harmonised. As consequence, a gas appliance must not only comply with the EU harmonisation legislation but must also be suitable for gas supply conditions at the place of installation. The alignment of Directive 2009/142/EC to Decision 768/2008/EC on a common framework for the marketing of products will be part of its revision. A Commission legislative proposal is expected at the end of 2012.

The ex-post evaluation of the Gas Appliances Directive is under preparation. The study aims to assess whether the Directive has achieved its objectives and whether it is cost-effective. The evaluation will greatly assist the revision process, in particular by identifying possible needs for further improvement of the framework conditions for products covered by the Directive or for bringing new products within its scope.

Evaluation results

(1) Priorities

The revision of Directive 2009/142/EC is a priority for the Commission services.

(2) Planned action (2011 and beyond)

The correct and effective implementation of the Directive (including infringement proceedings and safeguard clauses) will continue to be monitored in 2011.

Summary

Directive 2009/142/EC functions smoothly and there are no major problems. In general, Member States apply the *acquis* correctly and those problems that do arise tend to relate to non-harmonised aspects, such as gas types and supply pressures. However, experience with its implementation, together with technical progress and innovation, have made it necessary to revise the Directive. The revision process is a priority for the Commission.

1.6.2. ***Pressure equipment***

Current position

General introduction

The pressure sector deals with protection of health and safety in relation to risks presented by pressure equipment, covering an area ranging from the simple pressure cooker to the largest chemical installation. EU harmonisation legislation covers pressure equipment mainly through Directive 97/23/EC on pressure equipment and Directive 2009/105/EC (a codified version of Directive 87/404/EEC) on simple pressure vessels. This legislation regulates the design, manufacture and conformity assessment of the products defined as falling within their scope. Directive 97/23/EC covers pressure equipment as regards pressure hazards.

Directive 75/324/EEC on aerosol dispensers lays down the safety and labelling requirements that aerosol dispensers must satisfy in order to be placed on the market.

Other EU harmonisation legislation, covering other aspects, may also apply to these products.

Finally, four old directives on pressure vessels (framework directive 76/767/EEC and three specific instruments on gas cylinders, namely Directives 84/525/EEC, 84/526/EEC and 84/527/EEC), were repealed by Directive 2010/35/EU on transportable pressure equipment.

Report of work done in 2010

- Management of infringement proceedings

Infringement proceedings and issues relating to the correct implementation of the Directives were priority issues in 2010. Most infringement proceedings concerned the non-communication of national transposition measures.

Directive 2008/47/EC of 8 April 2008[22], adapted Directive 75/324/EEC to technical progress and has applied since 29 April 2010. Following communication of the national transposition measures, 10 infringement proceedings out of 13 were closed.

A case against Greece relating to obstacles to the free circulation of steam boilers was closed following a reasoned opinion, when the contested provisions were repealed.

- Expert groups

Two regular meetings of the Working Group on Pressure took place in 2010. Issues relating to the implementation of the directives were discussed and guidelines are adopted in order to ensure, where necessary, the coherent interpretation of the directives by all concerned parties. There were also meetings of the Coordination Group of Notified Bodies to ensure that conformity assessment procedures are correctly applied by all parties involved.

2010 saw improved cooperation between Member States through the meetings of the ADCO Group (Administrative Cooperation Group) which addressed matters such as the exchange and quality of information on market surveillance issues, with a view to ensuring better implementation of the Directives.

Evaluation

(a) Directives 97/23/EC and 2009/105/EC need to be aligned with Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products. A legislative proposal to this regard is scheduled for 2011.

(b) The repeal of Directive 67/548/EEC on the classification, labelling and packaging of dangerous substances on 1 June 2015 by Regulation (EC) No 1272/2008 on classification, labelling and packaging of mixtures (CLP Regulation) affects Directive 97/23/EC as the classification of pressure equipment is determined by reference to that Directive. Therefore, an alignment of Directive 97/23/EC is necessary to take into account (from 1 June 2015) the new classification of dangerous substances introduced by the CLP Regulation. This is expected to take place together with the alignment of this Directive with Decision No 768/2008/EC.

(c) Furthermore, as the CLP Regulation also sets out labelling requirements for aerosol dispensers, it is necessary to align Directive 75/324/EEC with these. At present, Directive 75/324/EEC contains references to Directive 67/548/EEC and takes up the flame symbol and some safety phrases from that Directive. However, the flame symbol has been changed and the safety phrases slightly modified. To avoid confusion and ensure legal clarity and consistency, it is therefore necessary to do an ATP for Directive 75/324/EEC. At the same time, some other technical adaptations are necessary, mainly concerning plastic aerosol dispensers and the maximum allowable pressure for aerosols using non-flammable propellants. A proposal is scheduled for 2011.

Summary

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[22] Directive 2008/47/EC amending, for the purposes of adapting to technical progress, Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers (OJ L 96, 9.4.2008, p.15).

The pressure equipment sector functions smoothly and there are no major problems. In general, Member States apply the *acquis* correctly and there are no particular problems with regard to the free circulation of pressure equipment, simple pressure vessels and aerosol dispensers. Infringement proceedings and issues relating to the correct implementation of the Directives will continue to be priority issues for the Commission services in the pressure sector in 2011, as well as the alignment of Directives 97/23/EC and 2009/105/EC with Decision No 768/2008/EC and the CLP Regulation.

1.6.3. ***Legal metrology***

Current position

General introduction

Legal metrology covers units of measurement and the metrological requirements that pre-packed products and measuring instruments must satisfy in order to be legally placed on the market and put into service.

The main directives relating to the design and manufacture of measuring instruments are Directive 2009/34/EC relating to common provisions for both measuring instruments and methods of metrological control (a recast of Directive 71/316/EEC), Directive 2009/23/EC (a codified version of Directive 90/384/EEC) on non-automatic weighing instruments and Directive 2004/22/EC on measuring instruments.

Units of measurement are harmonised at EU level by Directive 80/181/EEC on units of measurement which creates a harmonised regulatory framework throughout the EU with the aim of eliminating trade barriers between Member States.

Report of work done in 2010

- The transposition of Commission Directive 2007/13/EC of 7 March 2007[23] which modified Annex II to Directive 71/316/EEC to include drawings of the distinguishing letters of some Member States used for the EEC initial verification mark affixed on a measuring instrument and indicating that the latter conforms to EEC requirements is complete. Four remaining infringement proceedings for non-communication of national transposition measures were closed in 2010 by the Commission following communication of the measures.

- Directive 2007/45/EC of the Council and the European Parliament of 5 September 2007, laying down rules on nominal quantities for pre-packed products, repealing Council Directives 75/106/EEC and 80/232/EEC and amending Council Directive 76/211/EEC[24], aims to liberalise nominal quantities of pre-packaged products within the EU in line with ECJ jurisprudence, with the exemption of wine and spirits for which nominal quantities will continue to be defined at EU level. All Member States have now communicated their national transposition measures and the last opened infringement proceeding has been closed in 2010.

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[23] Commission Directive 2007/13/EC amending Annex II to Council Directive 71/316/EEC on the approximation of the laws of the Member States relating to common provisions for both measuring instruments and methods of metrological control (OJ L 73, 13.3.07, p.10).

[24] OJ L 247, 21.9.2007, p.17.

- Directive 80/181/EEC was modified by Directive 2009/3/EC of the European Parliament and of the Council of 11 March 2009, which. Member States should have transposed by 31 December 2009. Ten infringement cases relating to non communication of national transposition measures were closed following communication of the measures.

- Directive 2009/137/EC of 10 November 2009 amending Directive 2004/22/EC in respect of the exploitation of the maximum permissible errors, as regards the instrument-specific annexes MI-001 to MI-005 should have been transposed by Member States by 1 December 2010. At the end of 2010, 18 Member States had communicated national transposition measures.

Evaluation

(a) Discussions in Council and in the European Parliament continued on a Commission legislative proposal (COM(2008)801) for a Directive of the European Parliament and of the Council repealing 8 old metrology Directives[25] which were adopted under old framework Directive 71/316/EEC and co-existed with national provisions. Technical progress and innovation with regard to the measuring instruments covered by these Directives was reflected either by the voluntary application of international and European standards or by the application of national provisions implementing such new specifications. It was felt that free movement of these products within the internal market would be ensured by Articles 34 to 36 TFEU and the mutual recognition principle. However, the new legislative proposal explains that the existing Directive on Tyre Pressure Gauges for Motor Vehicles (Directive 86/217/EEC) is virtually obsolete technologically. In the absence of an up-to-date international standard, a standardisation mandate in the field of type pressure gauges for motor vehicles and tyre pressure management systems (measuring instruments) has been issued to the European Standardisation Organisations. The European Parliament adopted the proposal on first reading on 18 December 2010.

(b) A report on the implementation of Directive 2004/22/EC is being prepared in accordance with Article 25 of the Directive (the revision clause) and will contain inter alia, conclusions as to whether the Directive needs to be revised.

Evaluation results

(1) Priorities

The transposition of the Directives will continue to be the priority for 2011.

(2) Planned action (2011 and beyond)

- Following up cases against the two remaining Member States (Portugal and Austria) who have not yet communication transposition measures for Directive 2009/3/EC, will be a priority in 2011.

[25] The Directives that are proposed to be repealed are Directives 71/317/EEC, 71/347/EEC, 71/349/EEC, 74/148/EEC, 75/33/EEC, 76/765/EEC, 76/766/EEC and 86/217/EEC.

- Following up notifications of transposition measures for Directive 2009/137/EC and launching infringement proceedings where such measures have not been communicated will be a priority in 2011.

Summary

The measuring instruments sector is operating smoothly and presents no major problems with regard to the free circulation of measuring instruments. In general, Member States apply the *acquis* properly. In 2011 priority will be given to the correct implementation of the Directives and to the follow-up of remaining transposition problems.

1.7. Construction products

Current position

General introduction

Directive 89/106/EEC on construction products ("the CPD") has not been amended recently, which has allowed steady development of its implementation within the Member States.

Report of work done in 2010

Harmonisation through European standards, published in the OJ has proceeded and conditions for enterprises operating in this sector, whether as manufacturers or users of construction products, have seen stable progress during 2010. However, certain fundamental problems remain unresolved, resulting in different transpositions among the Member States and consequent inefficiencies in the harmonisation.

The revision of the CPD proceeded during 2010. The Council reached political agreement on its position in May and formally adopted the first reading position in September. The second reading agreement on the text was reached in December. The final adoption of the CPR is thus expected during the spring of 2011 and it should be fully applicable from mid-2013 onwards. In spite of certain delays in adoption and, consequently, entry into force of the CPR, the outcome will be a simplified and clarified regulatory structure for the future.

Progress with infringement proceedings has been patchy, complicated by the fact that the new Regulation is designed to address certain interpretative ambiguities with the CPD which are often at the centre of the complaints leading to infringements. Nevertheless, during 2010, one longstanding case against the UK was closed and another case against France was opened.

Evaluation results

Accelerating progress in the remaining open infringement cases under the CPD is a priority for 2011.

Summary

Pending the introduction of the CPR, legal uncertainties relating to the interpretation of the CPD will remain, making enforcement difficult. However, the intention is to continue to reduce the number of open infringement cases and to deal with any new cases more swiftly and efficiently than before. Closer contacts with Member States, including in the EU Pilot,

will undoubtedly be of assistance in reaching these objectives.

1.8. Textiles/clothing, footwear and wood

Current position

General introduction

Textiles and clothing are regulated by recast Directive 2008/121/EC on textile names, adopted on 14 January 2009 and repealing Directive 96/74/EC. It incorporates Commission Directives 97/37/EC, 2004/34/EC, 2006/3/EC and 2007/3/EC which amended Directive 96/74/EC. Directive 2008/121/EC has been amended by Commission Directive 2009/121/EC.

Other legislation in the textiles field is Directive 96/73/EC (adapted to technical progress by Commission Directives 2006/2/EC, 2007/4/EC and 2009/122/EC) and Directive 73/44/EEC specifying testing methods for the sampling and analysis of fibre mixtures in order to determine the conformity of information given on a label in accordance with Directive 96/74/EC. Due to the technical nature of the textiles directives, the Committee for textile names and labelling (composed of experts from Member States and other interested parties) assists the Commission in adapting them to technical progress.

In the ***footwear*** area, legislation (Directive 94/11/EC on the labelling of materials used in consumer footwear) is well-established and stable. Unlike the clothing and textile area, it is not necessary to amend this legislation often in the light of technical developments. There is no committee work in this area.

In the ***wood*** sector, there is no legislation at EU level.

Report of work done in 2010

In the textiles and clothing sector, eight letters of formal notice were sent to four Member States in November 2010 in relation to the non-communication of national measures transposing Directives 2009/121/EC and 2009/122/EC.

The Commission Proposal for a Regulation on textile names and related labelling of textile products [COM(2009) 31 final], adopted on 30 January 2009, followed the ordinary legislation procedure in 2010.

The European Economic and Social Committee having adopted a favourable opinion at the end of 2009, the European Parliament adopted its first reading opinion on 18 May 2010 and the Council adopted its common position on 6 December 2010.

Evaluation results

The major legislative work in the textiles sector will be the continuation of the work on the proposal for a Regulation on textile names and related labelling and the monitoring of its implementation and application once in force.

The infringement cases opened for the non-communication of national measures transposing Directives 2009/121/EC and 2009/122/EC will be followed-up in 2011.

Summary

The *acquis* is stable and poses few enforcement difficulties.

Links to legislation

http://ec.europa.eu/enterprise/sectors/textiles/single-market/textiles-names-legislation/index_en.htm

1.9. Toys

Current position

General introduction

The new toy safety directive, Directive 2009/48/EC, came into force on 20 July 2009. Member States had to adopt and publish implementing provisions by 20 January 2011 and must apply them from 20 July 2011. The later date of 20 July 2013 is laid down for the application of chemical requirements.

The objective of the new Directive is to ensure a high level of safety of toys, ensuring the health and safety of children, whilst guaranteeing the functioning of the internal market by setting harmonised safety requirements for toys and minimum requirements for market surveillance. The Directive applies to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age.

The main changes to the current legal framework concern: enhanced requirements, especially in relation to the use of chemicals in toys, mandatory safety assessment prior to the marketing of toys and stringent obligations for economic operators.

In July 2009, the Commission issued a mandate to CEN (European Committee for Standardisation) and CENELEC (European Committee for Electro-technical Standardisation) to review the existing harmonised standards and adapt them to the requirements of the new directive.

Report of work done in 2010

The process has still been under way in 2010 and revised standards should be available before Member States must begin applying the new provisions.

General and specific guidance documents aimed at facilitating the application of the new directive are currently being prepared and are available on the Commission website.

1.10. Food industry

Current position

General introduction

EU legislation governing the trade regime for non-Annex I goods (commonly referred to as processed agricultural products) devolves primarily from Council Regulation (EC) No 1216/2009 of 30 November 2009. This Regulation provides a general framework for trade

arrangements applicable to certain goods resulting from the processing of agricultural products.

It can be divided into trade arrangements governing imports from third countries and rules governing the payments of export refunds on exports to third countries. :

1. Trade arrangements on imports cover preferential import arrangements including TRQs, methods of analysis and special Inward Processing arrangements.
2. Rules governing the payment of export refunds on exports cover the determination of quantities, refund rates, methods of analysis, statistics and special rules for pasta.

The specific rules governing trade in processed agricultural products are established in close cooperation with the Management Committee on processed agricultural products in which all Member States are represented.

(2) Report of work done in 2010

a) Replacement of Regulation (EC) No 1043/2005 on the implementation of Council Regulation (EC) No 1216/2009 as regards the system of granting export refunds for certain agricultural products exported in the form of goods not covered by Annex I to the Treaty, and the criteria for fixing the amount of such refunds.

b) Amendment of Regulations (EC) No 900/2008 and 904/2008 on the analysis of imported and exported processed agricultural products respectively in order to replace the analysis method for starch in imported and exported.

c) Screening of the EU *acquis* and its simplification.

In the context of the ongoing simplification of the *acquis* and the adaptation of the current *acquis* to the Lisbon Treaty, a comprehensive screening of the *acquis* in relation to processed agricultural products was undertaken and identified 3 Council acts and 59 Commission acts that are no longer relevant and can be removed from the EU *acquis*.

Evaluation results

(1) Priorities

The ongoing simplification of the *acquis* and the adaptation of the EU *acquis* in the non-Annex I sector to the Lisbon Treaty are the two main priorities. As regards the non-Annex I sector, the priority will be to implement the important changes introduced by the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU) and in particular the extension of the ordinary legislative procedure to the trade arrangements applicable to processed agricultural products and the adoption of new rules on the Commission's delegated and implementing powers. The TFEU contains two provisions (Articles 290 and 291 TFUE) which entail modification of existing comitology procedures, which govern decisions in the area of trade in processed agricultural products.

(2) Planned action (2011 and beyond)

a) Ongoing simplification of the *acquis*

In 2011 as a result of the screening exercise:

- Two Council acts will be formally repealed by a Council act or by an act of the Council and the Parliament, as appropriate, while 43 Commission acts will be declared obsolete by the Commission.

- In addition one Council act and 16 Commission acts modifying other acts already repealed or to be declared obsolete will be withdrawn from the EU *acquis*.

b) Adaptation of the EU *acquis* in the non-Annex I sector to the Lisbon Treaty

Pursuant to the adoption of the Commission Communication of 09/12/2009 on the Implementation of Article 290 TFUE (COM (2009) 673 final), the Commission will progressively align non-Annex I legislation with the new mechanisms of delegated acts and implementing acts.

1.11. Cultural goods

In 2010, the *acquis* in this area remained stable. It consists of Directive 93/7/EEC on the return of cultural objects unlawfully removed from the territory of a Member State, as modified by Directives 96/100/EC and 2001/38/EC.

In accordance with the conclusions of the third report reviewing the application of Directive 93/7/EEC by the Member States (2009), the "Return of cultural goods" working group was created, composed of national authorities responsible for the Directive. During its mandate, the working group evaluated the application of the Directive, identified the main problems and suggested modifications with a view to the possible revision of the Directive.

The responsible service intends to proceed with a revision of Directive 93/7/EEC in 2012.

1.12. Weapons

The report on placing on the market of replica firearms, one of the tasks given to the Commission under the Directive has been prepared (COM/2010/404). The second meeting of the Contact Group of national experts on Firearms, set up by the directive, took place on 8 March 2010, allowing a useful exchange of information to take place on the implementation of the Directive.

Enforcement action is ongoing in relation to several infringement proceedings for non-communication of national transposition measures, due on 28 July 2010.

1.13. Product liability

Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products is a consolidated tool that strikes a fair balance between citizens and producers, assuring citizens of the safety of products put into circulation in the internal market. In 2010, the Commission's services began the preparation of the fourth report on the Directive by sending a questionnaire to Member States and to the members of the advisory groups on liability for defective products.

The Commission plans to submit the fourth report in 2011. The report will examine how the

27 EU Member States implemented the Directive between 2006 and 2010.

1.14. Defence goods

A working group of Member States' officials met several times to discuss common guidelines on the certification of defence-related undertakings. The discussions of this group led to the adoption on 11 January 2011 of Commission Recommendation 2011/24/EC on the certification of defence undertakings under Article 9 of Directive 2009/43/EC of the European Parliament and of the Council simplifying terms and conditions of transfers of defence-related products within the EU (OJ L11 of 15.1.2011, p. 62).

1.15. Non-harmonised area

Current position

General introduction

Articles 34-36 TFEU ensure the easy cross-border exchange of goods within the Internal Market in areas that are not subject to harmonisation by EU legislation. The Commission monitors the correct application of these rules and related Regulations and opens infringement proceedings against Member States when necessary.

Report of work done in 2010

In 2010, the Commission managed a total of 52 infringement proceedings in the various non-harmonised fields covered by Article 34-36 TFEU. This is a decline compared with the figures of previous years: 67 in 2009 and 73 in 2008.

The main areas of concern remain national rules on the registration of motor vehicles, obstacles to the free movement of pharmaceutical products and medical devices (in particular, parallel imports), obstacles to the free movement of food supplements and problems with customs controls and the transportation of goods.

In 2010, several infringement cases were closed after the Commission and the Member States found solutions to the problems complained of:

- Belgium amended its legislation in 2010 concerning the importation, exportation and transit of certain species of wild birds, in order to provide for the mutual recognition of markings permitted by other Member States.

- Poland modified its legislation on the protection of antiquities of more than 55 years of age, which required the production of a certificate showing that the antiquity in question should not be subject to a previous authorisation procedure.

- Spain modified its legislation to remove obstacles to the importation and marketing of structural concrete.

- New regulations entered into force in the UK in April 2010 increasing the maximum width for certain trailers from 2.3 metres to 2.55.

The Court of Justice of the European Union delivered a judgment on 9 December 2010 in a

preliminary ruling in case C-421/09 Human plasma, which concerned the free movement of goods. The Court was asked about the compatibility with Articles 34-36 TFEU of national rules prohibiting the importation of blood products provided from donations which were not entirely unpaid. The Court held that "Article 34 TFEU, read in conjunction with Article 36 TFEU, must be interpreted as precluding national legislation which provides that the importation of blood or blood components from another Member State is permitted only on the condition, which is also applicable to national products, that the donations of blood on which those products are based were made not only without any payment being made to the donors but also without any reimbursement of the costs incurred by them in connection with those donations".

The hearing in case C-462/09 Stichting de Thuiskopie took place on 15 December 2010. This case concerns several infringement cases concerning copyright levies and the free movement of goods. In a case touching upon copyright levies (C-467/08 SGAE), a Spanish court had asked the Court of Justice for guidance on the interpretation of the Copyright Directive 2001/29/EC in relation to Spanish requirements on copyright levies. The judgment of the Court of 21 October 2010 clarified several points relating to a number of infringement cases on copyright levies, declaring that they should be analyzed in the context of Directive 2001/29/EC.

The Commission continued to look for pro-active solutions outside or in parallel with infringement proceedings under Article 258 TFEU through the SOLVIT problem-solving network and the preventive mechanism of Directive 98/34/EC (whereby Member States are obliged to notify new national technical rules to the Commission at the draft stage).

Regulation (EC) 764/2008 (the “Mutual Recognition Regulation”) completed a full year of application in 2010 following its entry into force on 13 May 2009. The Regulation sets out procedural requirements for Member States that refuse to apply mutual recognition. It defines the rights and obligations of national authorities on the one hand and, on the other, enterprises wishing to sell in one Member State products lawfully marketed in another, when the competent authorities intend to take restrictive measures in relation to the product. Member States must notify to the Commission decisions affecting the marketing of products already lawfully marketed in another Member State. During 2010, a total of 800 notifications were received from the Member States.

The first annual reports of national authorities on the application of the Regulation were analysed and discussed at the 2nd meeting of the Advisory Committee on Mutual Recognition held on 19 November 2010. To date, all Member States have submitted reports, a necessary step in preparing the evaluation of the Regulation that is due to be presented by 13 May 2012.

In 2010, the area of free movement of goods was the subject of 9 petitions to the European Parliament, and 23 parliamentary questions.

Evaluation

Articles 34-36 TFEU remain the essential legal basis for tackling obstacles to trade among Member States. As these provisions apply only to the non-harmonised area, their ambit fluctuates in accordance with developments in secondary EU legislation.

In 2010, the trend observed in previous years towards a decrease in the number of open infringements against Member States continued. The success rate for problem-

solving in EU Pilot contributed significantly to this reduction for those Member States which participated in this system. Other reasons are a determined effort to address a backlog of old cases and the pursuit, when possible, of alternative solutions through dialogue and cooperation with the Member States outside the infringement procedure. Nevertheless, the volume of complaints and enquiries received show that there is still a significant degree of non-compliance with the principle of the free movement of goods and a lack of understanding of the concept of mutual recognition, resulting in practical barriers to cross-border trade in goods.

As regards mutual recognition, Regulation (EC) No 764/2008 is helping to raise awareness of the principle both among economic operators and national administrations in the Member States.

Evaluation results

(1) Priorities

In the light of positive results observed so far, the Commission is encouraged to engage in further dialogue with Member States with a view to reaching quicker solutions to free movement of goods issues.

The updated version of the 'Guide to the application of Treaty provisions governing the free movement of goods' was published in 2010 and distributed to a large external audience. The Guide has become a useful tool to explain the fundamental principle of free movement of goods and the latest interpretations handed down by the Court of Justice of the European Union.

Summary

The continued arrival at the Commission of complaints and requests for information confirms that monitoring the application of the free movement of goods principle in the non harmonised area remains an important task. The Treaty and related regulations are adequate tools to ensure that the fundamental freedom of free movement of goods is safeguarded. While any breach of this fundamental freedom must be pursued, priorities will continue to reflect any grouping of cases (for example the registration of vehicles) and areas having the greatest impact on intra-EU trade.

Legislation

Treaty provisions:
http://ec.europa.eu/enterprise/policies/single-market-goods/files/treaties/tfeu_en.pdf#page=15

Regulation Mutual recognition regulation:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0021:0029:en:PDF

Guide to the application of Treaty provisions governing the free movement of goods:
http://ec.europa.eu/enterprise/policies/single-market-goods/files/goods/docs/art34-36/new_guide_en.pdf

1.16. Preventive rules of Directive 98/34/EC

Important preventive work continued under Directive 98/34/EC with advice and guidance

provided by the Commission and Member States on over 800 national draft technical regulations of the 27 Member States, the EFTA countries and Turkey concerning non-harmonised products and information society services. The Committee on Standards and Technical Regulations established by the Directive met twice during 2010 to discuss its functioning and a working group composed of representatives of Member States met three times to evaluate the notification procedure and consider whether any adjustments or amendments should be made.

2. COMPETITION

2.1. Current Position

(1) General Introduction

During the course of 2010 Directorate-General for Competition dealt with around 30 active infringement cases, with 23 remaining at the end of the year. Although these cases obviously follow the standard infringement procedure (under Article 258 TFEU), cases in this sector differ from other sectors in that many of these cases concern the infringement of Commission decisions, rather than Directives or Regulations. Where the decision in question concerns the non-recovery of State aids, cases are based on Article 260 TFEU. These proceedings, which account for ca. 25% of infringement cases in competition field, are initiated where a Member State does not comply with a Commission decision requiring the recovery of incompatible State aid. They therefore serve the purpose of ensuring that an infringement of the competition rules by a Member State is remedied, and that the distortion of competition caused by the incompatible aid is removed. The procedure in these cases differs to some extent from the standard infringement procedure. In a first step, the Commission may refer the Member State directly to the Court under Article 108(2) TFEU, in derogation of Article 258 TFEU. If the Member State still fails to recover the aid, although the Court has held that this failure constitutes an infringement, the Commission may refer the Member State to the Court for the second time, this time pursuant to Article 260 TFEU. This Annual Report only covers the last stage of the recovery proceedings, *i.e.* from the sending of the Letter of Formal Notice under Article 260 TFEU onwards.

The majority of Article 258 cases have their origin in a complaint submitted by undertakings or citizens that are based on a breach of Article 106(1) TFEU in conjunction with Articles 101 and/or 102 TFEU by a Member State, with the remainder cases concerning the incorrect transposition of directives or non communication of implementing measures.

The relatively low number of infringement cases dealt with could be explained by the fact that the *acquis* in this sector has been very stable, with no new Directives or implementation deadlines in recent years. The two remaining cases on the implementation of the Financial Transparency Directive in the field of State aid (80/723/EEC, as amended), against the UK and Belgium, were referred to the Court. The current emphasis is on the correct application of the Directive on Competition in the Markets for Electronic Communications and Services (2002/77/EC)[26].

[26] OJ L 249, 17.9.2002, p. 21–26.

As regards complaints in 2010, Directorate-General for Competition was the lead service for 94 files. However, 58 of these are part of a group complaint concerning copyright collecting societies in Spain, and should therefore not be counted individually. It was decided to deal with all these complaints jointly by publishing a full reply in the Official Journal[27]. The remaining 36 cases concern a broad range of issues and sectors.

(2) Report of Work Done in 2010

The application of the competition rules plays an important role in sectors which have been recently liberalised or are in the process of liberalisation, such as energy or postal services, as well as in the media and electronic communication sectors. This is reflected in the infringement work carried out in 2010.

Postal Sector

The infringement proceedings under Article 258 TFEU against the Slovak Republic for the non-implementation of the Commission Decision of 7 October 2008 remained open[28]. Following the issue of a Reasoned Opinion on 29 October 2009[29], the Slovak authorities remained in discussions with the Commission on the measures to remedy the infringement as well as the proper implementation of the Third Postal Directive. The aim is to fully liberalize the Slovak postal market as of January 2012, *i.e.* one year ahead of the deadline imposed by the postal directive. The Commission closely follows the developments on the draft liberalisation law.

Energy Sector

On 31 January 2008, the European Commission sent Spain a Letter of Formal Notice for failure to comply with a Commission Decision of 5 December 2007, finding that Spain had breached Article 21 of the Merger Regulation[30] by subjecting the approval decision of the acquisition of control over Endesa by Enel and Acciona to a number of conditions, thereby unduly interfering with the Commission's exclusive competence to decide on a concentration with Community dimension. By withdrawing the contested conditions, the Commission decided to close the infringement procedures against Spain in relation to Art. 21 of the Merger Regulation on 17 March 2010. With this decision, the Spanish authorities finally complied with the Commission Decisions which considered illegal the conditions imposed by Spain on the E.ON/Endesa and the Enel/Acciona/Endesa mergers.

Electronic Communications Sector

The introduction of digital terrestrial television broadcasting (DTT) is freeing substantial spectrum resources (the 'digital dividend') that can be used for authorizing further digital television channels. Moreover the digital dividend represents a unique opportunity for the re-use of a premium part of the radio frequency spectrum for new electronic communications services such as broadband wireless telecommunication.

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27 OJ C353, 28.12.2010 p. 17.
28 OJ C 322, 17.12.2008, p. 10–11.
29 IP/09/1632.
30 OJ 2004, L 24/1.

The DTT platform provides television services to over 75 million households across Europe and is in many EU Member States the pre-dominant television reception platform. The DTT platform is the only platform throughout Europe that guarantees nearly all viewers access to a broad range of both public service and commercial television services.

In the context of the transition to digital broadcasting and the availability of spectrum for new electronic communications services, several complaints have been received against Member States that have assigned parts of the "digital dividend" to incumbent broadcasters under procedures which do not appear, *prima facie*, to be based on transparent, objective and non-discriminatory criteria. The broadcasting spectrum concerned is assigned for periods of 15 to 20 years. Therefore, unless properly monitored, the current procedures could fundamentally distort the competitive structure of the EU media markets over the longer term.

In September 2010, under the ongoing infringement procedure concerning the Italian broadcasting legislation, the Italian Authority for Communications put forward a draft laying down criteria and rules aimed at ensuring that a certain number of frequencies resulting from the "digital dividend" are assigned to newcomers and smaller existing companies. The tender for such frequencies should be launched in 2011.

In addition to the ongoing infringement procedure against Italy, the Commission also investigated in 2010, as a priority, several complaints under the Competition Directive relating to the spectrum assignment procedures in other Member States.

In this context, the Commission sent in November 2010 a letter of formal notice to the French authorities regarding the 2007 French law granting to existing analogue TV broadcasters the possibility to obtain an additional national TV channel in the digital switchover. In the absence of convincing evidence that such possibility was granted to TV broadcasters based on objective, transparent, non-discriminatory and proportionate criteria, the Commission considered the French rules to be in breach of EU law.

Taking into account the importance of ensuring undistorted competition in the framework of the digital switchover, the Commission will continue to monitor the assignment procedures for broadcasting spectrum as well as for spectrum for electronic communications services other than, and in addition to, broadcasting services as a priority in the course of 2011.

Article 260 TFEU Cases

On 31 January 2008, the Commission issued a Reasoned Opinion against Italy for failure to comply with a judgment of the Court[31], condemning Italy for non-execution of the Commission's recovery decision of 11 May 1999 regarding employment aid. As no sufficient progress was made in the recovery of incompatible aid, on 25 June 2009, the Commission decided to refer Italy for the second time to the Court and to propose the imposition of financial penalties against Italy (Article 260 TFEU). The written phase of the Court proceedings was concluded by the end of 2010.

In a similar case, which concerns the non-recovery of aid granted to publicly-owned utility companies ("municipalizzate"), the Commission sent a Reasoned Opinion to Italy on 1 February 2008. This was based on the fact that the Court had condemned Italy on 1 June 2006

[31] C-99/02, Commission v Italy.

for failure to comply with the obligations stemming from the Commission's recovery decision of 5 June 2002[32]. Following the judgment, Italy had still not managed to implement the recovery successfully. Considering these circumstances, on 23 October 2010 the Commission took the decision to refer the matter to the Court of Justice for the second time with financial penalties (Article 260 TFEU).

In a first series of six fiscal measures implemented in the Basque provinces, more than 9 years after the adoption of the Decisions and 4 years after the Court judgment, Spain had still not completed the full recovery of the aid. A Reasoned Opinion against Spain had already been issued on 26 June 2008 (for failure to comply with the Court's judgment of 14 December 2006). On 24 November 2010, the Commission therefore decided to refer the matter to the Court of Justice for the second time with financial penalties (Article 260 TFEU).

On 20 November 2009, the Commission sent a Letter of Formal Notice pursuant to Article 260 TFEU to Spain for failure to comply with a judgment of the Court of July 2002[33] condemning Spain for non-execution of the Commission's recovery Decision of 20 December 1989 as regards the four companies of the Magefesa Group. As the incompatible aid was not recovered, on 30 September 2010 the Commission decided to refer Spain to the Court for the second time with financial penalties (Article 260 TFEU). The Court action was filed on 22 December 2010.

On 13 November 2008 the Court of Justice condemned France for failure to implement within the prescribed period the Commission's recovery decision of 16 December 2003 on the aid scheme implemented by France for the takeover of firms in difficulty (Article 44septies CGI). Since following that judgment France still did not implement the recovery decision, the Commission adopted on 7 May 2010 a letter of formal notice against France for failure to comply with a judgment of the Court under Article 260 TFEU.

It is worth mentioning that in the area of recovery of incompatible state aid, the Commission has made significant progress with respect to the execution of recovery decisions by Member States. The amount of illegal and incompatible aid recovered has increased from EUR 2.3 billion in December 2004 to EUR 10.9 billion at 31 December 2010 (*i.e.* 86% of the total amount to be recovered). Accordingly, the percentage of illegal and incompatible aid still to be recovered at the end of 2010 has fallen from 75% to 14%. This is due to the efficient enforcement of recovery decisions by the Commission prompting Member States to recover incompatible aid from the beneficiaries.

2.2. Evaluation Based on the Current Situation

Against the background of the stable *acquis* in the competition law field and the relatively constant if not decreasing number of pending infringement cases, the situation can be described as stable and relatively satisfactory on the whole, not indicating any particular problems that would require urgent attention or the modification of priorities. Likewise, there are neither new measures due to be adopted in the near future, nor relevant implementation plans, guidelines, expert group meetings, transposition workshops or management networks.

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32 C-207/05, Commission v Italy.

33 Case C-499/99, Commission v Spain.

In the area of state aids, infringement cases will continue to be pursued on the basis of Article 260 TFEU to recover all incompatible state aid. This is necessary to ensure a level playing field between competitors and a market of undistorted competition – a requirement which becomes all the more important in the current economic circumstances where companies struggle to stay on the market even in conditions of undistorted competition. As already explained before, a very good track record has been achieved in the recovery field. The enforcement action can therefore focus on those instances where Member States have not yet shown the desired results in their recovery efforts, mainly because of national legislation creating obstacles to effective recovery.

The priorities for 2010 as set out in the 27th Annual Report – the improvement of the competitive conditions in the liberalised markets – have been fully taken up in the infringement work. There has been significant progress in some key infringement procedures in the energy and postal sectors.

In the field of electronic communications and the correct implementation of the Directive on Competition in the Markets for Electronic Communications and Services (2002/77/EC), efforts are continued to ensure effective competition, for example by actively monitoring changes to the relevant provisions in the broadcasting market of Member States.

2.3. Evaluation Results - Priorities and Planned Action

In 2011, focus will continue on sectors that have been recently liberalised or are in the process of liberalisation, such as energy or postal services, as well as the media sector.

Emphasis will also be placed on the correct application of the Directive on Competition in the Markets for Electronic Communications and Services.

Finally, long standing non-recovery cases will continue to be referred to the Court pursuant to Article 260 TFEU with a view to imposing a lump sum and daily penalty payments on the Member State concerned, to ensure effective recovery of the incompatible aid granted.

3. EMPLOYMENT, SOCIAL AFFAIRS AND INCLUSION

3.1. Free movement of workers and coordination of social security systems

3.1.1. Current Position

3.1.1.1. Introduction

In the field of free movement of workers and coordination of social security systems, the Commission deals with problems linked to incorrect application of the relevant provisions of the Treaty on the functioning of the European Union[34] and of secondary law existing in that area. Over the years, problems have been brought to the attention of the Commission through individual complaints, petitions of citizens to the European Parliament and Parliamentary questions which has led the Commission to increase its recourse to problem-solving mechanisms and it intensifies communication to prevent problems.

[34] Articles 45 and 48 TFEU.

3.1.1.2. Report on progress made in 2010 regarding free movement of workers

In 2010, the number of active long-lasting infringement cases in the field of free movement of workers was significantly reduced (5 out of 8 cases older than 3 years that were still open at the beginning of 2010 were closed during the year). Along the lines set out by the Commission in 2007, priority was given to the handling of the two procedures under Article 260 TFEU that were ongoing and contacts with the two Member States concerned were intensified.

The major issues dealt with in 2010 were the following:

The Commission carried out in the past years a systematic review of the legislation of all Member States following two preliminary judgments of the CJ regarding the nationality condition for posts of master and chief mate of ships where the prerogatives of public authority are exercised by private sector workers. Out of 20 procedures opened on this issue in 2004, 2 were still ongoing in 2010. After the Court of Justice confirmed its previous judgments also against Spain (in 2008)[35] and Greece (in 2009)[36] the Commission started the procedure to ensure compliance with those rulings (Article 260 TFEU). The case against Spain was closed in 2010 as the Spanish authorities adopted new rules that in the opinion of the Commission were in conformity with EU law on free movement of workers. As regards the case against Greece, the Greek authorities announced a reform of the legislation, which is being closely monitored by the Commission.

With a view to ensuring the correct transposition of the provisions of Directive 2004/38/EC, the Commission services kept monitoring the relevant national legislation and organised bilateral contacts with Member States. In the situation of economic crisis, more and more replies had to be provided concerning the rights of jobseekers and people retaining the status of a worker and their family members – e.g. questions on how long they are entitled to stay in the host Member State, or whether they have access to social benefits and social assistance.

A recurring topic of queries was again the application of transitional arrangements for workers from EU8 and EU2. There were requests for information and complaints about the existence of restrictions as such (by citizens) and calls to end them (parliamentary questions). On this basis, the Commission services identified an incorrect application of transitional arrangements concerning eligibility for benefits that is linked to a wider problem of compatibility with EU law in the UK legislation. Employment in the public sector represents in many Member States an important part of the labour market. Therefore, the action of the Commission in this field has a significant effect on the migrant workers' rights; in particular, there is a lot of labour mobility in the public teaching and health sectors.

The Commission dealt in particular with the following issues:

- Abolition of nationality conditions for access to posts in the public sector in line with the jurisprudence of the Court on Article 45 (4) EC. In 2010, two infringement procedures against Luxembourg were closed.

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35 C-94/08 Commission v. Spain, judgment of 20.11.2008.

36 C-460/08 Commission v. Greece, judgment of 10.12.2009.

- The follow-up of the Burbaud-judgment[37] led to the opening of the internal recruitment competition for many posts in the French public sector to fully qualified migrant workers with a certain length of work experience. The infringement against France regarding in particular the teaching sector was closed in 2010 following the adoption of the appropriate administrative rules.

- The issue of taking into account periods of employment acquired in another Member State for the purposes of access to the public sector and for determining working conditions (e.g. salary, grade) in the same way when comparable experience is acquired in the host Member State.

- Other complaints regarding the public sector concerned: discriminatory conditions of access to posts and discriminatory working conditions (unrelated to the issue of recognition of professional experience), absence of equal treatment in relation to the taking into account of foreign diplomas for the purpose of access to the public sector (e.g. additional points awarded in a recruitment procedure) and for determining working conditions, disproportionate language requirements in access to posts.

Sport: for many years the Commission has been dealing with the issues of EU law related to free movement of professional sportsmen and sportswomen. On the basis of several queries and complaints, the Commission services focused in particular on the issue of the quotas on nationality applied in professional sport.

Residence conditions for access to employment and access to social advantages were also the subject of queries and complaints in 2010. A case concerning the access to social advantages in the Netherlands (study grants for children of migrant workers) was still pending at the Court[38]. New complaints on this issue were received in 2010.

Regarding the issue of equal treatment of third country nationals, citizens from countries with which the European Union has signed an international agreement containing an equal treatment clause, the Commission ensured the follow-up of the case-law of the Court of Justice, namely in the cases Pokrzeptowicz-Meyer[39], Kolpak[40], and Simutenkov[41], where the Court stated that non-discrimination as regards conditions of employment and pay has direct effect and workers covered by such a clause in an agreement, once legally employed in a Member State, have a right to equal treatment as regards conditions of employment. An infringement against the United Kingdom on the discrimination of EU but also non-EU seafarers covered by such an equal treatment clause in international agreements as regards pay was ongoing in 2010.

Citizens' complaints concerned also the violation of their rights as migrant workers by private employers such as discriminatory treatment in access to work or working conditions. However, as in this case the Commission cannot intervene, it can only limit itself to provide the information about the migrant's rights and advise them to seek solutions through means

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37 C-285/01, judgment of 9.09.2003.
38 C-542/09.
39 C-162/00, ECR 2002 I-1049.
40 C-438/00.
41 C-265/03.

available at the national level. The Commission notes however that enforcement of these rights at a national level is often problematic.

3.1.1.3. Report on progress made in 2010 in the field of social security coordination

In 2010, the Commission services have received many queries and complaints concerning the application of Regulation (EEC) No 1408/71 and its implementing Regulation, as well as Regulation (EC) No 883/2004 and its implementing Regulation, which entered into force on 1 May 2010. Most queries and complaints concerned social security rights of migrant workers, e.g. which legislation applies to them, their entitlement to sickness insurance benefits and family benefits, how to apply for a pension. Complaints concerned also residence clauses in national legislation for various kind of social security benefits, incorrect application of the principle of aggregation of insurance periods, cumbersome or incorrect administration of cases involving an EU element.

In the area of applicable legislation, the queries mainly concerned persons who took up a new activity in another Member State and who inquired which legislation would be applicable according to the new rules on coordination of social security systems. The Practical Guide on applicable legislation has been developed by the Commission, in cooperation with the Member States, to be of assistance to citizens in the area of posting and activities in two or more Member States.

Major issues concerning sickness insurance benefits in 2010 were the following.

As in the previous years, the Commission services received many queries about the European Health Insurance Card (EHIC), namely how to apply for it or how to use it. As regards the procedures for issuing of the EHIC, at this stage, there is no common EU approach and it is up to the issuing Member State to determine the rules for issuing the EHIC. Similarly, institutions of the Member State determine the period of validity of the cards they issue. The Member States agreed that the period of validity of the EHIC should take into account the presumed duration of the insured person's entitlement. Currently, there is no automatic mechanism to verify the validity of entitlement of a person. Moreover, some Member States issue cards with very limited validity period. The Commission is aware of the effects of such short validity periods of the EHIC for the persons concerned. An ongoing discussion is taking place within the Administrative Commission for the coordination of social security systems and the possible scenarios for addressing this limitation will be examined within the framework of the system of the Electronic Exchange of Social Security Information (EESSI), which is currently under development. In addition, the Commission will further investigate reported cases of refusal of valid EHIC by the medical professionals, cases of disproportionate administrative procedures for issuing an EHIC and cases of non-acceptance of EHIC as a sufficient document for providing access of insured persons staying abroad to necessary healthcare and medicine under the same conditions as to insured nationals.

In the area of long-term care cash benefits, coordinated as sickness cash benefits (therefore exportable), the Commission has pursued an infringement procedure against the UK concerning export of benefits for disabled persons. In 2009, more than 50 persons contacted the Commission services to signal the application of a so called "past presence test" which in most cases prevents the exportability of these benefits from the UK. The "past presence test" is also subject of a preliminary ruling in front of the Court of Justice of the EU (C-503/09), for which a judgment will be delivered in the course of 2011.

Another sensitive issue dealt with by the Commission concerns the rules of access for EU nationals to the French universal sickness benefits scheme (Couverture Maladie Universelle – CMU). The rules for admission require the person to have "regular and stable residence" in France. The Commission has been in active contact with the French authorities to find a suitable solution, which would be in line with the principle of equal treatment.

As regards the export of pensions, the Commission received various complaints about the payment of pensions into the beneficiary's bank account in his or her Member State of residence. It seems that certain Member States have problems with such payments in another Member State. The SEPA (Single Euro Payment Area) should be the answer to this problem as regards countries in the Eurozone. The Commission opened an infringement procedure against Belgium, where national legislation does not allow the payment of the pension directly to an account without having the foreign bank guarantee that it will repay the amount, should payments have been wrongly made. An infringement procedure was opened against Greece, where difficulties were reported when pensions are exported, such as the obligation to open a bank account at the Greek national Bank and to be obliged to pay higher bank fees for payments outside Greece than within the country, which is in breach of EU social security coordination rules and EU payment rules (Regulation (EC) No 924/2009).

With regard to unemployment benefits, in view of the economic recession and the rise of unemployment rates, the Commission services received a large number of queries concerning the right of migrant workers to unemployment benefits under Union law. Migrant workers were in particular asking in which State they can claim unemployment benefits, method of calculation of the benefit's rate, special regime for frontier workers and the possibility to have benefits exported in case they were interested to look for work in other Member States. Some of the migrants complained about the cumbersome and time-consuming administration of cases involving an EU aspect.

In 2010, the Commission follow-up on complaints received from EU citizens, mostly EU-10 nationals, who were previously employed or self-employed in the UK and who were not granted certain social security benefits. The Commission sent a letter of formal notice to the UK authorities and encouraged the UK to eliminate this restriction to the access to the national benefits falling within the scope of Regulation (EC) No 883/2004.

In the area of family benefits it has been reported to the Commission that, if two Member States are competent for providing family benefits, the determination of primary competent State and possible payment of so called "differential supplement" from secondary competent State takes a long time. This is due to the fact that the national administrations need to exchange information concerning the composition and situation of the family and the benefits provided in the primary competent Member State. The situation can be mitigated by a better cooperation of national administrations and, in the future, also the electronic exchange of data. Also, in some Member State the understanding of "a family member" is based on the national legislation and the situation within one state only, without taking into account the specific situation of migrant workers, where one parent may be often active in another Member State than the state of the family's residence.

Modernised regulatory framework for the coordination of social security systems

In 2010, progress was made in view of the entry into application of the new Regulations (EC) No 883/2004 and No 987/2009 (Implementing Regulation) on the 1 May 2010, which

implied:

- adoption of the new Regulation (EC) No 1231/2010, which entered into force on 1st January 2011 and extended the modernised social security regulations, Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009, to third country nationals not already covered by these regulations and falling within the scope of the coordination rules. Regulation 1231/2010 replaces Regulation (EC) No 859/2003 for all Member States where it applied, except the United Kingdom, which will continue to apply Regulation (EC) No 859/2003 (and by extension the rules in Regulation (EEC) No 1408/1971 and Regulation (EEC) No 574/1972)[42].

The principles contained in Regulation (EC) No 1231/2010 are in essence the same as those contained in Regulation (EC) No 859/2003. Regulation 1231/2010 is a "bridge" that allows the EU coordination rules to apply to nationals of third countries who fall within its scope.

Regulation 1231/2010, unlike Regulation (EC) No 859/2003, does not contain derogations for Germany and Austria from the principle of equal treatment with regard to family benefits.

- intensive work to provide legal interpretation and guidance accompanying the entry into force of the new Regulations; within the framework of the Administrative Commission for the coordination of social security systems (Article 71 of Regulation (EC) No 883/2004);

- adoption of three new interpretative decisions for the application of the new Regulations;

- adoption of a Guide on Applicable Legislation, which should be considered as a reference document by the national administrations when interpreting the provisions of the new Regulations concerning posting and activity in two or more Member States;

- adoption of the Portable Documents (replacing former E-forms) and preparation of guidelines on Portable Documents for citizens.

The new coordination rules were designed with an electronic exchange of social security information between the national institutions. The Commission has been preparing a system of e-administration (EESSI), which will enable 31 countries to exchange electronically social security information among their administrations thereby fulfilling the ultimate aim of strengthening the protection of mobile citizens' social security rights. This will in turn facilitate and speed up the decision-making process for the actual calculation and payment of benefits to citizens who move around Europe.

3.1.2. **Evaluation of the current situation**

- Complaints and inquiries

EU Regulations on the coordination of social security systems do not harmonise, but only coordinate Member States' social security system. This leads inherently to a high number of requests and complaints from citizens about the application of these Regulations to 27 different national social security systems.

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[42] Note that Denmark, Iceland, Liechtenstein, Norway and Switzerland did not apply Regulation (EC) no859/2003 and similarly do not apply Regulation (EC) No 1231/2011.

In 2010, the entry into application of the new regulatory framework, Regulations (EC) No 883/2004 and 987/2009, as from the 1st of May 2010 lead to an increase of the number of queries due to requests for clarification.

In the field of free movement, the nature of the queries remains more or less identical than in previous years but takes into account the entry into force of Directive 2004/38/EC and the development of the economic crisis, followed by austerity measures in many Member States.

Therefore, a total of 239 cases were registered in the new complaint handling system (CHAP) for both sectors.

A number of complaints where Member States requiring further clarification or information about the national legislation or practice have been dealt with through EU Pilot, prior to initiating an infringement procedure. In the field of social security, the exchange though EU Pilot supplements the system of cooperation with the Member States in the framework of Administrative Commission put in place in 2005.

- Management of infringements

The infringement procedures dealt with by the Commission services in relation to the EU rules on free movement of workers concern the non-conformity of national legislation with article 45 TFEU, Regulation (EEC) 1612/68 and Directive 2004/38/EC and the incorrect application of these rules by national authorities. In relation to coordination of social security, the infringements concern the incorrect application by the national authorities of Article 48 TFEU and of existing Regulations in that area, namely Regulations 883/2004 and 987/2009 on social security coordination.

In that context, the Commission services use the work done by networks of academic experts, whose reports on the application of Community law in the field of free movement of workers and coordination of social security are published on a website[43].

In the field of free movement of workers, the current infringement procedures deal mainly with problems linked to access to posts (e.g. nationality and residence conditions, language requirements), transitional arrangements, working conditions, access to social advantages (e.g. study grants for children of migrant workers) and employment in the public sector (e.g. taking into account of professional experience and seniority for access to posts and for determining working conditions; taking into account of professional qualifications).

In 2010, 7 infringement procedures were closed, and 9 new cases were registered. Only a limited number of complaints were dealt with successfully through EU Pilot without initiating an infringement procedure.

In the field of social security coordination, the infringement procedures deal with problems linked to sickness insurance benefits, including the European Health Insurance Card, residence clauses for eligibility for social security benefits, calculation and payment of old-age pension, discriminatory practices for the payment of certain social security benefits.

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43 Network of experts on free movement of workers: http://ec.europa.eu/social/main.jsp?catId=475&langId=enTress network: http://www.tress-network.org/TRESSNEW/

In 2010, 6 infringement procedures were closed, while 9 new procedures were open.

At the end of 2010, the Commission services were dealing with 51 infringement procedures (compared to 46 procedures at the end of 2009): 18 in the field of free movement and 33 in the field of social security coordination.

- Guidelines and information

In line with its obligation to promote good practices and increased knowledge of EU rules on the ground and to step up the dissemination of information to EU citizens about their rights, the Commission undertook the following actions in 2010:

1. In view of the very high number of queries, substantial effort was made in terms to supplement monitoring with improved communication tools to better inform the citizens about their rights as regards free movement of workers and social security coordination.

2. In the field of free movement, the Commission adopted the Communication "Reaffirming the free movement of workers: rights and major developments"[44], which provides an overview of the rights that EU migrant workers enjoy and which updates the previous Communication of the Commission from 2002 by taking into account the legislative and the case-law developments in this field. The Communication was supplemented by the Commission Staff Working Document "Free movement of workers in the public sector"[45].

3. In the field of social security, the website has been redesigned and its content has been updated in order to fully reflect the new regulatory framework[46]. Several brochures have been updated and posted on the website: "The Community provisions on social security brochures: "The EU provisions on social security - Your rights when moving within the European Union - Update 2010)" and "Practical guide - Part 1 & 2: The legislation that applies to workers in the EU, the EEA and Switzerland".

4. The Commission published on the website a set of Explanatory notes, which give background and explanation of certain provisions and key concepts in the new rules. The notes are being constantly updated and complemented.

5. For the first time in 2010, the Commission published a call for proposals to financially support transnational actions, promoting the administrative exchange of social security information among EU countries, with a view to assisting them in their implementation of Regulations (EC) No 883/2004 and 987/2009; promoting transnational cooperation between institutions dealing with social security, exchanges of experience, dissemination of best practices and training initiatives developed at the national level; and raising awareness and providing a better service to the public. As a result the Commission has co-financed four transnational actions involving 12 different Member States. The call will be renewed, with an increased budget, in 2011 and will support, among others, also actions aiming to implement a new system of electronic exchange of data.

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44 COM(2010) 373 final, of 13.07.2010. http://ec.europa.eu/social/main.jsp?catId=25&langId=en

45 SEC(2010)1609 of 14.12.2010. http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=956&furtherNews=yes

46 http://ec.europa.eu/social/main.jsp?langId=en&catId=849

6. The Commission has set up an information campaign on the new social security coordination rules targeting on the one hand the European citizens and on the other hand the social security institutions of the Member States which have to apply the new provisions. The campaign was launched in November 2010. As an intermediate assessment, it can be said that the advertisement campaign in the media of seven target countries was able to reach an estimated readership of 25 million (November/December 2010).

3.1.3. **Evaluation results**

Priorities set up for 2010 have in general been met. Many infringements procedures were successfully closed and many issues resolved through problem-solving mechanisms. The forthcoming year should follow the same trend with the positive impact of the preventive approach based on administrative cooperation and on an increased communication towards citizens and national authorities.

As stated in the 2010 EU Citizen's Report, the Commission should further focus on improving information to citizens in order to increase their awareness of their rights and in order to allow them to enforce them better. Therefore, to supplement monitoring activities in 2011, the Commission will put a strong emphasis and carry on improving information to citizens in order to increase their awareness of their rights and in order to allow them to enforce them better. The Commission will also further promote Your Europe website and improve cooperation with Europe Direct.

The Commission will also assess the possibilities of proposing a new legislative instrument that would help EU citizens enforce the rights they enjoy according to EU law on free movement of workers.

3.1.3.1. Priorities regarding free movement of workers

In addition, the Commission sees all infringement procedures concerning the transitional arrangements as a priority and will pay particular attention to the question of access of EU migrant workers and members of their family to study grants.

As regards the working methods, the current tools will continue to be used. The expertise of the network of academic experts in the field of free movement of workers will also be used in order to obtain information about the national rules applicable.

3.1.3.2. Priorities regarding social security coordination

The objective in the area of social security is to monitor the correct application of the new Regulations 883/2004 and 987/2009 which came into force on the 1st May 2010, by the national institutions. In accordance with what is set out in the 2010 EU Citizen's Report, the Commission will, in order to facilitate the free movement of EU citizens, continue to act to ensure that the principle of non-discrimination is strictly enforced for EU citizens and their family members. This continues to be a point of particular importance in the social security field.

As regards its working methods, the Commission will better channel the individual cases though different ways of contact with Member States, namely EU Pilot and the cooperation with the Administrative Commission, to use the potential of both mechanisms. When dealing

with complaints it will carry on using the expertise of the network of academic experts (trESS) in order to obtain information on national legislation and context.

The Commission will continue to focus on finalising the development of the system for electronic exchange of social security information (EESSI) to enable the implementation of the new coordination rules. The EESSI system will enable countries to exchange electronically social security information between their administrations thereby fulfilling the ultimate aim of strengthening the protection of mobile citizens' social security rights.

During the first semester 2011, the Commission plans to publish a Communication on the external dimension of the EU social security coordination rules, which amongst other things will look at the effect of the EU rules on the rights of migrants from third countries to receive pensions from EU countries when they leave the territory of the EU. Regulation (EC) No 1231/2010 (and its predecessor, Regulation (EC) No 859/2003), which extend the principle of equal treatment to third country nationals within their scope, already have some effect in this respect. The Commission will therefore work to ensure a better enforcement of these rights for migrants from third countries.

The Commission will also release a Communication on the social security protection of groups of workers with high levels of intra-EU mobility (highly mobile workers). This communication will explain and interpret the flexibility and limits of the EU rules on coordination of social security schemes that determine the applicable social security legislation to groups of workers with high levels of intra-EU mobility and describe tools and initiatives to support, inform and guide on these issues.

3.1.4. **Summary**

The new system for complaints handling (CHAP) has demonstrated the high number of individual complaints and requests for information in this field of EU law. Therefore, the Commission is putting a strong emphasis and investments on improving information to citizens in order to increase their awareness of their rights and in order to allow them to enforce them better.

The forthcoming years should follow the trend presented above with the positive impact of the preventive approach based on administrative cooperation and on an increased communication towards citizens and national authorities. The objective for 2011 is to monitor a correct application of the new system of coordination by the Member States, with a focus on the new aspects of the Regulations on social security coordination.

3.2. Labour Law

3.2.1. **Current position**

3.2.1.1. Introduction

The 23 Directives applicable in the area of labour law cover a variety of issues and subjects, such as collective redundancies, European Works Council, information and consultation of employees, posting of workers in the context of the provision of services, fixed term and part-time work, temporary agency work, transfer of undertakings, employer insolvency, protection of young people at work, and working time. Some of these Directives implement framework agreements concluded between general cross-industry organisations at European level or

organisations representing management and labour in specific sectors.

At present, in the area of labour law, the deadline for transposition has expired for all directives in force, with the exception of the following three:

- Directive 2008/104/EC on temporary agency work[47], for which the transposition deadline will expire by 5 December 2011;

- Council Directive 2009/13/EC implementing the Agreement concluded by the European Community Shipowners' Associations (ECSA) and the European Transport Workers' Federation (ETF) on the Maritime Labour Convention, 2006 and amending Directive 1999/63/EC[48] for which the transposition deadline will expire not later than 12 months after the date of entry into force of the Maritime Labour Convention, 2006.

3.2.1.2. Report of work done in 2010

Monitoring the application of labour law implies different activities at various levels, such as the initiating and management of infringement procedures, the management of complaints, the preparation of monitoring and/or implementation reports and the involvement of various committees and expert groups.

- Management of infringements

Increased efforts continued in order to close a considerable number of open infringements for non communication and non conformity: 20 out of the 59 outstanding infringements could be closed in 2010.

With regard to non communication cases, the only outstanding infringement proceedings against Member States which *failed to notify* the national measures concern Directive 2005/47/EC[49] of 18 July 2005 on the Agreement between the Community of European Railways (CER) and the European Transport Workers' Federation (ETF) on certain aspects of the working conditions of mobile workers engaged in interoperable cross-border services in the railway sector, due to be transposed by 27 July 2008. 16 out of the 17 infringement proceedings for non communication initially launched against Member States that had failed to take the necessary transposition measures within the required time limit, could be closed following the adoption of the necessary national measures in 2010.

As regards problems of non-conformity of the national transposition measures of Directives in the area of labour law, a number of proceedings in progress continued or could be closed. For example, the case against Luxembourg for incorrect transposition of Directive 96/71/EC ('posting of workers') continued under Article 260 TFEU following the judgment of the Court of Justice[50]: an Article 260 TFEU letter of formal notice was sent and the case could finally be closed following the adoption of the necessary measures. The cases against Spain concerning the non transposition of the working time Directive 2003/88/EC in respect of non-civilian

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47 OJ L 327, 05.12.2008.
48 OJ L 124, 20.05.2009.
49 OJ L 195, 27.7.2005, p. 15–17.
50 Judgment 19.6.2008, case C-319/06, Commission vs. Luxembourg.

personnel in public authorities (Guardia civil) remained open under article 260 TFEU following the judgment of the Court of Justice[51].

- Monitoring reports

In order to have a comprehensive picture regarding labour law in Member States, a series of studies were commissioned, with a view to taking stock of the state of play regarding the transposition and application in the national legal orders of EU 10 member States of all labour law directives and finalised in 2009.

The contents of these studies has been used in the drafting of implementation reports required by Directives and the analysis has enabled the Commission to identify a number of outstanding issues where correct and full transposition of the Directive's requirements by Member States may be at stake, necessitating further clarification or verification. These issues raise either questions of interpretation of the Directive or doubts as regards the compliance of implementing measures with the Directive. On that basis, three implementation reports were prepared, submitted to Member States social partners and adopted in 2010, on the implementation of Directive 94/33/EC (Young People at Work), of Directive 2001/86 (employee involvement European company statute), as well as of Directive 2003/72/EC (Employee Involvement in the European Cooperative Society).

As regards the working time *Directive*, Commission's Report on the legal implementation of the working time *Directive* in the Member States[52] and its accompanying Working Paper of the Commission services[53] completed in 2008, cross-checked against expert reports, and provided to member states and social partners for comments in 2009, could finally be adopted at the same time as the consultation paper launching the second stage consultation of social partners at EU level[54] in accordance with article 154 (3) TFEU, on the possible content of a forthcoming EU action.

As a follow-up to a Staff Working Document[55] examining the implementation of Article 8 (concerning old-age benefits under supplementary company or inter-company pension schemes) and related provisions of Directive 80/987/EC ('employer's insolvency'), the Commission services finished in 2010 the investigation started in 2009[56]. A study was carried out and published relating to the protection of supplementary occupational pensions for book reserve schemes and defined benefit schemes. The Commission services also collected information directly from Member States as to the protection of contributions to defined contributions schemes. These two outputs will feed in the follow up of the Green Paper on pensions[57].

- European network of legal experts in the field of labour law

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51 Judgment 20.5.2010 , case C-158/09, Commission vs. Spain.

52 COM (2010) 802 final, 21.12.2010.

53 SEC (2010) 1611 final.

54 Communication 'Reviewing the Working Time Directive', COM (2010) 801 final, 21.12.2010.

55 SEC (2008) 475 of 11 April 2008.

56 Focussing on the following issues (1) how to protect employees and retired persons against the risk of under-funding of the pension schemes, and to what extent; (2) how to guarantee any unpaid contributions to the pension schemes; and (3) how to deal with cases where the supplementary pension scheme is managed by the employer himself.

57 COM 2010(365).

To complete the horizontal analysis of conformity of labour law, the European Network of Labour Law Experts created as of 23.12.2007, produced quarterly flash-reports providing information on recent key legal developments in the area of labour law, particularly in those areas that are most relevant for the control of EU legislation. This systematic reporting and monitoring of recent developments, carried out under Commission supervision allowed the Commission services to identify problems encountered in the national legislation, its application and administrative practice, if any. The 2010 thematic report and the Conference organised in November 2010 focussed on trends, problems and challenges for labour law in time in crisis, restructuring and transition under the headings 'protection, involvement and adaptation'.

- Strengthening pro-active co-operation: committee of experts

The four new expert groups created in 2009 continued their activities in 2010. Two are informal groups whose aim is to assist Member States in the transposition and implementation of Directives 2009/38 (' European Works Councils') and 2008/104 ('temporary agency work'). Their official mandate will end in 2011. A report finalised in December 2010 comprises the results of the activities, working documents and discussions of the Expert Group accompanying the transposition of the European Works Councils' Directive. Another informal group was created with the aim of discussing the issues raised by the conclusion and implementation of transnational company agreements.

Moreover, as regards the *posting of workers*, the formal expert committee set up by the Commission in 2008 continued its activities in 2010 examining a large number of questions and difficulties arising with respect to the implementation, application and enforcement in practice of Directive 96/71/EC concerning the posting of workers in the framework of the provision of services on the basis of a rolling work programme. A sub-group was set up in particular to carry out preliminary examinations in order to develop possible options for a specific information exchange system in order to reinforce and enhance administrative cooperation.

- "Fitness check"

As part of Work Programme 2010, the Commission has started to review the body of EU legislation in selected policy fields through so called "***fitness checks***". One of the pilot exercises launched in 2010 concerns the area of employment and social policy, covering in particular the area of *information and consultation of workers*. The aim is to carry out a robust review of the following 'family' of Directives in this area:

1. Directive 98/59/EC on collective redundancies[58];

2. Directive 2001/23/EC on transfers of undertakings, focusing on Article 7[59];

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[58] Council Directive 98/59/EC of 20 July 1998 on the approximation of the laws of the Member States relating to collective redundancies. OJ L 225 of 12.8.98, p.16.

[59] Council Directive 2001/23/EC of 12 March 2001 on the approximation of the laws of the Member States relating to the safeguarding of employees' rights in the event of transfers of undertakings, businesses or parts of undertakings or businesses, OJ L 82 of 22.03.2001, p.16. Article 7 deals with information and consultation of workers' representatives in cases of transfers of undertakings.

3. Directive 2002/14/EC establishing a general framework relating to information and consultation of workers in the EC[60].

The review will rely on an evidence based approach and integrate legal, economic and social effects of the existing legislation. An extensive set of studies exists already in this area which will be complemented, where necessary, by additional research and stakeholders' consultations.

Thematic discussions involving stakeholders are equally a very important element in the fitness check exercise. The first event in this regard, i.e. a *European Labour Law Network Seminar***,** was held in The Hague on 11-12 November 2010. It brought together labour lawyers and academics as well as Member States' and social partners' representatives.

A second step is the setting up of an *ad hoc Working Group* on ICW bringing together Member States' and Social partners' representatives foreseen for 2011. This could meet 3 times in 2011 (first meeting: 17.02.2011). The Working Group would examine and discuss the different studies on ICW and bring out the different national experiences with the implementation of the Directives in line with a work programme.

3.2.2. **Evaluation based on the current situation**

The importance of labour law for workers in Member States, as well as its importance for the perception of the European Union as a whole, has justified a horizontal analysis of the implementation of the Directives in Member States. Thanks to that systematic, horizontal analysis of the implementation of all labour law Directives, launched in 2005, and to the contribution of the experts' network and other expert groups, the Commission has a fairly good view of the legal situation in all Member States as regards the implementation of those Directives. While, by and large, all Directives are now transposed in all Member States, and the responsible Commission services have continued to make visible progress in 2010 to prioritise and accelerate the handling of open infringements (see above), there are still a number of areas where the application of Community law is not yet satisfactory and needs to be improved.

First and foremost, this is the case with the Working Time directive, where the law or legal and administrative practice in many Member States does not comply with jurisprudence or certain provisions of the Directive 2003/88/EC (in particular as regards on-call time, compensatory rest, multiple contracts, doctors in training, public sector workers and the individual opt-out). Therefore, a very substantial action has been undertaken in order to clarify the application of the Directive, to ensure effective conformity across the EU and to provide a response to the numerous complaints introduced by citizens or professional organisations.

Moreover, the implementation of Directive 96/71/EC concerning the posting of workers in the framework of cross-border service provision has raised some critical issues, given the variety of industrial relations systems, particularly in the light of recent case-law (Viking-Line, Laval, Rûffert and Commission vs. Luxembourg) which will be necessary to be closely followed.

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[60] Directive 2002/14/EC of the European Parliament and of the Council of 11 March 2002 establishing a general framework for informing and consulting employees in the European Community. OJ L 80 of 23.3.2002, p. 29.

The analysis of the implementation of Directives 99/70/EC on fixed-term work and 97/81/EC on part-time work, both resulting from agreements between social partners, revealed a number of deficiencies which are having being addressed via EU Pilot or administrative letters, had to be pursued under an infringement procedure.

Finally, the current economic crisis has put to a severe test those legal provisions which aim at providing protection to workers in the event of major restructuring operations. This is the case in particular of the Directives on information and consultation of workers, collective dismissals, transfer of undertakings and the protection of employees in the case of insolvency. It seems justified to inquire whether the objectives of such provisions have been effectively reached in 2010. Analysis of these and similar issues will be continued in 2011 either in the context of the 'fitness check' and/or the envisaged consultation of social partners on the more horizontal issue of restructuring.

3.2.3. **Evaluation results**

Two reports are expected to be adopted in spring 2011. One concerns Directive 91/383/EC (health and safety of a-typical workers), the other on Article 25 of Directive 2003/88/EC (working time of fishermen). Such reports may identify situations in Member States deserving further examination and eventually may justify the launch of infringements.

The Commission will equally continue its efforts to bring further clarity to the implementation, application and enforcement in practice of Directive 96/71/EC on posting of workers. Promoting exchange of information and debate on the implementation of the Directive in the framework of the Expert Committee which was launched in line with the Commission Decision of 19 December 2008, will continue in 2011: The report of the sub-group providing recommendations with respect to the most appropriate solution was approved by the Expert Committee and sent to the SQWP of the Council. Following the adoption of Council Conclusions (foreseen during the EPSCO Council in March 2011) a pilot project will be launched to further develop a separate and specific module of the Internal Market Information (IMI) system for the purpose of implementing the administrative cooperation provisions in the posting of workers Directive. Commission services will continue to provide the necessary support and assistance to the Member States during the follow-up process.
Furthermore, the first results of the ex-post evaluation studies on the application of the *posting of workers Directive* in all Member States, including the social, economic and legal aspects and impact focusing on sectors with high numbers of posted workers launched in 2009 were received late 2010. These will be complemented by a complementary legal study as well as an ex ante impact assessment in 2011 in view of the preparation of a legislative initiative by the end of 2011.

Actions undertaken on the basis of the contents of the implementation reports drafted following examination of the legal situation in the Member States after the 2004 enlargement, follow-up actions of clarification with respect to the fixed term work (Directive 99/70/EC), as well as part time work (Directive 97/81/EC) will be continued in 2011 (through bilateral contacts, via EU-PILOT or in the context of infringements). These activities will be supplemented by an ex-post evaluation and assessment of the impact of both Directives on the basis of a study to be launched in 2011. Specific reference will be given to the education and public sector for the fixed term Directive and the scope of coverage of the part-time work Directive.

Knowledge by management and labour of their respective rights and obligations in the area of information and consultation is an indispensable prerequisite for the full and

effective exercise of these rights in the workplace. Therefore the Commission also intends to undertake action geared to awareness-raising, as well as to promote exchange of best practices and to enhance capacity-building of all stakeholders, by way of seminars, training courses, studies and financial support for projects submitted by representatives of employers and employees.

In addition, the Commission services will finalise the report on the implementation of certain provisions of the employer's insolvency Directive which was submitted to consultation of Member States and social partners at the end of 2010. The expert working group established to discuss a number of outstanding issues regarding the application of the insolvency Directive (Council Directive 80/987/EEC and its codified successor European Parliament and Council Directive 2008/94/EC) in transnational situations contributed to this work and pursued its works for the enhancement of administrative transnational cooperation.

The Commission services will equally continue to provide technical assistance to the Member States in the process of transposition and implementation of the recently adopted Directive 2008/104/EC on temporary agency work. A group of governmental experts has been set up for this purpose which should finalise its activities in 2011.

3.2.4. **Summary**

With all the ongoing initiatives, including the establishment and running of several expert groups, the Commission has increased its capacity to analyse and identify problematic issues, pursue its activities of control of European legislation as well as to strengthen the range of preventive measures available.

Increased emphasis has been given to obtaining extensive knowledge concerning the implementation, control, enforcement and evaluation of the legislation either via the launching of ex-post evaluation or in the context of the fitness check of important parts of the *acquis* in the area of labour law.

This should further improve the implementation, application and enforcement in practice of the relevant *acquis*, with a special focus on the critical areas identified above. However, the sensitive and often highly controversial nature of the issues at stake may hamper achieving effective progress.

3.3. Health and safety at work

3.3.1. **Current position**

3.3.1.1. General Introduction

Under Article 153 of the Treaty on the Functioning of the European Union, the Union shall support and complement the activities of the Member States in the field of improvement of the working environment to protect workers' health and safety. To this end, the European Parliament and the Council may adopt minimum requirements by means of directives.

Health and safety at work is the most developed corpus of legislation in the field of employment and social affairs, with a multitude of directives (see Annex). Its application over the last 15 years contributed in particular to a substantial reduction of the accidents at work and thus to an improvement of the quality of work.

3.3.1.2. Report of work done in 2010

- Preparation of new legislation

In the framework of the preparation of a proposal of the Commission amending Directive 2004/40/EC on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (**electromagnetic fields**), a comprehensive Impact Assessment related was prepared and submitted to the Impact Assessment Board in December.

Work was also carried out on the minimum health and safety requirements on ergonomics at work particularly to prevent work-related **musculoskeletal disorders** and display screen vision conditions to review Council Directive 90/269/EEC and Council Directive 90/270/EEC. More specifically, as a preliminary study completed in 2008 was not satisfactory, new data collection was launched in 2010 through a Multiple Framework Contract study, focussing on cost/benefit ratio of the options considered.

The analysis and evaluation of the health, social, economic and environmental impact of a possible EU initiative on the protection of workers' health from risks related to **exposure to Environmental Tobacco Smoke** (ETS) was undertaken.

On 10 May 2010, the Council adopted Directive 2010/32/EU implementing the Framework Agreement on prevention from **sharp injuries** in the hospital and healthcare sector concluded by HOSPEEM and EPSU[61].

- Main actions being taken to control the correct application of the law

EU legislation needs to be supplemented by other policy tools and interventions designed to reinforce the impact of regulatory provisions and to provide the suitable context for practical application and enforcement. **The adoption of practical guides** contributes extensively to this objective and in 2010 the correctness of the different guides prepared as regards the relevant EU Directives was actively checked.

The Advisory Committee on Safety and Health at Work (ACSH) adopted the Guide to improve the application of Directive 92/57/EEC on "Construction", and the Guide to prevention and good practice in the Healthcare Sector.

The Guidance for employers on OSH and REACH aspects for controlling risks from chemicals was published and the drafting of the Guidance on nanomaterials and the potential risks to workers' health and safety was undertaken.

Work continued as regards the non-binding guide for the protection of workers in the agricultural and forestry sectors and the non-binding guide for the protection of workers in the fishery sector on board vessels less than 15 metres long, with the help of a contractor and in close collaboration with the Advisory Committee on Safety and Health at Work.

In addition, on a request of the ACSH, a working group was set up to examine the impact of existing guides to good practice in different sectors of activity, to evaluate the possibility of

[61] OJ L 134, 1.6.2010, p. 66.

developing a blue-print to ensure uniformity and quality improvement in the establishment and dissemination of these guides and to formulate proposals concerning the priorities to be established for the development of future guides, with an indicative schedule for action. A report was presented to the ACSH during the June plenary meeting and endorsed by the Committee. This report will serve as a basis for the preparation of future guides.

The monitoring of the progress made by the EU candidate and potential candidate countries in transposing the EU *acquis* on health and safety at work continued with particular emphasis on the assessment of the national law of Croatia and the former Yugoslav Republic of Macedonia where an external contractor submitted the results of the study in this respect.

- Management of the *acquis* through committees and expert groups

The Committee of Senior Labour Inspectors (SLIC) assists the Commission on problems relating to the enforcement of Community law on health and safety, and encourages its effective enforcement, notably by means of a closer cooperation between the national labour inspection services.

One mechanism to fulfil its tasks is the rapid exchange of inspection-related problems and solutions amongst the EU-27 Member States and EFTA countries. The Committee has developed an instrument called KSS (Knowledge Sharing System), where questions can be put to all the Labour Inspections participating.

The European information and risk awareness raising campaigns launched under the initiative of the Senior Labour Inspectors Committee (SLIC)[62] largely contribute to better compliance with EU legislation. European campaigns are indeed an effective means by which the labour inspection services can cascade a common message to stakeholders. In 2010, SLIC initiated a campaign designed to enhance risk management of dangerous substances in small- and medium-sized enterprises. It concentrates on 4 workplace activities: motor vehicle repair, furniture making, bakeries and cleaning, all widespread activities which, if not properly controlled, pose risks of serious ill-health e.g. from respiratory and skin disorders.

- Enquiries, problems and complaints management

During 2010 progress was made as regards the analysis of complaints for bad application mainly linked to Framework Directive 89/391/EEC: one case could be closed against the Netherlands and the analysis of some complaints against Spain, Italy and Greece, raising complex legal issues progressed. The analysis of some complaints resulted in the opening of files in EU Pilot with a view to receiving information from the Member States concerned and in one case, an infringements procedure had to be launched.

Two EU Pilot cases concerning transposition of some provisions of Directive 89/391 in Italy have been open and the replies of Italian authorities are under examination by the service. One of these files is likely to result in the launching of an infringement procedure against Italy.

It was also possible to progress with other EU-Pilot files. For instance, regarding the transposition of Directive 93/103/EC (fishing vessels) into Italian law, the national authorities

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62 Commission Decision 95/319/EC of 12 July 1995, OJ L 188, p. 11 (as amended).

communicated draft legislation which envisages certain amendments to the existing legislation transposing the Directive. In a case involving the transposition of Directive 92/29/EEC (medical assistance on board vessels) in the Netherlands, a meeting was held and information was received that the legislation would be brought in line with the Directive.

The management of complaints continued. Some of the complaints revealed violations of Health and safety EU law and therefore infringements procedures were launched. As regards a complaint against Sweden in respect of the implementation of Directive 89/391/EEC, a reasoned opinion was notified in January 2010. Management of infringements

The monitoring of the conformity of transposition of EU legislation focused on the non-communication of national measures due to transpose one Directive as well as the analysis of the conformity of the transposition measures of Directives in the highest risk sectors.

- *Non-communication infringement cases:*

As Directive 2006/25/EC[63] of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation) was due for transposition on 27 April 2010, 14 cases were opened in 2010 and 11 of these were closed during the year, further to the notification by the Member States of the national measures implementing Directive 2006/25/EC. Reasoned opinions were sent to Poland and the United Kingdom for the incomplete transposition of this Directive and the case against Austria will also have to be pursued.

- *Non-conformity infringement cases:*

There are currently several non-conformity infringement cases open, including several regarding Directive 92/57/EEC on construction sites. Other cases concern the Framework Directive 89/391/EEC, Directive 93/103/EEC on fishing vessels and Directive 2003/18/EC on asbestos. In 2010, two cases were closed further to a reasoned opinion under Article 260 TFEU, when the necessary national measures were adopted in Italy and France and communicated to the Commission.

3.3.2. **Evaluation based on the current situation**

It is essential that the European Union *acquis* is implemented effectively in order to protect the lives and health of workers and to ensure that the companies operating within the large European market are placed on an equal footing.

Accidents at work and work-related diseases are a heavy burden in social and economic terms, and action to improve health and safety standards at work offers great potential gains not only to employers, but also to individuals and society as a whole.

The implementation of the EU directives, in the field of health and safety at work, is bearing fruit at European level. Between 2000 and 2007 a reduction trend of 32.6% in the incidence of fatal and 28.7% in non-fatal accidents at work in the EU-15 was observed according to the harmonised data on accidents at work that are collected in the framework of the European

63 OJ L 114, 27.4.2006, p.38.

Statistics on Accidents at Work (ESAW)[64]. However, the statistics of 2007 show that around 3.8 million accidents at work resulting in more than three days of absence from work occurred in the EU-15.

3.3.3. **Evaluation results**

3.3.3.1. Priorities

A major priority for 2010 was the follow-up of the respect of the deadline for transposition of Directive 2006/25/EC (artificial optical radiation) in April 2010 and the resulting non-communication infringements. This priority will remain, as regards the 3 cases which are not yet closed.

Other priorities for 2010 were the ongoing analysis of the conformity of The Framework Directive 89/391/EEC and the 5 individual directives related to the highest risk sectors: construction (directive 92/57/EEC), the maritime sector (directives 92/29/EEC and 93/103/EC) and extractive industries (directives 92/91/EEC and 92/104/EEC), as well as further analysis of the transposition of the Asbestos Directive 2003/18/EC as exposure to asbestos is still a major concern for the protection of workers' health. These priorities remain.

Priorities set for 2010 were largely met but it should be borne in mind that the work planning has to be constantly adapted to new priorities introduced during the year which has an impact on the priorities set regarding the control and monitoring of the application of EU law.

While all health and safety at work Directives, except one, are transposed in all Member States and the Commission has made visible progress in 2010 to accelerate the handling of open infringements and to go further with the priorities set, major efforts should still be deployed to progress with the priorities established.

3.3.3.2. Planned action (2011 and beyond)

As previously mentioned, the analysis of the conformity of all the health and safety at work directives will continue to be a priority issue as an incorrect transposition could be a source of occupational accidents or diseases, with particular serious negative consequences in terms of human lives or physical integrity and/or important economic impact for the society and the concerned enterprises. Moreover, such analysis is also required due to the fact that often Member States are legislating in the fields covered by these Directives and there is a need to constantly follow-up the legislative developments that, sometimes, are not notified to the Commission.

As the analysis of the transposition of all provisions and annexes of the health and safety at work directives is a highly time-consuming task requiring highly specialised human resources (not only lawyers but also doctors, chemical engineers, mining engineers, etc.), a prioritisation is essential and the development of preventive actions is intensified such as the adoption of non-binding guidelines. In this context, also with a view to avoiding court proceedings, bilateral meetings with national authorities will be held where needed in 2011.

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64 http://epp.eurostat.ec.europa.eu/cache/ITY_SDDS/en/hsw_acc_work_esms.htm

The analysis of the conformity of the transposition of Framework directive 89/391/EEC, which establishes the main principles of prevention of occupational risks that apply to all sectors of activity, continues to be a major priority for 2011, in particular as regards the correct transposition in the 12 new Member States.

In 2011, the Commission will continue the analysis of the conformity of 5 individual directives related to the highest risk sectors: construction (directive 92/57/EEC), the maritime sector (directives 92/29/EEC and 93/103/EC) and extractive industries (directives 92/91/EEC and 92/104/EEC). In addition, it is also the intention to further analyse the transposition of the Asbestos Directive 2003/18/EC as an exposure to asbestos is still a major concern for the protection of the workers' health.

These priorities are in line with the main objectives of the Community Strategy 2007-2012 on Health and safety at Work[65] in particular those of reducing occupational accidents and diseases and guaranteeing the proper implementation of EU legislation.

The publication of a practical non-binding guide on the construction sites Directive 92/57/EEC is also foreseen, which will contribute decisively to the dissemination of good practices, being an assistance tool for better application of the EU legislation, with a view to improving application and consistency of the EU Directive among Member States.

A major priority mainly for 2012 will be the follow-up of the respect of the deadline for transposition of Directive 2009/161/EU (third list of indicative occupational exposure limit values) in December 2011 and the resulting non-communication infringements.

In addition, as regards the monitoring of the transposition of EU directives on health and safety at work in the EU candidate countries, a call for tenders will be launched, in 2011, to carry out a study on the transposition of the EU *acquis* concerned into the Icelandic national law.

3.3.4. **Summary**

The Commission has continued to develop several initiatives to strengthen the preventive measures with a view to significantly improving the level of effective and complete implementation, application and enforcement of the EU health and safety at work *acquis*. Therefore, successful results were, for example, the closing of virtually all non-communication infringements or the reduction trend in the accidents at work.

Further to the Resolution of the European Parliament of 15 January 2008 on the Health and Safety Strategy 2007-2012[66], which expressly requests to the Commission to intensify its works on the monitoring of the transposition of the health and safety at work directives, progress in this area has been intensified and the prioritising approach above indicated as well as the preventive initiatives undertaken, should allow to deal with a workload which is constantly increasing and therefore requesting major efforts to adequately manage it.

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65 COM(2007) 62.

66 Resolution 2007/2146.

4. AGRICULTURE AND RURAL DEVELOPMENT

4.1. Current position

4.1.1. General introduction

Since 1962 the Common Agricultural Policy (CAP) has established a comprehensive legal framework for European agriculture aiming to achieve the objectives set out in TFEU. As a fully integrated common policy it replaces a significant amount of national legislation. It has largely accomplished its objectives while alleviating the social impact of agricultural restructuring. As a corollary, farmers and administrations have to deal with a complex set of rules and measures contained in 1436 acts of secondary law currently in force. Most of those acts are Council or Commission Regulations that are "binding in their entirety and directly applicable in all Member States". Access to agricultural legislation has been improved by developments in IT tools. All EU legislation is now freely available via the EUR-Lex website. Consolidation and codification of legal texts both make the *acquis* more accessible to citizens and improves legal certainty.

The CAP is unique in the extent to which it is regulated and financed at EU level. Its common approach, in particular, to the single market, makes it possible to guarantee the functioning of an internal market of agricultural products. An EU framework ensures that rural development programs are carried out under common rules without creating unfair competitive advantages. Basic standards in the field, for example, of organic farming and labelling are settled on a common basis. This requires robust legislation, and effective financing and monitoring mechanisms to protect the public interest and ensure accountability.

Taking into account the significant volume of agricultural law and the more than 50 years history of the CAP (Stresa Conference dated July 1958), it may be considered as a quite stable *acquis* that, on the one hand, is subject to frequent technical modifications under the Comitology procedure, and on the other hand, undergoes on a regular basis, much more profound modifications. The last one of these, the 2003 reform, brought about radical change to the CAP, especially its income support policy. It established the single payment scheme and the single area payment scheme where direct income support for farmers is largely decoupled from production and introduced the cross-compliance system (see Council Regulation (EC) No 1782/2003[67] repealed by Regulation (EC) N° 73/2009). It also established comprehensive common rules for direct support in most sectors. The effect of these reforms has been reviewed in the "Health Check" 2008, on which basis the Council decided on adjustments in policy and budgetary priorities by Regulations (EC) No 72/2009[68]

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[67] Council Regulation (EC) No 1782/2003 of 29 September 2003 establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers and amending Regulations (EEC) No 2019/93, (EC) No 1452/2001, (EC) No 1453/2001, (EC) No 1454/2001, (EC) 1868/94, (EC) No 1251/1999, (EC) No 1254/1999, (EC) No 1673/2000, (EEC) No 2358/71 and (EC) No 2529/2001.

[68] Council Regulation (EC) No 72/2009 of 19 January 2009 on modifications to the Common Agricultural Policy by amending Regulations (EC) No 247/2006, (EC) No 320/2006, (EC) No 1405/2006, (EC) No 1234/2007, (EC) No 3/2008 and (EC) No 479/2008 and repealing Regulations (EEC) No 1883/78, (EEC) No 1254/89, (EEC) No 2247/89, (EEC) No 2055/93, (EC) No 1868/94, (EC) No 2596/97, (EC) No 1182/2005 and (EC) No 315/2007.

and 73/2009[69]. Agricultural policy also contributed significantly to the regulatory simplification process notably in 2007 - 2008 by the adoption of the Single Common Market Organisation Regulation. A common market organisation (CMO) in the agricultural sector governs 21 sectors which until 2007 were individual CMOs. It provides a single legal framework governing the domestic market, trade with third countries and rules regarding competition[70].

The policy is divided into two pillars: the first pillar consists of a framework for supporting the income of farmers through the payment of direct aid and a system for managing and supporting agricultural markets. The second pillar of the CAP provides a framework to support the development of rural areas of the EU. The first pillar is 100% financed by the EU budget, whereas the second pillar is co-financed by the EU budget and those of the Member States. Beginning on 1 January 2007 the programmes for rural development have been implemented on the basis of a new strategic planning model based on an EU framework position and national strategic plans (see Council Regulation (EC) No 1698/2005[71]).

To these two principal pillars could be added another important element of the policy consisting of the quality policy: notably four specific EU quality schemes have been introduced to develop geographical indications, organic farming, traditional specialities, and products from the outlying regions of the EU. These schemes identify products having specific qualities resulting from a particular origin and/or farming method.

Since the 2007 financial year the financing of the CAP is regulated by Regulation (EC) No 1290/2005[72], which introduced two distinct funds. The first pillar is now financed by the European Agricultural Guarantee Fund (EAGF) and the second pillar (rural development) is financed by the European Agricultural Fund for Rural Development (EAFRD).

The implementation of the CAP is a joint responsibility of Member States and the Commission, referred to as shared management. While the Commission is responsible for the overall legal framework and for implementation of the budget, under the shared management concept, the responsibility for implementation at the level of final beneficiaries has been delegated to the Member States. The extent of the responsibilities of the Members States may in particular be considered very extensive as regards the implementation of the measures of the second pillar for which a "bottom up" approach has been followed that leaves to the

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69 Council Regulation (EC) No 73/2009 of 19 January 2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers, amending Regulations (EC) No 1290/2005, (EC) No 247/2006, (EC) No 378/2007 and repealing Regulation (EC) No 1782/2003.

70 Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organization of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation).

71 Council Regulation (EC) No 1698/2005 of 20 September 2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) – See also Commission Regulation (EC) No 1974/2006 of 15 December 2006 laying down detailed rules for the application of Council Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and Commission Regulation (EC) No 1975/2006 of 7 December 2006 laying down detailed rules for the implementation of Council Regulation (EC) No 1698/2005, as regards the implementation of control procedures as well as cross-compliance in respect of rural development support measures.

72 Council Regulation (EC) No 1290/2005 of 21 June 2005 on the financing of the common agricultural policy.

Member States, regions and Local Action Groups much more latitude in adjusting the programmes to local needs.

As already mentioned, the CAP has been the subject of a continuing and regular process of reform. A new process of change has been launched in 2010. Indeed, the new financial framework for the EU and the "Europe 2020" strategy priorities of smart, sustainable and inclusive growth offer an opportunity to define the vision for European agriculture by 2020 and to prepare a reform path for the Common Agricultural Policy accordingly.

In this context, through its response to the new economic, social, environmental, climate-related and technological challenges facing our society, the CAP can contribute more to developing intelligent, sustainable and inclusive growth. The CAP must also take greater account of the wealth and diversity of agriculture in the EU's 27 Member States. The Commission Communication of 18/11/2010 on the "*Common Agricultural Policy towards 2020. Meeting the food, natural resources and territorial challenges of the future*" (COM(2010) 672 final) already highlighted the key challenges and the major policy issues regarding EU agriculture and rural areas and outlined possible policy orientations and options for the future. A new reform of the CAP has now to be decided.

4.1.2. Report of work done in 2010

(a) New legislation

2008 ended with the successful outcome of the "Health check" reflection process on how to improve the efficiency of the Common Agricultural Policy in the future. 2009 has been characterised by a very active legislative activity dedicated to the formalisation of the political agreement reached at the end of 2008. In 2010, with the entry into force of the Treaty of Lisbon, the main legislative task for the Commission consisted aligning of an important part of the existing legislation to the new legal bases. Indeed, the Treaty on the Functioning of the European union (TFEU) establishes a clear distinction between on the one hand the competence delegated to the Commission in order to adopt non legislative acts (delegated acts), which supplement or modify certain non-essential elements of the legislative act as provided by Article 290 TFUE, and, on the other, competence conferred to the Commission in order to adopt implementing acts pursuing to Article 291. In fact, Member States are responsible for the implementation of the legally binding acts of the European Union but if the application of the legislative acts requires uniform conditions for implementation, it is up to the Commission to adopt them by means of implementing acts. Pursuing the adoption of the Commission Communication of 09/12/2009 on the Implementation of Article 290 TFUE (COM (2009) 673 final), the Commission has to align progressively agricultural legislation with the new mechanisms of delegated acts and implementing acts, including in particular Regulation (EC) N° 1234/2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation).

Reform of specific market instruments

2010 saw several legislative initiatives adopted regarding specific sectors or horizontal rules. Concerning the latter, the single CMO provides a sound basis for grouping similar market management procedures applicable in different sectors in horizontal Commission Regulations.

It offers the opportunity to reconsider and harmonise the different variations in so far as this is considered to be useful, thereby achieving a degree of simplification.

In 2010 this resulted in replacing in the horizontal regulations on physical checks and on export refunds the written control findings by standard numerical codes, and in 11 Regulations the Member States' notifications to the Commission were standardised and transferred to the ISAMM electronic network. Besides simplification of CMO rules, the *acquis* concerning several sectors was modified to a greater or lesser extent in 2010.

As far as the food distribution programme to the most deprived persons of the European Union is concerned, the Commission adopted a new amended proposal (COM (2010) 486 final) in line with new provisions enshrined in the Lisbon Treaty and that took on board certain implementation adjustments requested by the EP such as the possibility to grant a priority to food produced in the EU and the obligation for distribution points to clearly display the participation of the EU. Furthermore, in an attempt to make the implementing rules clearer, these rules were codified through Commission Regulation (EU) N° 807/2010[73].

As for the milk and milk sector, the Commission has adopted the proposal for the Council and European Parliament on the contractual relations in the sector (COM (2010) 728final of 10.10.2010) in line with the conclusion of the Council Presidency (27.09.2010) and following the first four recommendations of the High Level Experts Group for Milk (delivered on June 15, 2010).

In the wine sector, legislation has been clarified, simplified and sometimes solved specific problems linked to particular situations (see notably Commission Regulation (EU) No 772/2010 of 1 September 2010 amending Regulation (EC) No 555/2008 laying down detailed rules for implementing Council Regulation (EC) No 479/2008 on the common organisation of the market in wine as regards support programmes, trade with third countries, production potential and on controls in the wine sector). The problem of illicit plantings addressed in the reform regulations is being dealt with. Penalties on vine growers who do not regularise or grub-up illegal vineyard plantings are provided for including possible sanctions on Member States if they do not provide information in a timely fashion. As regards PDO (protected designation of origin)/PGI (protected geographical indication), only a few product specifications relating to existing wine names where received by the Commission services, whereas, around 1800 files must be communicated to the Commission by the end of 2011. This will represent an important workload for the Commission in 2011. Furthermore, authorization of wine-making practices has been simplified – in general taking over those recommended by the OIV and the analytical methods of the OIV will likewise be used for analysis in the European Union. As regards the German Alcohol Monopoly, a progressive phasing-out of this State aid was decided by the Council and the European Parliament. This measure will definitively cease in 2013 for small distilleries and in 2017 for the others. For hops, in the absence of a new monitoring system to replace the present system of collecting information regarding the contracts, it has not been possible to eliminate the compulsory registration of contracts. Therefore efforts to find a suitable solution and to achieve simplification will continue in 2011.

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[73] Commission Regulation (EU) No 807/2010 of 14 September 2010 laying down detailed rules for the supply of food from intervention stocks for the benefit of the most deprived persons in the Union.

In the tobacco sector, the 2004 reform providing to completely decouple production and aid, and which was again confirmed by the health check regulation in 2009, was implemented as foreseen in January 2010.

In the fruit and vegetable sector, the fruit juice Directive (2001/112/EC[74]) has been amended by Directive 2009/106/EC[75]. Adaptation was needed to take account of technical progress and developments in relevant international standards, in particular the Codex Standard for fruit juices and nectars (Codex Stan 247-2005) which was adopted by the Codex Alimentarius Commission during its 28th session on 4- 9 July 2005 and the Code of Practice of the European Fruit juice Association (AUN).

A proposal for a second amendment of this Directive has been adopted by the Commission in September 2010 (COM (2010) 490 final).

Direct payments and cross compliance

In 2010 the legislative activity concentrated on the alignment of the Commission powers included in Council Regulation (EC) No 73/2009[76] to the differentiation introduced by the TFUE between delegated and implementing powers. This sorting out into the two categories of existing Commission powers was done on the basis of a thorough screening of the Council basic act and the relevant Commission implementing acts already in force (Commission Regulations (EC) No 1120/2009, No 1121/2009 and No 1122/2009[77]). Their delegated or implementing character was decided on the basis of objective legal criteria on the basis of the definitions in Articles 290 and 291 of the TFEU.

The result of this work was the Commission proposal amending Council Regulation (EC) No 73/2009 of 29 September 2009 (COM(2010)539 final) that was submitted to the European Parliament and the Council at the end of September .

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74 Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption, OJ L 10, 12.1.2002, p. 58–66.

75 Commission Directive 2009/106/EC of 14 August 2009 amending Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption, OJ L 212, 15.8.2009, p. 42–44.

76 Council Regulation (EC) No 73/2009 of 19 January 2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers, amending Regulations (EC) No 1290/2005, (EC) No 247/2006, (EC) No 378/2007 and repealing Regulation (EC) No 1782/2003.

77 Commission Regulation (EC) No 1120/2009 of 29 October 2009 laying down detailed rules for the implementation of the single payment scheme provided for in Title III of Council Regulation (EC) No 73/2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers - Commission Regulation (EC) No 1121/2009 of 29 October 2009 laying down detailed rules for the application of Council Regulation (EC) No 73/2009 as regards the support schemes for farmers provided for in Titles IV and V thereof.- Commission Regulation (EC) No 1122/2009 of 29 October 2009 laying down detailed rules for the implementation of Council Regulation (EC) No 73/2009 as regards cross-compliance, modulation and the integrated administration and control system, under the direct support schemes for farmers provided for that Regulation, as well as for the implementation of Council Regulation (EC) No 1234/2007 as regards cross-compliance under the support scheme provided for the wine sector in Council Regulation (EC) No 479/2008.

Delegated acts were used in all cases of "quasi legislative acts" in the sense that they regulate non essential elements of the legislative act, are of general application and amend or complete the legislative act. Implementing acts were used for all acts of an "executive" nature in the sense that Member States are responsible for the implementation and there is a need for a uniform application.

In addition to the alignment exercise, the proposal also includes some elements of simplification in the area of cross-compliance. In particular, the possibility for the Member States not to require the declaration of all the agricultural areas of their holding for farmers with a total area of the holding lower than 1 hectare is provided for.

Rural development

During year 2010, the legal procedures to align Council Regulation (EC) No 1698/2005 [78] on support for rural development by the European Agricultural Fund for Rural Development to the provisions of the Lisbon Treaty (TFEU) were launched. The proposal also contains a number of simplification proposals.

Commission Regulation (EC) No 1975/2006[79], which concerns control procedures and cross-compliance in rural development operations, was recast as a follow-up of the Commission staff working document on simplification. The main objective was to clarify a number of points and to increase the transparency of the text. The new Regulation (EC) No 65/2011[80] was adopted in January 2011.

Commission Regulation (EC) No 1974/2006[81] laying down detailed rules for the application of Council Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) was amended to include detailed implementation rules for payments related to the Water Framework Directive[82].

During the year, significant effort was also put into the development of the future Rural Development Policy and the Commission Communication on the future of the CAP. The work continues in 2011.

Quality policy

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78 Council Regulation (EC) No 1698/2005 of 20 September 2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD).

79 Commission Regulation (EC) No 1974/2006 of 15 December 2006 laying down detailed rules for the application of Council Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD).

80 Commission Regulation (EU) No 65/2011 of 27 January 2011 laying down detailed rules for the implementation of Council Regulation (EC) No 1698/2005, as regards the implementation of control procedures as well as cross-compliance in respect of rural development support measures.

81 Commission Regulation (EC) No 1974/2006 of 15 December 2006 laying down detailed rules for the application of Council Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD).

82 Commission Regulation (EU) No 108/2010 of 8 February 2010 amending Regulation (EC) No 1974/2006 laying down detailed rules for the application of Council Regulation (EC) No 1698/2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD)

Quality

Building on the strategic orientations for a coherent and comprehensive food quality policy set out by Communication (COM(2009)234) adopted in 2009, an impact assessment exercise (including the establishment of an Impact Assessment Inter-Service Group) was carried out in the first semester of 2010 in view of the adoption of appropriate legislative proposals.

On 10 December 2010 the Commission adopted the "Quality package" covering all facets of agricultural product quality policy. The "Quality Package" includes: a) two legislative proposals on agricultural product quality schemes and marketing standards, respectively; b) two Communications one of which established voluntary guidelines on labelling of foodstuffs with PDO-PGI ingredients (OJ C 341, 16.12.2010, p. 3) and on the other of which was on the best practice for voluntary certification schemes for agricultural products and food stuffs (OJ C 341, 16.12.2010, p. 5).

In 2010 the "Standing Committee on Protected Geographical Indications and Protected Designations of Origin" (Art. 15 of Regulation (EC) No 510/2006[83]) and the "Standing Committee on Traditional, Specialities Guaranteed" (Art. 18 of Regulation (EC) No 509/2006[84]) gave favourable opinions respectively on a number of Draft Commission Regulations entering names in the Register of PDOs-PGIs and of Draft Commission Regulations entering names in the Register of TSGs (traditional speciality guaranteed). Favourable opinions were also given on a number of cancellation of registration of names in the register of PDOs-PGIs.

Organic

The Community organic farming legislation framework is composed by Council Regulation (EC) No 834/2007 on organic production and labelling of organic products[85] and by implementing regulations (Regulations (EC) No 889/2008[86] on production, labelling and control and Regulation (EC) No 1235/2008[87] on import of organic products). It was further developed in 2010 with the adoption of amending Regulation (EC) No 271/2010[88] on the EU organic production logo, which became compulsory for pre-packaged organic food produced in the EU as from 1st July 2010. In the area of relations with 3rd countries, the Commission

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83 Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs.

84 Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed.

85 Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labeling of organic products and repealing Regulation (EEC) No 2092/91.

86 Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labeling of organic products with regard to organic production, labeling and control..

87 Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries.

88 Commission Regulation (EU) No 271/2010 of 24 March 2010 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007, as regards the organic production logo of the European Union.

examined the information submitted by Japan and decided to include it in the list of third countries recognised as having standards equivalent to the EU organic farming standards[89].

With a view to align the organic farming legislation to the provisions of the Lisbon Treaty, the Commission adopted on 17 December 2010 a proposal to amend Council Regulation No 834/2007[90].

(b) Preventive measures and actions taken to control the correct application of the law

In the field of prevention the Commission continues to be active as the following actions demonstrate.

Meetings with the Member States in the context of Comitology – Guidelines - Interpretations

In the agricultural sector, preparatory working contacts between experts, review of problems arising and multilateral and/or bilateral exchange of information all help to ensure and promote correct implementation and identifying and addressing potential problems as early as possible. Furthermore, the Management and Regulatory Committees, which meet regularly, acts not only as a body delivering its opinion on legal proposals for Commission regulations, but also serves as a privileged forum for the exchange of information and best practice between the Member States and the Commission, thus playing a key role in preventing implementation problems.

Where needed, missions to Member States capitals to get a global view of procedures and practices at national level were also organised. "Bilaterals" with Member States provided the competent services of the Commission with the opportunity to deal positively with some recurrent problems encountered by Member States in the drafting of applications as well as in the interpretation of a number of legislative provisions. The Commission also provided practical suggestions to improve the quality of applications, for instance in the quality sector, for registration and amendments. This contributed to reducing time-consuming formal exchanges concerning Commission requests for additional information, in particular in the agricultural quality policy sector. The wine sector regularly reviews the *acquis* in the Management Committee and where appropriate the Regulatory committee for certain aspects of the PDO/PGI/TSG decisions and wine-making practices. Stakeholders and the Commission services deal with issues in the Advisory Group and the Expert Group on wine-making practices deals with technical questions. All these measures provide a stable and clear legal framework for the sector for the coming years. They will contribute to improving competitiveness, increase subsidiarity by enabling Member States to select the measures in their national support programmes most suited to their conditions. The gathering of

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89 Commission Regulation (EU) No 471/2010 of 31 May 2010 amending Regulation (EC) No 1235/2008, as regards the list of third countries from which certain agricultural products obtained by organic production must originate to be marketed within the Union.

90 Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) no 834/2007 on organic production and labelling of organic products – COM(2010) 759 final.

information to monitor the sector has also been adequately provided for to ensure early detection of market movements and trends.

The Commission also provides guidelines in order to ensure consistent implementation of the rules throughout the EU and prevent deceptive and misleading practices, e.g. in the wine, quality policy and organic farming sectors. For instance, guidelines relating to Articles 9, 10 et al of Regulation (EC) No 110/2008[91] of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks were provided to Member States in the Spirit Drinks Committee and to the stakeholders in the Advisory Group on Spirit Drinks with a view in particular to ensuring consistent implementation of the rules throughout the EU and prevent deceptive and misleading practices.

Moreover, a register of interpretative notes on agricultural law (called RIPAC) has existed for a long time and new interpretative notes are regularly being created and put in that register which is accessible for the Member States. The notes are usually drawn up as a result of a written or oral question posed by a Member State.

Technical standards Directive (Directive 98/34/EC)

Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations requires Member States and Members of the European Free Trade Association who have signed the Agreement on the European Economic Area plus Switzerland and Turkey to give each other and the Commission prior notification of all draft rules containing technical standards or rules in order to avoid creating new barriers to trade in the internal market. As such, this Directive can be considered as an ideal preventive instrument enabling the filtering of any national technical rule that could jeopardize the functioning of the internal market.

In this context, in 2010 the relevant departments of Directorate-General for Agriculture and Rural Development were formally consulted on 106 notifications relating to the agricultural sector. Examination of these draft texts subsequently led to the issuing of 2 comments, 2 detailed opinions and one blockage.

Simplification

The Commission strategy for simplifying the regulatory environment [COM(2005) 535] set out an ongoing simplification programme of measures to be adopted with a view to improving the quality and effectiveness of the acquis. As far as the agricultural sector is concerned, the Communication on Simplification and Better Regulation for the Common Agricultural Policy [COM(2005)509] set out an ambitious programme for a significant simplification of the CAP. The Communication: "A simplified CAP for Europe - a success for all **(**COM(2009) 128

[91] Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89.

final) takes stock and looks at what has been accomplished. It highlights the activities that have been carried out since 2005, and gives indications of the resulting reduction in the administrative burden for farmers and administrations. The 2005 Communication led to the creation of the rolling Common Agricultural Policy Simplification Action Plan, which is used to identify, plan and monitor the implementation of simplification projects within the agricultural sector. Launched at the end of 2006, it has evolved from 20 to around 62 projects; 55 projects have already been implemented (as removal of the obligation to have a licence for beef exports without export refunds, end of the obligation for a farmer to have a plot of land at his disposal for at least 10 months in order to apply for direct payments, for imports, licence requirements were reduced from 500 to 65 and for exports, only 43 licence requirements remain, etc). On technical aspects, it is interesting to mention that in order to increase the transparency of EU law, which is an essential element of the better lawmaking strategy that the Institutions are implementing, Council Regulations (EC) No 1128/2009[92] and 1139/2009[93] repealed 33 Council acts that had become obsolete. At the end of 2010, the Commission adopted two other legislative proposals looking to repeal another 45 obsolete Council acts. These proposals follow a Commission Communication which declared more than 360 Commission acts obsolete. The adoption of the single CMO replaced 21 individual common market organisations with one, reducing the number of articles from around 1080 to around 350 and repealing 86 Council acts. At the end of 2009, the Commission's services presented a Staff Working Document SEC (2009)1601, on the assessment of 39 simplification suggestions submitted at the Agricultural Council of April 2009. The document provides an assessment of every simplification suggestion and, where possible, presents a solution to the problem raised. Most of the solutions have already been incorporated, for example in the new implementing regulations for direct payments or in the simplification package, which was adopted by the Commission at the end of September 2010. The Commission has adopted in November a Communication declaring a substantial number of Commission acts obsolete and on 20 December two legislative proposals repealing a number of Council acts related to the CAP. Together, these two exercises represent a considerable cleaning up and a step forward in simplifying the agricultural *acquis*.

Sectoral preventive measures

The following examples illustrate preventive actions taken in some agricultural sectors.

Quality

Controls of obligations of Member States under Regulation (EC) No 510/2006 remained an important issue in need of attention. The Commission services assessed the Multi Annual National Control Plans (MANCP) presented pursuant to the provisions of Regulation (EC) No 882/2004 and the annual reports submitted on the implementation of these plans. The Commission services' analysis provided the necessary feedback to the Member States on controls of PDOs and PGIs.

The Commission services informed the Member States regarding the interpretative note (No 2010-01) on the use in translation of a name registered under Regulation (EC) No 510/2006.

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92 Council Regulation (EC) No 1128/2009 of 20 November 2009 repealing certain obsolete Council acts in the field of the common agricultural policy.

93 Council Regulation (EC) No 1139/2009 of 20 November 2009 repealing certain obsolete Council acts.

The note clarified the distinction between names as entered in the register and names in translation.

In order to contribute to the smooth application of the existing legislation on PDO/PGI and TSG, bilateral meetings with Member States were organised in the margin of the Committees meetings. Such "bilaterals" provided the Commission services with the opportunity to continue the productive dialogue established in the last few years and tackle effectively some problems encountered by Member States in the drafting of applications.

A constructive exchange of views on general improvements needed to the processes and registration procedures for PDO, PGI and TSG applications took place also in the Committees' meetings, exceptionally in the presence of the Commissioner. Procedural questions were discussed with the Member States experts directly responsible for the implementation of EU sectoral legislation at national level.

The preparation of a guide for applicants of PDO/PGI applications was started in 2010, benefiting also from the contributions of Member States.

Organic farming legislation – monitoring guidelines

Regarding the implementation of the EU rules on organic products, discussions take place between the Commission and the Member States in the framework of the Standing Committee on Organic Farming (SCOF) and bilaterally. The legislative framework in place clearly delimitates competences between the Commission and the Member States and makes provision for a series of information and reports that are submitted regularly to the Commission.

With regard to controls, the responsibility lies with the Member States. Controls of the organic production are logically placed under the responsibility of the Official Food and Feed Control (OFFC) set up by Council Regulation (EC) No 882/2004[94]. To foster more efficient control systems, the Commission developed a document on control guidelines with a view to disseminate knowledge and appropriate guidance to the competent authorities, and possibly the control bodies, clarifying the relationship between the controls requirements deriving from the OFFC and those deriving from the regulations in the organic sector. The document, which will also help the Commission in its supervisory role, was finalised in December 2010 and is expected to be disseminated in the first quarter of 2011. In 2010, the Commission sent one letter to a Member State requesting it to provide a solution without delay to a deficiency in its control system. A solution was provided by the competent authority of the Member State concerned within a reasonable delay and the performance of its control system was subsequently improved.

Concerning the introduction of the new EU logo, a series of tools to assist operators were developed, namely a series of Frequently Asked Questions, a user manual and a document describing the terms and conditions for its use.

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94 Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

In the area of support to organic farmers a study on "the use and efficiency of public support measures addressing organic farming" was launched at the end of the year.

Rural development preventive measures

Preventing tasks under shared management with the Member States are permanent core task of Commission Rural Development services. Preventing tasks include regular monitoring through participation in Annual Review meetings and Monitoring Committee meetings, as well as the thorough analysis of Annual Progress Reports, Mid-Term Evaluation reports and summary reports of National Strategic Plans. Furthermore, preventing tasks include consultations regarding Rural Development Programme modifications, when the Commission must assess the compliance of the modifications with EU law. Moreover, numerous legal interpretations and guidelines were given to Member States in the form of exchange of letters.

During the year, increased attention was paid to policy implementation. Since 2010 was the mid-point of the programming period 2007-2013, taking stock of the Rural Development programme achievements so far was highlighted in the work of Member States and the Commission. The Member States submitted strategic summary reports on the progress made in the National Strategy Plan implementation to the Commission. Furthermore, the Member States conducted mid-term evaluations of their Rural Development programmes and submitted them to the Commission.

In September, a seminar on ensuring good management of the Rural Development programmes was organised in Brussels. The focus of the seminar was on knowledge-sharing amongst the Member States and illustrating best practises. The seminar brought together the policy planning and implementing authorities from the Member States, staff from the Commission services and the European Court of Auditors.

Clearance of accounts

EAGF and EAFRD expenditure is implemented under shared management through a comprehensive management and control system based on four levels consisting of[95]:

- A compulsory administrative structure at the level of the Member States: management and control of expenditure is entrusted to dedicated paying agencies, which prior to their commencement of operations must be accredited by the Member States on the basis of a comprehensive set of accreditation criteria laid down in EU law;

- Detailed systems for ex-ante controls and dissuasive sanctions: These systems are to be applied by the paying agencies and contain some common features and special rules tailored to the specificities of each aid regime. The systems generally provide for exhaustive ex-ante administrative controls of 100% of the aid applications, cross-checks with other databases where this is considered appropriate as well as pre-payment on-the-spot checks of a sample of transactions ranging between 1% and 100%, depending on the risk associated with the regime in question. If the on-the-spot checks reveal a high number of irregularities, additional checks must be carried

[95] For more explanations on the management of the agricultural budget and its audit tools, see: http://ec.europa.eu/agriculture/fin/clearance/factsheet_en.pdf

out. In this context, by far the most important system is the IACS (Integrated Administration and Control System). To the extent possible, the IACS is also used to manage and control rural development measures relating to parcels or livestock.

- Ex-post checks: in addition to the ex-ante controls, all aid measures other than direct payments covered by the IACS are subject to ex-post checks under either Council Regulation (EC) No 485/2008 or, for rural development measures, Commission Regulation (EC) No 1965/2011. Moreover, the paying agencies' annual accounts and the functioning of their internal control procedures are verified and certified on an ex-post basis by the certification bodies.

- Clearance of accounts: the clearance of accounts through the Commission consists of both an annual financial clearance and a multi-annual conformity clearance.

Taken together, these four levels are designed to ensure the legality and regularity of transactions at the level of the final beneficiaries. In the current context of the report on the application of EU law, the conformity clearance mechanism is particularly worth mentioning as it pertains to the correct application of the legislation establishing the common agricultural policy.

Indeed, while the financial clearance covers the integrality, accuracy and veracity of the paying agencies' accounts, the conformity clearance relates to the legality and regularity of the underlying transactions. It is designed to exclude from EU financing expenditure which has not been executed in compliance with EU rules, thus shielding the EU budget from expenditure that should not be charged to it (financial corrections). In contrast, it is not a mechanism by which irregular payments to beneficiaries are recovered, which according to the principle of shared management is the sole responsibility of Member States. Financial corrections are determined on the basis of the nature and gravity of the infringement and the financial damage caused to the EU. Where possible, the amount is calculated on the basis of the loss actually caused or on the basis of extrapolation. Where this is not possible, flat-rates are used which take account of the severity of the deficiencies in the national monitoring systems in order to reflect the financial risk for the EU. Where undue payments can be identified as a result of the conformity clearance procedures, Member States are required to follow them up by recovery actions against the final beneficiaries. However, even where this is not possible because the financial corrections only relate to deficiencies in the Member States' management and monitoring systems, financial corrections are an important means to improve these systems and, thus, to prevent or detect and recover irregular payments to final beneficiaries. The conformity clearance thereby contributes to the legality and regularity of the transactions at the level of the final beneficiaries.

In 2010, the Commission adopted three conformity clearance decisions:

- *Ad hoc* Decision 32: Commission decision No 2010/152/EU of 11/03/2010 excluding EUR 351.8 million from EU financing.

- *Ad hoc* Decision 33: Commission decision No 2010/399/EU of 15/07/2010 excluding EUR 271.9 million from EU financing.

- *Ad hoc* Decision 34: Commission decision No 2010/668/EU of 4/11/2010 excluding EUR 579.2 million from EU financing.

Moreover, in 2010, the Commission carried out 156 on-the-spot missions in the Member States and launched 129 desk checks.

While the financial consequences will only be determined at the end of the conformity clearance procedures, the results of the audits are already known throughout the year in question. Most of the audits performed in 2010 have not revealed any deficiencies in the monitoring systems which would suggest that those systems are ineffective in determining the eligibility of claims or preventing irregularities[96]. However, as regards direct payments, serious deficiencies have been detected in the IACS of 3 Member States. Those Member States have put in place action plans which are being closely followed by the Commission services. In parallel, the Commission is protecting the EU financial interests through conformity clearance procedures which are expected to result in significant financial corrections.

In the rural development sector, following the extensive audit program (37 audit missions of EAFRD financing in 2010) in the Member States and their systematic follow-up in terms of recommendations on controllability of measures or other weaknesses of the RD programmes, the Member State have taken various actions. Until end of October 2010 a total of 46 significant findings from audit reports relating to the weaknesses in implementation of the RD programs, compliance issues and controllability of measures were found. 24 of those cases have been closed from the follow-up after problems have been solved either by changing the RDP or by other means. The national rural development programs have been modified in 9 cases and the national framework in one case, which led to modifications into most regional programs of that Member State. The geographical units are continuously following new reports and taking new findings to the follow-up table when necessary. From the ECA reports 12 findings have been followed-up. One has been closed. Furthermore, action has been taken in several cases to clarify national implementing rules as well as to modify national legislation.

c) Management of the *acquis* through committees and experts groups

In the legal context prevailing in 2010, before the Commission adopts an act in the area of the Common Agricultural Policy, based on powers conferred upon it by the Council, it normally has to consult with Member State representatives and may also consult within expert groups.

In the case of consultation with the Member States representatives (Comitology), the Commission proposes the draft measure to a committee established by Council legislation and composed of representatives of the Member States. Committees give their opinion to almost every implementing act drafted by the Commission. In relation to the CAP, the management committee procedure is the type of procedure that applies almost exclusively and only in very few cases is the regulatory procedure applied with or without scrutiny by the European Parliament. This process gives multiple possibilities for consultation on different solutions for

[96] For a more detailed description of the conformity clearance activities, see 2009 Annual Activity Report in the domain of agriculture.

the implementation of agricultural law. It also has the effect that Member States are reminded of their duty to comply with EU law. Comitology has a long tradition in the agricultural sector, especially in the system of the management of the agricultural markets but Comitology also applies to the implementation of rural development and direct payments. It should however be noted that as of 1 December 2009 (entry into force of the Lisbon Treaty) new Treaty provisions are in force on the kind of competences which can be conferred by the legislator upon the Commission. However, pending the necessary adaptations of the existing Commission competences by the European Parliament and the Council, they have not yet taken effect so far and will gradually be introduced probably as of mid-2011. Meanwhile, the CAP continues to be implemented in accordance with the old (existing) rules provided in the Council Decision 1999/468/EC[97].

In 2010, 143 meetings of 14 management and regulatory committees presented the opportunity to discuss the implementation of CAP legislation with the representatives of the Member States. By securing the discussion of all market management related issues in a single Committee, discussions have benefited from cross-sectoral expertise and enhanced harmonisation and so the resulting implementing rules are simpler for Member States to put into practice.

The Commission therefore cooperates with Member States in a sophisticated manner which presents the opportunity to discuss and prepare the implementation of common rules and to prevent or solve problems related to their application at an early stage.

In addition the Commission administrates around 70 expert groups (56 active), including Civil Society Dialogue groups, dedicated to agriculture policies. These groups are not only composed of national administration experts but also by agricultural organisations, academics and independent experts. A major proportion of these groups are advisory groups where the Commission consults on measures with stakeholders such as producers, exporters, importers, wholesalers, retailers, nature preservation NGOs, consumers and other concerned parties. Article 3(1) of Commission Decision 391 of 23 April 2004[98] provides that all socio-economic organisations participating in the advisory groups must be listed in the Commission's register of interest groups. In 2010 all socio-economic organisations have been registered.

In 2010 the Commission was assisted by a number of advisory and working groups, as well as permanent and temporary groups' meetings of experts (in total 138) with a view to better adapting policies and implementing rules to the real situation. Above all, these groups provide the Commission with agricultural markets data and current production circumstances. A High Level Group of Experts in milk met ten times from October 2009 to June 2010 and produced a report with policy recommendations in June 2010. A dairy stakeholder conference was also held in March 26, allowing a wider range of actors in the supply chain to express their views.

d) Enquiries, problems and complaints management

Complaints from citizens and businesses (77 files related to the agricultural sector registered in the CHAP database in 2010) and internally detected cases led the Commission to examine cases of potential breaches of EU law covering various fields of the Common Agricultural

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97 1999/468/EC: Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.

98 2004/391/EC: Commission Decision of 23 April 2004 on the advisory groups dealing with matters covered by the common agricultural policy, OJ L120/50 of 24.4.2004.

Policy. In several cases the Commission referred questions relating to the application of EU law to Member States using the EU Pilot system. In 2010, 61 cases were dealt in EU Pilot system and concerned different sectors of the CAP.

Particular attention was drawn to the correct application of EU legislation in the field of direct payments, organic production and quality policy.

e) Petitions

In 2010 the Commission received 6 Petitions related to agriculture which covered a wide range of issues.

Four of them concerned EU support (rural development and the use of EU funds in Doñana National Park in Romania, support for young farmers in Bulgaria, aid for yak cows). The other two concerned legislation on the compulsory purchase of land and modernisation of a forest track on the 'Valea Șardului' ecosystem.

f) Management of infringements

In the area of agriculture and rural development, monitoring the application of EU law under the Article 258 TFEU procedure focuses on two main objectives: removing barriers to the free movement of agricultural products and ensuring that the more specific mechanisms of agricultural regulations are applied effectively and correctly.

In 2009, the Commission had to intervene in the context of the last objective by sending a reasoned opinion to the Czech Republic for the use of the sales designation "Pomazánkové máslo" (in English – 'butter spread') for a dairy product which does not comply with the requirements laid down in the Annex XV to Council Regulation (EC) No 1234/2007. Since no solution was found, the Commission decided to refer the case to the Court of Justice in September 2010.

Moreover, specific attention continued to be paid in 2010 to the application of the milk quota regime. Particular attention was devoted to its application in new Member States and to the situation prevailing in Italy regarding the recovery of levy due by milk producers.

Furthermore, the Commission intervened in the wine sector in order to ensure the correct implementation of EU rules regarding "protected geographical indication" that limit to exceptional cases, the possibility for the names of Member States to be protected as geographical indications (see Article 118(b) of Regulation (EC) No 1234/2007).

Particular attention has also been paid to the treatment of instances of non-compliance with Court judgments. In 2010, the Commission monitored the progress made by Portugal to implement a judgment of the Court in which the Court declared that, by levying charges on beneficiaries during the programming period 1994-1999 which were neither voluntary nor optional and which did not constitute remuneration for services rendered by the

administration, the Portuguese Republic failed to fulfil its obligations under Council Regulation (EEC) No 4253/88, as amended by Council Regulation (EEC) No 2082/93[99]. Portugal presented a plan programming the reimbursement of the amounts resulting from the charges illegally collected from the beneficiaries. The execution of the plan should be ended in 2011 by the payment of interests on the capital.

Furthermore the Commission continued monitoring the application of the so-called "Breakfast directives", which lay down particular compositional and labelling requirements for products including honey, chocolate, jams and fruit juices[100]. More specifically, concerning chocolate (Directive 2000/36/EC[101]), the Commission ensured the monitoring of the implementation by Italy of the judgement of the Court of Justice in case C-47/09 where the Court took the view that, by providing that the adjective 'pure' may be added to the sales name of chocolate products which do not contain vegetable fats other than cocoa butter, the Italian Republic had failed to fulfil its obligations under the Directive..

4.2. Evaluation

4.2.1. General evaluation

Taking into account the volume of EU law currently in force in the agricultural sector, the *acquis* in the agricultural sector may be considered as globally stable and manageable subject to technical up-dating or clarification effected through Comitology (see above). This updating is not generally expected to be controversial or difficult to implement due to the well-established and well-understood framework in which this will take place and in the light of previous experience of the relatively smooth adoption and timely entry into effect of this type of measure.

In the agricultural sector it may be considered that preparatory working contacts between experts, review of problems arising and multilateral and/or bilateral exchange of information constitute proportionate and sufficient means to ensure correct implementation. Furthermore, besides its role in the adoption of implementing rules, the Management Committees, which meet regularly, are a privileged forum for the exchange of information and best practise between Member States and the Commission.

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99 Judgement of 5 October 2006 in case C- 84/04, Commission v. Portuguese Republic, Rec 2006, p.I-9843.

100 The list of products is not exhaustive. The products referred to above due to their nature and constant consumption require particular supervision of the application of the following directives: Council Directive 2001/110/EC of 20 December 2001 relating to honey , Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption**,**Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption and Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption.

101 Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption.

In any case, as already explained, the agricultural sector makes use of the clearance of accounts mechanisms to monitor through its audits the application of secondary agricultural legislation and in particular the management and control systems thereof.

4.2.2. Sector based remarks

(a) Market instruments

As regards the functioning of this sector-based *acquis,* no major problems were encountered in 2010 as regard the application of the existing rules. The *acquis* can be considered as stable providing a generally satisfactory situation.

The simplification of horizontal regulations contributed to the aim of harmonised application and interpretation of Union law in all Member States. The discussions in the Committee on legal and technical issues and on the annual report on physical checks contributed to realising these aims as well. The audits performed in 2010 generally show a very high degree of conformity by Member States.In line with the priorities defined in the 27th report to EP for agricultural sector, the priorities indicated in the wine sector were realised. The grubbing-up scheme in the wine sector met with considerable success between 2008 and 2011. Only half the demand could be satisfied by the available budget. The national support programmes budgets were also almost completely allocated, indicating the attainment of many of the objectives set out. Member States fully used the possibility given in the wine reform in 2008 to establish their national support programmes with the measures necessary for the modification of their own wine sector. The budget execution reached 98, 5% of the available funds for 2010. The main measures remain restructuring measures (44%) and distillation (37, 5%). The part of the budget used for distillation should diminish in 2011 and onwards and therefore this part of the budget will be dedicated to other measures such as investments and promotion in third countries.

(b) Direct payments and cross compliance

Direct payments scheme

The *acquis* in the direct payments sector is stable and its application by the Member States in 2010 was generally satisfactory. However some specific issues have created implementing difficulties for Member States, for example regarding the assessment of the eligibility of certain marginal areas.

The legislation defines the agricultural area eligible for payments under the single payment scheme (SPS) and the single area payment scheme (SAPS) as well as what is considered agricultural activity. Following the principle of decoupling introduced by previous reforms, no production is required on the eligible hectares. This has lead to certain grey zones where it can be difficult for both farmers and national authorities to determine in practice whether the area in question is actually agricultural or whether the character and main purposes of the area are rather to be considered as natural, recreational or forest.

To help Member States face this challenge and also in reply to a request raised by the Member States in the context of the simplification exercise, the issue of eligibility was thoroughly examined in the Management Committee for Direct Payments. The examination which had already started in 2009 included presentations by the Member States, written description of the Member States implementation of eligibility rules and exchange of view and experiences as regards challenging situations as well as the best practices and methods to deal with such situations. In order to obtain more extensive background knowledge on the subject in view of possible future developments a number of without commitment alternative scenarios to the current eligibility rules were analysed as well. The Commission services elaborated a discussion paper resuming the main issues arising from the discussions. It appeared that the challenges were of a limited character and the best practices to deal with these challenges were identified.

During the year 2010, the Commission services have continued working in close cooperation with Member States to ensure the correct application of the rules governing specific support (Articles 68 to 72 of Regulation (EC) No 73/2009). The Commission services examined new measures notified by 01/08/2010 by two Member Sates to be implemented from 2011 and these services sent comments to them in order to ensure a correct application of the EU legislation, in particular as far as potential overlapping with supports under other CAP instruments and consistency with CAP measures were concerned.

Cross compliance

Regarding cross compliance the work undertaken during 2010 concerned the follow-up of the exercise of simplification of the system of management and control started in 2009. On the bases of the simplification proposals made by Member States the remaining proposals have been transformed into legislative or quasi-legislative. In this respect a first set of amendments of Commission Regulation (EC) No 1122/2009[102] has been drafted in order to improve controls and sanction rules as well as to adapt the system of maintenance of permanent pasture to better reflect the reality. A second set of amendments of the same Commission Regulation has been finalised early in 2010 in the Management Committee for Direct Payments in order to better take into account the certification schemes in the control system and to better make use of specific control systems. Certain simplification initiatives concern working documents which have been modified accordingly. Finally simplification proposals concerning Council Regulations (EC) N°73/2009 and 1698/2005 were dealt with under the Lisbon Treaty procedures in the course of 2010.

(c) Rural development

[102] Commission Regulation (EC) No 1122/2009 of 30 November 2009 laying down detailed rules for the implementation of Council Regulation (EC) No 73/2009 as regards cross-compliance, modulation and the integrated administration and control system, under the direct support schemes for farmers provided for that Regulation, as well as for the implementation of Council Regulation (EC) No 1234/2007 as regards cross-compliance under the support scheme provided for the wine sector.

The main risk factors identified in the rural development sector relate to error rates. The control statistics reported by the Member States for rural development measures under Axis 2 in 2009 show an error rate significantly above the materiality threshold presently used by the European Court of Auditors (2%).

All of the 90 Rural Development Programmes are up and running. However, there were been substantial delays in the implementation of certain measures in a number of programmes. The rate of budget implementation varies between Member States, the four thematic Axes of the policy, as well as between different measures within the Axes. By the end of 2010, Member States have implemented between 23% and 58% of their allocated EAFRD funds (including advance payments). The expenditure declared by the Member States so far focuses on measures related to improving the environment and the countryside. The differences in budget implementation between different measures clearly show that investment measures (Axis 1, 3, and Leader) are slower to get started than area or animal-related payments. Leader, in particular, has experienced a slow start, but the implementation has accelerated in 2010. Otherwise, the experience is not enough to base clear conclusions on the possible problems.

(d) Quality policy

Quality

EU agricultural product quality legislation constitutes a fairly stable *acquis* characterised by a globally satisfactory situation.

The reflection process leading to the 2009 Communication and the following impact assessment exercise showed, however, the need for enhancing the overall coherence of the food quality policy. Simplification and streamlining of existing EU quality schemes were also considered necessary to improve the schemes' take up and visibility in the market place.

The Quality package adopted in December 2010 intends to provide solutions to these needs.

Organic

The overall application of the organic production rules may be considered as stabilised and on the whole satisfactory. Legislation concerning the new EU organic logo was successfully introduced (see above). With regard to organic wine, the Commission launched the discussions within the Standing Committee for Organic Farming, the European Parliament and stakeholders.

(e) Technical standards directive (Directive 98/34/EC)

Following the information available to the Commission the functioning of Directive 98/34/EC in the agricultural sector appears to be satisfactory. In 2009 there were, for example, no infringement procedures launched against the Member States for not following detailed

opinions.

4.3. Evaluation results - Priorities and actions planed 2011

(a) Legislative and management priorities and action programming 2011

General comments

The main priority as regards legislative activity in the agricultural sector will be the legal drafting of the proposals required for the adoption and implementation of the new CAP reform. The Commission, after extensive consultation of the stakeholders will prepare legislative proposals to be presented in 2011. These will follow the ordinary legislative procedure applied for the first time to a reform of the CAP. This reform should enter into force in 2014.

One of the other main priorities for the Commission as regards legislative activity in the agricultural sector will still be to implement the important changes introduced by the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU) and in particular the extension of the ordinary legislative procedure (co-decision) to agriculture and the adoption of new rules on the Commission's delegated and implementing powers (Comitology). The alignment process of the CAP legislation to the new legal bases resulting from Lisbon Treaty will be continued: the aligned legal proposals adopted by the Commission in 2010 will be dealt with by the Council and Parliament in 2011. Furthermore, Commission will adopt the legal proposals for the alignment of the legal acts of the CAP not included by the proposals adopted in 2010.

Market instruments

Besides the ongoing pursuit of legal and operational simplification, the Commission will continue to work on the improvement of the *acquis* in order to be ready to adapt to the challenges it faces notably regarding the animal products sector where it will proceed to the follow up of the responses to the recommendations of the High Level Experts Group for Milk (report delivered on June 15, 2010 amid the Council Presidency Conclusion of the 27.09.2010). The Commission's legislative proposals for the milk package were adopted on 9 December 2010. The adoption by the EP and the Council is expected during 2011.

As regards wine, reports to be delivered by the Commission to the Council and the European Parliament one shall be delivered in 2011 relating to wine promotion measures, and a second one will be delivered in 2012 relating to the wine implementation of the reform of 2008. In addition, an external evaluation of the wine sector will be carried out in 2011 and discussions will be pursued to secure a Council mandate to negotiate membership of the OIV for the European Union and to successfully complete those negotiations.

Many product specifications on wine PDO/PGI and spirit drinks GI will have to be examined in accordance with EU law. Around 1800 files are expected to be received and then analysed.

On alcohol, the discussion on the Combined Nomenclature should be opened. Spirit drinks regulation will need to be modified for the sake of a better legal clarity. The working document on compound term could be legally adopted. The codification/recast of Council Regulation (EEC) No 1601/91 laying down general rules on the definition; description and presentation of aromatized wines, aromatized wine based drinks and aromatized wine product cocktails was not finally adopted in the co-decision procedure. The outcome was that a new proposal had to be prepared by the Commission. This proposal is scheduled in 2011. Legislation on seeds could be revised in 2011. Continuation of the effort to achieve simplification by eliminating the registration of hops contracts will require a modification to the Council CMO Regulation (EC) No 1234/2007[103].

In the fruit and vegetable sector, in order to ensure the smooth functioning of the *acquis*, a recast of the implementing rules (Commission Regulation No1580/2007) which incorporates interpretative notes and some technical adjustments was launched. Several issues are addressed such as price-reporting, the new crisis prevention and management tools for producer organisations and the annual reporting of sector specific data by Member States. Adoption of the recast is scheduled for Spring/Summer 2011.

As regards horizontal rules, revision and introduction of operational simplifications of existing horizontal Regulations will be initiated in the field of tariff rate quotas, licences, and export refunds / trade mechanisms.

The financial and economic situation in Member States and globally are having an impact on agricultural products. An additional priority for the moment is to monitor the market situation for each of the products concerned. Price volatility requires close market monitoring and quick reactions by using the existing market measures as reviewed under the "Health check".

Direct payments and cross compliance

A priority for 2011 will be to participate in the ordinary legislative procedure in order for the Council and the European Parliament to adopt the Commission proposal amending Regulation (EC) No73/2009.

The main task in 2011 will be the preparation of the legislative proposal for the new Direct payments scheme.

Rural development

The main task in 2011 will be the preparation of the legislative proposals for the Rural Development Policy after 2013, including an adapted Common Monitoring and Evaluation Framework (CMEF) and the Common Strategic Framework (CSF) with the structural funds. Having already started in 2010, the impact assessment process will be completed during 2011.

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[103] Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules of Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector , OJ L 350, 31.12.2007, p. 1–98.

Drafting and discussing of corresponding legal texts will constitute a major part of the work relating to future Rural Development Policy for the year.

The Commission, together with Member States, will also further continue the process of reducing the error rates in rural development. This will be done by identifying and sharing best practises regarding control issues, expanding audit activity, enhancing collaboration with geographical rural development units and by improving the verifiability and controllability of rural development measures in general and those under Axis 2 in particular.

Quality policy

Quality

The adoption of the Quality package on agricultural product quality policy adopted in by the Commission in December 2010 has opened the way to inter-institutional discussions on the content of the EU initiative on food quality. The presentation of the legislative proposal in the Council and the Parliament, within the context of the ordinary legislative procedure, will be at the centre of Commission's efforts to reinforce and improve the EU food quality policy.

Whilst progressing through the legislative procedure, the ongoing activities to ensure an efficient application of the Regulations in force will continue.

Building on continuous improvements in scrutinizing techniques applied to applications, the efforts made in accelerating the rate of reaching the final decision on applications - while ensuring the respect of sectoral EU legislation - will continue.

The scrutiny of third-country applications will contribute to the finalisation of international agreements on the protection of geographical indications.

The assessment of the Food Quality legislations of candidate countries and associated countries against EU legislation will also be carried out.

Organic

According to the provisions of the organic farming legislation, the Commission will present in 2011 a report to the European Parliament and to the Council reviewing the experience gained from the application of the organic farming legislation.

The Commission hopes that an agreement will be reached between the European Parliament and the Council on its proposal to align the organic farming legislation with the provisions of the Lisbon Treaty.

With regard to imports from third countries, the Commission intends to publish the first list of control bodies recognised for the purpose of equivalence.

Clearance of accounts

For 2011, the annual work plan foresees 119 conformity audits with missions and several desk checks of which the number is estimated to be around 20 based on last years' experience. For the conformity audits, the work program is based on a central risk analysis in which all the Directorate auditors were actively involved.

32 audits are planned of various market measures including the sugar restructuring fund, Article 69/68, wine, POSEI and fruit and vegetable operational funds.

24 audits will take place for area aids and entitlements of which 2 each to EL, BG, RO and PT of which the latter 3 have action plans in place for the IACS. 10 cross-compliance audits will take place. For non area coupled aids, 9 audits will be carried out covering animal premium schemes and Article 69.

44 audits will be carried out on Rural Development measures of which 12 cover Axes 1 and 3 and measures with flat rate support and 16 cover Axis 2 focusing on the "Agro-environment" and "Natural Handicaps" measures, additional 4 audits concern the SAPARD programme. Furthermore there will be 12 ex-post audits on rural development expenditure regarding the 2000-2006 programming period for EAGGF-Guidance.

(b) Enforcement priorities

As already mentioned, in the area of agriculture and rural development, monitoring the application of EU law under the Article 258 TFEU (ex Article 226 TEC) procedure concentrates on two main objectives: removing barriers to the free movement of agricultural products and ensuring that the more specific mechanisms of agricultural regulations are applied effectively and correctly.

Regarding recourse to the infringement procedure, priority will be granted to cases which raise issues concerning the compatibility of Member States' legislative, regulatory or administrative measures with EU agricultural rules and to cases where Member States concerned refrain from applying the common rules referred to above, thus jeopardizing the effectiveness of important mechanisms of the common agricultural policy, particularly regarding the 1st pillar.

For the year 2011, the Commission will in particular be vigilant in pursuing infringements of the type described in the previous paragraph challenging the application of the CMO's reform in the wine sector and those which would affect the application of the direct payment regime , and in particular "cross compliance".

4.4. Summary

Taking into account the significant volume of agricultural law and its more than 50 years history, it may be considered as a quite stable *acquis* that, on the one hand, is subject to frequent technical modifications under the Comitology procedure, and on the other hand, undergoes, on a regular basis, much more profound modifications. The last one of these was the 2003 reform that was subject to the "Health check" process.

The policy is divided into two pillars: the first pillar consists of a framework for supporting the income of farmers through the payment of direct aid and a system for managing and supporting agricultural markets. The second pillar of the CAP provides a framework to support the development of rural areas of the EU.

The implementation of the CAP is a joint responsibility of the Member States and the Commission, known as shared management under which the responsibility for implementation at the level of the final beneficiaries has been delegated to the Member States. In the agricultural sector, preparatory working contacts between experts, review of problems arising and multilateral and/or bilateral exchange of information all help to ensure correct implementation. Furthermore, the Management Committees, which meet regularly, acts not only as a body delivering its opinion on legal proposals for Commission regulations, but also serves as a privileged forum for the exchange of information and best practice between the Member States and the Commission, thus playing a key role in preventing implementations problems.

The detailed overview of the implementation of EU law in the agricultural sector shows that it can generally be considered as satisfactory while any problem with the implementation of the rules in the Member States is closely followed through the audit mechanisms and clearance of accounts procedure which acts as a direct incentive to Member States to comply with EU law.

Even so, the agricultural *acquis* is regularly subject to reforms and/or modifications in order to adapt the CAP to its new challenges. By Commission Communication of 18/11/2010 on the "*Common Agricultural Policy towards 2020. Meeting the food, natural resources and territorial challenges of the future*", a new process of reform has now been launched. In 2010, the main challenges that prompted action from the Commission as regards this *acquis* consisted of the alignment process of the CAP legislation to the new legal bases resulting from Lisbon Treaty. This process will be carried on: the aligned legal proposals adopted by the Commission in 2010 will be dealt with by the Council and Parliament in 2011. Furthermore, Commission will adopt the legal proposals for the alignment of the legal acts of the CAP not included in the proposals adopted in 2010.

Nevertheless deficiencies and infringements in the application of EU law by Member States in the agricultural sector occur and can be dealt with through infringement proceedings. The use of these proceedings concentrates on two main objectives: removing barriers to the free movement of agricultural products and ensuring that the more specific mechanisms of agricultural regulations are applied effectively and correctly.

Regarding the recourse to infringement proceedings, priority will be given to cases which raise issues concerning the compatibility of Member States' legislative, regulatory or administrative measures with EU agricultural rules and to cases where the Member States concerned refrain from applying these common rules, thereby jeopardizing the effectiveness of important mechanisms of the common agricultural policy, particularly regarding the 1st pillar.

For the year 2011, the Commission will in particular be vigilant in pursuing infringements of the type described in the previous paragraph challenging the application of recently reformed important CMO in the wine sectors and those which would affect the application of the direct payment regime, and in particular "cross compliance".

In the agricultural sector, the Commission will continue to make use of the clearance of

accounts procedure to convince Member States to adapt their management and control systems in the event that an infringement could be detected through conformity audit mechanisms.

5. ENERGY

The EU *acquis* in the field of energy has a daily impact on citizens and businesses in Europe. The Commission's services ensure that this legislation is properly applied and enforced so as to guarantee that citizens fully benefit from the existing legal framework, competitiveness is encouraged and a fully functioning internal energy market becomes a reality. Priorities focus on actions ensuring secure and competitive energy supplies and having a significant impact on the fight against climate change.

To safeguard the effective implementation of the *acquis* in 2010, the Commission's services continued to apply a combination of infringement actions and preventive mechanisms, such as, for example, guidance to the Member States on the interpretation and application of the legislation. Efforts to foster cooperation with the Member States and support national action persisted. Infringements proceedings remained a crucial tool for enforcing the existing framework. Cases of non-communication of national transposition measures were swiftly dealt with by launching systematically infringement proceedings against the respective Member States. Identified non-conformity cases have been tackled through initiating infringement action, based on developed and consistently applied prioritisation criteria.

In parallel to enforcement measures, considerable work towards streamlining and advancing the regulatory framework by adopting new legislation was carried out. New legislative actions came as a reaction to identified limitations of the existing legal framework or global events calling for coherent reply at EU level, e.g. the Deepwater Horizon.

5.1. ENERGY - INTERNAL ELECTRICITY AND GAS MARKET

5.1.1. Current position

5.1.1.1. General introduction

The completion of the internal market for electricity and gas enabling European companies to compete Europe-wide is one of the Commission's priority areas of its strategy for sustainable, competitive and secure energy. The second regulatory package adopted in 2003 introduced important changes in the internal energy market such as legal unbundling of TSOs, the preparation of the full opening of the market and the obligation of installing national regulators and reinforcing their powers. Several Member States, however, so far failed to properly implement it. The package comprised Directives 2003/54/EC and 2003/55/EC of 26 June 2003 concerning common rules for the internal market in electricity and gas, respectively and Regulation 1228/2003 of 26 June 2003, on conditions for access to the network for cross-border exchanges in electricity. A similar regulation was adopted for gas at a later stage, i.e. Regulation 1775/2005 of 28 September 2005 on conditions for access to the natural gas transmission networks.

The third package of legislative measures adopted in 2009 aims at responding to most of the problems identified in the failure of application of the second package. A demonstration of Member States' commitment to the internal energy market will be the timely and correct

implementation of this third package into national law. The Commission will assist Member States in implementing the third package and will continue to pursue the full and correct implementation of the second package, including through formal infringement procedures. The main aim of these efforts is to develop the internal energy market and to favour competition on the market.

Directives 2009/72/EC and 2009/73/EC, which form part of the third internal energy market package, are already in force and should be transposed by the Member States by 3 March 2011. Regulation (EC) 713/2009 establishing an Agency for the Cooperation of Energy Regulators (ACER), Regulation (EC) 714/2009 on cross-border exchange in electricity and Regulation (EC) 715/2009 on cross-border network access in gas are fully applicable as of 3 March 2011, except the organisational provisions on ACER which became applicable with the entry into force on 3 September 2009.

5.1.1.2. Report of work done in 2010

Enquiries, problems and complaints

Several complaints were received in 2010. Problems reported mainly refer to the supplier switching processes, price issues and the monopolistic structure of some national markets, malfunctioning of cross-border trade and network access in the electricity sector. In the gas sector, problems were reported as regards the access to the gas network and generally the malfunctioning of the gas market.

One of the issues raised by several complaints is the malfunctioning of the supplier switching processes and the fact that companies do not pass on reductions of wholesale market prices to customers. Therefore, overbilling might happen. This is still due to a lack of competition on energy markets, in particular where a major incumbent has a dominant position on the market.

The third legislative package has been adopted with the aim to, *inter alia*, ensure real and effective choice of supplier to the benefit of all EU consumers. It places consumer choice, competitive prices and security of supply at the centre of its approach. The proper implementation of the legislation is thus of great importance for safeguarding the interests of consumers in the gas and electricity markets.

Management of infringements

In order to complete the internal electricity and gas market and prepare the ground for the implementation of the third legislative package, it is essential that the rules of the second legislative package are implemented correctly. Therefore, the European Commission issued in June 2010 a reasoned opinion against 19 Member States for electricity and 16 Member States for gas in the infringement cases which were opened in June 2009. The key violations identified remained the same: lack of transparency, insufficient coordination efforts by transmission system operators to make maximum interconnection capacity available, absence of regional cooperation, lack of enforcement action by the competent authorities in the Member States and lack of adequate dispute settlement procedures for consumers.

The Court of Justice of the European Union gave its final judgment on a case in relation to regulated prices on the Italian gas market (*Federutility* case C-265/08, 20.4.2010). The Court stated that regulated prices can be in line with the Gas Directive provided that they are strictly proportionate and limited in time. The infringement proceedings already opened against some

Member States still applying regulated prices for gas and electricity are being reassessed in the light of this case law and will be continued where necessary.

Petitions

During 2010, 4 petitions were dealt with raising issues related to the internal market for gas and electricity.

New legislation

Following the adoption of the third legislative package in 2009, less new legislation followed in 2010. However, the European Commission adopted on 10 November 2010 a set of new transparency rules for the European gas market([104]). In relation with cross-border exchanges in electricity, the European Commission adopted also guidelines on inter-transmission system operator compensation (ITC) and on transmission charging[105].

In addition, the European Commission adopted on 8th December 2010 its Proposal for a Regulation on Energy Market Integrity and Transparency (COM(2010)726) in order to prevent market manipulation and insider trading on energy markets. The draft Regulation was adopted under Article 194(2) TFEU, its final adoption by co-legislators is expected for 2011.

As regards the security of supply for gas, the prevention and crisis response mechanisms were considerably strengthened through the adoption of Regulation (EC) No 994/2010 of the European Parliament and of the Council of 20 October 2010 concerning measures to safeguard security of gas supply and repealing Council Directive 2004/67/EC([106]) which entered into force on 2nd December 2010. The Commission started immediately to work in close cooperation with Member States on the implementation of the new Regulation. First steps have already been taken to speed up the implementation, notably with regard to the investments for enabling bi-directional capacity in the cross border interconnections. In this regard, the Commission together with the European Network of Transmission System Operations for gas (ENTSOG) is to prepare an inventory to take stock of the situation and to examine the capacity needed. To assist Member States in their implementation, the issue is discussed as a permanent point in the agenda of the meetings of the Gas Coordination Group (GCG). In addition, the Commission closely monitors the steps taken by the Member States to fulfil the provisions included in the Regulation and reports to the GCG. The Group is also a useful platform to exchange best practices in the preparation of the risk assessment and the Emergency and Preventive Action Plans.

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104 Commission Decision of 10 November 2010 amending Chapter 3 of Annex 1 to Regulation (EC) No 715/2009 of the European Parliament and of the Council on conditions for access to the natural gas transmission networks (OJ L 293, 11.11.2010, p. 67).

105 Commission Regulation (EU) No 774/2010 of 2 September 2010 on laying down guidelines relating to inter-transmission system operator compensation and a common regulatory approach to transmission charging (OJ L 233, 3.9.2010, p. 1); Commission Regulation (EU) No 838/2010 of 23 September 2010 on laying down guidelines relating to the inter-transmission system operator compensation and a common regulatory approach to transmission charging (OJ L 250, 24.9.2010, p. 5).

106 OJ L 295, 12.11.2010, p.1.

5.1.2. **Evaluation of the current position**

Following the adoption of the third legislative package, first steps were taken during 2010 in relation to the implementation of this legislation in order not to loose 18 months until its full application as this could be detrimental to the development of the internal energy market. The European Regulators Group for Electricity and Gas (ERGEG) was tasked – for the interim period – to develop draft framework guidelines on several issues in gas and electricity. These will provide the basis for the development of network codes by the ENTSOs, which could then be made legally binding and would allow the internal market to be completed. In parallel, the organs of the new Agency, i.e. the Administrative Board, the Board of Regulators and the Director, were installed and took up their functions. First staff members were recruited and the necessary agreements were made with the host country Slovenia to enable ACER to start full operation on 3 March 2011. The Commission is also assisting the Member States in the transposition of the third legislative package.

Regional initiatives were again an important tool for making progress towards the internal energy market. Focus was on improving congestion management allocation and calculation, in particular in electricity where several market coupling projects were implemented, improving and harmonising transparency, improving security of supply in the gas sector, access to pipeline capacity and other issues. In order to further improve the functioning of the regional initiatives, the European Commission launched a public consultation to get input from the market where adaptations are needed in order to enhance the efficiency and effectiveness of the regional markets for them to deliver an integrated energy market by 2014. Although the energy markets are developing and become more integrated and more competitive, progress is still slow and the full potential of liberalisation has still to be realised. Therefore, it was also important to progress with the work foreseen in the third package before it had to be legally applied. A lot of work has been done during this interim period already on the so-called framework guidelines and network codes. In order to partially remit this slow progress, the European Commission continued the infringement procedures started in 2009 in relation to the second legislative package. This is necessary to ensure the correct implementation of EU legislation at national level, in particular as regards the electricity and gas Regulations and the Annexes to the electricity and gas Directives.

5.1.3. **Evaluation results**

Infringement proceedings initiated in the gas and electricity sector have been successfully carried out and will be continued in 2011. As a consequence of the infringement procedures launched by the Commission in 2009, some Member States finally transposed the directives properly into their national laws. Consequently, for these countries the infringement procedures were closed.

The third energy package responds to most of the problems identified in the failure of application of the second package. The European Commission will closely follow the implementation of the third energy package by the Member States and will assist the Member States in order to ensure timely and proper implementation of the package. To support this process, the Commission has published interpretative notes on unbundling, national

regulatory authorities (NRAs), retail issues and gas storage[107]. Where necessary, infringement procedures will be launched.

5.1.4. Sector summary

While the situation in more mature markets is demonstrating the potential benefits of energy market liberalisation, there are still a number of areas and Member States where significant obstacles to the efficient functioning of the electricity and gas market persist. The need for new legislation was evident and led to the adoption of the third energy package.

The Commission's efforts concentrated and will continue concentrating on an efficient implementation of the existing and new legislation in both, the electricity and gas sector, by combining the following actions:

- Remedial action: Continue to pursue infringement procedures so as to ensure proper implementation of the electricity and gas legislation in the main areas where failures were registered such as: penalties, transparency and capacity allocation of networks, third party access and consumer protection, all in both sectors. This action will continue in 2011 for both sectors.

- Preventive action: In the context of the adoption of the third energy package, the services of the Commission will assist the Member States in the implementation of the legislation.

5.2. ENERGY – Coal and oil

5.2.1. Current position

5.2.1.1. General introduction

With regard to the legislation in the domains of coal and oil, the largest part of the Commission's work in EU law management in 2010 consisted in facing the challenge to reinforce the safety of offshore oil and gas activities, which led to the adoption of a Communication from the Commission to the European Parliament and the Council (COM(2010) 560 final; 12.10.2010).

The main relevant legislation for the oil sector is Council Directive 2009/119/EC (Council Directive 2009/119/EC of 14 September 2009 imposing an obligation on Member States to maintain minimum stocks of crude oil and/or petroleum products; OJ L 265, 9.10.2009, p.9).

Although Directive 2009/119/EC repeals Directive 73/238/EEC, Directive 2006/67/EC and Decision 68/416/EEC, it does so only with effect from 31 December 2012. Therefore currently applicable legislation still include Council Directive 2006/67/EC (Council Directive 2006/67/EC of 24 July 2006 imposing an obligation on Member States to maintain minimum stocks of crude oil and/or petroleum products – Codified version; OJ L 217, 8.8.2006, p 8), Council Directive 73/238/EEC of 24 July 1973 on measures to mitigate the effects of difficulties in the supply of crude oil and petroleum products (OJ L 228, 16.08.1973, p 1 -2) as well as Council Decision 68/416/EEC of 20 December 1968 on the conclusion and implementation of individual agreements between Governments relating to the obligation of

[107] http://ec.europa.eu/energy/gas_electricity/interpretative_notes/interpretative_note_en.htm

Member States to maintain minimum stocks of crude oil and /or petroleum products (OJ L 308, 23.12.1968, p.19).

Directive 94/22/EC (Directive 94/22/EC of the European Parliament and of the Council of 30 May 1994 on the conditions for granting and using authorizations for the prospection, exploration and production of hydrocarbons; OJ L 164, 30.6.1994, p 3) also continued to form part of the *acquis* in the sector.

5.2.1.2. Report of work done in 2010

Infringements - complaints

With regard to the application of Directive 94/22/EC, the Commission's services continued to welcome publication demands received from Member States but also followed the implementation of those provisions by the Member States. Further procedural steps concerning two infringements procedures were executed in 2010. Namely, infringement proceedings opened against Belgium for failure to comply with its obligation to duly notify competent authorities and for other grievances were closed as finally the Member State met the requirements set out by the Commission. An infringement case against Poland concerning national procedures for granting rights over oil and gas resources, in which the Commission sent a reasoned opinion to the Polish authorities in 2008, was referred to the Court of Justice of the European Union. Although the Commission continued contacts with the Polish authorities in the course of 2010, no effective progress without resort to litigation could be reached.

New legislation

Directive 2009/119/EC foresees a transition period until 31/12/2012 by which date all Member States shall have to ensure compliance with the Directive and the currently applicable Directive 2006/67 will be repealed. Consequently and with respect to oil, the activities in 2010 included active dialogues with Member States.

As the new system of emergency oil stocks brings EU rules much closer to IEA practices and provides better assurances of the availability and verifiability of the stocks, the Commission's services ensured that the necessary meetings or contacts with the services of IEA as well as with those of Eurostat took place.

The seriousness of the Deepwater Horizon accident led the Commission to launch in May 2010 an appraisal of safety in offshore exploration and production activities in European waters. On the basis of a review of applicable legislation as well as of consultations with both industry and competent authorities, the Commission identified in July five main areas where action is needed and adopted on 12th October 2010 the Communication "Facing the challenge of the safety of offshore oil and gas activities" (COM(2010) 560 final).

Tasks effected in relation to coal

As regards coal, regular monitoring of the coal sector and market continued as foreseen in the applicable provisions (namely, Regulation (EC) 405/2003). Information on import price indexes as well as coal import, production and consumption volumes were collected, analysed and discussed with stakeholders through the National Coal Experts committee and in the annual Coal Dialogue. The half-yearly price indexes and annual market report were published

in 2010 as foreseen[108].

5.2.2. Evaluation of the current position

Work has continued on amending the current oil stocks reporting procedures and instruments to provide for the use of a single reporting tool by the end of the transition period. The new reporting will be based on the Monthly Oil Stock (MOS) questionnaire which needs some update/streamlining in order to be suitable for the purposes of the new Directive, including the reporting of commercial stocks. In 2010, Eurostat and Directorate-General for Energy prepared a detailed proposal including the tables and definitions which is now discussed with the IEA. The possibility of developing an electronic tool is also envisaged to allow the consultation of the Coordination Group by electronic means, without convening a meeting in Brussels.

Furthermore, a specific external study of the feasibility of increasing the frequency of commercial oil stocks reporting to weekly has come to its end in 2010. The study found limited and mostly unquantifiable benefits; no evidence for reduced volatility or lower prices was found.

In oil (or gas) upstream, in the frame of the assistance given to Member States in the course of their implementation of Directive 94/22, some 46 demands for publications of notices from Member States were dealt with in 2010 under the provisions of the Directive.

Concerning offshore oil activities, the European Parliament has issued a resolution calling on the Commission to bring forward a comprehensive legal framework ensuring uniformly high safety standards apply across the EU and third countries and including proposals covering inter alia accident prevention, disaster response and liability (Resolution on EU action on oil exploration and extraction in Europe adopted on 7 October 2010).

In its communication of 12th October 2010, the Commission presented some initial steps towards such objective:

Namely, the Commission proposes to work towards a revised and more coherent legal framework ensuring the application of state-of-the-art practices across the whole of the EU. The main requirements for the licensing of hydrocarbon exploration and production need to be defined at EU level. The existing environmental legislation, as well as the health and safety framework should also be reviewed, and the feasibility to apply EU product safety legislation to equipments used on mobile offshore units needs to be examined. Proposals to amend the Environmental Liability Directive should be made and a new guidance document should address the applicability of the Waste Framework Directive to oil spills. The Commission also called upon the Member States to apply a precautionary approach in the licensing of complex operations and to assess the need to suspend such licensing, until the European safety regimes have been assessed in the light of the Deepwater Horizon accident. The EU's intervention capacity for offshore accidents would need to be reinforced, and further actions will also need to be promoted at the levels of the industry, of the regulatory and supervisory authorities as well as of EU neighbours.

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[108] Commission Staff Working Document – The Market for solid fuels in the Community in 2008 and Estimates for 2009 (SEC(2010)996,24.8.2010); http://ec.europa.eu/energy/observatory/coal/hard_coal_imports_en.htm

The Commission also announced that it will work with Member States, industry and other stakeholders to provide the public with easy access to continuously updated information on safety measures, risk management, contingency plans and company-specific statistics on key safety indicators.

As regards coal, Council Regulation (EC) 405/2003 has expired on 31 December 2010 as stipulated in its Article 12. The average coal import prices for the 2nd half of 2010 will therefore be the last information published on the topic by Directorate-General for Energy. Information on coal production, imports/exports and consumption will in the future still be available via Eurostat.

Regulation (EC) 405/2003 had originally been agreed in parallel with the current State aid for coal Regulation which also expired on 31 December 2010. While drafting the proposal for a new Regulation on State aid for coal, the Commission's services have analysed the information requirements and concluded that the new coal State aid regime will no longer necessitate the collection of data and elaboration of import price index up to then done on the basis of Regulation (EC) 405/2003. Furthermore, according to the reactions received to a questionnaire sent to Member States' coal experts, the use of the price index seems to have been rather limited in the coal sector. It has therefore been decided that maintaining such EU-wide reporting requirements on coal importers and Member States would not be justified.

5.2.3. **Evaluation results**

The Commission's resources will need to remain concentrated on the preparation and drafting of the package of measures to enhance offshore safety, as well as on the implementation of the new oil stocks legislation, both at EU level and at the level of Member States.

In 2010 the Commission carried out intensive stakeholder dialogues and an assessment of the regulator and industry practices in the European offshore oil and gas sector and the legislative framework applicable to the prevention, mitigation and liability for accidents on offshore installations. The issue was raised also during dialogues with key third countries such as Norway. The review of EU minimum standards for occupational health and safety, environmental liability, product safety, disaster response and hydrocarbon licensing resulted in a list of topics where further action should be taken to improve legislation and bring about more coherent offshore safety practices across the EU. The structure of the 2011 package of measures to enhance offshore safety is likely to comprise a comprehensive legislative proposal based on the best existing practices in Europe ,a proposal for the EU to become party to the Offshore Protocol to Barcelona Convention and the issuance by Directorate-General for Environment of guidelines on the application of the Waste Directive.

Concerning oil stocks, the main tasks that will deserve attention and follow-up in 2011 will be as follows:

- The revised Monthly Oil Stock (MOS) questionnaire has to be finalised and agreed first by the IEA and then by Member States. Eurostat is planning to start the comitology procedure in order to amend the Energy Statistics Regulation in the second half of the year.

- The review of internal emergency procedures, given the more active and central role given by the new Directive to the Commission in case of supply disruptions.

- Continuing the preparation of an electronic tool to allow the consultation of the Coordination Group by electronic means.

- Assisting Member States with the transposition of the Directive; a discussion workshop is envisaged to share experience and discuss questions.

- The examination of methodologies and standards for reviewing emergency preparedness and stockholdings of/in Member States.

5.2.4. **Sector summary**

The Commission continued its work related to the implementation of the oil stocks Directive which was adopted in 2009. In addition to assisting Member States, the Commission's efforts focused on the development of an oil stock reporting system which meets the requirements set in the Directive. In 2011, other aspects will be also addressed, including the preparation for its reinforced role in the coordination of emergency procedures and the reviews of emergency preparedness and stockholding of Member States.

In the field of offshore safety, a review conducted following the Deepwater Horizon accident has shown that the regime governing the offshore oil and gas activities in the EU is very fragmented and leaves areas of legal uncertainty. Legislative action appears to be needed to ensure the spread of best practices across the EU and filling the identified gaps. Therefore, in 2011 the services of the Commission will hold further consultations with stakeholders regarding proposed initiatives in view of tabling proposals for concrete measures.

5.3. ENERGY - Renewable energy sources

5.3.1. **Current position**

5.3.1.1. General introduction

Renewable energy is a key component of the EU energy strategy. Recognising that renewable energy will form the heart of any future low carbon energy sector, the EU introduced a comprehensive and robust supportive legislative framework.

Main pieces of EU *acquis* are:

– Directive 2001/77/EC of the European Parliament and of the Council of 27 September 2001 on the promotion of electricity from renewable energy sources in the internal electricity market[109]

– Directive 2003/30/EC of the European Parliament and of the Council of 8 May 2003 on the promotion of the use of biofuels or other renewable fuels for transport[110].

– Directive 2009/28/EC of the European Parliament and of the Council of 5 June 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC[111].

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109 OJ L 283, 27.10.2001, p. 33.
110 OJ L 123, 17.5.2003, p. 42.

5.3.1.2. Report on the work done in 2010

All existing complaints or cases launched under Directive 2001/77/EC or Directive 2003/30/EC were either pursued or closed in the course of 2010. Overall, 69 infringement proceedings and complaints relating to the renewable energy sources *EU acquis* were dealt with during year 2010, 47 of which were closed. At the end of 2010, 22 of these infringement cases or complaints were still ongoing.

Directive 2009/28/EC, which entered into force on June 25th 2009 and contained some preliminary reporting requirements (National Renewable Energy Action Plans), was due to be implemented by 5 December 2010. Enforcement of the reporting requirements is ongoing (infringements for non-reporting were opened, evaluation of plans began, followed by clarifying letters to some Member States). Scrutiny of national transposition began and will continue in 2011 (technical study launched in January to assist examination of national legislation).

To facilitate timely and correct implementation of the Directive the Commission undertook a number of studies and worked with stakeholders. Stakeholder "roadmaps" were produced to help Member States prepare their National Renewable Energy Action Plans, a "Concerted Action" network of Member State officials was launched, with active Commission participation, to enable discussion of best practice in implementing the Directive.

5.3.2. **Evaluation of the current position**

The new legal framework of Directive 2009/28/EC will replace Directives 2001/77/EC and 2003/30/EC which have been partially repealed as of April 1st 2010 and will be completely repealed on 1 January 2012. The Commission is firmly committed to close monitoring and enforcement of Directive 2009/28/EC.

The earlier need to pursue Member States for non-reporting and the inflow of complaints received suggests that several Member States have *not* been implementing the relevant Directives in a complete or appropriate manner. Continued failures of this nature risk to undermine the 2020 targets, and thus the EU's whole energy and climate strategy.

The Commission's Communication on renewable energy of 31/1/2011[112] included a progress report and highlighted Member States' failure to achieve the 2010 targets. It also highlighted the need for major efforts to correctly and fully implement the new Directive 2009/28/EC. Continued close monitoring and enforcement action by the Commission is therefore warranted.

5.3.3. **Evaluation results**

5.3.3.1. Priorities

Strong and rapid measures to encourage Member States to properly implement and apply the *acquis* continue to be needed.

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111 OJ L 140, 5.6.2009, p. 16.

112 COM(2011)31 final, 31.1.2011.

5.3.3.2. Planned action

During 2011, the Commission will complete its evaluation of National Renewable Energy Action Plans, undertake infringements and pursue complaints as appropriate. It will also scrutinise national legalisation to ensure complete and correct transposition of the Directive.

The Commission continues to do its utmost to assist Member States in implementing the Directive. In addition to the national action plan template published in 2009[113], it will prepare a template for Member States to help them to comply with their 2011 reporting requirements under the Directive.

A range of communications, guidance notes and studies will also be produced to help ensure Member States implement the Directive fully and appropriately. This includes the ongoing work of the "Concerted Action" project[114] in the framework of the Intelligent Energy for Europe Programme.

Member States' reporting requirements for 2011 include submission of progress reports. The Commission will thoroughly evaluate all these reports and take action against those Member States that fail to provide them.

5.3.4. **Sector summary**

The Commission continues to vigorously enforce the *acquis* on renewable energy. The Commission's progress reports over the years, the non-reporting of several Member States and the complaints received from industry stakeholders all indicate that there continue to be problems hampering the development of renewable energy and failures to take sufficient measures, in accordance with the *acquis*. Removing barriers and encouraging the growth of renewable energy by the Commission will continue to be an important priority of the Commission, as renewable energy development is a crucial and integral element of the EU's whole energy and climate strategy. In 2011 it will continue to monitor and help Member States in implementing the *acquis*, notably Directive 2009/28/EC.

5.4. ENERGY – ENERGY EFFICIENCY

5.4.1. **Energy performance of buildings**

5.4.1.1. Current position

a) General introduction

Buildings are responsible for 40% of energy consumption and 36% of EU CO_2 emissions. Energy performance of buildings is key to achieve the EU Climate & Energy objectives, namely the reduction of a 20% of the Greenhouse gases emissions by 2020 and a 20% energy savings by 2020. Improving the energy performance of buildings is a cost-effective way of fighting against climate change and improving energy security, while also creating job opportunities, particularly in the building sector.

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113 http://ec.europa.eu/energy/renewables/background_documents_en.htm

114 http://www.ca-res.eu/

The main piece of the EU *acquis* is Directive 2002/91/EC of the European Parliament and of the Council of 16 December on the energy performance of buildings[115]. The recast Directive 2010/31/EU on the energy performance of buildings was adopted in May 2010[116]. It will repeal the old Directive as of February 2012.

b) Report on the work done in 2010

The main achievement in the field of energy efficiency in the building sector in 2010 was the adoption of the recast Directive on energy performance of buildings (hereafter: "EPBD") on 19 May 2010 and its entry into force on 8 July 2010. The proposal intended to simplify and strengthen the provisions of the EPBD and thus to increase the energy efficiency of Europe's building stock, to tackle climate change and to contribute to an increased security of energy supply.

Implementation efforts regarding the existing Directive continued in 2010 with meetings of the 'Concerted Action' in Amsterdam in January 2010 and in Ljubljana in September 2010, hence continuing the work done in previous years. This instrument is intended to promote dialogue and exchange of best practice. Being an active forum of national authorities from 29 countries, it focuses on finding common approaches to the most effective implementation of this piece of EU legislation. In the meantime, Concerted Action is being replicated in other policy areas - such as energy services and renewable energy sources - as it has proven to be a successful instrument.

This effort in dissemination and consultation was continued with the launch of an internet based platform as an initiative to increase awareness of all parties in the building chain.

Infringement proceedings continued. In January 2010, eight cases were open, two of them for non-communication and six for incomplete/incorrect transposition. Five cases out of these eight have been closed in 2010: the two non-communication cases as well as three of the non-conformity cases. Of particular importance was the closure of the two non-communication cases as a result of the adoption of additional transposition legislation by the two concerned Member States. Directive 2002/91/EC is therefore now transposed in all 27 Member States.

The work of the Commission in 2010 focused on the completion of the conformity check of the Directive 2002/91/EC. The main problems detected concern the correct transposition/application of the Directive's provisions regarding the issue of energy performance certificates and the inspection of boilers and air-conditioning systems. The Commission received several complaints concerning the lack of issue of energy performance certificates in some Member States. As a result of it the Commission sent complementary letters of formal notice concerning two cases already open, and opened one new infringement case and five EU Pilot files. Additionally, two information letters have been sent to the countries not being at that moment members of the EU Pilot system.

Petitions

One petition was received concerning the independence of experts in charge of inspections for which a final response was given.

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115 OJ L 1, 4.1.2003, p. 65.
116 OJ L 153, 18.6.2010, p. 13.

5.4.1.2. Evaluation of the current position

The Commission's ambitious recast proposal that strengthens the current legislation relating to the energy performance of buildings has been adopted on 19 May 2010 (Directive 2010/31/EU) and has already entered into force. Member States have until 9 July 2012 to adopt transposition measures. In the meanwhile, the Commission will follow-up the open infringement cases on the Directive 2002/91/EC and continue to monitor its correct transposition.

5.4.1.3. Evaluation results

a) Priorities

Attention will focus on the enforcement of the existing legislation and the preparation of the subsequent implementation of the new Directive. After finalising the conformity assessment, more infringement procedures might be launched in 2011.

b) Planned Action

The Commission will adopt in 2011 a delegated act setting a methodology framework to assist Member States in setting cost-optimal minimum performance requirements. It also aims at adopting an implementing decision to establish an EU voluntary certification scheme for the energy performance of non-residential buildings.

5.4.1.4. Sector summary

The Energy Performance of Buildings Directive (EPBD) is the main EU legal tool that provides for a holistic approach towards efficient energy use in the buildings sector. The EPBD's main objective is to promote the cost-effective improvement of the overall energy performance of buildings. Improving the energy performance of buildings is a cost-effective way of fighting against climate change and improving energy security, while also creating job opportunities, particularly in the building sector.

The Commission's activities in this field are concentrated in the enforcement of the existing *acquis* while assisting the Member States in the correct and timely transposition of the recast Directive.

5.4.2. Energy efficiency of products

5.4.2.1. Current Position

a) General Introduction

The main pieces of legislation in this field are the following: (i) Directive 2009/125/EC of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-using products; (ii) Directive 2010/30/EU of 19 May 2010 on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products, and (iii) Decision 2006/1005 on the coordination of energy-efficiency labelling programmes for office equipment in the EU and USA ("Energy Star").

b) Report of work done in 2010

The work covered three distinct areas:

On ecodesign, the implementation of Directive 2009/125/EC[117] continued. Three detailed measures implementing the Directive were adopted in 2010 as regards:

– domestic dishwashers (Commission Regulation (EU) No 1016/2010)[118];

– domestic washing machines (Commission Regulation (EU) No 1015/2010)[119];

– amendment of Commission Regulation (EC) No 245/2009[120] on fluorescent lamps without integrated ballast, for high intensity discharge lamps and for ballasts and luminaires able to operate such lamps (Commission Regulation (EU) No 347/2010)[121] .

In addition to the adoption of legislative measures there was on-going work, such as preparatory studies, impact assessments, stakeholder meetings for the preparation of additional implementing measures for some 12 product groups. Member States had to transpose the Directive by 20 November 2010.

On labelling, the recast of Framework Directive 92/75/EEC has been adopted on 19 May 2010 as Directive 2010/30/EU[122] on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products. The measure extended the scope to include labelling of commercial and industrial products, regulated the layout and unauthorised use of the label, and simplified the legislation to ensure a uniform implementation on the internal market by using (directly applicable) Regulations instead of Directives. Member States have to transpose the Directive by 20 July 2011.

On energy labelling, the implementation of Directive 2010/30/EU continued. Four detailed delegated acts implementing the Directive were adopted in 2010 as regards:

– domestic refrigerators/freezers (Commission Delegated Regulation (EU) No 1060/2010)[123];

– televisions (Commission Delegated Regulation (EU) No 1062/2010)[124] ;

– domestic dishwashers (Commission Delegated Regulation (EU) No 1059/2010)[125];

– domestic washing machines (Commission Delegated Regulation (EU) No 1061/2010)[126].

On requirements on the labelling of tyres with respect to fuel efficiency and other essential parameters, the regulatory committee voted on the implementing regulation of the Tyre

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117 OJ L285 of 21.10.2009, p.10.
118 OJ L293 of 11.11.2010, p.31.
119 OJ L293 of 11.11.2010, p.21.
120 OJ L76 of 24.3.2009, p.17.
121 OJ L104 of 24.04.2010, p.20.
122 OJ L153 of 18.06.2010, p.1.
123 OJ L314 of 30.11.2010, p.17.
124 OJ L314 of 30.11.2010, p.64.
125 OJ L314 of 30.11.2010, p.1.
126 OJ L314 of 30.11.2010, p.47.

Labelling Regulation 1222/2009[127]. This implementing regulation is replacing the current testing method of wet grip of C1 tyres (tyres mainly fitted to passenger cars) by a more accurate testing method. The aim is to improve accuracy of testing for the purpose of tyre labelling.

Petitions

During 2010, one petition was dealt with regarding Eco-design, but has not yet been closed.

5.4.2.2. Evaluation of the current position

The activities carried out in 2010 resulted in the adoption of a significant number of legislative acts together with considerable development of legislative proposals for additional legislative activity in 2011.

5.4.2.3. Evaluation results

a) Priorities

The twin priorities will be to ensure the enforcement of the existing legislation, as well as adopting further implementing measures to extend the scope of measures to products not yet covered by ecodesign and labelling requirements.

b) Planned action

Work will be concentrated on the development and, where appropriate, adoption of implementing acts or voluntary agreements for air conditioners, domestic lighting, personal computers, imaging equipment, complex set-top boxes, fans, pumps, water heaters, boilers, laundry dryers, vacuum cleaners and commercial refrigerators.

5.4.2.4. Sector summary

In the context of the Second Strategic Energy Review adopted in November 2008, the Commission's activities in the field of energy efficiency of products are concentrated in the enforcement of the existing *acquis*. It is also anticipated that the Commission will continue adopting several implementing measures under Directive 2009/125/EC and Directive 2010/30/EU.

5.4.3. Energy end-use efficiency and energy services

5.4.3.1. Current position

a) General introduction

The European Union (EU) has adopted a framework for energy end-use efficiency and energy services. Among other things, this includes an indicative energy savings target for the Member States, obligations on national public authorities as regards energy savings and energy efficient procurement, and measures to promote energy efficiency and energy services. The main piece of the EU *acquis* in this field is Directive 2006/32/EC of the European

[127] OJ L 342 of 22.12.2009, p.46.

Parliament and the Council of 5 April 2006 on energy end-use efficiency and energy services[128].

b) Report on the work done in 2010

With regard to energy end-use efficiency and energy services, the efforts on the implementation of the existing legislation were continued. The focus was on the development of common methods and indicators for measurement and verification of energy savings as well as the template for the second National Energy Efficiency Action Plans (NEEAPs). For that purpose, the Commission organised two Energy Demand Management Committee meetings and a number of bilateral meetings and other exchanges with relevant Member States. Because of the lack of the consensus between Member States, formal harmonisation of methods and indicators for measuring energy savings was not possible. However, the work has led to the development of a recommended set of indicators and formulas for measurement and verification of final energy savings.

The Commission also prepared an extended template for the second NEEAP, which covers now reporting obligations arising from Directive 2006/32/EC, Directive 2010/31/EU[129], as well as other areas covered by national energy efficiency policies. In October and November 2010 the Commission organised training workshops for officials from all EU Member States as well as Croatia and Norway on the preparation of the second NEEAP. Also a special telephone helpline and an internet helpdesk were set up to provide Member States with on-line assistance with the preparation of their new NEEAPs.

Follow-up on the implementation of Directive 2006/32/EC and exchanges on good practices are carried out through regular exchanges supported and facilitated by the Commission in the framework of the Concerted Action on Directive 2006/32/EC. In 2010 three meetings of the Concerted Action were held.

Regarding transposition of the Directive, at the end of 2008 the Commission started infringement proceedings for non-communication against 24 Member States. In January 2010, ten of these cases were still open. In order to have a better insight on how the transposition had been made, the Commission engaged at the end of 2009 in regular bilateral discussions with those Member States not having completed the transposition of the Directive. These bilateral meetings continued in 2010. In December 2010 the number of the Member States having not completed the transposition was reduced to four.

Petitions

During 2010, answers were provided for two petitions relating to individual metering and are still under examination by the European Parliament's Petitions Committee.

5.4.3.2. Evaluation of the current position

Despite significant efforts, consensus between the EU Member States on harmonisation of methodologies for measurement and verification of energy savings on the basis of the Annex

128 OJ L 114, 27.4.2006, p. 64.

129 Directive 2010/31/EU of the European Parliament and of the Council of 19 May 2010 on the energy performance of buildings (recast), OJ L 153, 18.6.2010, p. 13.

IV of Directive 2006/32/EC could not be reached. As such, the Commission came to the conclusion that the methodology for the measurement of verification of energy savings should be extended beyond the current scope of Directive 2006/32/EC to all energy savings including measurement of the progress in Member States towards the strategic objective of 20% by 2020.

Concerning the establishment of the Second NEEAPs, the key issue is related to reporting on already achieved energy savings. As indicated in various Communications from the Commission[130] [131], the NEEAPs should become a central tool for Member States as regards planning and reporting on national measures and achieved energy savings. This has been already confirmed in recent parallel EU legislation: e.g. the recast of the Energy Performance of Buildings Directive refers to NEEAPs as the main reporting tool. In 2010 the Commission proposed a common template for the second NEEAP, due by end of June 2011, which extended the scope of reporting beyond the scope of energy savings as currently defined by Directive 2006/32/EC to energy savings and energy saving measures addressing all sectors (end-use energy efficiency, energy transmission/distributions and energy generation).

Based on parallel studies carried out on the occasion of the preparation of the new EU Energy Efficiency Plan as well as feedback from the Member States on problems with the implementation of their first NEEAPs, it has become clear that the impact of the current Directive 2006/32/EC to achieve EU 2020 target for energy efficiency is insufficient. In order to cover all the potential for energy savings in all sectors and strengthen the existing framework for the development of energy services market the Commission will analyse ways for a possible recast of Directive 2006/32/EC.

5.4.3.3. Evaluation results

a) Priorities

Primary attention will be paid to the assessment of the impact of the Directive 2006/32/EC and identification of ways to strengthen the current EU framework legislation on energy savings. At the same time, the Commission will continue encouraging Member States to adopt strong and comprehensive second NEEAPs.

b) Planned Action

Efforts will be concentrated on the preparation of a legislative proposal for the revision of Directive 2006/32/EC. The Commission will investigate possible strengthening of this legislation including investigating on the creation of a suitable legal basis for the 20% strategic objective for primary energy savings by 2020.

In parallel, the Commission will continue providing its assistance to the Member States in the preparation of the second NEEAPs and the use of recommended methods and indicators for the measurement and verification of energy savings. In the second part of 2011, after receipt

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130 Communication from the Commission to the Council and the European Parliament on Energy efficiency: delivering the 20% target, COM(2008) 772 final.

131 Commission Staff Working Document, Synthesis of the complete assessment of all 27 National Energy Efficiency Action Plans as required by Directive 2006/32/EC on energy end-use efficiency and energy services. Moving forward together on saving energy, SEC(2009) 889 final.

of the second NEEAPs, the Commission will start thorough analysis of each national Action Plan.

5.4.3.4. Sector summary

Efforts on the implementation of the existing legislation were continued with a focus on the development of common methods and indicators for measurement and verification of energy savings and a template for the second National Energy Efficiency Action Plans.

Consensus between the EU Member States on harmonisation of methodologies for measurement and verification of energy savings on the basis of the Annex IV of Directive 2006/32/EC could not be reached. It has become clear that the impact of the current Directive 2006/32/EC to achieve EU 2020 target for energy efficiency is insufficient. Preparations of a legislative proposal for the revision of Directive 2006/32/EC are underway, which will investigate in a possible strengthening of this legislation.

5.4.4. Combined heat and power generation (CHP, cogeneration)

5.4.4.1. Current position

a) General introduction

The main piece of legislation is Directive 2004/8/EC of 11 February 2004 on the promotion of cogeneration based on a useful heat demand in the internal energy market ("CHP Directive")[132], complemented by two Commission Decisions - one on harmonised efficiency reference values for the separate production of electricity and heat (2007/74/EC)[133], and the other one containing detailed guidelines for the calculation of electricity from cogeneration (2008/952/EC)[134].

b) Report on the work done in 2010

Efforts on enforcing the transposition and implementation of the CHP Directive have continued in 2010. In the beginning of 2010, 18 infringements procedures were ongoing for failure to implement the Directive's provisions (non-communication of transposition measures and no submission of the reports required). At the end of 2010 all Member States completed the transposition, but there were still five cases open for failure to communicate the necessary reports.

Discussions with Member States and stakeholders started on the future development of CHP policy, on the potential of CHP and on the review of the reference values for separate production of electricity and heat (in accordance with Article 4 of the CHP Directive). Preparatory works have been launched to complement the analysis of the Commission on these issues.

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132 OJ L 52, 21.2.2004, p. 50.
133 OJ L 32, 6.2.2007, p. 183.
134 OJ L 338, 17.12.2008, p. 55.

5.4.4.2. Evaluation of the current position

From a legal perspective, the situation regarding cogeneration is evolving positively. Most of the Member States have been completing the transposition of the Directive and providing the information required by the Directive.

However, from an operational perspective, the situation of the CHP sector is not improving in real terms. According to statistical data[135], there is no real development of the sector at EU level since the adoption of the CHP Directive in 2004.

5.4.4.3. Evaluation results

a) Priorities

Primary attention will be paid to the enforcement of the existing legislation. In addition, it will be necessary to work further on how to strengthen the current EU framework legislation in order to significantly support the development of CHP in the EU, and consequently contribute as much as possible to the future EU energy saving objective.

b) Planned action

The Commission will continue its efforts with regard to the follow-up and enforcement of the existing legislation, including an analysis of conformity of the notified legislation.

The Commission will review the reference values for the separate production of electricity and heat.

The Commission will also prepare a report on the implementation of the Directive and present, if appropriate, further proposals to foster cogeneration, in relation to the future Energy Efficiency Plan.

5.4.4.4. Sector summary

Monitoring of the implementation continues. Infringement procedures have been opened to support this objective. The level of transposition and implementation in Member States is improving.

The reference values for the separate production of electricity and heat will be reviewed.

A report on the implementation of the Directive will be prepared and further proposals to foster cogeneration will be indicated if appropriate.

[135] Eurostat - annual statistics based on data submitted by Member States according to Article 10(3) of the Directive 2004/8/EC.

5.5. ENERGY - NUCLEAR ENERGY

5.5.1. Current position

5.5.1.1. General introduction

The Commission has significant responsibilities under the Euratom Treaty on nuclear safety and security. In particular, the Commission has to monitor nuclear material used for civil purposes so that it is only used for the uses their users have declared them to be used for (i.e. nuclear security); and to protect citizens against the dangers from ionising radiation by ensuring the respect of EU legislation on radioprotection and by having a high level of nuclear safety in all Member States. Nuclear energy can play a role in enhancing competitiveness, promoting sustainable development, fighting climate change and reducing external energy dependence. While it is up to the Member States to choose whether or not to use nuclear energy, the role of the EU is to develop in the interest of all Member States the most advanced legal framework for nuclear energy, meeting the highest standards for safety, security and non-proliferation.

The Lisbon Treaty amended the Euratom Treaty by its Protocol No 2. The Euratom provisions continue to have their full legal effect and Euratom keeps its own legal personality outside the framework of the EU. The amendments are only intended to adapt the Euratom Treaty to the new rules laid down in the Lisbon Treaty, in the institutional and financial fields, which were inserted to the TFEU and made applicable to Euratom Treaty through new Article106a of the Euratom Treaty. In particular, Articles 141 to 143 of the Euratom Treaty defining the infringement procedure are repealed and Articles 258 to 260 TFEU are now applicable for Euratom. Accordingly, Article 82 of the Euratom Treaty also refers to new Articles 258 to 260 TFEU.

Most of the activities in the nuclear field are based on Chapter 3 (Health and Safety) and Chapter 7 (Safeguards) of the Euratom Treaty and on the *acquis* derived thereof.

A comprehensive list of primary and secondary legislation applicable in the field of nuclear energy is given in Annex.

5.5.1.2. Report of work done in 2010

Management of the acquis, in particular through committees and expert groups:

The Group of Experts (GoE) provided for in Article 31 adopted its opinion in February 2010 on the revision and recast of the Euratom Basic Safety Standards Directive. As the five years mandate of this group expired, a newly nominated Group of Experts met twice in June and November 2010. Main topics were medical exposures and the revision of the international Basic Safety Standards.

As regards the European Nuclear Safety Regulators Group (ENSREG), the main achievements of the Group were: (i) the launching of the dedicated ENSREG Website (www.ensreg.eu), where the activities of the Group are presented in detail and (ii) the presentation to the Commission of expert advice on the then envisaged Euratom legislation in the area of radioactive waste and spent fuel management. This guidance has been reflected in

the November 2010 Commission proposal for a Directive on the management of spent fuel and radioactive waste[136]. Also, during 2010, several activities were initiated (to be further pursued in 2011), e.g. (i) the support for the transposition and implementation of the Nuclear Safety Directive, by suggesting a unified structure for the Member States' Reports on the implementation of the Directive, facilitating the consultation and cooperation of the national regulatory authorities, establishing a common methodology for the periodic safety self-assessments and a system for the coordination of the international peer-review; (ii) the elaboration of Guidelines for regulators' transparency and (iii) the preparations for the first European Nuclear Safety Conference (28-29 June 2011, Brussels).

The European Nuclear Energy Forum (ENEF)([137]) is conceived as a platform to promote a broad discussion among all relevant stakeholders on the opportunities and risks of nuclear energy. In 2010, during the fifth ENEF plenary meeting held in Bratislava in May 2010, the role of nuclear in the gradual transition of Europe towards a low-carbon economy was discussed also taking into account security of supply and competitiveness considerations. ENEF called for improved transparency of nuclear energy and reflected good practices in siting decisions for geological repositories showing how important early and open involvement of the public in such a long-term process is.

As regards risks of nuclear energy ENEF has recognised the need for a legally binding Euratominstrument for radioactive waste. Among the essential elements, ENEF underlines that each Member State should develop and implement an adequate national plan for nuclear waste management in line with the subsidiarity principle. It is equally important to ensure a sufficient level of training and qualified staff, in particular for technicians and engineers in the nuclear industry, but also for radioprotection and medical applications of nuclear.

On the opportunities of nuclear energy ENEF discussed the contribution of nuclear to a low-carbon economy.

A concrete result of preparatory work is the European Nuclear Energy Leadership Academy (ENELA) founded in early 2010.

Chapter 7 (Safeguards) of the Euratom Treaty: The Commission continued to satisfy itself that in the territories of the Member States nuclear materials were not diverted from their intended use as declared by the users and that the international safeguards obligations assumed by Euratom were complied with. On 1st May 2010, Romania acceded to INFCIRC/193, the trilateral safeguards agreement between the Euratom Community, the IAEA and the EU's non-nuclear weapons states. From March 2010 all EU operators of nuclear facilities make their regular reports of nuclear material holdings and transactions in a manner which complies fully with the requirements set out in Regulation (Euratom) No 302/2005.

A nuclear liability workshop was held in June 2010 with the aim to explore possibilities to harmonise the nuclear liability regime in the EU. As a conclusion of the workshop, it was suggested to create an expert group to build consensus for a possible legislative proposal.

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136 COM(2010)618, 3.11.2010.

137 Detailed information on the ENEF activity is available at http://ec.europa.eu/energy/nuclear/forum/forum_en.htm

The European Commission hosted a Meeting on the Security of Supply of Medical Radioisotopes in EU Member States held in Luxembourg on 4-5 May 2010. The purpose of the meeting was to provide a forum to exchange information on possible medium-term solutions and on details of the most promising reactor opportunities for securing Molybdenum-99 (Mo-99) production in the long term.

Management of the acquis (incl. enquiries, problems and complaints)

The submission of draft texts under Article 33 Euratom Treaty allows the Commission to make appropriate recommendations before the finalisation of the national procedure for the adoption of transposition measures, so that possible instances of non-compliance can be identified even before the texts are adopted. In 2010, 19 notifications were dealt with under Article 33. Most of them concerned the implementation of Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations. Likewise, other notifications aim at updating Member States' legislation transposing previous Euratom Directives, e.g. Basic Safety Standard Directive and Directive 97/43/Euratom.

Under Article 35 of the Euratom Treaty, Commission services conducted 7 verification missions. The purpose was to provide an independent assessment on the adequacy of facilities intended to monitor levels of radioactivity in the environment. All verifications started with a preliminary audit of the monitoring and inspection activities carried out by the relevant national authorities and of the legal framework in force.

Eleven opinions were drafted by the Commission in accordance with Article 37 of the Euratom Treaty, concerning plans for the disposal of radioactive material.

An update of the nuclear illustrative programme (PINC 2010) is being prepared – in the context of the 2050 Roadmap – in order to review the latest situation regarding Member States' policies, nuclear investment decisions and requirements, as well as to highlight some key aspects for future investments.

Articles 41-43 of Euratom Treaty establish notification procedure on nuclear investments: in 2010 2 new notifications were received, 8 were under examination and 8 were finalised, in particular the Commission point of views on Cernavoda nuclear power plant.

Article 103 is part of the Euratom Treaty's Chapter on external relations. It establishes a procedure for the preliminary examination by the Commission of the compatibility with the Euratom Treaty of draft agreements or contracts which are about to be concluded, within the scope of the Euratom Treaty, between a Member State and a third party. In 2010, 15 notifications pursuant to Article 103 Euratom, were dealt with.

Management of infringements

Concerning the complaints management, 6 new complaints were received in 2010.

In 2010, the two remaining infringement cases initiated in 2009 for non communication of final transposing measures for Council Directive 2006/117/Euratom were closed as the Member States concerned completed the transposition.

Monitoring of the safeguards situation continued in the case of a Commission Directive based

on Article 82 Euratom Treaty, concerning another installation on the Sellafield site. To this end, a detailed work programme to improve the situation was prepared by the United Kingdom and accepted by the Commission services in the first half of 2010. If progress continues to be satisfactory (the UK has provided 13 progress reports so far), the Commission will refrain from referring the case to the Court of Justice.

Petitions

During 2010, 15 petitions in total concerning the nuclear energy sector were dealt with. For all petitions, an adequate answer was provided (often in close cooperation with other DGs). However, the European Parliament's Petitions Committee did not analyse all answers yet and could therefore not accept the closure of these cases. Hence, most petitions take several years before being formally closed.

New legislation

DG Energy has contributed to the development of an even more advanced EU legal framework for nuclear energy meeting the highest standards of safety, security and non-proliferation. On 3 November 2010 the Commission has adopted *a revised proposal for a Council Directive on the management of spent fuel and radioactive waste*. The general objective of the proposal is the establishment of Euratom framework for the responsible management of spent fuel and radioactive waste, ensuring that Member States provide for appropriate national arrangements guaranteeing a high level of safety while maintaining and promoting public information and participation. EU will become the first regional nuclear actor having binding rules for nuclear safety and waste management. This proposal is planned to be adopted by June 2011.

In 2010 a *Council Regulation*[138] has been adopted as new legal basis for the *extension of financial EU support to the Kozloduy Programme (Bulgaria)* with an additional commitment of €300 million for the period 2010 – 2013. On the implementation of the EU support, a total sum of €255 million has been made available: €155 million to the European Bank for Reconstruction and Development (EBRD) and €100 million to the Lithuanian Central Project Management Agency (CPMA).

A *Communication* from the Commission to the European Parliament and the Council *on medical applications of ionizing radiation and security of supply of radioisotopes for nuclear medicine*[139] was adopted by the Commission in August 2010. The Communication proposes a way forward to resolve the urgent issue of shortage of supply of radioisotopes for nuclear medicine. The Council adopted Conclusions on 6 December 2010.

The *revised Commission Recommendation on the application of Article 37 of the Euratom Treaty* was adopted in October 2010[140]. It improves some terminology to ensure consistency and clarity of the provisions and simplifies the general data to be provided by Member States to the essential information necessary for the Commission to issue its opinion. In addition, it excludes from the scope of Article 37 a limited number of trivial operations having no or

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138 Council Regulation on the extension of financial support to Bulgaria for the decommissioning of units 1 to 4 of the Kozloduy Nuclear Power Plant and for the mitigation of the economical consequences.

139 COM/2010/0423 and SEC/2010/0974.

140 2010/635/Euratom, OJ L 279, 23/10/2010 p. 36 – 67.

negligible radiological impact in other Member States. It strengthens the assessment of accidental situations by introducing a new requirement for safety related information on unplanned releases from nuclear reactors and reprocessing plants. Concerning dismantling operations, in addition to nuclear reactors and reprocessing plants, a submission of general data for the dismantling of mixed-oxide fuel fabrication plants is now required.

The *Agreement between the European Atomic Energy Community and the Government of Canada for cooperation in the peaceful uses of atomic energy* is now being renegotiated based on the Council mandate adopted on 27 July 2009. The initial Agreement was signed in 1959 and, due to the continuous development of nuclear trade between the Parties, has been amended five times.

The *Agreement between the European Atomic Energy Community and Austra*lia is due to expire in January 2012. The Council adopted the negotiating mandate for a revised agreement between the European Atomic Energy Community and the Government of Canada for cooperation in the peaceful uses of atomic energy on 12 July 2010, and the renegotiations of the existing agreement were finalised. The scope of the agreement covering only transfers of nuclear materials was extended to transfers of equipment and technology, and nuclear cooperation in general. The text of the agreement will be submitted to Council for approval during the 1st quarter of 2011.

Negotiations for a new *Agreement between the European Atomic Energy Community and South Africa* are ongoing. The negotiating mandate was adopted by the Council on 25 October 2010. A new agreement between Euratom and South Africa will create a stable long-term framework for co-operation between the two Parties and their governments and industrial operators in the peaceful uses of nuclear energy.

Preparatory meetings took place resulting in the start of the negotiations of a new and comprehensive *cooperation agreement in peaceful uses of nuclear energy between Euratom and the Russian Federation*, setting up an overall framework for political, technical and industrial cooperation.

In the framework of the continuing cooperation with Ukraine on energy and nuclear safety matters, a *joint European Commission-IAEA-Ukraine project on the evaluation of the nuclear safety of the Ukrainian Nuclear Power Plants* was finalised in 2010.

Preventive measures being taken in relation to newly adopted legislation

In 2010, Directorate-General for Energy ensured support and oversaw the correct and timely transposition of the Directive 2009/71/Euratom (the 'Nuclear Safety Directive') into the Member States' legislation, through a continuous cooperation with the responsible national authorities. In addition, DG Energy has organised in Luxembourg on 7 May 2010, a seminar where the Member States' experts were invited to raise, seek clarifications and discuss with the Commission any legal issues that they considered of relevance in the transposition process. The dialogue with the Member States has also been ensured at the level of the Council Atomic Questions Group, where several transposition procedural clarifications were presented, as well as at the level of the European Nuclear Safety Regulators Group (ENSREG) to whose activities Directorate-General for Energy actively contribute.

Implementation of EU energy policy priorities

The priorities in the field of energy focus on actions having a significant impact on the fight against climate change and ensuring secure and competitive energy supplies.

The implementation of the Euratom *acquis* generally benefits both objectives: it regulates the use of an energy source which has virtually no carbon emissions and it contributes substantially to the security of supply.

The Strategic Energy Technology Plan of the EU is the technology related "implementation tool" to meet the ambitious 3x20 Energy Policy Target. The SET Plan recommends launching European Industrial Initiatives to develop and bring to the market innovative low carbon energy technologies. The Nuclear Initiative under the SET Plan is fostering the long term sustainable contribution of nuclear energy to the low carbon energy mix, by proposing the building of prototype fast breeder reactors and closed fuel cycle. The first prototypes are foreseen to start operation in 2020. This is directly related to one of the axis of actions of the Sustainable Nuclear Energy Technology Platform, the two other ones being connected with the plant lifetime management and waste management of existing installations, and with the production of nuclear heat via cogeneration and the potential of High Temperature Reactors.

The European Sustainable Nuclear Energy Initiative has been officially launched on 15 November 2010 under the Belgian Presidency.

5.5.2. **Evaluation of the current situation**

a) The current situation for the control of the existing *acquis* is stable.

b) Cases could all be managed in the normal timeframe and fell roughly under the same level of priority, i.e. normal.

5.5.3. **Evaluation Results**

5.5.3.1. Priorities and Planned Actions

Assist the Member States to comply with their legal obligation for a timely and correct transposition of the Nuclear Safety Directive.

Complete the adoption of a Council Directive on safe management of radioactive waste and spent fuel followed by correct transposition.

5.5.4. **Sector summary**

In the nuclear sector the Commission is called to accompany the expected massive development with an advanced legal framework for nuclear energy based on the Euratom Treaty that maintains and improves the high standard of regulation achieved in the EU Member States. The Commission's priority is to be up-to-date concerning the legislation for the protection of the health and for nuclear security and to fully use our competences in the field of nuclear safety. As main achievement to be mentioned is the adoption of the Nuclear Safety Directive.

The key action in the near future, for which a lot of work was already achieved during 2010, is therefore the follow-up of proposal for a Council Directive (Euratom) on safe management of radioactive waste and spent fuel which was adopted on 3 November 2010.

On the other hand, the recast of the Basic Safety Standards, which will consolidate the legislation in the field and set modern, unified standards for the protection of the health of the citizens in the EU made good progress.

(see also Annex I - List of measures in force and other relevant instruments referred to in the text of the document)

6. MOBILITY AND TRANSPORT

6.1. Passenger rights

6.1.1. Current position

6.1.1.1. General introduction

Since the 2001 White Paper, where the Commission announced the establishment of passengers' rights in all modes of transport and its intention to place users at the heart of transport policy, four Regulations are in force by the end of 2010, in the sectors of aviation and rail transport:

- Regulation (EC) No 889/2002 of the European Parliament and of the Council of 13 May 2002 amending Council Regulation (EC) No 2027/97 on air carrier liability in the event of accidents

- Regulation (EC) Nº 261/2004, establishing common rules on compensation and assistance to passengers in the event of denied boarding and of cancellation or long delay of flights;

- Regulation (EC) Nº 1107/2006 concerning the rights of disabled persons and persons with reduced mobility when travelling by air;

- Regulation (EC) Nº 1371/2007 on rail passengers' rights and obligations, applicable as from December 2009.

Furthermore, in the field of maritime transport, Regulation (EU) 1177/2010 on passenger rights in maritime and inland waterways transport has been adopted and will apply as from December 2012 and, in the field of road transport, Regulation (EU) No 181/2011 concerning the rights of passengers in bus and coach transport has been published in February 2011 and will apply as from March 2013.

The overall regulatory background on air passenger rights also includes other legislation, for example: Regulation 1008/2008, on common rules for the operation of air services in the Community; Directive 96/67, which defines the conditions for access to the ground-handling market at European airports, and therefore could be used as leverage to improve the quality of baggage handling in order to prevent baggage damage or mishandling; and Regulation (EC) No 2111/2005 of the European Parliament and of the Council of 14 December 2005 on the establishment of a Community list of air carriers subject to an operating ban within the Community and on informing air transport passengers of the identity of the operating air carrier, and repealing Article 9 of Directive 2004/36/EC.

6.1.2. **Report on the work done**

The Commission continued its efforts to guarantee the correct implementation of the provisions protecting passengers' rights in the following modes of transport:

Rail Transport

Two meetings with NEB in charge of the application of Regulation 1371/2007 took place in January and November.

Preliminary interpretative guidelines of the main provisions of Regulation 1371/2007 have been prepared.

Maritime and inland waterways Transport

Regulation (EU) 1177/2010 on passenger rights in maritime and inland waterways transport has been adopted and published in December 2010. It will apply as from December 2012.

Coach and Bus Transport

After an agreement was reached on 30 November 2010 in conciliation between the Council and the European Parliament, Regulation (EU) 181/2011 concerning the rights of passengers in bus and coach transport has been published in February 2011 and will apply as from March 2013.

Air Transport

Regarding Passengers rights legislation, the Commission kept working towards a homogeneous application of the relevant Regulations in all the Member States. The Commission has been constantly in contact with Member States to ensure the good application of all legal developments in the field of APR, in the light of the recent case law from the European Court of Justice (rulings C-402/07 and C-432/07, Sturgeon and Others and follow up of the case C-549/07, Wallentin-Hermann).

As a consequence of the ash cloud crisis of April 2010 and in order to alleviate its impact on the industry, interpretative guidelines on the application of Regulation 261/2004 in the framework of the ash crisis have been agreed with all NEBs (National Enforcement Bodies). Two ad-hoc meetings in the framework of the volcano crisis as well as a regular meeting took place with NEBs of Regulation 261/2004; one meeting took place with NEBs of Regulation 1107/2006.

Three studies on air passenger rights (APR) legislation have been concluded in 2010: 1) study on the application of Regulation 261/2004, 2) study on the application of Regulation 1107/2006, 3) study on national penalty schemes on Regulation 1107/2006.

Two Commission communications on APR have been prepared for adoption in 2011: a communication (ex post assessment) on Regulation 261/2004 as well as a communication (application report) on Regulation 1107/2006. The communication on Regulation 261/2004 will be accompanied by a staff working paper on national measures of enforcement of the

Regulation.

A public consultation on five pieces of APR legislation, which was launched in December 2009, was carried out in early 2010. A stakeholder hearing to present the results was organised on 28/6.

Public Service Obligations (Regulation 1370/2007)

A general contract on a study concerning the application of the Regulation has been launched and followed up. A specific contract on the interpretation of the main provisions of the Regulation has been executed.

There have been regular contacts with national authorities (+/- 10 Member States) and stakeholders.

Information Campaign on passenger rights

A Europe wide information campaign to raise citizen's awareness of their rights when travelling was launched in Brussels on 29 June. The information campaign is carried out in cooperation with a contractor and includes the setting up of a specific website, the production of video clips, information brochures and gadgets such as luggage tags as well as the participation in events such as travel fairs etc. Four events in Member States capitals (DE, SE, UK, BG) have already been organised between September and December 2010.

6.1.3. **Evaluation of the current position**

The Commission works actively to promote the application and enforcement of the current regime of protection of passenger rights by monitoring national authorities and by enabling them to exchange best practice. Meetings and workshops are organized on a regular basis with stakeholders. Inquiries from citizens received are analysed either by the Commission services themselves or by the Europe Direct Contact Centre (EDCC) with whom the Commission has concluded a specific contract in order to cope with the high number of citizens' inquiries, mainly in the field of air and rail passenger rights. In addition, the Commission monitors studies and consultations to have a better view of the opinion of the public on these matters.

However, the outcome of these actions show that full implementation and enforcement of the regulations protecting passenger rights is not yet sufficiently ensured in all situations and Member States and further efforts are requested both by national authorities and by the industry.

6.1.4. **Evaluation results**

Air transport

The results from the various studies, consultations, surveys etc. have provided valuable which can be generally summarized in the following three main conclusions: 1.) Given the complexity of the Regulation and a lack of definition of some controversial terms, there is still a lack of uniform interpretation by co-legislators (although the CJEU rulings as well as the

interpretative guidelines from the Commission have provided some clarity); 2.) Enforcement throughout the EU is still not carried out in a uniform manner, although it has improved thanks to the Commission efforts and increasing cooperation between and from NEB. 3.) There is still a lack of awareness by passengers about their rights and how to claim them through easily accessible complaint handling procedures and effective means of redress (this is one of the reasons for the launch of the information campaign for passengers in 2010).

Rail Transport

The information campaign with the aim of informing all EU passengers on the rights that they enjoy pursuant to EU legislation on passengers' rights highlights in particular the EU rail passenger rights which derive from Regulation 1371/2007.

The Commission has continued to keep close contacts with the NEBs ("National Enforcement Bodies") already designated and has requested those Authorities that are lagging behind to designate NEBs in order to ensure an effective enforcement of rail passengers' rights as established by the Regulation.

6.1.5. **Sector summary**

In line with the overall Commission political strategy to put citizens at the heart of Europe and also according to the priorities set out in the future White Paper on Transport Policy the priority for passenger rights remains guaranteeing the full and effective application of passenger rights in all modes of transport. With the adoption of legislation for maritime and land transport (bus and coach) in 2010, a legislative framework providing a minimum set of rights in all modes has now been achieved. The objective of the White Paper on Transport of 2001 to put the citizen at the heart of this policy has hence been achieved.

This legislative framework offers a more and more effective regime of protection to passengers within the EU. The main objective for 2011 consists in the consolidation of this framework, by harmonising application and enforcement across Member States, by providing interpretative guidance to all relevant parties and by raising awareness among passengers about their rights. An impact assessment will be launched in 2011 to evaluate the impact of various policy options regarding the application of Regulation 261/2004, including the implications of recent case law of the ECJ.

6.2. Inland Waterway Transport

6.2.1. **Current position**

6.2.1.1. General introduction

Inland waterway transport plays an important role for the transport of goods in Europe. More than 37 000 kilometres of waterways connect hundreds of cities and industrial regions. Some 20 out of 27 Member States have inland waterways, 12 of which have an interconnected waterway networks. The potential for increasing the modal share of inland waterway transport is significant. Compared to other modes of transport which are often confronted with congestion and capacity problems, inland waterway transport is characterized by its reliability, its low environmental impact and its major capacity for increased exploitation.

The main pieces of *acquis* in this field are the following:

- Directive 2006/87/EC of the European Parliament and of the Council of 12 December 2006 laying down technical requirements for inland waterway vessels, as amended. It establishes harmonised conditions for issuing technical certificates for inland waterway vessels. It is aimed at increasing the safety of passengers and freight transport by inland waterway in Europe. This Directive repealed and replaced Directive 82/714 as from 30th December 2008;

- Directive 2005/44/EC on harmonised river information services (RIS) on inland waterways in the EU. It established a framework for the deployment and use of RIS in the EU and for the establishment and further development of technical requirements and specifications for harmonised and interoperable RIS. It defines further the minimum requirements to be fulfilled by Member States to enable the setting-up of RIS.

6.2.1.2. Report on the work done in 2010

In 2010, the *acquis* was further developed.

A follow-up of the transposition of Directive 2005/44 was performed and continuous monitoring of the implementation of the Directive was ensured via frequent meetings with Member States' authorities and stakeholders, expert group meetings and conformity checks. A Commission Regulation defining technical specifications was discussed and amendments of existing Commission Regulations defining technical specifications were prepared. The process of ensuring the proper implementation of the Directive will continue along the same line.

The technical Annexes to Directive 2006/87/EC laying down technical requirements for inland waterway vessels continued to be further aligned with legislation agreed in the framework of the Central Commission for Navigation on the Rhine. For this purpose 4 meetings of the Joint meeting of experts from EU Member State and the Central Commission for Navigation on the Rhine were held. A study has been commissioned and finalised on the subject of approval of three classification societies.

For the proper implementation of the Directive, regular communication with Member States is maintained. Workshops have been attended in Member States and a number of questions from citizens and inspection bodies were answered. Good cooperation with the International River Commissions and the UN-ECE on technical requirements for inland waterway vessels was kept.

6.2.2. **Evaluation of the current position**

The situation keeps evolving, and an increased workload is foreseen due to necessary legislative developments. Four infringement procedures had been launched (United Kingdom, Poland, Luxembourg and Germany) due to the fact that the transposition deadline for new directives had elapsed. Due to positive reactions from the mentioned Member States, these procedures have been closed.

6.2.3. **Evaluation results**

As in the past, priority will be given to strengthening the competitive position of the inland waterway transport in the transport system and to facilitate its integration into the intermodal logistics chain.

Directive 2006/87/EC should be amended following the agreement reached on several subjects in the technical working party which will be adopted after a favourable opinion of the Committee. The procedure for the recognition of classification societies has to be completed. The relation with the River Commissions, and especially the shared secretariat of the Joint Working Group, should be reflected upon. A seminar on the interpretation of requirements in the annexes of Directive 2006/87/EC is to be organised. This was already the subject of the seminar in 2008 in Budapest to prepare Inspection Bodies from Member States. The Directive is in force since the end of 2008 and experiences from inspection bodies with difficulties in interpreting the requirements are appearing. This requires again a Joint Seminar of Inspection Bodies from the Member State of the Danube Commission, the Central Commission for the Navigation on the Rhine and the EU. Such seminar was foreseen in 2010 but has been postponed till 2011.

Infringement procedures have been closed against Member States not having transposed the Directive 2006/87 and its amendments.

6.2.4. **Sector summary**

With a view to strengthening the competitive position of the inland waterway transport in the transport system, and to facilitate its integration into the intermodal logistic, the Commission will consider reinforcing its administrative capacity in order to keep developing the harmonisation of additional technical requirements on zone 1 and 2, on the one hand, and to monitor the individual implementation of Directive 2006/87, as amended, on the other hand.

6.3. **Maritime Transport - Internal market**

6.3.1. **Current position**

6.3.1.1. General introduction

The principle of freedom to provide services had been applied to the maritime transport services gradually. The liberalisation of intra-EU maritime transport preceded by a few years the liberalisation of maritime transport within Member States (maritime cabotage). The main pieces of the *acquis* in this field are the following:

- Council Regulation (EEC) No 4055/86 of 22 December 1986 applying the principle of freedom to provide services to maritime transport between Member States and between Member States and third countries (OJ L 378 of 31.12.1986, p.1-3). The Regulation gives Member State nationals (and non-EU shipping companies using ships registered in a Member State and controlled by Member State nationals) the right to carry passengers or goods by sea between any port of a Member State and any port or off-shore installation of another Member State or of a non-EU country.

- Council Regulation (EEC) No 3577/92 of 7 December 1992 applying the principle of freedom to provide services to maritime transport within Member States (maritime cabotage), (OJ L 364 of 12.12.1992, p. 7-10). This Regulation grants freedom to provide maritime transport services within a Member State (maritime cabotage) for EU ship owners operating ships registered in a Member State and flying the flag of that Member State, subject to these ships complying with all the conditions for carrying out cabotage within that Member State. While liberalising the cabotage services, the Regulation takes into account the issue of public service obligations, in view of ensuring that islands and far distant maritime regions have adequate connections with the mainland territories.

6.3.1.2. Report on the work done in 2010

During 2010 the Commission continued monitoring the correct application of Regulation N° 4055/86. In terms of thematic areas, the Commission focused on ensuring respect of the principle of non-discrimination in regard to port dues. In the framework of this exercise, the Commission decided to take action before the Court of Justice and on 4 February 2010 the Court issued its judgment sanctioning the discriminatory system of port dues charged by Spain (Case C-18/09).

As regards Regulation N° 3577/92, following the complaints it has received, the Commission scrutinised national legislation of four Member States with the objective to ensure compliance with the principle of non-discrimination between ship owners, and assisted Member States in aligning their legislation with the provisions of the Regulation.

In 2010 the Commission continued to support accession countries, in particular Croatia, in their efforts to align to and implement the relevant *acquis*.

Furthermore, work has started on preparing a new interpretative communication on maritime cabotage. The Commission has published its first interpretative communication on maritime cabotage in 2003 (amended in 2006). However, following the consultation on the fifth report on maritime cabotage undertaken in 2009, it became apparent that the interpretation of Regulation 3577/92 still raises questions and requires further clarification. The new communication will update the 2003 communication in line with the experience gained during practical application of Regulation and include recent developments in the EU law and case-law.

6.3.2. **Evaluation of the current position**

Compared to the liberalisation of intra-EU maritime transport, which traditionally has been rather liberal and open to competition across the EU even before the adoption of Regulation N°4055/86, the liberalisation of maritime cabotage required substantial changes in the legislation of several Member States which used to reserve the provision of cabotage only to national ship owners.

After the end of transitional periods in 2004, Regulation No 3577/92 has been fairly evenly implemented across the EU. However, there still exists a need to monitor the national

provisions concerning public service contracts and obligations in order to ensure full respect of the principle of non-discrimination between ship owners.

6.3.3. **Evaluation results**

6.3.3.1. Priorities

The priorities for the Commission in achieving the internal market in maritime transport services consist in continuing monitoring and helping Member States to implement the relevant *acquis*.

6.3.3.2. Planned action

The main objective for 2011 is to publish a new interpretative communication (updating and clarifying the one of 2003) and the fifth report on the application of Regulation No 3577/92.

6.3.4. **Sector summary**

The priority remains guaranteeing the full application of the freedom to provide services to maritime transport between Member States and within Member States (maritime cabotage).

6.4. Maritime Safety

6.4.1. **Current position**

6.4.1.1. General introduction

The maritime safety EU *acquis* aims at enhancing the safety of ships in European waters, protecting the marine environment and ensuring appropriate living and working conditions on board. The main relevant pieces of legislation in this area are:

- Directive 2009/15/EC of the European Parliament and of the Council of 23 April 2009 on common rules and standards for ship inspection and survey organisations and for the relevant activities of maritime administrations, (OJ L 131 of 28.5.2009, p. 47). This directive addresses the responsibility of Member States as flag States by establishing measures to be followed by the Member States and organisations concerned with the inspection, survey and certification of ships for compliance with the international conventions on safety at sea and prevention of marine pollution;

- Council Directive 95/21/EC of 19 June 1995 on port State control of shipping (OJ L 157 of 7.7.1995, p.1), repealed on 31/12/2010 and replaced by Directive 2009/16/EC of the European Parliament and of the Council of 23 April 2009 on port State control (OJ L 131 of 28.5.2009, p. 57). The directive sets out rules applicable to Member States in their capacity of port States. It provides for increased compliance with international and relevant Community legislation on maritime safety, protection of the marine environment and living and working conditions on board ships of all flags and for the establishment of common criteria for control of ships by the port State and harmonised procedures on inspection and detention;

- Directive 2002/59/EC of the European Parliament and of the Council of 27 June 2002 establishing a Community vessel traffic monitoring and information system (OJ L 208 of 5.8.2002, p. 10), recently amended by Directive 2009/17/EC of the European Parliament and of the Council of 23 April 2009 (OJ L 131 of 28.5.2009, p.101). The system established in accordance with this directive aims at improving the response of the authorities to incidents, accidents and potentially dangerous situations at sea, including search and rescue operations, and at better preventing and detecting pollution by ships.

Other relevant legislation includes directives on:

- marine equipment (Directive 96/98/EC as amended),
- harmonised safety rules and standards for passenger ships (Directive 2009/45/EC),
- safety regime for fishing vessels (Directive 97/70/EC),
- safe loading and unloading of bulk carriers (Directive 2001/96/EC),
- registration of persons on board passenger ships (Directive 98/41/EC),
- mandatory surveys for the safe operation of regular ro-ro ferry and high speed passenger craft services (Directive 99/35/EC),
- enforcement of seafarers hours of work (Directive 1999/95/EC),
- stability requirements for ro-ro passenger ships (Directive 2003/25/EC),
- accident investigation (Directive 2009/18),
- insurance of ship owners for maritime claims (Directive 2009/20/EC),
- compliance with flag State requirements (Directive 2009/21/EC).

The following Regulations are also part of the *acquis*:

- accelerated phasing-in of double hull or equivalent design oil tankers (Regulation (EC) n° 417/2002),
- prohibition of organotin compounds on ships (Regulation (EC) n° 782/2003),
- transfer of cargo and passenger ships between registers within the Community (Regulation (EC) n° 789/2004),
- common rules and standards for ship inspection and survey organisations (Regulation (EC) No 391/2009),
- liability of carriers of passengers by sea (Regulation (EC) No 392/2009).

Finally, environment-related directives on port reception facilities for ship-generated waste (Directive 2000/59/EC) and on ship-source pollution and on the introduction of penalties for infringements (Directive 2005/35/EC as amended by Directive 2009/123) should also be listed.

6.4.1.2. Report of the work done in 2010

The Committee on Safe Seas (COSS) set up under Regulation (EC) no. 2099/2002 met in March, May, July, September and December. The meetings provided the opportunity for Commission services to discuss with representatives of Member States virtually all aspects of maritime safety. Favourable opinions were issued on several proposed texts (marine equipment, recognition of classification societies, port State control, implementation of the International Safety Management Code, training of seafarers, establishment of criteria for the use by LNG carriers of technological methods as an alternative to using low sulphur marine fuels and vessel traffic monitoring system).

Regular meetings on maritime policy took place in 2010 with Member States. These meetings also provided an opportunity to foster clarification and better implementation of the *acquis*.

The High Level Steering Group on SafeSeaNet, set up in July 2009 in accordance with Directive 2002/59/EC on vessel traffic monitoring[141], also met in June and in October 2010 to discuss issues related to this maritime information exchange system with a view to improving its effectiveness.

The European Maritime Safety Agency continued its broad program of inspection visits in the Member States. This program was initiated in 2004 at the request and in co-operation of the Commission and it currently covers the following areas: classification societies, training of seafarers, port State control, port reception facilities and vessel traffic monitoring and information systems (started in March 2009). The reports produced by the EMSA teams serve as basis for further Commission follow-up with the Member States either through requests for clarification or the launching of infringement procedures. In an area where there is a reduced number of complaints received from citizens or enterprises, these inspections are of great value to the Commission as they allow it to assess how the EU maritime safety *acquis* is implemented in the Member States.

The number of infringement procedures declined in 2010 from around 40 at the beginning of the year to around 20 at the end of 2010. This was essentially due to the corrective measures introduced by Member States in order to improve the quality of the transposition of the *acquis* and its implementation, following pre-judicial initiatives by the Commission. The remaining procedures concern essentially port State control issues. They will be affected by the change of legislation on 1 January 2011 (date of implementation of the new port State control Directive n°2009/16/EC).

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[141] Commission Decision of 31 July 2009 establishing the High Level Steering Group on SafeSeaNet (OJ L 201 of 1/8/2009, p.63).

6.4.2. **Evaluation of the current position**

The EU maritime safety law is relatively young. This is all the more true as it was significantly completed and renewed in May 2009 with the publication of the Third Maritime Safety package comprising two Regulations and six Directives, two of which had to be transposed by the end of 2010. It is however based on international conventions and other instruments, for some of which there is considerable implementation experience in the Member States. Current implementation situation thus ranges from relatively stable, whilst not yet entirely acceptable (for instance, for Directive 95/21/EC on port State control of shipping which is closely related to the rules of the Paris MOU to which most Member States have been party to for several years) to more difficult cases as Directive 2000/59/EC on port reception facilities, where key provisions such as those on the coverage of costs by all ships, the monitoring of deliveries and the performance of inspections are still implemented unevenly throughout the EU.

The situation tends to become more complex as it is imperative to ensure a smooth implementation of the Third Maritime Safety Package. This package covers a broad range of issues, some of which consist of improvements of current *acquis* (port State control, vessel traffic monitoring and information system, classification societies), while others are essentially new (accident investigation, Flag State obligations, liability of carriers of passengers by sea, insurance of ship owners).

6.4.3. **Evaluation results**

6.4.3.1. Priorities

There is a clear continuity in the efforts to ensure an appropriate transposition and implementation of the maritime safety *acquis*. In terms of thematic areas, emphasis continues to be put on the traditional areas of the monitoring of classification societies and of the implementation of directives on the training of seafarers, port State control, vessel traffic monitoring and information system, port reception facilities and ship source pollution and penalties. Particular attention was given to the effort by Member States to ensure timely and adequate transposition and implementation of the Third Maritime Safety Package. Member States lagging behind will be pursued in 2011 and the transposition measures adopted will be checked. The Commission will also continue to rely on the systematic assessment of implementation in the Member States based on the inspections by EMSA to be followed by contacts with Member States and, when appropriate, direct pre-judicial initiatives.

A pre-emptive approach is also taken in relation to the alignment to and implementation of the *acquis* by accession countries, in particular Croatia, through dialogue and assessment of administrative capacity (visit of EMSA at the end of 2010).

6.4.3.2. Planned action

Contact with national administrations will be ensured through COSS meetings as well as meetings of the High Level Steering Group on SafeSeaNet. Particular attention will be given to the transposition and implementation of the newest legislation.

Follow-up of EMSA inspection reports will be ensured leading to clarification actions and/or infringement procedures in the key areas mentioned under point 1.

6.4.4. **Sector summary**

The monitoring and promotion of the implementation of the maritime safety *acquis* concentrates on the traditional key areas (classification societies, training of seafarers, port State control, vessel traffic monitoring and information system and port reception facilities). Dialogue with Member States continues in different *fora* (COSS, meetings with the Directors-Generals of national administration, SSN, technical co-operation through EMSA). When appropriate, infringement procedures are also undertaken. Considerable effort is to be devoted to controlling the implementation of the new *acquis* (Third Maritime Safety Package published in May 2009) with a view to ensuring its correct implementation by all Member States.

6.5. Maritime Security

6.5.1. **Current position**

6.5.1.1. General introduction

The main objective of the EU legislation on Maritime Security is to implement· measures aimed at enhancing ship, port facility and port security in the face of the threats posed by intentional unlawful acts. The EU legislation intends to provide a basis for harmonised interpretation and implementation of international measures to enhance maritime security adopted by the International Maritime Organization (IMO) in 2002, with the establishment of the International Ship and Port Facility Security Code (ISPS Code) and the ILO[142]/IMO Code of Practice on Security in Ports**.**

The main pieces of Community *acquis* in this field are the following:

- Regulation (EC) No 725/2004[143] of the European Parliament and of the Council of 31 March 2004 on enhancing ship and port facility security: The Regulation takes into account amendments to the 1974 International Convention for the Safety of Life at Sea (the SOLAS Convention). The maritime security measures established by the Regulation are only some of the measures necessary in order to achieve an adequate level of security across all parts of maritime transport. The Regulation is limited in scope to security measures onboard vessels and the immediate ship/port interface.

- Directive 2005/65/EC[144] of the European Parliament and of the Council of 26 October 2005 on enhancing port security: The Directive is mainly based on the recommendations contained in the ILO/IMO Code of Practice on Security in Ports.

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142 International Labour Organization.

143 Regulation (EC) No 725/2004 of the European Parliament and of the Council of 31 March 2004 on enhancing ship and port facility security, OJ L 129, 29.4.2004, p. 6.

144 Directive 2005/65/EC of the European Parliament and of the Council of 26 October 2005 on enhancing port security, OJ L 310, 25.11.2005, p. 28.

The Directive completes the mechanism provided for under the Regulation by establishing a security system for all port areas, in order to ensure a high and comparable level of security for all European ports. The aim of the Directive is to improve security in port areas not covered under the Regulation and to ensure that the enhancement of port security will support the security measures taken under the Regulation, without creating additional obligations in areas already governed by the Regulation.

- Regulation (EC) No 324/2008[145] of 9 April 2008 laying down revised procedures for conducting Commission inspections in the field of maritime security: In 2005, in order to monitor the application by Member States of the Regulation and to verify the effectiveness of national maritime security measures, procedures and structures, the Commission adopted Regulation (EC) No 884/2005[146], laying down procedures for conducting Commission inspections in the field of maritime security. On 9 April 2008, the Commission adopted Regulation (EC) No 324/2008 laying down revised procedures for conducting Commission inspections in the field of maritime security, which also laid down *"procedures for the monitoring by the Commission of the implementation of Directive 2005/65/EC jointly with the inspections at the level of Member States and port facilities in respect of ports..."*. This Regulation, repealing Regulation (EC) No 884/2005, came into force on 1 May 2008.

6.5.1.2. Report on the work done in 2010

During the year 2010 the work done on monitoring the application of Community law in the field of maritime security had considerable developments.

- The Maritime Security Committee (MARSEC) met 5 times which provided occasions to discuss with the Member States issues in the common interpretation of the security standards defined at the international level. The common interpretation issues are recorded in a manual regularly updated. Furthermore, these issues are also addressed with the stakeholders from the advisory group on maritime security (SAGMaS).

- Concerning the implementation of the Port Security Directive, the majority of the Member States required to transpose the provisions of the Directive only did it after the deadline (15 June 2007) had passed. Taking into account the initial delays in the transposition into national laws, it occurs clearly that the effective implementation in all the EU ports could not be entirely completed within particularly short times.

Upon request of some Member States, the Commission organised, on 21 October 2010, a seminar on the implementation of the Port Security Directive, which 19 Member States attended (plus Norway, Iceland and the EFTA Surveillance Authority). This seminar was the second event after a first workshop held in September 2006 in order the help the Member States in implementing the Directive. The purpose of the seminar was to give Member States

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145 Commission Regulation (EC) No 324/2008 of 9 April 2008 laying down revised procedures for conducting Commission inspections in the field of maritime security, OJ L 98, 10.4.2008, p. 5.

146 Commission Regulation (EC) No 884/2005 of 10 June 2005 laying down procedures for conducting Commission inspections in the field of maritime security, OJ L 148, 11.6.2005, p. 25.

an opportunity for exchanging views, experiences and information as well as for discussing pertinent issues with regards the implementation of Directive 2005/65/EC.

- In 2010, the Commission's services carried out 126 inspections in the field of maritime security. The inspections permitted to check the implementation of the security legislation on the ground by the operators concerned, as well as the supervision of it by the Member States. The inspections have been focused mainly on port facilities and ships in order to check that assessments and security plans have been drawn up in line with Regulation (EC) No 725/2004, that they have been effectively implemented on the ground, and that the national authorities are conducting the necessary inspections and checks.

6.5.2. **Evaluation of the current position**

- Considering the implementation of the Port Security Directive, it should be noted that the delays in preparing and adopting national transposition measures in a variety of Member States have had a knock-on effect, in that the relevant port authorities were not able to implement the Directive until the national measures had been finally approved and adopted. However, on request of the Commission, action plans and progress reports are regularly asked to Member States to understand the achievement of key provisions of the Directive.

- Since the end of 2008, the Commission carried out inspections for the monitoring of the implementation of Directive 2005/65/CE in accordance with the provisions of Regulation (EC) No 324/2008. These inspections are conducted jointly with the inspections to the level of Member States and port facilities. These inspections were carried out in 53 ports of 19 Member States. The principal failures are related to the port security assessments and the definition of the boundaries of the port.

- Regarding Regulation (EC) No 725/2004, the inspection team reported on several occasions a lack of control exerted by the Member States to check the correct application of EU legislation in the port facilities and ships under their competence. This will remain a priority in 2011.

6.5.3. **Evaluation results**

The EU inspections are mainly intended to verify whether the legal requirements are being properly and effectively implemented by the Member States.

In 2010, the Commission conducted 126 inspections (71 port facilities, 15 ports, 33 ships and 7 national administrations). Maritime security inspections have again proved to be particularly useful. On the one hand, inspections have permitted to further increase compliance of the objects inspected. On the other hand, statistical analysis could identify areas where non-compliance occurs above average and maritime security policy took adequate steps as a remedy; best practices identified during inspections were disseminated to all Member States as a very cost-effective way of further improving maritime security; the participation of national inspectors at inspections outside of their country also contributed to the exchange of best practice and to mutual trust building.

The inspections have a double benefit. They highlight vulnerabilities and the remedies required regarding the EU legislation on maritime security. It has been noted an improvement of the situation following the inspections carried out.

Furthermore, the working programme for the performance of maritime security inspections carried out by the Commission systematically includes a section for verifying that the procedures for monitoring the application of the Directive have been correctly applied.

6.5.4. **Sector summary**

While the situation in maritime security sector is demonstrating the benefits of harmonised rules, enhancing ship, port facility and port security in the face of the threats posed by intentional unlawful acts, there are still a number of areas where some obstacles to efficient maritime security persist.

The efforts are concentrating in ensuring an efficient implementation of the existing maritime security legislation, by combining action in two fields:

- permanent contact with national administrations on the one hand through the work of the Maritime Security Committee and on the other hand in the context of preparation and follow up of inspections;
- based on the results of the inspections carried out by the Commission and on the on-going conformity checks, an action plan identifying the main areas where there is failure to comply with the Directive and Regulation will be the basis for initiating different actions, including infringement proceedings as necessary.

6.6. Inland Transport

6.6.1. **Current position**

6.6.1.1. Road Transport sector

In road transport the control of the application of EU law centred on the correct transposition by Member States of the social rules, including working time (Directive 2006/22/EC[147], Directive 2009/4/EC[148], Directive 2009/5/EC[149], Directive 2002/15/EC[150]), of rules on road charging (Directive 2006/38/EC[151] amending the Directive 1999/62/EC[152]) and of rules on the mutual recognition of professional qualifications and freedom of establishment (Directive 96/26/EC[153]).

147 OJ L 102, 11 April 2006, p. 35.
148 OJ L 21, 24 January 2009, p. 39.
149 OJ L 29, 31 January 2009, p. 45.
150 OJ L 80, 23 March 2002, p. 35.
151 OJ L 157, 9 June 2006, p. 8.
152 OJ L 187, 20 July 1999, p. 42.
153 OJ L 124, 23 May 1996, p. 1.

As regards the transposition of Directive 2006/22/EC the Commission pursued infringement proceedings initiated in the previous years against five Member States who failed to communicate the transposition measures or who did not properly transpose the measures of the Directive[154]. The proceedings against one of those Member States were initiated because of failure to implement the Directive which had been already declared by the Court in 2009. The Member States in question at last communicated their transposition in the course of the year and the cases have been closed.

As regards working time in road transport, the Commission continued the control of implementation concerning the Directive 2002/15/EC where only one Member State (The Netherlands) was not in conformity and this led to initiating infringement proceedings in 2008. The case was assessed in-depth and could be closed in 2010.

In 2008 the Commission had adopted a proposal to modify Directive 2002/15/EC. The aim of this proposal was four-fold: to clearly put false self-employed drivers in the category of mobile workers, to exclude genuine self-employed drivers from the directive, to make the enforcement more harmonised and to clarify the night time provisions. Since the European Parliament rejected the Commission proposal in June 2010, the Commission started enquiries with Member States about the transposition of the Directive 2002/15/EC concerning the application to self-employed drivers.

As regards Directive 2009/4/EC and Directive 2009/5/EC on social rules and tachograph the Commission has opened infringement proceedings against four Member States[155] but all of them had been closed since the Member States communicated the transposition measures already in the course of 2010.

As regards Directive 96/26/EC on admission to the occupation the Commission continued proceedings against two Member States[156] where the cases are still under proceeding.

6.6.1.2. Rail Transport sector

Rail Transport sector

Member States had to transpose the Directives of the first railway package (91/440/EEC as amended, 95/18/EC as amended and 2001/14/EC) by 15 March 2003 or upon accession in the case of the new Member States. The first railway package defines basic requirements such as the independence of the essential functions of an infrastructure manager from rail operators, the charging scheme for infrastructure charges, the setting up of rail regulatory bodies. On this basis, it provides for the opening of the rail freight market to all EU-licensed operators, from 2003 on the Trans European Rail Freight Network, from 1 January 2006 for all international rail freight transport and from 1 January 2007 for all rail freight transport.

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154 Italy, Malta, Austria, Luxembourg were not in conformity. Portugal did not communicate the measures and a procedure under Art. 260 TFEU was initiated since there was a previous judgment under Art. 258 TFEU.

155 Bulgaria, Cyprus and Czech Republic for Directive 2009/4/EC and Bulgaria, Cyprus and Slovakia for Directive 2009/5/EC.

156 Germany and Belgium.

The Commission adopted on 3 May 2006 a report on the implementation of the 1st railway package (COM(2006) 189 final) which contained important findings on the state of implementation in the Member States and announced the criteria that the Commission would apply for controlling implementation in each individual member state, in particular on the issue of independence of essential functions.

In order to complement the general findings of the report with concrete data from Member States, and to evaluate whether these Directives had been correctly and completely transposed into Member States' law and regulations, questionnaires were sent out to Member States in June and November 2007. After analysing the replies to these questionnaires, the Commission sent letters of formal notice to 24 Member States on 27 June 2008.

After sending these letters, the Commission services met with representatives from all 24 Member States to discuss possibilities to remedy the shortcomings identified in these letters. On the basis of these meetings, the replies of Member States to the letters and formal notice, and after changes have been made in some Member States, the Commission sent reasoned opinions to 21 Member States on 6 October 2009. These reasoned opinions addressed in many cases a reduced number of infringements in relation to the letters of formal notice due to the efforts of some Member States in the meanwhile to remedy some of the infringements.

After the analysis of the replies of the Member States to which reasoned opinions had been sent out in 2009, the Commission decided on 24 June 2010 to refer 13 of these Member States to the Court of Justice.

Member States had to transpose the Directives on the interoperability of the rail system within the EU (2008/57/EC and 2009/131/EC) by 19 July 2010. The Commission opened 41 cases of non-communication (letters of formal notice sent on 20 September 2010) concerning these two directives.

6.6.1.3. Road Safety and Transport of Dangerous Goods sector

The legislation on road safety covers the driving licence, the initial qualification and periodic training of professional drivers, roadworthiness testing, the compulsory use of safety belts, the registration of vehicle documents, the safety of tunnels and the safety of road infrastructure.

The main pieces of legislation in this area are therefore:

- Directive 91/439/EEC of 29 July 1991 on driving licences as amended as well as Directive 2006/126/EC on driving licences (recast) as amended.
- Directive 2003/59/EC of 15 July 2003 on the initial qualification and periodic training of drivers as amended.
- Directive 2000/30/EC of 6 June 2000 on the technical roadside inspection as amended.
- Directive 2009/40/EC of 6 May 2009 on roadworthiness tests for motor vehicles and

their trailers (recast) as amended.

- Directive 91/671/EEC of 16 December 1991 relating to compulsory use of safety belts in vehicles of less than 3,5 tonnes as amended.

- Directive 2004/54/EC of 29 April 2004 on minimum safety requirements for tunnels in the Trans-European Road Network.

- Directive 2008/96/EC of 19 November 2008 on road infrastructure safety management.

In July 2010 the Commission adopted a Communication "Towards a European road safety area: policy orientations on road safety 2011-2020" (COM(2010)389 final). The proposed policy orientations up to 2020 take full account of the results obtained during the 3rd road safety action programme 2001-2010 and aim to provide a general governance framework and challenging objectives which should guide European, national and local strategies for implementation, in line with the principle of subsidiarity.

The year 2010 was also largely devoted to the Council negotiations on the proposed Directive facilitating cross-border enforcement in the field of road safety (which was adopted by the Commission in March 2008). Although the discussions were blocked in Council since the end of 2008, work resumed under Belgian presidency in the second half of 2010 and brought to a positive political conclusion in first reading at the December meeting of the Transport Council. This breakthrough in the negotiation is an important step towards the fulfilment of the strategic objective concerning the increased enforcement of traffic rules, in line with the policy orientations on road safety for the decade 2011-2020. When adopted, this new piece of legislation is expected to have a strong deterrent effect by encouraging all drivers to respect traffic law and therefore to contribute to a further reduction of fatalities on EU roads.

Several committee meetings were organized by the Commission during 2010 and provided the opportunity for the Commission services to discuss with representatives of Member States their preparation as regards the transposition of Directive 2006/126/EC on driving licences and Directive 2008/96/EC on road infrastructure safety management, in view of the upcoming deadlines for both Directives (respectively 19 December 2010 for Directive 2008/96/EC and 19 January 2011 for Directive 2006/126/EC).

With regard to the Driving License Committee, the meetings organized during 2010 were focused on the state of preparation for the transposition. In addition, Member States were also requested to report back to the Commission possible implementation difficulties at an early stage.

In the road safety sector, two past infringements were closed in 2010, namely one relating to the late transposition of an amendment to Directive 91/439/EEC on driving licences introduced by Directive 2008/65/EC, the other concerning the incorrect application of Directive 2000/30/EC of 6 June 2000 on technical roadside inspection.

30 new infringement proceedings were however open in 2010, all for non-communication of the national measures transposing Directive 2009/112/EC of 25 August 2009 amending

Council Directive 91/439/EEC on driving licences (14 infringements) and Directive 2009/113/EC of 25 August 2009 amending Directive 2006/126/EC of the European Parliament and of the Council on driving licences (16 infringements). Both Commission Directives introduce amendments to the Annex III of Directive 91/439/EEC and of Directive 2006/126/EC regarding minimum standards of physical and mental fitness for driving a power-driven vehicle to include additional minimum requirements on eyesight, diabetes and epilepsy.

6.6.2. **Evaluation**

6.6.2.1. Road Transport

In 2009 the legislator successfully completed the revision of the EU road transport legislation with the adoption of the "road package" comprising of three new regulations. Regulation (EC) 1071/2009[157] establishes common rules that road transport operators have to fulfil in order to be allowed to engage in the profession. Regulation (EC) 1072/2009[158] governs the rules for access to the international road haulage market and in particular also the rules on cabotage. Finally, Regulation (EC) 1073/2009[159] lays down the rules for carrying out international passenger transport services by road. The new rules will apply as from December 2011 with the exception of the cabotage rules which became applicable in May 2010.

Following the adoption of Commission Regulation 1266/2009[160] on digital tachograph, the Commission organised a number of initiatives to facilitate its smooth implementation as from October 2011 and 2012.

In July 2010 the Commission adopted Regulation 581/2010[161] on the maximum periods for the downloading of relevant data from vehicle units and from driver cards in relation to Regulation (EC) No 561/2006 on harmonisation of certain social rules. The new rules apply as from end of July 2010.

In December 2010 the Commission adopted Regulation (EU) 1213/2010[162] on the ERRU (European Register of Road Transport Undertakings) so that the exchange of information through ERRU will become operational by 2013 as foreseen by the legislation.

6.6.2.2. Rail Transport sector

In the railway sector the reasoned opinions sent to 21 Member States for incorrect transposition of the first railway package targeted three main shortcomings: 1) the lack of independence of the infrastructure manager in relation to railway operators, 2) insufficient implementation of the rules of the Directive on track access charging, such as the absence of a performance regime to improve the performance of the railway network and the lack of incentives of the infrastructure manager to reduce costs and charges and 3) the failure to set

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157 OJ L 300, 14 November 2009, p. 51.
158 OJ L 300, 14 November 2009, p. 72.
159 OJ L 300, 14 November 2009, p. 88.
160 OJ L 339, 22 December 2010, p. 3.
161 OJ L 168, 2 July 2010, p. 16.
162 OJ L 335, 18 December 2010, p. 21.

up an independent regulatory body with strong powers to monitor competition in the railway sector and rule on complaints.

6.6.2.3. Road Safety and Transport of Dangerous Goods sector

Despite continuous efforts undertaken by the Commission, in particular in the driving licence committee to underline the obligation from Member States to notify their national measures within the agreed deadlines, the Commission is faced with a regular situation of late transposition of Directives by a significant number of Member States.

In view of encouraging a timely transposition of Directive 2008/96/EC on road infrastructure safety management and of Directive 2006/126/EC on driving licences, the Commission organised several committee meetings with representatives of the 27 Member States to remind them of their transposition obligations. These meetings were also devoted to identifying, together with the Member States, possible implementation problems at an early stage; under this perspective, it was decided to set-up an expert group to review the Annexes of Directive 2006/126/EC, which will meet several times in 2011.

Apart from the infringement procedures, the Commission is requested to take positions on numerous petitions on road safety addressed by citizens to the European Parliament. They mainly concern the non-recognition of driving licences and the respect of road traffic laws.

6.6.3. **Evaluation results**

6.6.3.1. Road Transport

For the road transport sector, following the adoption of the "road package", in May 2010 new amended rules became applicable in two areas: road cabotage and driving times and rest periods for occasional service of international carriage of passengers. In both areas the Commission will continue to closely monitoring the application of the new rules by Member States and assists Member States' authorities as well as operators in correctly applying these new regimes. The Commission will also pay a particular attention to the correct implementation as of 10 October 2011 of the new specifications on tachograph introduced by Regulation 1266/2009.

In addition, as regards the road transport Directives special attention will be given to the following areas:

- Directive 2006/38 amending Directive 1999/62/EC on the charging of heavy goods vehicles for use of certain infrastructures. The control of the correct application of the new rules which had to be transposed by June 2008 will continue[163].
- Directive 2002/15 on the organisation of working time of persons performing mobile road transport activities as a consequence of the rejection of the Commission proposal by the European Parliament.

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[163] The following Member States are currently under review as regards their tolling arrangements: Bulgaria, Czech Republic, France, Greece, Portugal, Romania, Slovenia, Spain, UK.

- Directive 2006/22 determining the minimum level of enforcement for the European provisions on driving times and rest periods, and on the use of the tachograph. After all Member States' transposing measures have been verified, attention will be given to the functioning of risk rating systems. Further potential infringement actions will be taken against two Member States[164] who have not yet notified to the Commission the introduction of such system in accordance with Art. 9 of the Directive.

- Commission Decision 2009/750/EC on the definition of the European Electronic Toll Service (EETS) and its technical elements, and implementing Directive 2004/52/EC on the interoperability of electronic road toll systems. The Decision lays down rights and obligations on Member States, EETS providers and toll chargers. Attention will be given to the availability of the elements necessary for EETS to be deployed and enter into operation, such as the possibility for an organisation to become registered as an EETS provider, the designation or establishment of Conciliation Bodies in order to facilitate mediation between EETS providers and toll chargers. Member States having national electronic toll collection systems must ensure that EETS is available for all vehicles exceeding 3,5 tonnes or allowed to carry more than nine passengers at the latest three years after Decision 2009/750/EC entry into force and for all other types of vehicle, at the latest five years after the Decision's entry into force. Decision 2009/750/EC entered into force the 8 October 2009. The respective deadlines are thus 7 October 2012 for the heavier vehicles and 7 October 2014 for all the other vehicles.

- Directive 2010/40/EU on the framework for the deployment of Intelligent Transport Systems in the field of road transport and for interfaces with other modes of transport. The Directive empowers the Commission to adopt delegated acts in accordance with Article 290 of the TFEU in respect of the adoption of specifications for actions within the 4 priority areas referred to in Article 2 of the Directive, as well as for the development, where appropriate, of necessary standards. Attention will be given to the transposition of the Directive by 27 February 2012, and to the provision by Member Sates of reports referred to in article 17(1) and (2) of the Directive. According to the Decision (C(2011) 289 final) of 15 February 2011 concerning the adoption of the Working Programme on the implementation of Directive 2010/40/EU, the Commission will work in priority on the specifications for the priority actions eCall, free minimum universal information services and information services for safe and secure parking, including appropriate consultations with Member States experts. The Commission will also continue the implementation of the ITS Action Plan[165], i.a. by launching several studies related to the 24 priority actions and supporting the work of the Urban ITS Expert Group.

6.6.3.2. Rail Transport sector

The Commission services will follow the cases in the Court of Justice in order to achieve positive decisions of the Court on the interpretation of the rules of the First Railway Package.

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164 Italy and Portugal.

165 COM(2008)887.

6.6.3.3. Road Safety and Transport of Dangerous Goods sector

In the legislative field, the priority will be to build on the progress made in 2010 on the negotiations regarding the proposed Directive facilitating cross-border enforcement in the field of road safety, the main objective for the Commission being to facilitate an agreement in second reading between the two co-legislators.

With regard to infringements, a close follow-up will be given by the Commission to the infringement procedures launched in 2010 for non-communication of the national measures transposing two Directives, namely Directive 2009/112/EC of 25 August 2009 amending Council Directive 91/439/EEC on driving licences and Directive 2009/113/EC of 25 August 2009 amending Directive 2006/126/EC of the European Parliament and of the Council on driving licences.

In addition, two Directives will require special attention in 2011, namely Directive 2008/96/EC on road infrastructure safety management and Directive 2006/126/EC on driving licences so as to ensure a timely and appropriate transposition by the Member States. Contact with national administrations will be ensured through regular committee meetings and a follow-up meeting regarding the transposition of Directive 2006/126/EC will be organised in the course of 2011 (in the form of a committee meeting). This meeting will also be the opportunity to examine with Member States possible implementation difficulties at an early stage. Expert group meetings on the Annexes of Directive 2006/126/EC will also be organised in 2011.

6.6.4. **Sector summary**

6.6.4.1. Road Transport

The majority of the new rules regulating market access for transport of goods and passengers by road will become applicable in 2011. By then the regulatory framework of the road transport sector will be modernised and streamlined. The Commission will continue to control the implementation and application of the social rules in close cooperation with the Member States. It will also continue to monitor the tolling arrangements in each individual Member State.

6.6.4.2. Rail Transport sector

In the rail sector and on the basis of the replies of Member States to the reasoned opinions (1st railway package), and information on legislative changes or commitments, the Commission will consider in which cases it is necessary to initiate court procedures in relation to the 8 cases for which no referral decision was taken yet.

Conformity assessments of national legislation transposing the Railway Safety Directive 2004/49/EC were initiated in 2009 and have been progressing during 2010. Requests for clarifications of the national legislation will be made to individual Member States either through administrative letters or the submission of queries through EU Pilot during 2011.

The non-communication cases concerning the interoperability Directives will be further

followed-up in 2011.

6.6.4.3. Road Safety and Transport of Dangerous Goods sector

In the road safety sector, special attention will be dedicated to the main issue of late notification by Member States. Efforts will continue to be undertaken to remind the Member States of their transposition obligations within the agreed deadlines and to point out that timely, correct and complete notifications are a priority for the Commission to ensure the proper functioning of EU law. Therefore, a close follow-up will be given to the infringements procedures initiated in 2010 for non-communication of the national measures.

Finally, priority will also be given to the finalisation of the inter-institutional negotiation on the Directive facilitating cross-border enforcement in the field of road safety.

6.7. Sector: Air Transport

6.7.1. Current position

6.7.1.1. General Introduction

Single Sky and Modernisation of air traffic control

The creation of the Single European Sky aims at achieving a better performing and seamless sky in Europe and is based on two successive packages of basic regulations adopted in 2004 and completed in 2009: Regulations No 549/2004 laying down a framework for the creation of the Single European Sky (SES), Regulation No 550/2004 on the provision of air navigation services, Regulation No 551/2004 on the organisation and use of the airspace, Regulation No 552/2004 on interoperability.

These initial Regulations have been amended by Regulation 1070/2009 which introduced new concepts such as a performance scheme for air navigation services or the centralisation of network management functions at European level.

As a result of the ash cloud crisis in April 2009, the Single European Sky has been accelerated in order to complete the regulatory work by end of 2010 and deliver benefits at the latest by 2012. More than twenty implementing rules have been adopted since 2004 to complement the basic regulations.

The efforts of the Commission will focus in the future on the implementation of the measures.

Air safety

The main activities in the sector of EU air safety policy, based on Article 100(2) of the TFEU, are the revision and completion of EU rules in the field of air safety, monitoring the implementation of the EU legislation and the continuous improvement of safety in the EU and abroad.

A description of the different components of this policy is available at http://ec.europa.eu/transport/air/safety/safety_en.htm.

Infrastructures and airports

This sector implements and supervises the implementation of the "action plan for airport capacity, efficiency and safety" that the Commission adopted in 2007 to increase the output of the existing infrastructures and to optimize the planning of new infrastructures, whilst raising safety standards at highest levels and enhancing the environmental compatibility of airports. Within this context, the sector notably supervises the Community Observatory on airport capacity which it set up in 2008.

The sector also involves the implementation of the following legal regulatory instruments:

- Council Regulation (EEC) N° 95/93 of 18 January 1993 on common rules for the allocation of slots at Community airports;
- Council Directive 96/67/EC of 15 October 1996 on access to the groundhandling market at Community airports;
- Directive 2009/12/EC of the European Parliament and of the Council of 11 March 2009 on airport charges;
- Some of the requirements of Regulation (EC) No 1008/2008 on common rules for the operation of air services in the Community (Recast).

Aviation security

Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 establishes common rules in the field of civil aviation security. It applies since April 2010 and replaces the previous aviation security legislation under Regulation (EC) No 2320/2002. The Regulation is complemented by detailed implementing rules taking the form of several Commission Regulations and a Commission Decision. A list of applicable legislation is contained in the Annex. In particular, the rules require Member States to establish and implement a national civil aviation security programme complemented by a quality control programme in order to ensure the application of the common basic standards on aviation security. Member States also have to designate a single appropriate authority responsible for the coordination and the monitoring of the implementation of the common basic standards and ensure the availability of sufficient resources to monitor compliance. Regulation (EC) No 300/2008 also requires from the Commission to carry out inspections of national administrations and a suitable sample of airports in all Member States.

6.7.1.2. Report on the work done in 2010

Internal Market, Air transport Agreements and Multilateral relations

- Non-conformity of the bilateral Air Services Agreement (ASA) between the Member

States and the Russian Federation with EU law

Following the 'Open Skies' judgements of the European Court of Justice (ECJ) of 5 November 2002 and the adoption of Regulation (EC) No 847/2004 on the negotiation and implementation of air service agreements between Member States and third countries, Member States need to bring their bilateral agreements with third countries in line with EU legislation. While this process is well advanced in the case of the agreements with most third countries, the bilateral agreements with the Russian Federation have to date not been modified and continue to infringe EU law in two respects.

Firstly, according to the ASA with Russia, a carrier established in an EU Member State of which substantial ownership or effective control do not remain with this Member State or its nationals does not have the right to exercise the traffic rights granted under the ASA. Such a restriction of the right to establish and manage an undertaking is not compatible with Article 49 of the Treaty on the Functioning of the European Union (TFEU) as confirmed by the judgments of the ECJ of 5 November 2002.

Secondly, the ASAs of Member States with Russia include provisions which violate competition law. In particular, the ASA mandates the designated airlines to enter into commercial agreements to specify additional details of their commercial relationship. In many cases, the ASA mandates the airlines to agree on the Siberian over-flights charges as well as on other tariff elements. By prescribing such commercial agreements between the designated airlines and encouraging them to agree on certain charges and price elements, Member States seems to have enacted measures which jeopardise the functioning of the internal aviation market and undistorted competition therein contrary to Article 4(3) TFEU in combination with Article 101 TFEU.

Since the adoption of Regulation No 847/2004, the Commission has continuously reminded Member States to bring their ASAs with Russia in line with EU legislation. Whenever Member States have notified air service negotiations with Russia to the Commission according to Regulation 847/2004, the Commission has reminded them in writing of their obligations.

In June 2010, the Commission invited all Member States to comment on these issues and most Member States responded to this request. The responses, however, confirmed the continuous infraction of EU law so that - in October 2010 - it was decided to launch formal infringement procedures against four Member States. Similar proceedings against all remaining Member States shall be launched by mid-2011.

- Allocation of limited air traffic rights

On 17 January 2011, the European Commission has sent a Reasoned Opinion letter against Poland for non compliance with Regulation 847/2004 and the absence of a non-discriminatory procedure for the allocation of limited air traffic rights in Poland. The article 5 of Regulation 847/2004 obliges Member States to lay down transparent and non-discriminatory national procedures for the allocation of limited air traffic rights. Six years after the adoption of the Regulation, Poland has still not laid down such procedure and is the last EU Member state

without any rules regarding the allocation of limited traffic rights

The absence of such a procedure in Poland prevents an EU air carrier, coming from another Member state that Poland, to compete for traffic rights between Poland and third countries. The non implementation of Article 5 of Regulation 847/2004 allows a potential exclusion of other EU air carriers desiring to operate from an establishment in Poland and infringes the very basic rules of the aviation common market.

Single Sky and Modernisation of air traffic control

As a result of the acceleration of the Single European Sky in 2010, the Single Sky Committee (Article 5 of Regulation No 549/2004) met seven times in plenary sessions and nine times in working sessions on dedicated regulatory issues. The Industry Consultation Body (Article 6 of Regulation No 549/2004) met six times during last year.

This considerable work led to the adoption of major measures contributing to building and reinforcing the Single European Sky, notably:

- The establishment of a **performance scheme**, with the adoption of Regulation No 691/2010 laying down a performance scheme for the air navigation services, the amendment of Regulation No 1794/2006 on a common charging system, the adoption of a Commission Decision on the designation of the Performance Review Body, the nomination of a Chairman for this Body and the adoption of EU-wide performance targets binding on the EU States;

- the acceleration of the creation of **functional airspace blocks** (FABs), to be achieved by end of 2012, with the adoption of a Regulation on the information to be provided before the establishment and modification of a functional airspace block (not yet published), the production of Guidance Material for the establishment and modification of FABs, as required by Article 9a of Regulation No 550/2004 and the nomination of a FAB Coordinator;

- the centralisation of **European Air Traffic Management network functions**, including network crisis management , through the preparation of an implementing rule on the network functions, of a Commission Decision on the nomination of a Network Manager;

- The consolidation of **relations with Eurocontrol**, through the signature of two specific contracts under a Framework Agreement for provision of support to the implementation of the Single European Sky and other EU aviation policies, the creation of a European Aviation Coordination Crisis Cell, the opening of an EU Liaison Office and the coordination of tasks between the Commission, the European Aviation Safety Agency and Eurocontrol on safety regulatory activities;

- Preparation of a strategy for the **deployment of SES new technologies**, including scenarios for the governance and the financing.

Air safety

On 20th October 2010, the European Parliament and the Council adopted Regulation (EU) No 996/2010 on the investigation and prevention of accidents and incidents in civil aviation that repealed Directive 94/56/CE. The main objectives of this Regulation are to: enhance the investigating capacity of the EU and independence of accident investigation; clarify the role of European Safety Aviation Agency (EASA) in accident investigation; strengthen implementation of safety recommendations; alleviating potential tensions between accident investigation and judicial proceedings, while maintaining separation and independence of investigation. This Regulation came into force on 10 November 2010.

In the field of continuing airworthiness (maintenance) of aircraft, Commission Regulation (EC) No 2042/2003, was amended twice, on 5 February and 26 October 2010, in order to enhance the existing rules and the corresponding levels of safety.

The implementation by Member States of Directive 2004/36/EC regarding the conduct of ramp inspections on aircraft using Community airports (SAFA) is satisfactory and in constant improvement, mainly due to a number of supporting activities carried out by the Commission and EASA: in 2010 the SAFA steering committee met three times. In 2010, efforts were undertaken to improve the functioning of the EU SAFA programme, in particular through the carrying out of quality review analysis of SAFA reports or by the initiation of a Standardisation programme, which *in fine* aims at ensuring that all SAFA inspections are done in a standardised manner in all countries.

The transposition of Directive 2008/49/EC regarding the procedures for conduct of ramp inspections was completed by the EU Member States in 2010 and the 3 infringement procedures pending were duly closed.

The Commission has worked together with EASA to ensure a correct and harmonised implementation of the *acquis* under the scope of the EASA (so called "standardisation inspections") with special attention to those safety areas which revealed problematic. For example, the Commission analysed some 150 reports stemming from 120 standardisation inspections carried out by the Agency in 2010 and ensured the appropriate follow-up. This allowed the Commission to identify a number of significant non-compliances to the safety rules and to request urgent action from the Member States concerned.

On 11 January 2010, the Commission presented a report on the application of Regulation (EC) No 2111/2005 on the establishment of a Community list of air carriers subject to an operating ban within the Community over the past three years. The application of the EC list has demonstrated that it is a successful tool to contribute to ensuring a high level of safety in the Community but the report recommends to promote the exchange of verifiable and reliable information at the international level as well as to better coordinating efforts to grant technical assistance to those States where it is mostly needed. In relation with the implementation of the Regulation (EC) No 2111/2005, the EU list of air carriers subject to an operating ban was up-dated 4 times (Regulations 1071/2010, 791/2010, 590/2010 and 273/2010). These updates are the outcome of a fruitful cooperation between the Commission, the Member States and EASA. More than 450 air carriers were examined during the year.

The Commission has treated in 2010 an important number of derogations and exemptions from the provisions of Regulations (EEC) No 3922/91 (13 cases) and (EC) No 216/2008 (around 39 cases) notified by Member States. This has been done with the support of EASA. The control of such cases is essential for the harmonised implementation of the common rules.

In 2010, the EASA Committee established by Regulation (EC) No 216/2008 met 5 times with the following objectives: analysing and agreeing on amendments to current legislation in the fields of airworthiness and on new EU rules in the area of pilot licences; discussing on interpretation issues related to current legislation and discussing on the strategy for forthcoming rulemaking activities.

3 formal complaints were treated in 2010 by the European Commission in the field of air safety and a number of queries and parliamentarian questions related to the implementation of the *acquis* or to forthcoming new legislation, mainly related to flight time limitations, quality of air in aircraft cabins, seat pitch, pilot licences, accident investigation and trans-boundary private flights.

– Infrastructures and airports

– *The Action Plan for airport capacity, efficiency and safety*

The Community Observatory on airport capacity continued to work on the slot allocation process, on airport capacity assessment methodologies and on the potential of intermodality in fighting airport congestion and linking different transport modes at airports.

Measures aiming at enhancing the consistency between airport slots and flight plans which had been approved by the "Single Sky Committee" in December 2009 were adopted by the Commission with the *Regulation (EU) No 255/2010 of 25 March 2010 laying down common rules on air traffic flow management*[166]. The new Regulation will apply from September 2011. Its Article 9 contains provisions to enhance the consistency between flight plans and airport slots which will permit a proper implementation of Article 14(1) of Regulation 95/93/EC: such a mechanism will allow airports to ask for the rejection of flight plans of aircraft intending to operate without slots in the meaning of Regulation 95/93.

– *Capacity*

– In relation to the creation of an inventory of airport capacity, the Commission launched the preliminary works, while pertinent works on the related cartography had been finalized before. A test questionnaire on airport capacity was sent to all Member States with a view to its possible use as an inventory tool in the future. The Commission received answers from 23 Member States covering 59 airports. These responses were then analysed from the point of view of assessing the quality/utility of the questionnaire which was revised accordingly.

– *Slots*

166 OJ L80, 26.3.2010, p. 10.

The main objective for 2010 was to carry out an in-depth assessment of the functioning of the Slot Regulation[167]. In this sense, the following actions were undertaken: An online public consultation was carried out and a stakeholders' hearing took place in November. A study undertaken by an external consultant has been launched to feed into an impact assessment process.

Another key objective was to ensure the proper implementation by Member States. The situation at several airports was assessed notably by asking annual reports for the majority of slot coordinators.

Several investigations on possible infringements took place. One case was closed and three others are under investigation.

– For the first time since 1993, the provision of the Slot Regulation relating to the external dimension of the slot regime has been successfully activated. After receiving a complaint from the Austrian authorities regarding the situation of Austrian airlines in Ukraine and their difficulty in securing slots, the Commission intervened urgently to create and convene the Slot Comitology Committee. The action at the EU level proved very valuable since the matter was solved in cooperation with the Ukrainian authorities after receiving unanimous support of the Member States.

– *Airport Charges/taxes*

Directive 2009/12 EC on airport charges was adopted by the Council and European Parliament on11 March 2009 (OJ L 70, 14.3.2009, p. 11). This Directive aims to require transparency, user consultation and the application of the principle of non-discrimination when calculating charges levied on users. The Directive lays down minimum requirements in the calculation and levying of airport charges at all airports with more than 5 million passenger movements per year, in addition to the largest airport in each Member State. Member States have previously signed up to the principles behind the Directive (transparency, non-discrimination and cost-relatedness of airport charges) at international level (ICAO).

Member States are currently preparing implementation measures (Deadline set by the Directive: 15.03.2011)

In 2010, a number of files have been analysed regarding the compatibility of taxes/charges with the EU law, in particular with Regulation 1008/2008 and existing case-law. One case was closed, another was opened, and two complaints were received by the Commission towards the end of the year.

Groundhandling

[167] Council Regulation (EEC) N° 95/93 of 18 January 1993 on common rules for the allocation of slot at Community airports.

Efforts to ensure the proper implementation of Directive 96/67/EC by Member States were intensified and the situation at several airports was assessed. As a result eight Member States were affected as follows:

Four reasoned opinions were sent to four of them. In one case the Member State concerned started immediately to implement the corrective actions proposed by the Commission and accepted to amend accordingly the relevant national law. Pending this modification the case has been suspended. The three other cases were still under scrutiny at the end of 2010;

A letter of formal notice was sent to one Member State, and preliminary investigations into another one started;

In the aftermath of Commission's intervention, two Member States have implemented corrective actions to comply with the Directive: the corresponding cases were therefore closed.

In addition, further work has been carried out in 2010 to assess the functioning of the groundhandling market, notably through a public consultation (December 2009-February 2010).

Aviation security

The Commission continued to fulfil its monitoring obligations and conducted inspections (including follow-up inspections) of 5 national administrations and 21 airports.

Two letters of formal notice were sent following inspections of national administrations. In one case, the concerned Member State failed to maintain its national aviation security programme while the second case relates to the application of the EU rules at small airports. Two infringement cases were closed following rectification of the identified shortcomings. Three infringement cases remained open during the year and were being closely followed. In all these cases, several informal contacts with the Member States have already taken place in order to assist them in a swift rectification of deficiencies and good progress has been observed.

In order to achieve a reduction in the number and severity of deficiencies identified during Commission inspections the following measures have been taken in 2010:

- Detailed implementing rules complementing Regulation (EC) No 300/2008 were developed in close cooperation with all stakeholders. These new implementing rules apply since April 2010. This major revision improves clarity and consistency, thus paving the way for an even higher compliance level.

- The change in applicable rules was accompanied by several workshops assisting Member States in preparing the transition.

- The Commission organised three training courses for national auditors of Member States on the new compliance monitoring requirements and provided them with a new hand book including guidance.

- The implementation of a peer-review system with an active participation of national auditors from all Member States in Commission inspections was continued.

6.7.2. **Evaluation of the current position**

Single Sky and Modernisation of air traffic control

Annual reports on the SES implementation: in application of Article 12 of Regulation No 549/2004 and Article 7 of Commission Regulation No 2150/2005, Member States have the obligation to submit to the Commission annual reports on their implementation of the actions required by the SES legislative package.

The second reporting exercised covered the year 2009 and allowed to collect information from the 27 EU Member States as well as from Norway and Switzerland. The national reports were collected, consolidated and analysed in a General Report on the SES legislation implementation prepared with the support of Eurocontrol. Some of the national reports were subject to a follow-up by a letter through correspondence.

Overall, this exercise has been deemed very useful to assess the exact stage of implementation of the SES legislation at national level, to raise awareness on the importance given to this matter by the European Commission and to attract the Commission's attention on deficiencies and on areas requiring support action at European level.

Infringement procedures

Only one infringement case remains open out of the five still pending early 2010.

This case concerns a "non-conformity" infringement procedure against Greece for non-compliance with basic Single European Sky legislation, in particular for the absence of establishment of en effective and independent national supervisory authority.

The annual reports from the Member States as well as the decrease in the number of pending infringement procedures indicate an overall enhanced compliance with the Single European Sky legislation.

Some areas still need to be improved, for instance the resources and capability of national supervisory authorities, the legal frameworks for cross-border provision of air navigation services, the certification of these services, the implementation of effective flexible use of airspace and civil-military coordination and the establishment of Functional Airspace Blocks.

Air safety

Overall, transposition of the *acquis* in the fields of air safety and environmental requirements is good at present.

Concerning the day to day implementation of the legislation, the situation could be considered preoccupying in a limited number of Member States concerning mainly the requirements related to air operations and continuing airworthiness. The main causes are linked with the insufficient capacity of national competent authorities to oversee the entities under their responsibility, either due to lack of adequate number or qualified staff or to deficient procedures. In some cases, the entities themselves are circumventing EU rules either due to incorrect understanding or on purpose, for administrative or commercial reasons. This has been identified and corrective actions have been requested.

The consequences of the non compliances with regard to technical safety requirements under the scope of EASA are the decline of the safety level, which can be corrected through appropriate measures ranging from action plans to revocation of certificates or even withdrawal of the mutual recognition or fines imposed by Member States. In case of persistency, an infringement procedure against the Member State concerned can also be initiated. The Commission is closely following any such potential safety threat but no formal infringement procedure has been required up to now.

The national competent authorities are always the ultimate body responsible for overseeing the entities under their jurisdiction as well as for taking the necessary corrective actions. The Commission and EASA should be able to detect some type of deficiencies with the different tools for oversight on their hands (inspections, ramp checks, complaints, etc) and when identifying cases of concern, get in contact with the competent authorities and take any actions necessary in order to put an end to the potential breach, as explained above.

In some cases, the need to clarify or amend the EU rules is identified. The Commission works continuously with EASA and the Member States, in the context of the relevant Committees, with a view to address these cases. In the fields of air operations and pilot licensing the situation should improve with the upcoming adoption of new harmonised rules by 2012.

Regarding the implementation of the EU *acquis* concerning occurrence reports in civil aviation (Directive 2003/42/EC and its implementing rules), the situation has improved but is not yet optimal. The Commission acted in 2010 against 5 Member States (3 via EU Pilot and 2 letters of formal notice), which served to put an end to the incompliance.

Infrastructures and airports

In 2011, priority will be granted to the Strategic initiative on airports in accordance with the European Commission's work programme for 2011 ('Airport package') as well as to the correct implementation process of the Airport charges Directive.

Groundhandling

The implementation of the Directive on groundhandling is under close monitoring. The situation has improved after action of the Commission but remains essential to continue a close surveillance of Member State's transposition instruments and the way they are applied.

The implementation of the Directive still raises a number of questions. To this end, an

evaluation of the current functioning of the Directive has been undertaken and an impact assessment process has been launched.

Slots

The implementation of the Regulation on airport slots raises a number of questions. To this end, the European Commission is assessing the situation at several Member States airports and is working to an evaluation of the current functioning of the Slot Regulation has been undertaken and an impact assessment process has been launched.

Airport Charges

Member States are obliged to transpose the Directive[168] into national law by 15 March 2011. The Commission is therefore closely monitoring this process and will intervene in cases of incorrect or delayed implementation.

Aviation security

Since the introduction of Community rules in 2002 and of Commission inspections in 2004, results of aviation security inspections have steadily improved. The compliance with main provisions during aviation security inspections of airports rose from 62% to 85% in 2009. Due to the fact that security provisions in the new aviation security regulations have been regrouped and combined the figure of the compliance rate for 2010 is not directly comparable to the figures of previous years which was based on a higher number of individual provisions. In 2010 the compliance rate was 80% which still constitutes a very encouraging result. It confirms that the transition to the new regulatory framework went smoothly.

It is expected that the improved aviation security legislation and clearer rules on national quality control will further improve compliance levels in the European Union. However, a continued effort in inspections, enforcement and advice will remain vital to ensure a positive evolution. In particular, the Commission will have to closely follow availability of sufficient resources for compliance monitoring to fulfil national quality control obligations. The Commission will therefore continue to take a strict and coherent approach to the rectification of deficiencies identified during Commission inspections.

6.7.3. **Evaluation results**

6.7.3.1. Priorities

Single Sky and Modernisation of air traffic control

The priorities for the Commission in the field of ATM do not change, they consist in developing a total-system approach in line with the gate-to gate concept to ultimately improve

[168] Directive 2009/12/EC of the European Parliament and of the Council of 11 March 2009 on airport charges.

the performance of the European Aviation System in key areas such as the environment, capacity and cost-efficiency, having due regard to the overriding safety objectives.

The legislative package will be soon completed and the Commission will focus in 2011 on the effective implementation of the concepts defined and the actions required by the regulations.

Air safety

In 2010, the main priorities, which remain valid, were:

- the revision and completion of EU rules in the field of air safety;
- monitoring the implementation of the EU legislation; and
- the adoption of a safety management system at EU level.

Infrastructures and airports

In 2011, priority will be granted to the Strategic initiative on airports in accordance with the European Commission's work programme for 2011 ('Airport package') as well as to the correct implementation process of the Airport charges Directive.

Aviation security

The priorities for the Commission in the field of aviation security remain unchanged, namely to further develop harmonised rules in aviation security that provide an adequate level of protection whilst limiting the negative impact on facilitation and to ensure the application by all Member States of the common basic standards contained in Regulation (EC) No 300/2008.

6.7.3.2. Planned action

Single Sky and Modernisation of air traffic control

The Commission plans in 2011 to support the effective implementation of the Single European Sky on the basis of five pillars:

- a regulatory pillar with the implementation of the performance scheme, of the network Manager, the Functional airspace block as well as through consolidated relations between the institutions and organisations active in the ATM field (EASA, EU, SESAR JU and Eurocontrol);
- A safety pillar based on the extension of EASA's competences to ATM;
- A technology pillar, related to the development and deployment of the ATM Master Plan under the aegis of the SESAR JU;
- An airport capacity pillar integrating airports in the performance scheme, the

adoption of measures coordinating ATFM and airport slots and contribution to the 'Airport package';

- A Human Factors pillar aimed at associating more effectively the social partners.

Air safety

The Commission intends to complete by end 2013 the adoption of all basic rules governing all the areas directly linked with air safety, which are airworthiness of aircraft, air crew certification, air operations, air traffic management, air navigation services, air traffic controllers and aerodromes. This should allow to ensure consistency of rules applicable in the different areas, improved safety and efficiency by the completion of the so called "total system approach".

It is also essential to improve the gathering and assessment of safety relevant information (mainly coming from accident investigation, occurrence reporting and SAFA) as well as the efficiency of EU actions in the field of air safety through the development of a safety management system at EU level. The latter system should be launched in 2011, based on the technical expertise of EASA and prepared in coordination with Member States and stakeholders concerned.

New legislation

- Adoption of a series of new harmonised rules in the fields of flight crew licensing, air collision avoidance system, air operations, air traffic management, air navigation services , air traffic controllers and aerodromes; and

- Amendment of the Directive 2003/42/EC on occurrence reporting in civil aviation, review of existing legislation related to aircraft airworthiness, inspections conducted by EASA and funding of EASA certification activities (fees and charges);

- Review of the airport noise directive (Directive 2002/30/EC on the establishment of rules and procedures with regard to the introduction of noise-related operating restrictions at Community airports) with the view to enhance the consistent application of the ICAO so-called "balanced approach" and clarify the relationship with the environmental noise directive (Directive 2002/49/EC relating to the assessment and management of environment noise). The review of this Directive will be part of the airport package, whose adoption is planned for mid 2011.

Infrastructures and airports

The Airports Package

In accordance with the European Commission's work programme for 2011, an 'Airport package' will be presented as part of the flagship initiative "*Restoring growth for jobs*" and more particularly of the thematic area *"Tapping the potential of the Single Market for growth"*.

Depending on the conclusions of ongoing impact assessments the package could include

comprise:

- A proposal on airport capacity assessment and inventory;
- The revision of Council Regulation (EEC) 95/93 of 18 January 1993 on common rules for the allocation of slots at Community airports;
- The revision of the Council Directive 96/67/ec on access to the groundhandling market at community airports;
- The revision of Directive 2002/30/EC of the European Parliament and of the Council of 26 March 2002 on the establishment of rules and procedures with regard to the introduction of noise related operating restrictions at Community airports.

Aviation security

The Commission will continue to apply a strict compliance monitoring and enforcement policy to ensure an adequate protection of its citizens. The Commission therefore intends to continue its inspections at a frequency comparable to previous years but to increase the number of inspections of cargo security regimes, which have shown certain vulnerabilities. Particular emphasis will be given to ensuring that Member States have an adequate number of resources to fulfil their obligations.

In order to assist Member States in its compliance monitoring effort the Commission will continue the implementation of its peer-review system and regularly inform Member States of non-compliances found during inspections in the Regulatory Committee on aviation security, which meets 6 times per year. These updates on non-compliances identified during inspections help Member States to identify critical areas where deficiencies occur repeatedly.

6.7.4. **Sector summary**

Single Sky and Modernisation of air traffic control

The priorities of the commission in this sector remain unchanged: the key objective is the effective implementation of the requirements of the Single European Sky package. Good progress has been made so far by the Member states and the various stakeholders concerned, but the action of the European Union needs to be reinforced in order to bring concrete support to States of stakeholders facing difficulties in some implementation areas, now that the legislative foundations are almost completely laid down.

Air safety

Objectives:

- Immediate reaction to safety threats identified (recurrent);
- Follow-up of the correct transposition and implementation of the *acquis* through a number

of different tools, including inspections (recurrent);

- Updating and complement the *acquis* whenever necessary (recurrent).

– Legislation in preparation

- Proposal for a Directive of the European Parliament and of the Council amending Directive 2003/42/EC on occurrence reporting in civil aviation to be presented in 2011.

- Commission Regulation concerning fines and periodic penalty payments for non-compliance with provisions of Regulation (EC) No 216/2008 and its Implementing Rules to be adopted in 2011.

- Commission Regulations in the fields of air crew licensing, Air Collision Avoidance System, Air Operations, Air Traffic Management, Air Navigation Services, Air Traffic Controllers and Aerodromes, to be adopted between 2011 and 2013.

Aviation security

The priorities for the Commission in the field of aviation security remain unchanged, namely to further develop harmonised rules in aviation security that provide an adequate level of protection and to ensure the application by all Member States of the common basic standards contained in Regulation (EC) No 300/2008.

The planned key actions are the continuation of the well established inspection regime at current frequencies, the strict enforcement of EU rules following the identification of deficiencies and the assistance of Member States in applying an adequate national quality control system.

7. CLIMATE ACTION

7.1. Emission Trading Scheme (ETS Directive)

The EU ETS legislation is the cornerstone of the Climate Change policy. Particular attention is therefore dedicated to this legislation within the present Report.

The EU ETS was established with the adoption of the Emissions Trading (Directive 2003/87/EC[169]). It is a market-based instrument aiming at gradually reducing emissions in selected sectors. It should help the EU and the Member States meet their Kyoto Protocol commitments to reduce greenhouse gas emissions in a cost-efficient manner. The EU ETS started operating in January 2005. A revision of the ETS Directive (Directive 2009/29/EC[170])

[169] Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC (OJ L 275, 25.10.2003, p. 32–46).

[170] Directive 2009/29/EC of the European Parliament and of the Council of 23 April 2009 amending Directive 2003/87/EC so as to improve and extend the greenhouse gas emission allowance trading scheme of the Community (OJ L 140, 05.06.2009, p.63-87).

was prepared and negotiated in 2008 and entered into force in June 2009. This revision broadly amends the EU ETS design as from 1 January 2013 (i.e. the beginning of the third trading period 2013-2020). In addition, Directive 2008/101/EC[171], which amended Directive 2003/87/EC by providing for the inclusion of the aviation sector in the EU ETS, entered into force in February 2009.

7.1.1. **Report of work done in 2010**

In 2010 the EU ETS-related work continued to focus on two main sets of activities: (a) ensuring that the current ETS works properly and that its rules are correctly applied by Member States and (b) preparing the implementing measures for the revised ETS Directive to be implemented from 2013 for and for EEA-wide implementation of aviation activities covered by the EU ETS from 2012.

(a) Ensuring proper implementation of the ETS by Member States

Conformity assessments

On the basis of conformity assessment initiatives related to the ETS Directive, the Commission services indentified various issues requiring clarification in respect of national legislation transposing the Directive. As of January 2010, 21 Member States had replied to administrative letters of inquiry sent in the course of 2009 asking for clarification of the national legislation. Following further exchange of views, the necessary clarifications were provided to the Commission.

Implementation and legal enforcement

Cases related to the ETS Directive - National Allocation Plans:

The individual national allocation plans (NAPs) adopted by Member States fix the total number of emission allowances and set out the methodologies to allocate them to individual installations covered by the EU ETS. NAPs for the period between 2008 and 2012 are thus an important element in the Member States' strategies for achieving their relevant emission reduction targets under the Kyoto Protocol.

In 2007 several Member States opposed the Commission decision on their respective NAP. In essence, they claimed that the upper limit set by the Commission on the total quantity of allowances they may allocate was too low, and that the Commission had exceeded the limits of its discretion when assessing the proposed NAPs by using its own methodology.

Consequently, 9 Member States brought annulment actions on the basis of Article 263 TFEU before the European Court of Justice. The Slovak Republic subsequently withdrew its case, and in early 2010 the following cases were pending before the General Court: T-221/07 Hungary, T-194/07 Czech Republic, T-369/07 Latvia, T-368/07 Lithuania, T-499-500/07 Bulgaria, T-483-484/07 Romania. For each of these cases, the written procedure has ended.

[171] Directive 2008/101/EC of the European Parliament and of the Council of 19 November 2008 amending Directive 2003/87/EC so as to include aviation activities in the scheme for greenhouse gas emission allowance trading with the Community (OJ L 8, 13.01.2009, p.3-21).

In Cases T-183/07 and T-263/07, the General Court annulled the Commission's decisions rejecting the respective NAP on 23 September 2009. The Commission lodged appeals to Cases T-183/07 and T-263/07 on 3 December 2009. Those appeals were still pending in 2010 and are based on several legal grounds. Most importantly, the Commission considers that the General Court interpreted the powers of the Commission in the NAP assessment process too narrowly. The Commission also submits that the General Court did not sufficiently taken into account the fundamental purpose of the EU ETS – to reduce overall EU emissions of greenhouse gases – and the need to ensure the equal treatment of Member States during the NAP assessment process.

As a result of the judgements in Cases T-183/07 and T-263/07 (see above), the Commission adopted new decisions on the originally notified Estonian and Polish NAPs on 11 December 2009. As the NAPs were rejected, both Estonia and Poland had to submit new NAPs for further assessment by the Commission. Poland notified a new national allocation plan on 8 April 2010. On 19 April 2010, the Commission decided not to raise any objections with regard to this NAP. With regard to the Estonian NAP, at the end of 2010, the Estonian authorities had not yet submitted a new NAP for assessment to the Commission.

Some companies covered by the EU ETS also brought actions. By judgment of 2 March 2010, the General Court dismissed the action brought by Arcelor (T-16/04) for partial annulment of Directive 2003/87/EC for compensation for the damage suffered by the applicant following the adoption of that directive. This case was the last case still pending before the General Court.

In its judgment, the General Court found that Arcelor was not individually or directly concerned by the contested provisions of Directive 2003/87/EC within the meaning of the fourth paragraph of Article 263 TFEU and declared the application inadmissible. The claims for damages was considered admissible, but rejected as, according to the Court, Arcelor had failed to demonstrate that, in adopting the contested directive, the legislator acted unlawfully or committed a sufficiently serious breach of a rule of law designed to confer rights on the company.

Other cases related to the ETS Directive

Several administrative inquiry letters regarding the application of the EU ETS Directive were sent to Member States in 2010.

One inquiry related to the application of the fine provided for in Article 16 of the EU ETS Directive. Other inquiries concerned the adoption of tax law provisions or similar with respect to EU ETS allowances. Such provisions may be equivalent to a non-permissible ex-post adjustment of the relevant national allocation plan. The relevant national authorities were therefore invited to provide further information on this legislation. Any appropriate follow-up will be decided in 2011.

Cases related to the Aviation ETS Directive

Infringement cases for non-communication of national measures of transposition for Directive 2008/101/EC including aviation activities into the EU ETS were opened against 18 Member States after the expiration of the transposition deadline – 2 February 2010.

Non- communication cases have progressed during year 2010 through closure or further steps

in the infringement procedures (seven Reasoned Opinions against those Member States still lagging behind transposition were adopted and notified in November 2010).

Communication by Member States in early 2011 of national measures of transposition for Directive 2008/01/EC will enable the Commission to close a number of the above mentioned cases. In parallel, the Commission will be proposing the continuation of the infringement procedures against those Member States still lagging behind full transposition by the end of the third trimester of 2011.

(b) Preparing the timely implementation of the revised EU ETS

Before 2013, 15 comitology procedures, 7 legislative proposals and a variety of reporting requirements are foreseen to implement the EU ETS for the third trading period.

During 2010, the Commission continued to hold a number of separate stakeholder and expert meetings regarding the list of (sub-)sectors deemed to be exposed to a significant risk of carbon leakage, the auctioning regulation, the harmonised rules for transitional free allocation (benchmarks), the need for measures to prevent market abuse and the regulations on monitoring and reporting of emissions and on verification of emission reports and accreditation of verifiers.

In 2010, implementing measures and further guidance for the revised EU ETS from 2013 were prepared in the following areas.

Carbon leakage

A list of sectors and subsectors deemed to be exposed to a significant risk of carbon leakage was adopted by the Commission on 24 December 2009 as Commission Decision 2010/2/EU.

Benchmarking

According to Article 10a(1) of the revised EU ETS Directive, the Commission has to adopt transitional EU-wide rules for harmonised free allocation (benchmarks). During 2010 the Commission held a number of broad stakeholder meetings and bilateral consultations with industry and NGOs as well as expert meetings with Member States' representatives to ensure a thorough and correct understanding of the various technical issues to be addressed in that Decision.

The relevant text was proposed by the Commission's services and approved by the Climate Change Committee on 15 December 2010. After scrutiny by the European Parliament and the Council it was adopted by the Commission on 27 April 2011 (ref. Commission decision C(2011) 2772).

Preparations for large-scale auctioning as from the 3rd trading period

Article 10(4) of the revised EU ETS Directive requires the Commission to adopt a Regulation on the auctioning of allowances. The Commission adopted the Auctioning Regulation on 12 November 2010.

The Commission and the Member States have now begun the implementation of the Auctioning Regulation (e.g. the preparation of joint procurement agreements for the common

auction platforms and for the single auction monitor, an amendment of the Auctioning Regulation to determine the volume of 'early auctions').

Protection from insider dealing and market manipulation

Article 12(1a) of the revised EU ETS Directive provides that the Commission, by 31 December 2010, shall examine whether the market is sufficiently protected from insider dealing or market manipulation and, if appropriate, bring forward proposals to ensure such protection.

On 21 December 2010, the Commission published a Communication on carbon market oversight. It provides for an assessment of the carbon market structure, the level of market oversight, the level of protection of the carbon market from market abuse and the available options (incl. the classification of allowances as a financial instrument). The Commission concluded that a major part of the carbon market is subject to appropriate oversight, but that more may be needed in the spot market.

An internet-based stakeholder consultation will be conducted in the first half of 2011, the results of which will feed into a thorough impact assessment. This work will inform the decision on whether to come forward with a legislative proposal.

Registries

- On 7 October 2010, the Commission adopted Regulation 920/2010 for a standardised and secured system of registries pursuant to Directive 2003/87/EC and Decision No 280/2004/EC. It mainly contains the rules and the technical modalities deemed necessary to adapt the registries system and particularly the EU Registry to accommodate the introduction of aviation into the scheme for greenhouse gas emission allowance trading within the EU from 1 January 2012 onwards. Furthermore, it addresses the need to provide more detailed and robust rules to fight against fraud and other criminal activities.

- The revised EU ETS Directive provides that all allowances will be held in the Community Registry as from 2012. This will transfer the bulk of Member State-level ETS-related IT-operations to the Commission, a process which will require a significant expansion of the Registry related IT-capacities of the Commission. Further amendments to the Registry Regulation (Regulation 916/2007/EC) are therefore currently prepared to be adopted in 2011.

Quantitative restrictions on the use of JI/CDM credits

- Article 11a(9) of the revised EU ETS Directive refers to the measures which can be applied to restrict the use project types. In 2010, the Commission prepared and proposed a Regulation determining certain restriction applicable to the use of international credits from projects involving industrial gases. These projects raise concerns relating to their environmental integrity, value-for –money and geographical distribution. The aim of the Commission proposal is to ensure a better quality and distribution of credits in the international carbon market. The proposal was adopted on 21 January 2011.

EU ETS for aviation activities

In 2010, implementing measures and further guidance for the revised EU ETS for aviation

activities (under the EU ETS from 2012) were prepared in the following areas:

- Updating of the list allocating aircraft operators to States for administrative purposes;
- Frequently asked questions addressing key issues encountered in the implementation of the system and guidance from the compliance forum regarding verification.
- Working on the extension of the aviation activities covered by the EU ETS to the EEA area according to the same timeline than the EU -27 ETS.

Linking with other GHG trading schemes

Article 25 of the revised EU ETS Directive enables the EU to conclude agreements with third countries to provide for the mutual recognition of allowances between the EU emissions trading scheme and other GHG emissions trading schemes. Such agreements may be concluded with third countries that have implemented compatible mandatory GHG emission trading systems with absolute emissions caps. The Commission has presented in 2010 a Recommendation to the Council to authorise the Commission to open negotiations on linking with the Swiss emissions trading system. The Council adopted its authorisation to the Commission to start negotiations by a decision adopted on 21 December 2010.

7.1.2. **Evaluation based on the current situation**

(a) Ensuring proper implementation of the ETS by Member States

For the current ETS, the following problems and corrective actions were identified:

Conformity assessments

The conformity studies on the transposition by Member States of the ETS directive as amended by Directive 2004/101/EC of the European Parliament and of the Council of 27 October 2004 and the administrative letters of inquiry that were issued focussed on those provisions of the ETS Directive that were not likely to be modified as a consequence of the adoption of the revision of the ETS Directive in 2008 and 2009. The assessment of the replies received revealed a few issues of concern. The Commission services have inquired about these issues with the Member States concerned and will take the appropriate steps to ensure full compliance.

Implementation and legal enforcement

Despite the ongoing court cases related to some national allocation plans, the allowance market works properly.

The security of the national registries from an IT perspective has become more and more a concern over the past few months. So-called phishing attacks, whereby the credentials of the administrators were stolen, have taken place in 2010. Immediate action was taken both by the Commission and by the national administrators as EU legislation requires that Member States take all necessary steps to ensure the security of their own registry.

In order to counter the threat of so-called 'carousel fraud', whereby VAT and goods are passed around between companies and jurisdictions to exploit the way VAT is treated within multi-

jurisdictional trading, in the context of emissions allowances trading, the Council has amended Directive 2006/112/EC on the common system of value added tax in March 2010. It has provided for an optional and temporary application of a reverse-charge mechanism in relation to supplies of certain services, including namely the transfer of emission allowances under the EU Emissions Trading Scheme (EU ETS), susceptible to fraud. The aim is to reverse VAT liability for all types of emission allowances and making it payable by the buyer of the emission allowances.

(b) Preparing the implementation of the revised EU ETS

The revised EU ETS was adopted to improve some specific areas of the current EU ETS. These areas for improvement were identified through a review and extensive stakeholder consultations during the first trading period (2005-2007), as follow:

- Emissions trading can only exploit its environmental strength and justification, if there is scarcity on the allowance market. However, the lack of verified emissions data when setting up the National Allocation Plans (NAPs) for the first trading period (2005-2007) combined with over-optimistic projections of emissions led to the issuance of more allowances than was justified to ensure the necessary scarcity on the market.

- Member States had different levels of ambition for the emission reductions required of the sectors included in the EU ETS, and consequently different Member States set different levels of allocation for the same sector. They also applied widely differing allocation methods.

- The Commission's approval of NAPs turned out to be a long-lasting, cumbersome and complex process.

- Some sectors pass the market value of the allowances through to their customers in their product prices and received significant free allocations.

The issues identified during the review of the EU ETS justified a revision of the ETS design itself. They have been largely addressed in the revised ETS Directive. The Commission proposed a fully harmonised approach including an EU-wide and annually shrinking cap on allowances - to replace the prevailing bottom-up approach based on NAPs - leading to an emission reduction of 21% by 2020 as compared to 2005 levels, with reductions continuing thereafter. The Commission also proposed to phase-in auctioning over a period of time as the principal allocation method for all operators, and provided for harmonised rules for the transitional free allocation. These elements do not only guarantee that the required emission reductions are achieved, they also increase the certainty and predictability in the system, thereby fostering investments to reduce emissions.

Thus, the ETS revised Directive sets up the general framework for the corrective action to the problems identified with the current ETS. In 2010, the European Commission has continued the preparatory work to define all the detailed implementing measures and further guidance to enable the revised ETS to work from 2013. Specific problems raised during the preparatory work have been intensely discussed with Member States (via informal meetings and Comitology) and stakeholders throughout the year. The Commission will endeavour to address these problems in the measures and guidance that it will propose in 2011.

7.1.3. **Perspectives**

Transposition and implementation processes are well under way and according to plan. The Commission will continue to defend its decisions and the integrity of the EU ETS Directive in ongoing Court proceedings.

With respect to the reverse-charge mechanism for VAT, the Commission will reiterate the importance of the implementation of this mechanism and plans to inquire about the implementation of Member States.

During 2011, the following measures are planned to be adopted or implemented to ensure the proper and timely implementation of the ETS.

A proposal for the harmonised rules on transitional free allocation (benchmarking) was submitted to the Council and the European Parliament for scrutiny. It was adopted on 27 April 2011. Ensuring harmonised implementation by Member States will be a priority for the rest of 2011.

By 30 September 2011, Member States are required to send their intentions in terms of free allocation as of 2013 for each installation on their territory to the Commission. Upon submission, the Commission will assess the proposed allocation and may reject it.

The Registries Regulation needs to be further amended to fully take account of the revised EU ETS.

A Regulation for the monitoring and reporting of emissions and, where relevant, activity data, from the activities listed in Annex I, as well as for the monitoring and reporting of tonne-kilometre data is to be adopted by 31 December 2011.

Furthermore, a Regulation on accreditation and verification of emission reports is also to be adopted by 31 December 2011.

Concerning the list of sectors and subsectors deemed to be exposed to a significant risk of carbon leakage, the Commission has analysed further sectors and subsectors during 2010 and proposed to add a number of sectors and subsectors to the list. The proposal was agreed by the Climate Change Committee on 19 May 2011. The draft decision is now under scrutiny by the Council and the European Parliament.

The Commission is also to update and publish the total quantity of allowances for the year 2013 and the estimated quantity of allowances to be auctioned as of 2013.

With regards to the protection from insider dealing and market manipulation, following the organised cyber-attacks on national registries between November 2010 and January 2011, protection will be improved by means of continuously adapting security measures based on experience and new technologies.

Furthermore, transactions in the EU ETS carbon market relate both to the allowances themselves and to derivative products based on allowances, e.g. futures. In general, such derivatives qualify as financial instruments and are usually traded on one of a number of specialised exchanges. Some of these exchanges qualify as regulated markets. This means that a significant part of the trade in the EU ETS carbon market is already covered by the

applicable financial markets legislation. However, financial market legislation does not apply to the spot market, and for some of the provisions there are exemptions for non-investment firms.

The Commission's ongoing work in the field of financial markets regulation will also affect the level of protection of the EU ETS carbon market.

The focus of the work going forward will be to assess whether additional measures are needed to protect the types of transactions in the EU ETS carbon market that are currently not covered by existing legislation or legislation in the pipeline in the field of financial markets. Further analysis and stakeholder consultations will take place in 2011.

Generally, during 2011 the Commission plans to continue holding a number of broad stakeholder meetings and further bilateral consultations with industry and NGOs as well as expert meetings with Member States' representatives on the implementation of the transitional EU-wide rules for harmonised free allocation (benchmarks) and on other issues, such as the regulations on monitoring and reporting and on accreditation and verification as well as on the security of the registries.

EU ETS for aviation activities

Year 2011 represents an important milestone concerning the implementation of EU ETS on aviation from January 2012 onwards.

The following measures are planned to be adopted or implemented to ensure the proper and timely implementation of the ETS on aviation in 2011:

- An update of the list determining the aircraft operators' administering State in an EEA-wide area is to be finalised and published further to the inclusion of the Directive 2008/101/EC into the EEA agreed in April 2011, so as to ensure the smooth functioning of the EU ETS for aviation, once the EEA EFTA countries are fully included in the system.

- Calculation of the EU 27 figures for allowances and the EEA wide benchmarks for the periods 2012 and 2013-2020 are also due by 30 September 2011. These will be derived from the verified benchmarking data (measured in "tonne-kilometres") being collected by aircraft operators for the year 2010 and reported to the Member States by 31 March 2011.

- Preparation of the review of the functioning of the Directive in relation to aviation activities (e. g. impacts, functioning, effectiveness, special reserve, thresholds, exemptions) in the second trimester 2011 with the small emitters study.

Negotiations with Switzerland on linking with the EU ETS aviation will start in the first trimester 2011.

7.2. Monitoring and Reporting

7.2.1. Introduction

Together with the Emissions Trading Directive, Decisions 280/2004/EC[172] (the Monitoring Mechanism Decision – MMD) and 2005/166/EC[173] are among the most important cross-cutting measures in this area of climate change. With the adoption of these decisions, the EU established a mechanism for the monitoring and reporting of the Member States' greenhouse gas (GHG) emissions and their projected progress towards GHG targets. This mechanism has enabled the Commission to more accurately, rigorously and regularly evaluate the (quality of the) progress made in reducing emissions under the UNFCCC and the Kyoto Protocol. As a result, Member States have improved timeliness and quality in the submission of their data.

7.2.2. Report of work done in 2010

Monitoring and Reporting

In relation to the implementation of the Monitoring Mechanism Decision (MMD), the Commission continued its efforts to ensure the complete and timely submission of data by the Member States. Under Article 3 (1) of Decision 280/2004/EC, read in conjunction with Decision 2005/166/EC, Member States must submit to the Commission by 15 January 2010, the first main elements of their national greenhouse gas (GHG) inventory report of actual progress (NIR). By 15 March 2010, Member States must submit their complete NIR. These reports are required by the Commission so it can compile, in collaboration with the Member States an assisted by the European Environment Agency (EEA), the EU's annual inventory report on the EU's actual GHG emissions in compliance with the UN Framework Convention on Climate Change and the Kyoto Protocol In 2010 there was no reporting obligation (biennial requirement) under Article 3(2) of the MMD.

With respect to Monitoring and Reporting in 2010 the Climate Change Committee voted in favour of amending the existing Commission Decision 2007/589/EC, the so-called Monitoring and Reporting Guidelines in order to include monitoring and reporting guidelines for greenhouse gas emissions from new activities and gases pursuant to Directive 2003/87/EC. Apart from relatively minor changes to existing annexes to the Decision, the current amendment adds six new annexes providing activity-specific guidelines for the production of: soda ash and sodium bicarbonate; ammonia; hydrogen and synthesis gas; bulk organic chemicals; ferrous and non-ferrous metals; primary aluminium. Final adoption by the Commission is planned in the first half of 2011.

Enforcement: ensuring complete and timely reporting by the Member States

In early 2010, the Commission has closed pending infringement cases against 4 Member States that had failed to submit their 2008 annual and 2007 biennial reports. New

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172 Decision 280/2004/EC of the European Parliament and of the Council of 11 February 2004 concerning a mechanism for monitoring Community greenhouse gas emissions and for implementing the Kyoto Protocol (OJ L 49, 19.2.2004, p. 1–8).

173 Commission Decision 2005/166/EC of 10 February 2005 laying down rules implementing Decision No 280/2004/EC of the European Parliament and of the Councilconcerning a mechanism for monitoring Community greenhouse gas emissions and for implementing the Kyoto Protocol (OJ L 55, 1.3.2005, p. 57–91).

infringement cases had been launched in 2009 against 24 Member States on the ground that they had communicated to the Commission no or incomplete 2009 annual reports on GHG emissions or 2009 biannual report on policies and measures.

In view of the Copenhagen Climate Change Conference (COP 15/CMP 5) the Commission found it important to take a strict approach in this regard. In 2010 the Commission was able to close all cases. In 2010 some Member States still continued to submit incomplete data. Also in 2010, the enforcement branch of the UNFCCC Compliance Committee concluded that Bulgaria was in non-compliance with its UNFCCC obligations, resulting in the suspension of Bulgaria's eligibility to participate in the mechanisms under the Kyoto Protocol.

Still, it is the Commission's view that the emphasis of its enforcement action should not be exclusively on the start of new infringement proceedings, but also on a constructive collaboration with the Member States resulting in the Member States submitting their complete reports on time. This is the approach that the Commission will continue to follow concerning the 2011 annual reports due for 15 January 2011 as well as the 2011 biennial reports due for 15 March 2011.

7.2.3. **Perspectives**

Ensuring timely and proper provision of climate-relevant data

Accurate, up-to-date information is an essential basis for climate change policy. Under Decisions 280/2004/EC and 2005/166/EC, Member States must provide the Commission with annual reports on their actual emissions of greenhouse gases and biennial reports on domestic climate change policies and measures and emission projections, so that the Commission can accurately report on the progress made by the EU as a whole. To that end the Commission has rigorously checked whether national reports are submitted on time and whether the data are correct and complete. As a result of the enforcement action, reporting continues to improve in terms of timing and content.

One of the challenges for the Commission will therefore be to ensure that reporting of national greenhouse gas emissions improves still further, so that all Member States communicate complete reports to deadline to ensure an effective follow-up to the United Nations Convention on Climate Change and its Kyoto Protocol.

In line with the above, further studies were carried out to examine the revision of Decisions 280/2004/EC and 2005/166/EC in the light of the adopted Climate and Energy Package and the developments at international level. The experience gained so far has shown that the current system, although it has its merits, is not always fully effective and no longer suffices. As the EU's commitments become more stringent and its emission reduction goals more ambitious, it is imperative that the EU is able to deliver on those goals in a more effective and efficient manner. The revision of the Monitoring Mechanism Decision currently underway (se below) will significantly enhance the monitoring, reporting and review system that was first introduced under the Kyoto Protocol and it will ensure that the EU continues to lead by example.

Revision of the Monitoring Mechanism Decision

The adoption of a new monitoring and reporting scheme is mandated by the experience gained through the implementation of the Kyoto Protocol, which shows that the current

system is not fully effective, the implementation of the Climate and Energy package adopted by the European Parliament and Council in December 2008 and future possible reporting obligations resulting from the ongoing international discussions and negotiations following the Copenhagen Accord.

In 2010, the Commission identified and assessed policy options on the basis of previous and new studies and took preparatory steps to launch an online stakeholder consultation and to complete an impact assessment. The Commission also organised a workshop with Member States to discuss the main issues linked to the revision of the Monitoring Mechanism Decision.

In 2011, the Commission will also continue its work on the revision of Decision 280/2004/EC through an online stakeholder consultation, preparation of an impact assessment and of a legal proposal.

Other implementing measures on monitoring and reporting under ETS

In 2010, preparatory work has been carried for drafting a new Commission Regulation on ETS Monitoring and Reporting in compliance with Article 14 of Directive 2003/87/EC. Adoption by the Commission is expected by December 2011.

A new Commission Regulation on ETS Accreditation and Verification in compliance with Article 15 of Directive 2003/87/EC is also being prepared. Adoption by the Commission is expected by December 2011.

7.3. Ozone depleting substances and Fluorinated Gases

7.3.1. Introduction

The Regulation on Ozone Depleting Substances sets out controls on production, importation, exportation, supply, use, leakage, recovery and lays down the phasing-out in line with the obligations under the Montreal Protocol. Regulation (EC) No 1005/2009 recast and replaced Regulation (EC) No 2037/2000 as of 1 January 2010, clarifying, simplifying and streamlining the previous provisions and procedures to the extent possible.

Regulation (EC) No 842/2006 on certain fluorinated greenhouse gases (F-Gases) aims at reducing emissions of three groups of fluorinated greenhouse gases: hydrofluorocarbons, perfluorocarbons and sulphur hexafluoride through a series of targeted sector-specific measures such as systematic checks for leakage and recovery from equipment by certified personnel; labelling of products and equipment; the prohibition of placing on the market of certain products containing such gases and of the use of those gases in certain applications. The Regulation is complemented by 10 Commission Regulations adopted between 2007 and 2008.

7.3.2. Report of work done in 2010

Revision of the existing legal framework

The Regulation on Ozone Depleting Substances applies since 1 January 2010 (Regulation (EC) No 2037/2000 was repealed from the same date). The Commission adopted Regulation (EU) No 744/2010 amending Regulation (EC) No 1005/2009 with regard to the critical uses

of halons, which introduces cut-off and end-dates for all exempted uses of these substances.

The Regulation on F-Gases requires the Commission to publish a report in 2011 based on the experience of its application and, where necessary, present proposals for revision of the relevant provisions of the Regulation. A technical study was launched in the context of the preparatory phase of the review and a targeted Expert Group composed of Member States authorities, industry organisations and environmental NGOs was also established to assist the Commission services, particularly in relation to the ongoing study.

Compliance promotion and legal enforcement

Implementation of the Regulation on Ozone Depleting Substances

During 2010 no new infringement cases relating to the Regulation on Ozone Depleting Substances were launched. Four infringement cases (against Cyprus, Denmark, Greece and Italy) were closed regarding the failure to fulfil the obligations in relation to the decommissioning of halons used in fire extinguishers of ships. One case on this issue (against Malta) was further pursued and referred to the Court of Justice.

Implementation of the Regulation on F-Gases

The Commission monitored attentively the implementation by the Member States of certain requirements laid down in the Regulation and in the implementing Commission Regulations. In particular, some delays observed in the establishment of national certification systems for personnel and companies working with F-Gases and in the adoption of rules on penalties by the Member States have required appropriate follow-up action from the Commission.

Implementation of the Regulation on *Ozone Depleting Substances*

Regarding the implementation of the Ozone Regulation, Member States were found in compliance with the Regulation and no major difficulties have been encountered with the enforcement of the Regulation.

7.4. Transport related emissions

7.4.1. Introduction

Commission strategy to reduce CO2 emissions from cars and vans

The European Commission has a comprehensive strategy (COM/2007/0019 final) to reduce CO2 emissions from new cars and vans sold in the European Union, to ensure that the EU meets its greenhouse gas emission targets under the Kyoto Protocol and beyond.

This strategy, which was adopted in 2007, aims to tackle CO2 emissions from both the production and consumer sides and is designed to help the EU reach its long-established objective of limiting average CO2 emissions from new cars to 120 grams per km by 2012 - a reduction of around 25% from 2006 levels.

Regulation (EC) 443/2009 (CO2 from cars Regulation)

Regulation (EC) 443/2009 of the European Parliament and of the Council setting emission

performance standards for new passenger cars as part of the Community's integrated approach to reduce CO2 emission from light-duty vehicles is the cornerstone of the EU's strategy to improve the fuel economy of cars and ensure that average emissions from new passenger cars in the EU do not exceed 120 gCO2/km.

The key elements of that legislation are the limit value curve, long-term target, phasing-in requirements, excess emissions premiums, eco-innovations, pool acting jointly to meet emission targets, monitoring CO2 emissions from new passenger cars.

Directive 1999/94/EC (Labelling Directive)

Directive 1999/94/EC of the European Parliament and of the Council of 13 December 1999 relates to the availability of consumer information on fuel economy and CO2 emissions in respect of the marketing of new passenger cars. The main requirements of the Directive are the provision of information on CO2 emissions and fuel economy for all new cars at the point of sale: car label, a poster and a guide informing on CO2 emissions of all cars offered on sale; and mandatory consumer information regarding CO2 and fuel economy of new cars in printed advertisements.

Directive 98/70/EC (Fuel quality Directive)

As part of the integrated approach set out in the strategy, it was foreseen that a contribution to the 120g/km objective would come from use of low greenhouse gas fuels. In view of the fact that complementary measures had to be measurable, monitorable and a party needed to be accountable for them, the Fuel quality Directive (Directive 98/70/EC) was modified to include a greenhouse gas reporting and reduction requirement. This modification set out in article 7a of the Directive requires a 6% reduction in the greenhouse gas intensity of the fuel supplied by 2020 as a contribution to the strategy to reduce greenhouse gas emissions from light duty vehicles.

7.4.2. **Report of work done in 2010**

Commission strategy to reduce CO2 emissions from cars and vans

The Commission has adopted a progress report (COM/2010/0656 final) in November 2010, concluding that most of the measures contained in the 2007 strategy have already been implemented or are in the process of being implemented. The goal of reducing new car emissions to 120 gCO2/km by 2012 is however not likely to be achieved because some measures have been implemented late. Despite a low probability of achieving the 2012 target, the strategy, and the measures it includes, has played an important role in reducing CO2 emissions from light-duty vehicles.

Regulation (EC) No 443/2009 (CO2 from cars Regulation)

In 2010 the work was focused on preparing measures implementing Regulation (EC) No 443/2009, including on monitoring of CO2 emissions, derogations for small volume and niche manufacturers and eco-innovations.

Commission Regulation (EU) No 1014/2010 on monitoring and reporting of data on the registration of new passenger cars pursuant to Regulation (EC) No 443/2009 of the European Parliament and of the Council was adopted on 10 November 2010.

Decision (EC) 1753/2000 of the European Parliament and of the Council establishing a scheme to monitor the average specific emissions of CO2 from new passenger cars

The Commission also adopted as part of the implementation of Decision (EC) No 1753/2000 a report on the monitoring of CO2 emissions from new passenger cars in 2009.

Proposal for a regulation on CO_2 from vans

In 2010 the proposal on CO2 from vans, adopted by the Commission in October 2009, was in co-decision. Negotiations between the co-legislators were concluded by the end of 2010 in a series of informal trilogue discussions leading to a first reading agreement. The European Parliament voted on the compromise amendments in February 2011 and the formal approval by the Council took place on 31 March. The main provisions of the Regulation mirror Regulation (EC) 443/2009 on CO_2/cars and include a 2-step approach to setting CO_2 emission standards for new vans, i.e. a target of 175g/km in 2017 and 147g/km in 2020. In addition, the legislation includes other key elements from the cars Regulation such as the limit value curve, phasing-in of the first target, excess emissions premiums, eco-innovations, pools acting jointly to meet emission targets, monitoring CO_2 emissions from new light commercial vehicles.

Directive 98/70/EC (Fuel Quality Directive)

Following adoption of the amendment to this Directive in April 2009 a number of issues required further work. The methodology for reporting GHG intensity of energy used within the scope of the Directive other than biofuels is foreseen in the Directive to be adopted through Comitology. The Commission held a public consultation in September 2009 followed by an expert meeting early in 2010 to provide input to this work. Following extensive deliberations a draft implementing measure has been the subject of consultation within the Commission. Further information of relevance to this measure became available at that time with the completion of a study on the GHG intensity of fuel production from tar sands and oil shales.

The Directive also foresaw the need to correct the lack of accounting for greenhouse gas emissions due to Indirect Land Use Change. The Commission adopted a report on its work in December 2010 in which it stated it will present an impact assessment if appropriate together with a legal proposal by July 2011.

Compliance promotion and legal enforcement

Directive 1999/94/EC (Labelling Directive)

During 2010 no new infringement cases relating to Directive 1999/94/EC were launched. Three cases against Spain, Italy, and Belgium concerning the absence of enforcement by the authorities, however, remained open from previous years and were further pursued accordingly.

Regulation (EC) 443/2009 (CO2 from cars Regulation)

In 2010 the European Commission has started the preparatory work in order to develop all the

detailed implementing measures and further guidance where required to enable an efficient monitoring system. In order to ensure that the data collected and reported by Member States to meet requirements set out in the legislation, the Commission followed up with several Member States where missing data or data quality had proven to be an issue of concern.

The Commission will continue to work closely with Member States to improve the quality of their reporting.

Directive 1999/94/EC (Labelling Directive)

Regarding the implementation of Directive 1999/94/EC, it can be said that while a limited number of infringement cases have remained open from previous years and individual issues may persist, in general Member States are in compliance with the Directive.

Directive 98/70/EC (Fuel quality Directive)

In 2010 the Commission has continued work on the implementation measures. In particular this concerns the methodology for reporting GHG intensity of energy used other than biofuels. It has also continued with the evaluation of vapour pressure derogation requests under Article 3(4) of the Directive. Fuel Quality reporting required under the Directive continues and the Commission has not identified any specific problems.

7.5. Other climate related legislation

7.5.1. Carbon Capture and Storage (CCS)

CCS Directive

Directive 2009/31/EC on the geological storage of carbon dioxide (CCS Directive) is one of the world's first comprehensive legal frameworks for the regulation of the environmental risks of carbon capture, transport and storage. It entered into force on 25 June 2009. Although it covers the full chain of activities arising in CCS, carbon capture and transport are comparable to other activities already regulated at EU level. The CCS Directive therefore regulates these activities by introducing them into the scope of the existing legislation. Carbon capture is regulated under Directive 2008/1/EC (IPPC Directive) and under Directive 85/337/EC (EIA Directive', and pipeline transport is regulated under the EIA Directive.

The Directive establishes an authorisation regime for geological storage sites and covers site exploration, characterisation, selection, monitoring, closure and post-closure management, as well as composition of the CO2 stream. One notable provision included is that draft permit decisions for storage sites (and also decisions on transfers of responsibility, see below) are to be submitted to the Commission, which is to issue - within 4 months - an opinion on whether the draft permit decisions meet the requirements of the Directive. The Commission has established a Scientific Panel to assist it in its assessment (see below).

There are no implementing provisions required under the CCS Directive, but the Commission has **in 2010 finalised a guidance document** on a number of issues (composition of the CO2 stream, conditions for transfer of responsibility to Member States, and financial contributions required of the operator at the point of transfer of responsibility).

The Commission also intends to produce guidance on a number of other issues.

More specifically**,** monitoring and reporting guidelines (MRGs) were adopted[174] for CCS under the Emissions Trading Directive for the purposes of quantifying the emissions for which allowances must be surrendered for capture, transport and storage activities, including in the case of leakage

Commission has also started working on the review of draft storage permits under article 10 of the Directive.

During 2010 the Commission also **established a Scientific Panel** to provide technical input into the Commission opinions on draft permit decisions and decisions on transfer of responsibility. Guidance documents on the key aspects of implementation were also adopted.

In 2011, **conformity checking** will be carried out to check transposition of the CCS Directive in the Member States.

7.5.2. **EU Effort Sharing Decision (ESD)**

Decision 406/2009/EC[175] (Effort Sharing Decision, ESD) lays down **binding annual targets for greenhouse gas emissions outside the scope of the ETS**, for the period 2013-2020, for each Member State. It entered into force on 25 June 2009. About 60% of the total EU-27 greenhouse gas emissions are covered by the ESD. The most important emitting sectors are transport (about 30% of total ESD emissions), private households and services (25%), and agriculture (15%).

By way of contrast with the EU ETS, which is EU-wide market-based instrument already in place with well established rules and procedures for installations and Member States, the Effort Sharing Decision is a new legal instrument with far-reaching consequences for Member States' obligations to reduce greenhouse gas emissions. Though the ESD will rely on both EU-wide and national measures, the most **mitigation actions will have to be prepared and implemented at Member State level**.

By 2013, the following key actions will be necessary to implement the ESD and prepare for the 2013-2020 compliance period:

– Determining the exact targets for Member States for the period between 2013 and 2020 (comitology decision);

– Amending the Monitoring Mechanism Decision (ordinary legislative procedure);

– Establish modalities for transfers of emission allocations between Member States (comitology decision);

– Prepare for the inclusion of land use, land-use change and forestry (LULUCF) in the EU reduction commitment (co-decision, see below).

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174 Decision 345/2010/EC of the European Commission of 08 June 2010 concerning the inclusion of monitoring and reporting guidelines for greenhouse gas emissions from the capture, transport and geological storage of carbon dioxide (OJ L 155, 22.6.2010, p. 34-47).

175 Decision No. 406/2009/EC of the European Parliament and of the Council of 23 April 2009 on the effort of Member States to reduce their greenhouse gas emissions to meet the Community's greenhouse gas emission reduction commitment up to 2020.

In 2010 the Commission services have started preparations for a number of implementing provisions under the ESD for decision in 2011 / 2012.

In 2011 the Commission will present a decision to be adopted through comitology procedure (including a vote in the Climate Change Committee) in order to determine the annual emission allocations expressed in absolute tonnes of CO_2 equivalents for the period between 2013 and 2020 in accordance with Article 3.2 of the Decision. The Commission will also prepare for a Comitology decision to establish "modalities" for transfers of emission allocations between Member States and increase their transparency under the ESD as required by Article 3.6 of the Decision.

7.5.3. **Land use, land-use change and forestry (LULUCF)**

Articles 8(1) and 8(6) of the ESD and Article 28(1) of the ETS Directive require the Commission to consider, in the absence of an international agreement, a number of issues regarding LULUCF. The Commission will report in 2011 and assess options for the possible inclusion of emissions and removals from activities related to LULUCF in the Community reduction commitment. If considered necessary, the Commission will make a legislative proposal.

8. ENVIRONMENT

8.1. Nature Conservation

8.1.1. Current position

8.1.1.1. General introduction

The most important pieces of nature conservation legislation are the Birds Directive, 2009/147/EC (codified version replacing Directive79/409/EEC[176]) and Habitats Directive, 92/43/EEC[177]. The former sets out measures for the protection, management and control of all species of naturally occurring European wild birds, as well as introducing rules to protect their habitats. The latter protects natural habitats and wild flora and fauna throughout the European Union and establishes a European ecological network known as “Natura 2000”.

Nature conservation legislation constitutes a fairly stable part of the EC environmental *acquis*. Developments in this sector mainly concern the annexes to the Birds and Habitats Directives that have been adapted on a number of occasions in response to scientific and technical progress and to the successive enlargements of the European Union. The most recent adaptation is in response to the Accession of Bulgaria and Romania to the European Union on 1 January 2007. The Union is at present very close to the completion of the Natura 2000 network and regulatory stability is required in order to focus on the sustainable management of the areas.

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176 Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds OJ L 103, 25.4.1979, p. 1-18.

177 Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora OJ L 206, 22.7.1992, p. 7–50.

8.1.1.2. Report of work done in 2010

Establishment of the Natura 2000 network and designation of Special Areas of Conservation

Further progress was made in 2010 in the establishment of the Natura 2000 network, consisting of Special Protection Areas (SPAs) under the Birds Directive and Sites of Community Importance (subsequently to be designated as Special Areas of Conservation) under the Habitats Directive. On 10 January 2011, the Commission adopted six Decisions updating existing Biogeographical Lists of Sites of Community Importance (SCIs). The additions include 739 new sites and a total area of 27,000 km². More than half of the area added is made up of marine sites. This means that further significant progress has also been made as regards the designation of marine areas. Substantial designations of marine, especially offshore, sites are, however, still expected in 2011 and 2012. Taking also into account new SPAs, the Natura 2000 now covers almost 18% of the EU's landmass and almost 180.000 km² of marine areas, making it the largest interconnected network of protected areas in the world.

Several Member States have increased the number of designated areas following infringement procedures launched by the European Commission and several of these procedures have been closed in 2010. A Marine Biogeographical Seminar for the outstanding sea regions (Mediterranean, Black Sea, Macaronesian Atlantic) was organized in 2010 and the proposals of SCIs in these regions have been evaluated.

Most Member States are still in a process of designating their Sites of Community Importance as Special Areas of Conservation (SACs) according to Article 4(4) of the Habitats Directive. This exercise includes the establishment of detailed conservation objectives for the individual sites and the design of appropriate management instruments according to Article 6(1) of the directive. Member States have to designate their SCIs as SACs not later than six years after the inclusion of the sites in a Community list. That deadline was 28 December 2007 for most sites of the Macaronesian biogeographical region, 22 December 2009 for most sites of the Alpine biogeographical region and 7 December 2010 for most sites of the Atlantic and Continental regions. An infringement procedure was launched in 2008 against Portugal and Spain for not having designated sites in that region as SACs. Following this procedure, Portugal adopted the necessary legal acts in order to approve the designation of SACs and the Commission took the decision to close the infringement case. On the contrary as the progress in the Spanish case was considered as insufficient, the Commission decided to refer the case to the Court of Justice *(case C-90/10)* and is currently awaiting its ruling.

The Commission will consider launching new infringement procedures against Member States which still have not provided sufficient designations for the Natura 2000 network or which have not designated their SCIs as SACs within the deadline required by the Habitats Directive.

Non-conformity with the Birds and Habitats Directive

In 2010, the Commission pursued infringements dealing with non-conformity of national transposing legislation with the Birds and Habitats Directive. As regards the Birds Directive, the Commission decided in 2010 to address a complementary Letter of Formal Notice (under article 258 of the Treaty on the Functioning of the EU) to the United Kingdom, and a

Reasoned Opinion (under the same article) to Poland and Romania. Furthermore, on 15 July 2010 the Court ruled that Italy has failed to adequately transpose the directive

As regards the Habitats Directive, a Reasoned Opinion (under article 258 of the TFEU) was sent to Denmark and Poland.

Insufficient designation of Special Protection Areas

Under the Birds Directive, Member States are obliged to designate all of the most suitable sites as Special Protection Areas to conserve wild bird species. The designation must be based on objective, verifiable scientific criteria. To assess whether Member States have complied with their obligation, the Commission uses the best available ornithological information. Where the necessary scientific information provided by Member States is lacking, national inventories of Important Bird Areas (IBA) compiled by the non-governmental organisation Birdlife International, are used. While not legally binding, the IBA inventory is based on internationally-recognised scientific criteria. The Court of Justice has already acknowledged its scientific value, and in cases where no equivalent scientific evidence is available, the IBA inventory is a valid basis of reference in assessing whether Member States have classified a sufficient number and size of territories as Special Protection Areas.

In 2010, the Commission sent a complementary Letter of Formal Notice (under article 260 of the TFEU) against Greece for failing to designate enough Special Protection Area (SPA) on its territory. In 2010 the Court of Justice also ruled against Austria for not having designated 1 SPA and for insufficiently designating another one.

Bird Hunting

Hunting is regulated in the European Union by the Birds Directive. Although the Directive contains a general prohibition on the killing of wild birds, it does allow certain species to be hunted provided this does not take place during the breeding season or migration periods. Hunting periods are set at national levels, and vary according to species and geographical location. Exceptionally, Member States may allow the capture or killing of birds covered by the Directive outside of the normal hunting season for a limited number of reasons, although such derogations are only available when there is no alternative solution.

As regards huntable species, the Commission has prepared further management plans on such species with an unfavourable conservation status. They are not legally binding but give guidelines to Members States to fulfil their obligations on species' conservation.

The Court of Justice ruled on 20 September 2009 (case C-76/08) that, although autumn hunting did not in the specific case of Malta provide a satisfactory alternative solution to spring hunting, Malta had nonetheless breached the specific conditions for derogation under Art 9 of the Birds Directive and the principle of proportionality in permitting spring hunting. Following this ruling, the Commission decided to pursue the infringement procedure and to send in 2010 a Letter of Formal notice (under article 260 TFEU) to Malta.

In 2009, the Commission decided to take Italy to the Court of Justice in relation to certain regional hunting legislation. On 11 November 2010, the Court ruled (case C-164/09) that the legislation passed by the region of Venice violates the obligations of the Member State under article 9 of the birds directive.

Species protection

The Habitats Directive comprises an important pillar which is related to the protection of species. In particular, Articles 12 and 16 are aimed at the establishment and implementation of a strict protection regime for animal species listed in Annex IV(a) of the Habitats Directive within the whole territory of Member States. Focus is mainly on developing guidance documents such as the Guidance document on the strict protection of animal species of Community interest under the 'Habitats' Directive 92/43/EEC that was finalized in February 2007. Specific guidance documents have also been developed for the protection and management of large carnivores. An initiative for preparing species protection plans for a number of priority species has been further pursued.

Furthermore, the Commission is preparing further new or revised action plans for globally threatened bird species.

In order to reduce the conflicts between Cormorants and fisheries, the Commission is currently finalising guidance on the appropriate use of derogations under Article 9 of the Birds Directive and has also launched a contract with a view to establishing a platform for exchange of best practices on the issue and to gathering reliable monitoring population data.

Further judgments of the Court of Justice in 2010

In case C-491/08 of 19 June 2010, against Italy and concerning a planned tourist complex in Narbolia located in an SCI (site of Community importance), the Court found that Italy failed to adopt the necessary conservation measures and measures to avoid deterioration of the habitats for which the site is designated (breach of Art.6(2) of the Habitats directive).

In case C-164/09 of 11 November 2010, against Italy, the Court concluded it (Venice region) did not respect the conditions of Article 9 of the Birds Directive by adopting and applying the present hunting derogations.

In its judgement C-308/08 the Court found that the Commission failed to prove that the implementation of the road upgrading project at issue has actually had a real impact on the habitat fragmentation of the Iberian lynx. According to the Court, the evidence before the Court was not sufficient for it to find that the project for upgrading the country road, accompanied by the corrective measures, constitutes in itself intervention of a kind which places the Iberian lynx on the site concerned in danger of extinction and which, accordingly, risks seriously compromising the ecological characteristics of that site. Therefore the Court dismissed the action.

It should also be brought to the fore that by Order of 10 December 2009 (in case C-573/08) , the Court requested that Italy suspends the application of a Regional hunting law in one Lombardia Region. This is the second case where the Commission successfully obtained interim measures against Italy.

Finally, in a preliminary ruling (C-226/08) of 14 January 2010, the Court rejected an attempt by the municipality of Papenburg in Lower Saxony to prevent the German authorities from designating parts of the Ems river as protected sites under the EU's Natura 2000 network. In this preliminary ruling the Court confirmed that member states can only refuse to include a site in the Natura network on environmental grounds, not for economic or social reasons. The Court also ruled, in this same case, that Article 6(3) and (4) of Directive 92/43, as amended by

Directive 2006/105, must be interpreted as meaning that ongoing maintenance works in respect of the navigable channels of estuaries, which are not connected with or necessary to the management of the site and which were already authorised under national law before the expiry of the time-limit for transposing Directive 92/43, as amended by Directive 2006/105, must, to the extent that they constitute a project and are likely to have a significant effect on the site concerned, undergo an assessment of their implications for that site pursuant to those provisions where they are continued after inclusion of the site in the list of sites of Community importance pursuant to the third subparagraph of Article 4(2) of that directive.

Petitions

In 2010, the Commission received 32 petitions related to the issue of nature protection (Austria, Bulgaria, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Poland, Portugal, Slovakia and Spain). The subjects raised in these petitions ranged from the measures for the protection of Natura 2000 sites themselves to the environmental effects of infrastructure projects on designated sites. A proportion of the nature protection petitions concerned projects with a potential impact on designated sites in Spain, Portugal and Hungary. Responding to concerns raised within the Petitions Committee, Directorate-General for Environment organised a nature conservation seminar for Bulgarian officials in Sofia in spring 2010.

8.1.2. **Evaluation based on the current situation**

Despite the small number of legal instruments in this field, nature conservation legislation accounts for between a fifth and a quarter of environmental infringements. The nature sector accounts for the highest number of open environmental cases. The high number of cases in the nature sector is due mainly to the extent of the network, which now includes around 26, 000 sites: there are Natura 2000 sites in the vicinity of nearly every EU citizen. This is positive in as much as it brings the EU close to its citizens but it also means that the Commission receives a lot of complaints about threats to these sites. Although the demand from citizens, specialised and active NGOs and the European Parliament is high, the complaint and legal enforcement mechanisms for nature conservation in the Member States are often weak or inappropriate.

In order to rationalise the handling of this high number of cases and ensure the effective implementation of the nature directives, the Commission has taken several measures, which can be divided into three categories:

- *Focus on the main implementation priorities*: the core obligations of the directives were effectively addressed (i.e. correct and complete transposition and establishment of the Natura2000 network), while systemic problems of bad implementation were tackled (e.g. hunting derogations).

- *Proactive cooperation with Member States*: this includes the drafting of interpretative guidance documents for the main provisions of the nature directives; the development of targeted guidance for economic sectors such as the port sector, wind energy, the non-energy extractive industry, and inland waterways, which have particular challenges in relation to the legislation; training of the competent authorities; regular contacts with the national, regional and local authorities, establishment of the *"GreenEnforce Network"*.

- *Improvements in the handling of complaints*: specific methods have been developed with the purpose of helping the complainants (i.e. ad hoc nature supplementary information form, which guides the complainants as regards the information needed to evaluate a complaint) and making more effective use of complaints (i.e. grouping of complaints in order to focus on systemic breaches).

Those measures have had a significant effect, as they resulted in the reduction of the implementation deficit.

8.1.3. **Evaluation results**

8.1.3.1. Priorities and Planned action (2011 and beyond)

Priorities and planned actions will be the following:

- *Completing the establishment stage of the Natura 2000 network.* The terrestrial part of the Natura 2000 network is either established or close to establishment in accordance with the Habitats and Birds Directives. Habitats and species coverage still needs to be extended in places, mainly in the EU-12 Member States, and legal action will be pursued against Member States when necessary. The process to finalise the establishment of marine sites is well underway. In order to facilitate the marine site identification process, a guidance document has already been prepared by the Commission services. Marine Biogeographic Seminars covering all European sea regions took place in 2009 and 2010. The Member States are expected to have made substantial marine designations, both for SCIs and SPAs, by 2012.

- *Ensuring a systematically correct approach to Natura 2000 site protection.* To enable the Natura 2000 network to achieve its goal of conserving key elements of Europe's biodiversity, there needs to be proper scrutiny and minimisation of, the impacts of potentially damaging plans and projects in line with ECJ case-law. Ensuring application of best scientific knowledge for appropriate assessments, examination of alternatives and, where appropriate, provision of compensatory measures are all major challenges. In this regard, the Commission services have issued guidance on relevant key provisions of the nature directives. In 2010 the Commission issued guidance to promote best practice within specific economic sectors, such as wind energy and non-energy extractive industries; further guidance is being finalised (port development) or under preparation (inland waterway transport and agriculture).

- *Ensuring overall positive management of Natura 2000 network.* Apart from vetting potentially damaging plans and projects, Member States need to set up effective management systems for Natura 2000, supporting human activities such as conservation-sensitive farming that are beneficial to conservation objectives while also meeting socio-economic needs. In 2009 a new expert group on the management of Natura 2000 was established. Meetings were held throughout 2010 with an aim to develop and exchange information on best practice in Natura 2000 management, focusing in particular on SAC designation, integrated management approaches and reconciling nature conservation and economic development objectives. The Commission intends in 2011 to launch a new process

at biogeographical level in order to address jointly with Member States the conservation needs of the respective Natura 2000 sites. Work to assure adequate financing of Natura 2000 through EU funds is underway and a Communication on that issue is scheduled by mid-2011.

- *Prioritisation of Commission's legal enforcement work.* In the coming years, the Commission will continue to pursue its legal enforcement action to help meet the main objectives of the nature conservation legislation. To this effect, high priority will continue to be given to pursuing infringement cases concerning significant non-conformity of national implementing legislation with the Birds and Habitats Directives, insufficient site designations (mainly in the EU-12 Member States and for marine sites), including lack of designation of SCIs as SACs where the deadline has expired, and the lack of adequate legal protection and management regimes for the Natura 2000 sites. Focus will also be on addressing breaches concerning big infrastructure projects or interventions involving EU funding that have significant adverse impacts on Natura 2000 sites. In this context, the Commission will take into account considerations such as irreversible ecological damage and, where appropriate, seek interim measures from the European Court of Justice[178]. Infringements concerning unsustainable hunting practices in some Member States will also be followed up closely. In order to better handle individual complaints pointing to widespread problems of bad implementation, the established practice of launching horizontal infringement cases will continue to be followed. The approach in implementing EU legislation in general is set out in the Commission Communication "A Europe of results – Applying Community law" (COM(2007)502 final)[179]. The approach to be taken in the implementation of EC environmental law in particular is laid down in the Commission Communication on implementing European Community Environmental Law (COM(2008)773 final)[180]. In addition to legal action, the Commission is taking several proactive actions to promote enforcement, including dissemination of good practices, awareness-raising and communication, increased integration in other policies.

8.1.4. **Sector summary**

As regards the designation of Special Protection Areas and Sites of Community Importance as part of the Natura 2000 network, further substantial progress was made in 2010. In January 2011, the Commission adopted six decisions updating existing Biogeographic Lists of Sites of Community Importance (SCIs). The additions include 739 new sites representing a total area of 27,000 km². More than half of that is made up of marine sites, indicating further significant progress as regards the designation of marine areas, although substantial efforts are still needed, especially offshore.

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178 In the last 3 years the Commission has three times sought for interim measures in nature protection cases. In cases C-503/06, *Commission v. Italy* and C-76/08, *Commission v. Malta*, the Court ordered the Member States to halt illegal hunting activities on 19 December 2007 and 24 April 2008 respectively. In case C-193/07, *Commission v. Poland*, the Commission sought interim measures from the ECJ to prevent a Polish motorway project causing serious habitat damage: the request was dropped when Poland agreed to halt the relevant works pending an ECJ judgment

179 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0502:FIN:EN:PDF

180 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0773:FIN:EN:PDF

Most Member States are now in a process of designating their Sites of Community Importance as Special Areas of Conservation (SAC) according to Article 4(4) of the Habitats Directive. Member States have to designate their SCI as SACs not later than six years after the inclusion of the sites in a Community list. The deadline for designation as SAC was 28 December 2007 for most sites of the Macaronesian biogeographical region and 22 December 2009 for most sites of the Alpine biogeographical region. For most sites of the Atlantic and Continental regions it was 7 December 2010.

Effective management of Natura 2000 sites will be increasingly a priority in the coming years. In that regard the Commission is focusing on proactive measures such as exchange and dissemination of best practices, awareness-raising and communication, assuring adequate financing of Natura 2000 needs, improved integration in other major EU policies.

Species protection continues to constitute a challenge when implementing the Nature Directives. The species listed in the Directives shall be strictly protected but they can also be hunted provided the conditions in the Directives are fulfilled. The proper functioning of the Natura 2000-network is ensured by hunting derogations granted on correct grounds and by appropriate protection regimes and management of protected sites, including of the species present there.

The priorities in the Nature sector have largely remained the same from previous years. Legal enforcement work in this sector, as in other environment sectors, must be prioritised in the interest of the efficient pursuit of the objectives of environment legislation. The approach to be taken in the implementation of EC environmental law in particular is laid down in the Commission Communication COM(2008)773 final on implementing European Community Environmental Law.

Therefore, in the coming years, the Commission will continue to pursue its legal enforcement action to help meet the main objectives of the nature conservation legislation. To this effect, high priority will continue to be given to pursuing infringement cases concerning significant non-conformity of national implementing legislation with the Birds and Habitats Directives, insufficient site designations (mainly in the EU-12 Member States) and the lack of adequate legal protection and management regimes for the Natura 2000 sites, including the lack of designation of SCIs as SACs where the deadline has expired. Focus will also be on addressing breaches concerning big infrastructure projects or interventions involving EU funding that have significant adverse impacts on Natura 2000 sites. In this context, the Commission will take into account considerations such as irreversible ecological damage and, where appropriate, seek interim measures from the European Court of Justice[181]. Infringements concerning unsustainable hunting practices in some Member States will also be followed up closely. In order to better handle individual complaints pointing to widespread problems of bad implementation, the established practice of launching horizontal infringement cases will continue to be followed.

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[181] In the last two years the Commission has three times sought for interim measures in nature protection cases. In cases C-503/06, *Commission v. Italy* and C-76/08, *Commission v. Malta*, the Court ordered the Member States to halt illegal hunting activities on 19 December 2007 and 24 April 2008 respectively. In case C-193/07, *Commission v. Poland*, the Commission sought interim measures from the ECJ to prevent a Polish motorway project causing serious habitat damage: the request was dropped when Poland agreed to halt the relevant works pending an ECJ judgment

8.2. Waste Management

8.2.1. Current position

8.2.1.1. General introduction

EU waste policy aims to turn the EU into a resource-efficient recycling society. This is a policy area which has a huge potential to make the EU more resource-efficient. Collection and recycling of waste save the use of virgin materials and reduce CO2 emissions. Studies published during 2010 and in the beginning of 2011 indicate that proper implementation of EU waste legislation could have significant economic, financial and social benefits in terms of increased access to valuable secondary raw materials, less unfair competition in the market and strong encouragement for innovative equipment manufacturers and services. The significant costs of having to clean up after illegal dumping and its negative impacts on air and water could be avoided. In addition to the waste-related benefits, full implementation of EU waste legislation would reduce emissions of greenhouse gases, including methane from landfills, equivalent to almost 200 million tons of CO2 a year. This would save €2.5billion annually at a carbon price of around €13 per tonne.[182]

EU waste legislation covers a large share of the entire EU environmental *acquis* and includes thirteen main legislative acts adopted by the European Parliament and the Council and a large number of related decisions adopted through comitology procedures.[183] The overall scope of this legislation is the prevention or reduction of waste production, the re-use, the recycling, other types of recovery than recycling and the disposal of different categories of waste; permitting and control of disposal operations, mainly landfills; and shipments of waste within the EU as well as to and from third countries.

Two main instruments directly addressing waste management operations are the new EU waste framework directive which became due for transposition on 12 December 2010[184] (2008/98/EC) and the EU landfill directive[185] (1999/31/EC and Council decision on waste acceptance criteria 2003/33/EC). The waste framework directive modernises and simplifies the EU waste *acquis*. This Directive, when properly implemented, will be an important tool to make the EU more resource-efficient. The directive contains key provisions on the prevention of waste (Articles 3.12 and 9), waste prevention programmes (Article 29 and Annex IV) and the establishment of waste management plans (Article 28). The EU waste framework directive sets out a hierarchy promoting waste prevention over its recovery, with disposal as the last recourse, and lays down basic requirements for waste management including permit obligations for waste handling. The directive obliges Member States to ensure that waste is

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182 Progress report on the thematic strategy on the prevention and recycling of waste, COM(2011)13 final, Commission staff working document, available at http://ec.europa.eu/environment/waste/pdf/Commission%20Working%20Doc.pdf, study on the feasibility of a waste implementation body, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/113&format=HTML&aged=0&language=EN&guiLanguage=fr

183 http://ec.europa.eu/environment/waste/index.htm.

184 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008pn waste, OJ L 312, 22.11.2008.

185 Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste, OJ L 182, 16.7.1999, p. 1, Council decision of 19 December 2002 establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive 1999/31/EC.

managed without endangering human health and the environment, and prohibits the abandonment, dumping or uncontrolled management of waste (Art. 13, 36). It requires adequate networks of waste treatment installations (Art. 16).

The EU landfill directive is intended to prevent or reduce the adverse effects of landfilling on the environment, particularly on surface water, ground water, soil, air and human health. It specifies requirements for landfill sites and targets for diversion of biodegradable municipal waste from landfills in order to reduce methane emissions, coupled with technical requirements for capture and treatment of landfill gas.

Further, EU waste legislation contains specific rules for waste shipments[186] and a series of directives on different waste streams: waste electrical and electronic equipment; end-of-life vehicles; packaging waste; batteries; persistent organic pollutants (POPs); including e.g. polychlorinated biphenyls (PCBs); mining waste and sewage sludge.[187]

8.2.1.2. Report of work done in 2010

The new waste framework directive

Member States had to notify the transposition of the new waste framework directive by 12 December 2010. The Commission monitored the transposition of the directive closely and urged Member States for a timely transposition indicating that it would take the necessary legal steps against Member States failing to communicate their national transposition measures. At the beginning of 2011 cases were launched against 23 Member States (all except Czech Republic, Denmark, Italy and Austria) for failure to adopt and notify transposition measures by the prescribed deadline.

The Commission actively supported Member States with the transposition of the waste framework directive. During 2010, three multilateral meetings were organised by the Commission with the Committee of the Member States established under the waste framework directive. Awareness-raising events and information exchanges with Member States and stakeholders were organised to take place in 15 Member States during 2010-2011 concerning the implementation of the EU waste framework directive. The Commission's representatives also presented the directive on numerous workshops and conferences in Member States.

The Commission prepared during 2010 a number of comitology decisions relating to the new waste framework directive, in particular on end-of-waste criteria (submitted to Council for adoption), the calculation of targets set by the directive, an implementation questionnaire, the notification format for waste management plans and waste prevention indicators. Guidelines on waste prevention programmes, an update of the existing guidance on waste management plans and guidance on life-cycle-assessments were also prepared in order to be published during 2011.

The proposed recast of the WEEE Directive

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186 Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2009 on shipments of waste, OJ L 190, 12.7.2006, p.1.

187 For more information on specific regulations, directives and decisions, see http://ec.europa.eu/environment/waste/index.htm

The Commission's proposal for the recast of the WEEE Directive (Directive 2002/96/EC on waste electrical and electronic equipment) is in the co-decision process. The proposal aims to contribute to a better regulatory environment by providing further clarity on the legislation, reducing administrative burden, improving coherence among EU legislation and strengthening enforcement.

The Council has in first reading proposed to apply a definition of producer that builds on the concept of national markets. This national concept can lead to a situation of multiple registration, multiple payments for the same product, multiple requirements for treatment information and marking of products, as well the obligation for producers to be legally represented in more than one Member State. The Commission had proposed to clarify that a concept based on the Community market should be used to avoid such burdens, and still considers that a European approach to the producer obligations should be agreed. This applies especially to the obligations of cross-border distance sellers.

The Commission proposal will also result in significant benefits for the environment. In order to address the environmental problem caused by the "leakage" of electronic waste to substandard treatment and to illegal exports, the Commission proposed a new waste collection rate in the WEEE Directive. The rate is proposed to be set at the level of 65% by weight of what has been placed on the market in the two preceding years on average, which implies an ambition level of 85% of WEEE generated. National targets would therefore take into account the economies of each individual Member State. The target would become binding by 2016.

The collection target is one of the crucial issues of the Directive and needs to be ambitious, while at the same time it must be ensured that the reality of each Member State is reflected in the appropriate ambition level. This is especially the case for problematic WEEE fractions. The Commission proposed that the option of a specific target for cooling and freezing equipment should be looked into separately at a later date. A report on this issue could be extended to include further categories such as mercury containing lamps, small equipment, or others.

The enforcement of the WEEE Directive was proposed to be strengthened in order to specifically address the problem of illegal waste shipments. The WEEE proposal includes rules to avoid illegal shipments of electrical and electronic waste, especially when falsely declared as used products. Minimum monitoring requirements for shipments of WEEE are proposed and minimum inspection requirements are reinforced. In order to improve effective border controls against illegal exports, the Commission has here proposed to reverse the burden of proof at the port of exit: exporters of "equipment for reuse" would in the future be obliged to show proof of testing through mandatory documentation. This would make it easier for officials at port authorities to decide whether equipment must be considered as e-waste or not, and to stop illegal exports effectively where necessary.

The Commission proposed the recast procedure in order to tackle specific issues arising with the directive. An extension of the scope was not part of the Commission proposal nor of the impact assessment carried out in the context of the Commission proposal. The Commission does not support to amend substantial parts of the Directive without a proper impact assessment. An open scope could make a number of new exclusions necessary. The establishment and interpretation of these would risk increasing un-clarity compared to the current, well established, situation.

The Commission received in the second half of 2010 reports from Member States as regards implementation of the WEEE Directive in the years 2007 and 2008. The Commission is currently analysing this information, and will take the necessary steps as soon as possible.

With regard to the transposition of the WEEE Directive, conformity is achieved for 13 Member States. In 2010 the Commission continued legal enforcement actions opened in 2007 horizontally against a number of Member States. As of end of 2010, infringement cases were open for 11 Member States (Czech Republic, Denmark, Finland, France, Ireland, Italy, Lithuania, Latvia, Portugal, Sweden and Slovakia). A case was open in 2010 for bad application of the Directive in Romania. In 2011, the Commission in cooperation with the remaining Member States (Malta, UK, Belgium) will assess their national legislation. Legal enforcement action will be taken in 2011 where necessary.

The proposed recast of the RoHs Directive

The RoHS Directive (Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment) sets strict limit values for lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls or polybrominated diphenyl ethers in various specified types of electrical and electronic products.

RoHS has prevented many thousands of tonnes of banned substances from being disposed of and potentially released into the environment since it came into force in 2003. It has led to important changes in product design in the EU and worldwide. RoHS has also served as a model for similar laws outside the EU. RoHS currently covers a vast spectrum of products that use electricity.

In 2008, the Commission launched the recast of this Directive. A first reading agreement with the European Parliament was reached on 24 November 2010. Key elements included the gradual extension of the scope to all electrical and electronic equipment; a mechanism for reviewing or amending the list of banned substances; clearer rules for granting exemptions from the substance ban; coherence with REACH; clarification of important definitions; and alignment with the legislative package for marketing of products. The Commission made four declarations on scope, review, nano-materials and correlation tables.

The Commission prepared to launch studies for an impact assessment of the changes in scope that were not impact assessed, and to provide for potential new exemption requests under the current scope. In order to facilitate implementation, the Commission gathered ideas for an update of the RoHS Frequently Asked Questions (FAQ) document.

With regard to the transposition of the RoHS Directive, correct transposition is achieved by 27 Member States, for 11 of them after legal enforcement actions were launched.

The RoHS Annex – Review of the current RoHS exemptions

The Annex to the RoHS Directive lists specific applications where the use of restricted substances under RoHS is allowed, as long as the substitution is technically or scientifically impracticable. The RoHS Directive requires the Commission to carry out a review of all exemptions every four years to verify if the exemptions are still justified.

Directorate-General for Environment prepared this review through a study (technical and scientific assessment of 29 exemptions) accompanied by a series of extensive stakeholder

consultations. The review was subject to comitology procedure with scrutiny (vote by the Member States experts in the Technical Adaptation Committee, followed by three months scrutiny of the European Parliament). The Commission proposal was fully based on technical and scientific evidence, as well as on coherence with other established EU policies such as Ecodesign requirements. The reviewed Annex was adopted and published as Commission Decision 2010/571/EU of 24 September 2010 amending, for the purposes of adapting to scientific and technical progress, the Annex to the RoHS Directive as regards exemptions for applications containing lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls or polybrominated diphenyl ethers (OJ L 251, 25.9.2010). A corrigendum was published on 29 September 2010.

Additionally, Directorate-General for Environment currently review five new requests by industry for exemptions or modifications of existing exemptions.

The waste shipment regulation

In order to strengthen the implementation and application of the EU waste shipment regulation, support services were established including a forum, a help-desk and a Frequently Asked Questions (FAQ) site. The aim of these measures was to enable national authorities to rapidly exchange information/best practices and discuss questions concerning the day-to-day application of the EU waste shipment regulation, including also matters pertaining to the prevention of illegal shipments of waste. It is accessible to Member States and also open to other stakeholders.

A comitology decision was adopted extending the derogation period for Bulgaria to raise objections to shipments of certain waste to Bulgaria for recovery under the EU waste shipment regulation (OJ L210, 11.8.2010, p.35).

The Commission completed two studies regarding criteria and requirements for waste shipment inspections in June 2010 and prepared a stakeholder consultation on the feasibility of strengthening EU legislation on these matters. Currently, inspections and controls of waste shipments appear to vary significantly between Member States. In some countries only very few and insufficient controls are carried out. The waste chain is only as strong as its weakest link and waste is suspected to be illegally exported via the EU sea-ports having the least effective controls. The studies contain a detailed assessment of the environmental, economic and social impacts of the criteria which were considered as amongst the most appropriate, see http://ec.europa.eu/environment/waste/shipments/reports.htm. Council conclusions (JLS) of 3 June 2010 invited the Commission to "consider strengthening the European requirements on inter alia inspections and spot check carried out under Regulation (EC) No 1013/2006 on shipments of waste, in order to fight illegal waste shipments"[188] The Commission was also invited to "suggest the development of additional measures to support Member States with the enforcement of Regulation (EC) No 1013/2006 on shipments of waste".

The Regulation on Persistent organic pollutants (POPs)

Following a comitology decision, the EU regulation on persistent organic pollutants 850/2004/EC (the "POPs regulation") was amended by Commission regulation No 756/2010 of 24 August 2010, as regards Annexes IV and V. By this amendment, new substances were

188 Council of the European Union, CRIMORG/ENV/ENFOCUSTOM/ENFOPOL, 3.06.2010

added to the list of persistent organic pollutants. As a consequence of substances being covered by the POPs Regulation, their production, placement on the market and use will be severly restricted and the management of wastes contaminated with these persistent organic pollutants is strictly regulated (substances exceeding a given POP concentration have to be destroyed or treated in a way that the POPs substances are irreversibly transformed, i.e. in most cases they will have to be incinerated).

The End-of-Life Vehicles Directive

Directive 2000/53/EC on end-of-life vehicles (the "ELV directive"), prohibits the use of lead, mercury, cadmium or hexavalent chromium in materials and components of vehicles put on the market after 1 July 2003, Article 4(2)(a). Annex II to this directive lists vehicle materials and components exempted from the prohibition set out in Article 4(2)(a).The fourth revision of Annex II was adopted on 23 February 2010 amending Annex II.

Commission Decision 2008/689/EC specified that in the case of solder in electronic circuit boards and other electrical applications except on glass and solder in electrical applications on glass, the exemptions in Annex II should be reviewed. Technical and scientific assessment demonstrated that these two exemptions should be split into 10 more specific applications. Out of these, five materials and components containing lead should continue to be temporarily exempted from the prohibition set out in Article 4(2)(a) since the use of these substances in those specific materials and components is still technically or scientifically unavoidable. It was therefore appropriate to prolong the expiry date of these exemptions until the use of the prohibited substances becomes avoidable. Five other materials and components containing lead should continue to be exempted from the prohibition set out in Article 4(2)(a) without an expiry date since the use of these substances in those specific materials and components is technically or scientifically unavoidable and no viable alternatives are envisaged in the near future. These exemptions should be reviewed in 2014 in the light of technical and scientific progress to assess when the use of these substances will become avoidable. The exemption concerning lead in solders in electrical glazing applications on glass except for soldering in laminated glazing should be reviewed by 1 January 2012 since substitutes for this application exist but their technical properties need to be further tested and confirmed. In the case of lead and lead compounds in components in bonding agents for elastomers in power-train applications containing up to 0,5 % lead by weight, the exemption should not be prolonged because the use of lead in this type of applications has become avoidable. In addition, it was considered technically impossible in certain cases to repair vehicles with spare parts other than original ones as this would require changes in dimensional and functional properties of entire vehicle systems. Such spare parts cannot fit into the vehicle systems originally manufactured with parts containing heavy metals and these vehicles cannot be repaired and may need to be prematurely disposed of. For reasons of consumer safety and environmental benefits derived from the extension of the product’s lifetime it was therefore appropriate to allow the repair of these vehicle components with the original parts.

A further proposal as regards exemptions under Annex II (the use of lead in automotive thermoelectric materials in application reducing CO2 emissions by recuperation of exhaust heat) was opposed by the Council. Although the Council supported the substance of the draft Commission directive, a qualified majority of delegations opposed its adoption on the grounds that, by requiring member states to draw up correlation tables, the Commission had exceeded

the implementing powers provided for in the basic act, i.e. the ELV Directive. A new Commission Directive 2011/37/EU[189] amending Annex II to the ELV Directive was adopted on 30 March 2011.

With regard to the transposition of the ELV Directive, conformity has been achieved for 15 Member States. In 2010 the Commission has continued enforcement actions concerning non-conform national legislation. As of December 2010, 12 infringement procedures were ongoing (Belgium, Czech Republic, France, Italy, Cyprus, Lithuania, Latvia, Poland, Slovenia, Slovakia, Sweden and the United Kingdom).

The Batteries Directive

The Batteries Directive (2006/66/EC) prohibits placing on the market of batteries and accumulators containing mercury and cadmium. This prohibition applies above set thresholds and is subject to a number of exemptions. One specific exemption is for use of cadmium in portable batteries and accumulators intended for use in cordless power tools (for example, tools used by consumers and professionals for turning, milling, cutting, drilling or gardening activities).

The Batteries Directive requires the Commission to review the exemption for the use of cadmium in cordless power tools. The Commission submitted a report to the European Parliament and to the Council in December 2010 and concluded that at this stage, although alternative technologies exist, it is not appropriate to bring forward proposals to withdraw the exemption for cordless power tools from the ban on cadmium in batteries and accumulators because not all the technical information (notably costs and benefits of the use of cadmium and its substitutes in portable batteries and accumulators for cordless power tools) is yet available in support of such a decision. The Commission ordered in October 2010 a comparative life-cycle analysis, to gather this information beyond the existing scientific literature and including a peer review, as required by scientific quality standards, which will provide the missing information in order to decide on whether or not to keep the exemption for the use of cadmium batteries in cordless power tools. Based on that information, the Commission will, if appropriate, then proceed with proposals for legislation with a view to prohibiting cadmium in batteries and accumulators in cordless power tools by withdrawing the existing exemption.[190]

Commission Regulation No 1103/2010 was adopted establishing, pursuant to Directive 2006/66/EC of the European Parliament and of the Council, rules as regards capacity labelling of portable secondary (rechargeable) and automotive batteries and accumulators.

During 2010, an updated document on Frequently Asked Questions regarding the Batteries Directive was prepared for publication in 2011.

With regard to the transposition of the Batteries Directive, full transposition has been achieved by all Member States. The last infringement cases for failure to communicate

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189 Commission Directive 2011/37/EU of 30 March 2011 amending Annex II to Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles, OJ L 85, 31.3.2011, p. 3.

190 See more; Commission report of 2 December 2010 on the exemption from the ban on cadmium granted for portable batteries and accumulators intended for use in cordless power tools [COM(2010) 698 final - Not published in the Official Journal].

measures of transposition of the Directive were closed in 2010, for two of those after a condemning judgment by the Court of Justice in cases C-512/09 against Greece and C-513/09 against Belgium. The deadline for Member States to transpose Directive 2008/103/EC amending the Directive 2006/66/EC on batteries and accumulators expired in January 2009. Full transposition has been achieved by all Member States. In 2011 the Commission in cooperation with the Member States will carry out an assessment of the conformity of national legislation of all Member States and take legal enforcement action where necessary.

Bio-waste

On 18 May 2010, the Commission adopted a Communication in which it assessed issues relating to bio-waste and proposed a set of measures for bio-waste based on existing legislative possibilities. On 3 December 2010, a round of stakeholder consultations was launched in order to prepare an impact assessment (and potential proposal) aimed at setting a recycling targets for bio-waste as an element of modification of recycling targets in the waste framework directive. An examination of end-of-waste criteria for compost (i.e. compost standards) was initiated in accordance with the waste framework directive.

Landfills Directive

With regard to transposition of the Landfill Directive 1999/31/EC, as of December 2010 full conformity had been achieved in almost all Member States, except France, who was referred to the Court of Justice, the United Kingdom, whose final measures to achieve conformity are under assessment and Bulgaria whose legislation is under assessment.

With regard to horizontal cases concerning structural illegal landfilling Greece was followed up with an additional letter of formal notice on the basis of Article 260 TFEU. Cases for illegal waste disposal were started or followed up against Greece, Spain, Ireland and Slovakia.

With regard to the serious situations in Italy, specifically concerning deficient implementation of waste legislation in the Campania region, in 2010 the Commission has worked very closely with Italian authorities. In June 2007, the Commission launched legal action against Italy over the chronic waste crisis affecting Naples and the rest of the Campania region. In view of the continuation of the infringement, the Commission referred the case to Court of Justice in July 2008. On 4 March 2010 the Court of Justice ruled that Italy had failed to set up an adequate and integrated waste management system in the Campania region and to guarantee that waste is collected, treated and disposed of without endangering human health and the environment. The Commission is now assessing the measures adopted by Italy to comply with the judgment and will decide the follow up of the case further the results of the ongoing assessment.

Packaging Directive

With regard to the Directive 94/62/EC on packaging and packaging waste, in 2010 the Commission in cooperation with the Member States carried out an assessment of the conformity of national legislation of all Member States but Italy and Cyprus. Legal action has been taken against two Member States (Latvia and Slovakia). The assessment will continue in 2011 covering also the remaining Member States.

Mining Directive

Concerning the Directive 2006/21/EC on the management of waste from extractive industries

full transposition has been achieved for all Member States but France who was condemned by the Court of Justice in the case C-35/10 and the United Kingdom, condemned by the Court in the case C-259/09. In 2010, as a horizontal exercise for 19 Member States the Commission carried out an assessment of the conformity of national legislation in cooperation with the relevant Member States. The Member States concerned are Denmark, Hungary, Italy, Lithuania, Latvia, the Netherlands, Poland, Romania, Slovenia, Luxembourg, Malta, Spain, Slovakia, Bulgaria, Germany and Sweden. Legal action has been taken against three countries (Slovakia, Slovenia and Latvia). The assessment will continue in 2011 covering also the remaining Member States.

Judgments of the Court of Justice in 2010

In 2010 the Court delivered judgment in nine cases related to waste sector. The United Kingdom and France were condemned for failure to transpose the Directive 2006/21/EC on the management of waste from extractive industries (4 February 2010, C-259/09 *Commission v United Kingdom* and 29 July 2010, C-35/10 *Commission v. France*). Belgium and Greece were condemned for failure to transpose the Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators (15 July 2010, C-512/09 *Commission v Greece*; 29 July 2010, C-513/09 *Commission v Belgium*). France was condemned for non-conform transposition of the Directive 2000/53/EC on end-of life vehicles (15 April 2010, C-64/09 *Commission v France*). Italy was condemned for failure to fulfil its obligations under the Directive 2006/12/EC on waste over the waste crisis affecting Naples and the rest of the Campania region (4 March 2010, C-297/08 *Commission v Italy*). The Court concluded that Italy has not fulfilled its obligations under the Waste Directive 2006/12/EC by failing to set up an integrated and adequate network of disposal installations in Campania region and to ensure that waste is recovered and disposed of without endangering human health and the environment. Portugal was condemned for failure to fulfil its obligations under the Directive 2006/12/EC on waste concerning waste tipping in disused quarries (10 June 2010, C-37/09 *Commission v Portugal*). In addition, the Court judged on a preliminary reference of an Italian court on the interpretation of the polluter pays principle in the framework of Article 10 of the Directive 1999/31/EC on the landfill of waste (25 February 2010, C-172/08 *Pontia Ambiente*) and of a Finnish court on the interpretation of the Directive 2000/76/EC on the incineration of waste (25 February 2010, C-209/09 *Lahti Energia*).

Petitions

During 2010, almost twenty petitions concerned alleged infringements of EU waste legislation, in particular the landfill directive and the waste framework directive. Majority of the petitions concerned situations in Italy, Spain and United Kingdom. These petitions related to a number of cases of illegal waste disposal and, in the case of the waste framework directive, transposition of EU waste requirements in national law.

8.2.2. **Evaluation based on the current situation**

Significant deficits in the implementation and enforcement of EU waste legislation remain in large parts of the EU, particularly as regards illegal waste dumping, inadequate waste disposal- and recovery infrastructure and illegal waste shipments. Implementation of EU waste legislation thus continues to be notoriously deficient, which is well reflected in the high number of infringements, complaints, court proceedings, petitions and questions from the European Parliament. Some of the infringement cases and court proceedings concern

horizontal cases on hundreds of illegal landfills in Europe.

The implementation of the new waste framework directive which is crucial for modern European waste policy poses a new big challenge for implementation in the years to come. In addition, the implementation of the waste shipment regulation, the landfill directive and the future recast of the WEEE- and RoHS Directives are particularly important pieces of legislation which could if properly implemented make significant progress towards achieving EU waste policy objectives.

Overall waste generation is still growing although this is now at a rate slower than GDP growth, showing a certain decoupling between waste generation and economic growth. Over the past 10 years, the recycling rate of municipal solid waste has doubled (from 19% to 38% between 1998 and 2007) and landfilling has decreased significantly.

A large disparity between Member States on how EU waste requirements are applied in practice and 'on-the-ground' was shown to exist through information exchanges and awareness-raising events organised with national authorities and stakeholders as well as in statistics from the EEA and Eurostat. For example, large differences exist between the recycling performances of Member States: from few percent to up to 60 to 70% for the most advanced Member States. In a first analysis, it seems that the most performing Member States have set in place a range of legal and economic instruments which were very efficient, such as landfill taxes, 'clever' charging systems linked with waste generation, producer responsibility schemes and landfill bans.

8.2.3. **Evaluation results**

8.2.3.1. Priorities

Future focus should be on full implementation of existing legislation and support to Member States so that they can learn from each other. As proper waste management also has a huge potential in terms of reduction of greenhouse gas emissions and economic, financial and social benefits this should be followed up with specific measures, *inter alia*, linking climate and waste policies and ensuring consistency between product design and waste policies.

It is key to ensure that the experiences from the most performing Member States beneficiate to other Member States notably for what concerns the application of performing instruments such as taxes or charges, landfill bans and application of producer responsibility principles.

8.2.3.2. Planned action (2011 and beyond)

The Commission will continue and reinforce its up-stream support for Member States in the field of waste. It will also pursue an assessment of options on how to improve such support. A list of best-practices for permitting and inspections under the waste framework directive, the landfill directive and the WEEE- and RoHS directives will be drawn up and tested during 2011.

The implementation of the new waste framework directive, crucial for modern European waste policy, will be closely monitored. It will be examined how to provide effective support to Member States' development of waste management plans and waste prevention programmes. During 2011, a risk/fact-based assessment of waste management plans will be started in order to assess and improve Member States performance. An update will also be

made of the existing guidance on waste management planning.

Life-cycle thinking could justify deviations from the established waste hierarchy (Article 4) since different waste treatment methods can have different environmental and health outcomes. The Commission will use the life-cycle assessment tool when assessing the national waste management plans and will in 2011 publish a set of guidance documents on how life-cycle methodology can be applied to decisions on waste management options.

Member States' national measures transposing the new waste framework directive will be assessed by the Commission with a view to ensure their conformity with the directive.

Important cases concerning infringements by Member States of EU waste legislation, such as regards the serious situations in Italy's Campania region and in Sofia, Bulgaria, will be treated with high priority by the Commission until satisfactory solutions are achieved and the situations have been rendered in compliance with EU legislation. In addition, horizontal cases covering large numbers of individual waste disposal operations will also be treated with high priority. During 2010 such cases were pending regarding France, Italy, Spain, Ireland, Greece.

The high rates of illegal waste shipments shall be brought down by effective measures and the feasibility of strengthening criteria and requirements at EU level will be examined.

An in-depth assessment of the economic, financial and social benefits of properly implementing the EU waste *acquis* will be prepared. This will contain an overarching assessment of the entire EU waste *acquis* as well as a number of specific case-studies in Member States. A detailed overview will also be delivered of the different tasks needed to strengthen implementation and enforcement of this *acquis* and the appropriate arrangements to carry out these tasks. The Commission will thus continue to assess the feasibility of a dedicated structure to support waste implementation.

EU waste targets have to be reviewed in the mid-term in order to face the challenge of increasing resource demand as well as to better take into account environmental impacts of materials to move towards 'sustainable material management'. This is also an opportunity in terms of activity and job creation.

Member States' compliance with the targets set in the landfill directive for diverting biodegradable waste from landfills will be closely monitored. In addition, the Commission will closely monitor Member States' closure of sub-standard landfills not complying with the requirements of the landfill directive (deadline by 16 July 2009, see Article 14 of the directive). The Commission has already taken and will continue to take action as required in order to ensure that these key requirements are fulfilled.

8.2.4. **Sector summary**

The large disparity between Member States on application, implementation and enforcement of EU waste requirements continues to exist. Overall waste generation is still growing although at a rate slower than GDP growth. Future focus should be on full implementation of existing legislation and support to Member States. A detailed assessment is needed in order to be able to reap the economic, financial and social benefits from proper implementation of the EU waste *acquis*. The different tasks needed to strengthen implementation and enforcement of the EU waste *acquis* and the appropriate arrangements to carry out these tasks should also be

examined.

8.3. Environmental Assessment of Plans, Programmes and Projects

8.3.1. Current position

8.3.1.1. General introduction

There are two important pieces of legislation in this sector: Council Directive **85/337/EEC**[191] on the assessment of the effects of certain public and private projects on the environment, as amended by Directives 97/11/EC[192], 2003/35/EC[193] and 2009/31/EC[194] (known as the EIA Directive) and Directive **2001/42/EC** of the European Parliament and of the Council on the assessment of the effects of certain plans and programmes on the environment (known as the SEA Directive[195]).

The EIA Directive obliges Member States to carry out environmental impact assessments before certain types of **public and private projects** which are likely to have a significant impact on the environment are authorised. The SEA Directive seeks to ensure that the environmental consequences of **certain public plans and programmes** that are likely to have significant environmental effects are identified and assessed while they are being prepared and before they are approved.

8.3.1.2. Report of work done in 2010

The EIA Directive

The Commission is continuously assessing the conformity of the national transposition measures communicated and initiates, when necessary, infringement procedures. Due to its large scope of application, the EIA Directive can generate a relatively high number of complaints. However, given the essentially procedural character of the obligations laid down by the Directive, only a small number of complaints lead to infringement cases. The majority of the infringement cases concern bad (incomplete or incorrect) transposition of the Directive's provisions or failure of the Member States to apply the screening mechanism (article 4(2) and Annex III of the Directive).

In 2010, the Commission opened in total 5 new infringement procedures on the basis of the EIA Directive. Cases were opened against Ireland, Spain, and Portugal concerning bad application of the EIA Directive, three of which were based on a complaint. One case was launched against Netherlands for non-conform transposition of the EIA Directive. Four cases out of those opened in 2009 and 2010 have already been closed.

Article 2(3) of the EIA Directive allows Member States to exempt specific projects in exceptional circumstances (e.g. for unforeseen civil emergencies; threats to human health and the environment; security risks) from the provisions of the Directive in whole or in part, and to notify the Commission.

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191 OJ L 175, 05.07.1985, p.40.
192 OJ L 073, 14.03.1997, p.5.
193 OJ L 156, 25.06.2003, p.17.
194 OJ L 140, 5.6.2009, p.114.
195 OJ L 197, 21.7.2001, p. 30.

In 2010, this provision has been used by Spain. On 12 November 2010, the Spanish authorities informed the Commission of their intention to exempt the project *"Emergency Works: recovery of sand from the beaches damaged by storms 2009-2010 in the province of Cadiz"* from the EIA procedure. According to the information received, the request was justified by an exceptional circumstance – the emergency situation arising from the westerly storms, which have affected the area of the province of Cádiz from December 2009. These storms have had an exceptional duration and have caused serious damage to beaches. The loss of sand caused endangers the stability of the beaches, and may endanger, in turn, infrastructures close to them (boardwalks, access, etc...) and the safety of people. The Spanish authorities have indicated that no EIA would be carried out for this project because of the emergency situation. They explained that another form of assessment has been done and that information has been made available to the public concerned relating to the exemption decision and the reasons for granting it. It should be stressed that, the recommendations of the Commission's Guidance document on the *"Clarification of the Application of Article 2(3) of the EIA Directive"*[196] have been followed in this case.

The EIA Directive has been identified as a **potential instrument for a future simplification** exercise[197], the aim being to identify overlaps, gaps and potential for reducing regulatory and administrative burdens, in particular regarding transboundary projects. Adopted 25 years ago, the EIA Directive should be adapted to reflect the experience gained as well as changes in EU legislation and policy, and European Court of Justice case law.

The process for the **review of the EIA Directive** started in 2009 through the adoption by the Commission of the fourth Report on the application and effectiveness of the EIA Directive (COM(2009)378)[198]. The Commission's report confirms that the objectives of the EIA Directive have generally been achieved, indicates areas where improvements are needed (e.g. screening, public participation, quality of the EIA, EIA transboundary procedures, coordination between the EIA and other environmental directives and policies, such as climate change and biodiversity) and presents possible recommendations for action. The future review will aim to improve environmental protection, increase the degree of harmonisation and simplify existing procedures (for instance a "one-stop-shop" procedure, i.e. possibility for coordination of assessment procedures resulting from the existing EU Directives under the EIA umbrella).

In June 2010, a **wide public consultation on the review of the EIA Directive** has been launched, on the basis of an on-line questionnaire, which was translated in all official languages of the EU. The consultation covered a broad variety of issues (e.g. quality of the EIA process, harmonisation of assessment requirements between Member States, assessment of transboundary projects or projects with transboundary effects, role of the environmental authorities, and development of synergies with other EU policies). More information on the consultation can be found on the website of Directorate-General for Environment[199].

The phase of public consultation was concluded by a **Conference for the 25th anniversary of the EIA Directive**. The European Commission organised this Conference with the Belgian Presidency. The Conference took place on 18-19 November 2010 in Leuven (Belgium) under

196 The Commission's Guidance can be found at: http://ec.europa.eu/environment/eia/pdf/eia_art2_3.pdf
197 COM(2009)15.
198 The report can be found at: http://ec.europa.eu/environment/eia/eia-support.htm
199 http://ec.europa.eu/environment/consultations/eia.htm

the headline *"25th Anniversary of the EIA Directive: Successes – Failures – Prospects"*. On 18/11, there was a high level panel of stakeholders, which took stock of the 25 years of implementation experience. On 19/11, the Conference concentrated on three key themes: scope of the EIA Directive, quality of the EIA process and links of the EIA with international conventions (mainly the Aarhus and Espoo Conventions). The speeches delivered during the Conference are available on the website of Directorate-General for Environment[200].

The SEA Directive

The deadline for transposing the SEA Directive expired on 21 July 2004. The Commission's action initially focused on launching non-communication infringement proceedings against Member States which had failed to transpose the Directive into their national law. Subsequently, the Commission started a systematic assessment of the conformity of the national transposition measures communicated and initiated, when necessary, infringement procedures for non-conform transposition.

Thus, in 2008 infringement proceedings for non-conform transposition of the SEA Directive were opened against the following eleven Member States: Bulgaria, Czech Republic, Denmark, Estonia, Ireland, Latvia, Lithuania, Malta, Poland, Slovenia and United Kingdom. This action continued in 2009 and infringement proceedings for non-conform transposition were opened against the following Member States Spain, Belgium, Germany, Greece, Finland, France, Netherlands, Sweden, Slovakia, Austria, Italy and Portugal. For some Member States the cases have been already closed following clarification of national authorities and/or adoption of necessary amendments ensuring compliance with the Directive's requirements. Cases are still open against Belgium, France, Italy, Portugal, Slovakia, Finland and Sweden. In three cases (Belgium, Portugal and Slovakia), the Commission continued the infringement procedure by issuing reasoned opinions.

Petitions

The EIA and SEA Directives generate a relatively high number of petitions, due to their large scope of application. In 2010, 42 petitions were registered. Most of them are related to the implementation of the Directives in Spain and Italy.

On the basis of the experience in handling petitions, the Commission would like to draw the attention on the following general observations:

Apart from the nature protection legislation (i.e. Birds and Habitats Directives), it appears that most of the petitions are related to the implementation of both the EIA/SEA Directives.

There are still several open petitions concerning the implementation of the EIA Directive in the Member States which joined the EU in 2004 and 2007. These petitions are often linked to projects which have been initiated or approved prior to the accession to the EU. The Commission has constantly referred to the settled case-law of the Court, according to which the principle that projects, likely to have significant effects on the environment, must be subjected to an environmental assessment **does not apply** where the application for authorisation for a project was formally lodged before the expiry of the time-limit for

200 http://ec.europa.eu/environment/eia/conference.htm

transposition of a Directive[201]. This implies that the EIA Directive does not apply to projects, for which the application for authorisation was formally lodged before 1 May 2004 (for the 10 Member States which joined the EU at this date) or 1 January 2007 (for Bulgaria and Romania). The Petitions Committee is invited to carefully assess the implications of the abovementioned settled case-law and draw the appropriate conclusions as regards the follow-up of open petitions and the petitions to be received.

The petitions related to the Nord Stream pipeline project (952/2006 and 614/2007) and the resolution adopted in Plenary on 8 July 2008 gave the possibility to the Commission to explain the obligations under the EIA Directive and its own role in the EIA process.

The central issue of the petitions and of the resolution was the alleged need for the Commission to provide for an independent environmental impact assessment/study of the project to be discussed with all interested parties. In this regard, the Commission has stressed that it had neither the competence nor the responsibility to undertake a full analysis of the environmental issues for such a project in substitution of the Member States who are primarily responsible for ensuring that this private project complies with the requirements of the EU legislation. Indeed, it is the strict responsibility and obligation of Member States first to assess the available information with their competent environmental services, second to organise extended consultations with the public, including transboundary ones as in this case, and third to decide with respect to granting or not the final development consent within their respective territories, making, at the same time, available to the public all relevant documentation justifying their decision.

Another important issue was related to the objectivity of the studies and information, considering that it is the private developer that pays the consultant to prepare the EIA environmental report. The Commission recalled that the EIA legislation is a procedural directive which sets the framework for a complete environmental assessment of public and private projects. The Commission explained that the safeguards for the objectivity of the studies and information prepared are to be found, on the one hand, in the description of the minimum information to be included in the environmental impact assessment documentation (Annex IV of the EIA Directive and Appendix II of the Espoo Convention) and, on the other hand, in the consultations with the competent environmental authorities and the public, including the transboundary ones. Indeed, all the information provided by the developer has to be made available to the environmental authorities and the public, which have to be consulted. The accuracy of this information can be challenged at any point of the consultations, before the final decision is taken. This means that the competent environmental authorities can use their own capacity to proceed with a proper assessment of the information provided, while NGOs or interested parties can – and very often do – challenge the whole assessment on the basis of the data provided, in case they do not reflect the real situation or omit clearly to conform to the requirements of the EIA provisions. The final decision to grant or refuse development consent must take into consideration the results of consultations and the information gathered and must contain the main reasons on which it is based. All this is also made available to the public.

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[201] See Case C-431/92, Commission/Germany, paragraphs 29 and 32, and Case C-81/96 Gedeputeerde Staten van Noord-Holland, paragraph 23.

The Commission is confident that the abovementioned observations can facilitate the work of the Petitions Committee and will be duly taken into account when deciding on the follow-up to petitions.

Judgments of the Court of Justice in 2010

The Commission services have prepared a booklet which contains the statements of the most important Court ruling, as they were pronounced in each particular case, concerning appropriate articles of the EIA Directive[202]. This document will be regularly updated with a view to facilitating the implementation of the EIA Directive.

In 2010, the number of judgements delivered by the European Court of Justice in relation to the EIA Directive was relatively low. It is worth mentioning the Case C-378/09 (Judgement of 10/6/2010) concerning the failure of Czech Republic to transpose correctly Article 10a on access to justice. The Commission initiated an infringement procedure because the national legislation was restricting the right of action of the public concerned, mainly NGOs, against decisions in the environmental field. Given that the Member State has not contested the Commission's action, the Court declared that the Czech Republic had failed to fulfil its obligations under the EIA Directive. In 2011, the Court is expected to deliver several rulings on Article 10a and the Aarhus Convention.

In 2010, the Court has delivered its first important ruling as regards the interpretation of the SEA Directive. The Judgement of 17/6/2010 in Cases C-105/09 and C-110/09 will contribute to a better understanding of the definition of *"plans and programmes"* within the meaning of Directive 2001/42/EC.

In these cases, the Court replied to the reference for a preliminary ruling from the Belgian Conseil d'État and clarified the requirements under Articles 2(a) and 3(2)(a) of the SEA Directive. In essence, the reference for a preliminary ruling was related to whether a programme for the management of nitrogen in agriculture, which is required under Directive 91/676/EEC concerning the protection of waters against pollution caused by nitrates from agricultural sources, is liable to constitute a plan or programme covered by Article 3(2)(a) of Directive 2001/42. The Court ruled that an action programme adopted pursuant to Article 5(1) of Directive 91/676/EEC **is in principle a plan or programme covered by Article 3(2)(a) of Directive 2001/42/EC,** since it constitutes a 'plan' or 'programme' within the meaning of Article 2(a) of the latter directive and contains measures, compliance with which is a requirement for issue of the consent that may be granted for carrying out projects listed in Annexes I and II to Directive 85/337/EEC.

First of all, the Court verified whether the action programme for the management of nitrogen was a plan within the meaning of Article 2(a) of the SEA Directive; hence, the Court found that that action programmes are (i) subject to preparation by an authority at national, regional or local level or prepared by an authority for adoption, through a legislative procedure by Parliament or Government, and (ii) required by legislative, regulatory or administrative provisions (paragraphs 35-42 of the Judgement).

Subsequently, the Court examined whether the conditions of Article 3(2)(a) of Directive 2001/42 were fulfilled. This provision provides that a systematic environmental assessment is

202 http://ec.europa.eu/environment/eia/pdf/eia_case_law.pdf

to be carried out for all plans and programmes which (i) are prepared for certain sectors and (ii) set the framework for future development consent of projects listed in Annexes I and II to the EIA Directive. With regard to the first condition contained in Article 3(2)(a) of Directive 2001/42, it was apparent from the very title of Directive 91/676 that action programmes are prepared for the agricultural sector.

The most relevant part of the ruling is the one where the Court assesses whether the second condition is fulfilled, i.e. **whether action programmes set the framework for future development consent of projects** listed in Annexes I and II to Directive 85/337 (paragraphs 45-55 of the Judgement). In this regard, the Court examines the **content** and **purpose** of those programmes, taking into account the **scope of the environmental assessment of projects** as provided for by that directive. The Court concluded that the action programme is to be regarded as setting the framework for future development consent of projects listed in Annexes I and II to Directive 85/337. It seems that **the Court focused on the content of the action programmes**, which embody a comprehensive and coherent approach and which contain specific and mandatory measures; in particular, the Court noted that *"it is clear from Article 5(4) of Directive 91/676 that action programmes adopted under Article 5(1) must provide for a set of measures compliance with which can be a requirement for issue of the consent that may be granted for projects listed in Annexes I and II to Directive 85/337, and in respect of the definition of which Directive 91/676 gives Member States a certain discretion"*.

This interpretation of the Court will be relevant when determining whether an SEA is needed for other types of plans and programmes, in particular as regards the condition according to which plans and programmes set the framework for future development consent of projects.

8.3.2. Evaluation based on the current situation

8.3.2.1. Implementation and enforcement of the EIA Directive

In July 2009, the Commission adopted the fourth Report on the application and effectiveness of the EIA Directive (COM(2009)378)[203]. The Commission's report confirms that the objectives of the Directive have generally been achieved. In some areas, improvements are still needed (e.g. screening, public participation, quality of the EIA, EIA transboundary procedures, coordination between the EIA and other environmental directives and policies, such as climate change and biodiversity). The majority of the infringement cases related to the EIA Directive concern bad (incomplete or incorrect) transposition of the Directive's provisions or failure of the Member States to apply the screening mechanism (Article 4(2) and Annex III of the EIA Directive).

However, in terms of compliance of the Member States with the EIA, the situation is satisfactory. The principles of environmental assessment have been integrated into the national EIA systems. All Member States have established comprehensive regulatory frameworks and implement the EIA in a manner which is largely in line with the Directive's requirements; in many cases, Member States have built on the minimum requirements of the Directive and have gone beyond them. As a result, environmental considerations are taken into account in the decision-making process, which has become more transparent.

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[203] The report can be found at http://ec.europa.eu/environment/eia/eia-support.htm

With a view to adapting the Directive to the EU and international policy and legal contexts, the Commission has initiated the review process (see above). In the meantime, the Commission will develop guidance documents in order to facilitate the implementation of the EIA Directive. The guidance documents developed by the Commission services in previous years were often used as a reference in contacts with national authorities. The Commission services prepare two new guidance documents: the first one will be related to the implementation of EIA to large-scale transboundary projects; the second one will include practical guidelines and methodologies for integrating climate change and biodiversity into EIA/SEA.

Implementation and enforcement of the SEA Directive

In September 2009, the Commission adopted the first Report on the application and effectiveness of the SEA Directive (COM(2009)469)[204]. According to the Commission's Report, it appears that the overall picture of the application and effectiveness of the SEA Directive across all Member States is a varied one, in terms of the institutional and legal arrangements of the SEA procedure, and in terms of how Member States perceive its role. The Directive is relatively recent and there is still not sufficient experience on its implementation.

On the basis of the implementation experience, it seems that problems in the correct application of the SEA Directive are similar to those encountered in applying the EIA Directive (i.e. whether smaller plans and programmes or modifications require an SEA and definition of "plans and programmes"). The Court Judgement delivered in June 2010 has provided useful clarifications. In addition, the Guidance of the Commission services on the implementation of the SEA Directive has been often used[205].

Despite the above concerns, in terms of compliance of the Member States with the requirements of the SEA, the situation is satisfactory. This has also been confirmed by the Commission's report which showed that, overall, the SEA Directive contributes to the systematic and structured consideration of environmental concerns in planning processes and better integration of environmental considerations upstream; in addition, the SEA Directive ensures better and harmonized planning procedures, and contributes to transparent and participatory decision making processes.

8.3.3. Evaluation results

8.3.3.1. Priorities

In 2010, the Commission services continued applying the broad priorities[206] which were identified in the previous reports and which were highlighted by the Commission in its

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204 The report can be found at http://ec.europa.eu/environment/eia/sea-support.htm

205 It can be found at http://ec.europa.eu/environment/eia/sea-support.htm (available in 11 languages).

206 It should be recalled that those priorities include the following:Non-conformity of transposing measures for the EIA/SEA Directives likely to affect the attainment of the legislative objectives. These cases now mainly concern the EU-12 Member States;Breaches concerning big infrastructure projects or interventions involving EU funding;Breaches linked to bad transposition of certain provisions of the environmental impact assessment legislation likely to affect overall the attainment of the legislative objectives;Breaches that reveal interpretation problems concerning certain provisions of the environmental impact assessment legislation which could have a significant influence on the impact of the legislation that would justify seeking clarification from the Court of Justice.

communication COM(2008)773 and the Commission staff working document accompanying the communication. Individual breaches of certain provisions of the environmental impact assessment legislation, which are not covered by the abovementioned priorities, should primarily be addressed through the existing review mechanisms at Member State level.

On the basis of the implementation experience, it is not necessary to modify the priorities already identified regarding the enforcement of the EIA and SEA Directives. The Commission services will therefore continue implementing the priorities identified in the sectoral communication COM(2008)773 and the Commission staff working document accompanying it.

8.3.3.2. Planned action (2011 and beyond)

EIA Directive

The process for the **review of the EIA Directive will continue.** Following the adoption of the fourth Report on the application and effectiveness of the EIA Directive (COM(2009)378) in 2009 and the public consultation in 2010, the Commission services will carry out the impact assessment of the future Commission proposal in 2011. The Commission's proposal is likely to be tabled in 2012.

In the meantime, the Commission services will continue the implementation of the existing Directive on the basis of the priorities already identified.

SEA Directive

No legislative change is envisaged in the short term. The application of the SEA in Member States is still in its infancy and further implementation experience is needed. The next report on the application of the SEA Directive, which should be prepared in 2013, will be a good opportunity to assess its effectiveness.

In the meantime, the Commission services will continue the implementation of the existing Directive on the basis of the priorities already identified.

8.3.4. **Sector summary**

The EIA Directive has achieved its objectives. However, since the development of EIA is an evolving process, the challenge of ensuring that the Directive is implemented in an effective and consistent manner across all Member States is continuous. The review of the EIA Directive has started and the legislative impact assessment is ongoing. The Commission's proposal can be expected in 2012.

No legislative change is envisaged as regards the SEA Directive, which is still in its infancy.

For both Directives, the Commission services will continue applying the implementation priorities identified in the sectoral communication COM(2008)773 and the Commission staff working document accompanying the communication.

8.4. Protecting Water and Marine Resources

8.4.1. **Current position**

8.4.1.1. General introduction

Water legislation in the European Union entered a new era following the adoption of the ***Water Framework Directive***[207] which establishes a strategic framework for the protection of all water bodies, i.e. rivers, lakes, coastal waters and groundwater in a highly integrated manner. As the cornerstone of EU water policy, the Water Framework Directive provides that all water bodies must meet the standard of "good status" as a rule by the end of 2015. To this end, Member States must draw up a river basin management plan (RBMP) and a programme of measures for each river basin district. The draft plans and programmes were to be submitted to the public for consultation by December 2008 at the latest. They should have been adopted by 22 December 2009 and reported to the Commission 3 months thereafter, at the latest.

The Water Framework Directive (WFD) will repeal several pre-existing EU water acts by December 2013, except the *Urban Waste Water Directive*, *Drinking Water Directive, Bathing Water Directive* and *Nitrates Directive*. The implementation of the Water Framework Directive must not jeopardise the achievement of the objectives of these EU water acts and vice-versa. Under the WFD, complementary Directives have been adopted on the protection of groundwater against pollution and deterioration (***Groundwater Directive***)[208] and on environmental quality standards (***Environmental Quality Standards Directive)***[209] establishing the standards which constitute the chemical status criteria for the Water Framework Directive.

The ***Urban Waste Water Directive***[210], in particular, is a key element of EU water policy for achieving the Water Framework Directive environmental objective of good status. The Urban Waste Water Treatment Directive requires that wastewater generated by settlement areas ('agglomerations') is collected and made subject to secondary treatment before being discharged into the natural environment. More stringent treatment must be applied when wastewater is discharged into so called sensitive areas. The original EU15 Member States should have achieved the objectives of the Directive in 1998 for sensitive areas, in 2000 for large towns and cities discharging in normal areas and by 2005 for smaller towns discharging in normal areas. Regarding EU12 Member States, which joined the EU in 2004 and 2007 respectively, the Accession Treaties provide for transitional periods similar to the compliance deadline established in the Directive upon adoption in 1991. The transitional periods are staggered and go as a rule not beyond 2015, in the case of Romania for small agglomerations below 10000 until 2018.

The ***Drinking Water***[211] ***and Bathing Water***[212] ***Directives*** require Member States to meet binding quality standards to ensure safe drinkable water from the tap and clean water for

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207 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1–73).

208 Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19–31).

209 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84–97).

210 Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L 135, 30.5.1991).

211 Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L330, 5.12.1998).

bathing, to monitor whether the standards are complied with and to inform consumers and the public accordingly.

The ***Nitrates Directive***[213] is also an important instrument which deals with the relationship between agriculture and water quality. In order to reduce and prevent water pollution caused by nitrates originating from agricultural sources, Member States must monitor waters, designate so called nitrate vulnerable zones and then adopt and implement action programs and codes of good agricultural practices with the aim of improving fertiliser management that should result in the prevention and reduction of nitrate leaching towards waters. Monitoring programs are required to be set up to assess the efficiency of these action programs.

The directive on the assessment and management of flood risks (***Floods Directive)***[214] requires Member States to assess flood risks and to establish flood risk management plans by 2015, with the aim to reduce flood risk for human health, economic activity, the environment and cultural heritage.

The ***Marine Strategy Framework Directive***[215] is the culmination of the thematic strategy on the marine environment contained in the 6th Environment Action Plan. By addressing all marine waters, it completes the full water cycle throughout the European Union. It expands EU environmental law to a geographical area equivalent to its land territory. The Directive establishes a strategic framework for the protection of the marine environment in a highly integrated manner, based on the ecosystem approach. It provides that all marine waters must meet the standard of "good environmental status" as a rule by 2020, and that coordination and cooperation between Member States has to take place in shared marine regions. To this end, Member States must carry out a series of preparatory stages from 2012 (comprehensive assessment, targets, indicators, monitoring programmes) and draw up the necessary programmes of measures by 2015.

8.4.1.2. Report of the work done in 2010

Management of the acquis, new legislation and preventive measures

In 2010, Directive 2000/60/EC establishing a Framework for Community action in the field of water policy (***Water Framework Directive***) reached a crucial milestone in implementation, with the publication of the 1st River Basin Management Plans (RBMPs) and their submission to the European Commission, which was due by 22 March 2010 at the latest. To improve transparency and benchmarking, the status and content of the RBMPs has been made publicly available (and is regularly updated) at:

http://ec.europa.eu/environment/water/participation/map_mc/map.htm

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212 Directive 76/160/EEC of 8 December 1975 concerning the quality of bathing water (OJ L031, 5.2.1976). This Directive is in the process of being replaced by Directive 2006/7/EC of 15 February 2006 concerning the management of bathing water quality and repealing Directive 76/160/EEC (OJ L of 4.2.2006).

213 Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources, OJ L 375, 31.12.1991, p. 1–8.

214 Directive 2007/60/EC of the European Parliament and of the Council of 23 October 2007 on the assessment and management of flood risks (OJ L 288, 6.11.2007, p. 27–34).

215 Directive 2008/56/EC of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19-40).

The main aim of the ***Water Framework Directive*** (WFD) is to achieve good status in all European waters. Member States are required to include in their River Basin Management Plans environmental objectives for all water bodies and a programme of measures to achieve these objectives. These Programmes of Measures have to be operational by 2012. The majority of the Member States (fifteen) have delivered their RBMPs on time and carried out the required public consultation process on the draft plans. For twelve Member States there have been delays – in a few cases, serious ones- and the Commission has therefore started infringement procedures. At the end of 2010, the most serious delays were those affecting Spain, Portugal, Greece, Denmark and Belgium.

In the meantime, the Commission and the Member States continue their cooperation in the Common Implementation Strategy (CIS) for the ***Water Framework Directive***. The Common Implementation Strategy, an informal process set up in 2001, has delivered extensive guidance to promote the implementation of the WFD. Its objective is to provide a forum for Member States, stakeholders and Commission's experts to work together towards a successful implementation of the core water law at EU level. In 2010, several additional guidance documents were agreed by the Water Directors in the framework of the CIS, including one on chemical monitoring of sediment and biota, and another one on risk assessment and the use of conceptual models for groundwater. In the framework of the CIS work programme for the period 2010-2012, *inter alia,* 2 workshops were organised, one on biodiversity and water, and the other one on economic issues under the WFD.

The implementation of the ***Water Framework Directive*** has also been further promoted in 2010 as Member States had to bring into force on 13 July 2010 at the latest all the domestic laws, regulations and administrative provisions necessary to comply with the ***Environmental Quality Standards Directive*** (EQS).

The deadlines for notification of national transposing legislation for the ***Groundwater Directive*** expired on 15 January 2009 and for the ***Floods Directive*** on 26 November 2009. For the Floods Directive, compliance promotion took place in the form of the development of a transposition checklist, which was circulated to Member States. A transposition checklist was also developed for the EQS Directive. The Commission furthermore adopted a Directive on technical specifications for chemical analysis and monitoring of water status[216].

On the ***Drinking Water*** Directive, the consultation process commenced in 2008 on the need for reviewing the parameters and values (obligation by the Commission under article 11(1)) as well as on the future eventual revision of the Directive was in 2010 complemented by the compilation of data for compliance of larger supplies (serving >5000 consumers) and smaller supplies (serving 50-5000 consumers), as well as an economic impact assessment study. In conclusion, compliance with quality standards is very high for larger supplies, however distinctly lower for smaller supplies, though in the latter case varying from region to region. The Commission published its Synthesis Report for 2005-2007 drinking water data reported by Member States for supplies >5000 consumers[217]. The Commission also published its annual report[218] on bathing water quality data under the ***Bathing Water Directive***. Under the

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216 Commission Directive 2009/90/EC of 31 July 2009 laying down, pursuant to Directive 2000/60/EC of the European Parliament and of the Council, technical specifications for chemical analysis and monitoring of water status. OJ L 201, 1.8.2009, p 36.

217 http://ec.europa.eu/environment/water/water-drink/reporting_en.html

218 http://ec.europa.eu/environment/water/water-bathing/report_2010.html

Urban Waste Water Directive, the next reporting exercise took place in 2009/2010, with the 6th report on the implementation of the Directive foreseen for 2011.

As to the implementation of the ***Nitrates Directive***, the Nitrates Committee made up of Commission and Member State representatives was convened four times in 2010 mainly to discuss derogation files for Ireland, UK for the region of Northern Ireland, Belgium for the region of Flanders and Italy. These meetings resulted in positive opinions of the Nitrates Committee for draft Commission Decisions for Ireland and UK for Northern Ireland that will allow those Member States to apply higher amounts of livestock manure to land. The procedure for final adoption of these two decisions was still ongoing at the end of 2010. The files related to derogations for Italy and Belgium were not yet mature for vote at the end of 2010. The Commission published in February 2010 its four yearly implementation report, referring to the period 2004-2007[219]. In addition, the Commission continued to assess the implementation of the Nitrates Directive in the various Member States which resulted in several meetings and written exchanges with the Member States concerned.

The first action undertaken under the ***Marine Strategy Framework Directive*** was the adoption by the Commission of a Decision on criteria and methodological standards to achieve good environmental status in marine waters (Decision 2010/477/EU). This Decision was based on substantial scientific research and will be used by Member States in developing the next stages of implementation due from 2012 (comprehensive assessment, characteristics of good environmental status, targets and associated indicators). The Decision also recognises the need for regular update based on scientific information and adoption of management measures, in line with the 6-year cycle underlying the Directive.

Because it is a recent Directive, the Commission set up, together with Member States, an informal Common Implementation Strategy, with a series of meetings (including a high level meeting of Marine Directors for each EU Presidency), to develop common understanding in the process of policy development. This is accompanied by increased activity by the European Commission in the various Regional Sea Conventions around Europe, which are taken the role of facilitating regional coordination by Member States in the implementation of the Directive.

Management of complaints and of infringements

Despite the close cooperation with the Member States, infringement actions were necessary in 2010.

Concerning the ***Water Framework Directive,*** infringement action was concerned in 2010 with both non-conformity and bad implementation issues.

Assessment of conformity of national legislation: In 2010, the Commission pursued further the infringements that were open against 19 Member States for incorrect and/or incomplete transposition. In particular, four letters of formal notice (one of them being a complementary letter of formal notice) were addressed to Germany, Italy, Ireland and the United Kingdom

[219] Report from the Commission to the Council and the European Parliament on implementation of Council Directive 91/676/EEC concerning the protection of waters against pollution caused by nitrates from agricultural sources based on Member State reports for the period 2004-2007 (COM(2010)47final); Commission Staff Working Document, accompanying document to the Report from the Council and the Parliament COM(2010)47.

while four reasoned opinions were sent to Belgium, Denmark, Finland and Poland. Conversely, five infringement procedures were closed as the Member States concerned – The Netherlands, Hungary, Lithuania, France and Estonia - had adopted / amended national legislation that led to a correct and complete transposition of the ***Water Framework Directive*.** The Commission also monitored the transposition progress made by other Member States, which may lead to a closure, in 2011, to relevant infringement cases.

Bad implementation: Infringements were open in 2010 against twelve Member States for having failed to submit on time their river basin management plans. While some Cases could be rapidly closed, reasoned opinions proved necessary for ten Member States: Belgium, Cyprus, Denmark, Greece, Malta, Slovenia, Spain, Romania, Poland and Portugal.

Complaints: A horizontal complaint submitted against 11 Member States, on the scope of the term "water services" is addressed by way of conformity cases.

Court rulings: A letter of formal notice was sent to Spain under Article 260 of the Treaty as this Member State had not taken all necessary measures to comply with the Court ruling of 7.5.2009 (Case C-516-07) on the implementation of Article 3 (designation of relevant competent authority in each river basin district) of the Water Framework Directive. By ruling of 22 December 2010 (Case C-351-09) the Court ruled against Malta for its failure to comply with the monitoring requirements of the WFD.

The ***Environmental Quality Standards Directive*** (EQS) had to be transposed into the law of the Member States by 13 July 2010 at the latest. Infringement procedures have been initiated in autumn against the twenty-two Member States that had not communicated its national transposing measures to the Commission. While 2 Cases could already be closed in 2010, the Commission envisaged, by the end of 2010, in the light of the information provided by Member States, to close in the first trimester of 2011 a majority of those non-communication cases. For reminder, the list of priority substances contained in this Directive is being reviewed as required by the WFD and a Commission proposal is expected in 2011.

In respect of the ***Groundwater Directive***, letters of formal notice for non-communication of national measures deemed to transpose it were sent to twenty Member States in April 2009. By the end of 2010, the transposing measures were communicated by all Member States with the exception of Germany and the Czech Republic. A reasoned opinion was addressed to both, and a Court application has been lodged against the Czech Republic. Germany notified due legislation following the reasoned opinion. As concerns Czech Republic, by ruling of 22 December 2010 (Case C-276/10), the Court ruled in favour of the Commission. The transposition measures are being systematically checked with a view to addressing any instance of non compliance (bad transposition) in the first semester 2011.

As far as the ***Floods Directive*** is concerned, the transposition deadline was 26 November 2009, and a transposition checklist had been shared with the Member States to facilitate compliance. In January 2010, a number of non-communication cases were opened. By November 2010, only one Member State had not transposed at all the Directive, with some Member States having partially transposed it. Reasoned opinions have been addressed to FI, FR, PL, CZ, AT, LU. Following the Reasoned opinion, Finland has notified the transposing legislation. Two applications to Court have been lodged, against Poland and France.

Regarding the ***Urban Waste Water Directive,*** the Commission's enforcement work has

continued to focus firstly on ensuring full compliance with the Directive's obligation to ensure that more stringent treatment is provided to discharges from agglomerations into areas designated as sensitive by the 31 December 1998 deadline set for the older EU 15 Member States. In June 2010, the Commission took the decision to refer Belgium to the Court of Justice for a second time under Article 260 of the TFEU with a request for financial penalties for its failure to ensure compliance with the earlier judgment of the Court of Justice in case C-27/03. In June 2010, the Commission also decided to send an additional Letter of Formal Notice under Article 260 of the TFEU to Luxembourg for its failure to ensure compliance with an earlier judgment of the Court of Justice in case C-452/02.

The Commission secondly continued to follow up compliance with the 31 December 2000 deadline in the ***Urban Waste Water Directive*** requiring collecting systems and appropriate treatment to be provided for urban waste waters discharges emanating from larger agglomerations of over 15,000 population equivalent. The Commission took the decision in March 2010 to refer both France and Spain to the Court of Justice under Article 258 of the TFEU. Similarly, it was decided in November 2010 to refer Italy to the Court of Justice.

In 2009 the Commission launched the first phase of legal action for the EU 15 Member States with regard to ensuring compliance with the collecting and treatment obligations for smaller agglomerations of 2,000 to 15,000 population equivalent for which the deadline of compliance was 31 December 2005. Sweden was added to the group of Member States for which action was already launched in 2009, with a letter of formal notice being sent in January 2010.

In addition to this, an additional letter of formal notice was sent under the new Article 260 of the TFEU to Greece in May 2010 with regard to its failure to ensure compliance with the first judgment of the Court of Justice in case C-119/02. Furthermore, the Court of Justice gave its judgment against Portugal in case C-526/09 in December 2010 for its failure to ensure that industrial waste waters from sites in the town of Matoshinhos were adequately treated and authorised under Article 11 of the ***Urban Waste Water Directive***.

For the ***Drinking Water Directive,*** the Commission decided to refer Luxembourg to the Court of Justice in June 2010 (now case C-458/10) for its failure to fully and correctly transpose the Directive. A letter of formal notice was sent to Slovakia for the same failure. Furthermore, in 2010 the Commission decided to close its case against Ireland after it was satisfied that the Member State had sufficiently implemented Court ruling C-316/00 for the violation of the "old" Drinking Water Directive (80/778/EEC).[220]

Concerning the new ***Bathing Water Directive***: *Non-communication of transposing national measures:* Member States were required to transpose the new ***Bathing Water Directive*** and notify these transposing measures to the Commission by 24 March 2008 at the latest. At the end of 2009, only two Member States, the Czech Republic and Poland had still not notified full transposing measures and the Commission referred these two Member States to the Court of Justice. In the meanwhile, Poland notified transposition measures, while on 30 September 2010, the ECJ declared (Case C–481/09) that by failing to adopt all the laws, regulations and

[220] Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption (OJ L 229, 30.8.1980, p.11). Directive 80/778//EEC was repealed and replaced by Directive 98/83/EC on 25 December 2003.

administrative provisions necessary to comply with Directive 2006/7/EC, the Czech Republic has failed to fulfil its obligations under that directive.

Commission's enforcement work in 2010 focused on the analysis of the conformity of transposition measures. This work is still ongoing as regards 19 MS. The Commission is continuing this exercise in 2011 and depending on Member States' replies, infringement proceedings for non-conformity might be launched.

As to the ***Nitrates Directive***, five Member States were involved in an infringement procedure, including Luxembourg, Spain, Greece, France and Poland. In its ruling of 29 June 2010 against Luxembourg (case C-526/08), the Court declared that Luxembourg failed to adopt the laws, regulations and administrative provisions necessary to comply with Articles 4 and 5 of the Nitrates Directive. Following this judgement and in the absence of information on the measures taken in order to correct the breach, a letter of formal notice was addressed under Article 260 of the TFEU to Luxembourg in November 2010 with regard to its failure to ensure compliance with the judgement of the Court in case C-526/08.

The Commission sent in October 2010 a reasoned opinion to Spain regarding its non-compliant designation of vulnerable zones and nitrates action programmes. By the end of 2010 substantial progress was made by the Spanish authorities in amending legal texts but the required amendments to legislation were not yet completed for all regions involved. The Commission sent in March 2010 to Greece a letter of formal notice with regard to its non-compliant action programmes. The Commission sent in September 2010 a letter of formal notice to Poland regarding its failure to a sufficient extent to designate the vulnerable zones and to adopt adequate nitrate action programmes.

The ***Marine Strategy Framework Directive*** had to be transposed by 15 July 2010 at the latest. Infringement procedures have been initiated against eighteen Member States that had not communicated its national transposing measures to the Commission. At the end of 2010, the Commission envisaged, in the light of the information provided by Member States, to close in the first trimester of 2011 several of those non-communication cases. The reason behind the delay seems to be the difficulty of taking forward such an integrated instrument, which requires the agreement of a series of national institutions at various governance levels (from national to regional and local) and various sectors.

Petitions

In 2010, the Commission received 14 new petitions related to water quality management and resource protection. The petitions concerned Finland, France, Ireland, Hungary, Italy, Spain, Germany and the United Kingdom. While the overall number is stable, their content show an increased interest for flood related issues.

8.4.2. **Evaluation based on the current situation**

Emission-oriented legislation, such as the ***Urban Waste Water and Nitrates Directives***, has achieved great progress in protecting water quality. Much progress on integrated water management has been made with the gradual implementation of the ***Water Framework Directive*** and the publication of River Basin Management Plans. However, considerable challenges remain. These include addressing issues of water scarcity, droughts and floods, ensuring that waste water in the EU 12 and also originating from small towns in the EU 15 is properly collected and treated and bringing about the achievement of good chemical,

ecological and quantitative status by 2015 as required by the ***Water Framework Directive***.

On the implementation of the ***Water Framework Directive,*** the situation as regards the delivery of the 1st River Basin Management Plans, at the end of 2010, can be summed up as follows: seventeen Member States had submitted their Plans, five had started public consultation but not yet submitted their plans, and five had not even started public consultation. As this is a key milestone for achieving the environmental objectives in 2015, all instances of non compliance have been timely addressed by way of infringement procedures (summarised above, in the previous section).

One key implementation challenge was identified in the 2nd implementation report on the ***Water Framework Directive*** in relation to monitoring, i.e. the absence of exhaustive national methods for assessing the ecological status of surface water bodies or the existence of non-compliant monitoring networks. This is an obstacle to the assessment of the ecological status.

The non-communication cases brought forward on the ***Groundwater Directive***, have prompted the notification of almost all the transposition measures to the Commission (with only two Member States still missing). These are being the subject of conformity assessment aimed at addressing all instances of non conformity in 2011. The same approach and timing is being followed for ***the Floods Directive.*** Delays in transposing the ***Groundwater Directive*** could in a few cases lead to delays in the implementation of certain groundwater related aspects of the ***Water Framework Directive***. The implementation of the ***Groundwater Directive*** will be assessed in relation to the River Basin Management Plans referred to above.

Water quality has improved following EU 15 Member States' encouraging progress in implementing the ***Urban Waste Water Directive.*** Yet, there are still many agglomerations, for instance, in Belgium, Italy and Spain that lack complete waste water collecting systems and treatment facilities As to the EU12 Member States, the implementation of the Directive is characterized by staggered transitional periods foreseen in the Accession Treaties regarding the building of the necessary waste water infrastructure, by the fact that the EU has made financial support available and by supportive action on capacity building and technical advice. However, the first of the staggered transitional deadlines for EU12 have expired by the end of 2009 (Cyprus, Hungary, Latvia, Lithuania, Malta, Poland and Slovenia).

Concerning the ***Bathing Water Directive***, monitoring data annually published show continuing high compliance of bathing waters with the legally binding standards, with compliance during the 2009 bathing season reaching 95.6% for coastal bathing waters and 89.4%. Concerning the ***Drinking Water Directive***, EU-wide data for larger supplies (serving >5000 consumers) and smaller supplies (serving 50-5000 consumers) show a distinctly different pattern, with larger supplies showing very high compliance whilst smaller supplies in many regions show up to one third of supplies not fully complying, thus necessitating further targeted implementation and enforcement action.

As to the ***Nitrates Directive,*** significant progress has been made in the recent years, including in 2010, regarding the designation of "vulnerable zones" and the elaboration and implementation of monitoring programmes. However, further improvements are clearly needed, in particular, with regard to the quality of action programmes as nitrate concentrations are still major concerns in some intensively farmed areas. The Commission published on 9

February 2010 its report[221] to the European Parliament and Council on the implementation of the Directive for the period 2004-2007.

The initial cycle of implementation of the ***Marine Strategy Framework Directive*** is showing to be challenging for several reasons, and actions are being taken to address them on a continued basis. The various stages and deliverables under the Directive require substantial conceptual policy development, as there is a need to elaborate on the basis of a legislative instrument which was crafted as a framework instrument. In addition, the Directive aims at addressing a range of human activities affecting the marine environment, thereby tackling a multi-sectoral challenge involving all the cumulative impacts on the marine environment. This requires increased coordination efforts and enhanced scientific support that need to be gradually articulated. To address these challenges, the Commission is taking an active role in an informal Common Implementation Strategy where the actions of Member States, and across the various marine regions, are being coordinated in these initial stages of policy development.

8.4.3. **Evaluation results**

8.4.3.1. Priorities

The Commission will prepare the third and major report on the implementation of the ***Water Framework Directive*** in 2012 (as required by article 18 of the Directive), including a review of how Member States have tackled their river basin management planning. This will be part of the Blueprint to Safeguard Europe's Waters, which will also include a review of the EU policy on Water Scarcity & Droughts and an assessment of the vulnerability of environmental resources such as water, biodiversity and soil to climate impacts and man-made pressures.

This review will consider issues such as Member States' implementation of river basin based management approaches, water pricing policies, including full account and internalisation of environmental and resource costs, cooperation on trans-boundary rivers, public consultations, land use changes, setting of ecologically based objectives, protected areas, analysis of all pressures on water resources, integration of water concerns into sector policies, degree of achievement of good ecological and chemical status, good ecological potential and good groundwater, chemical and quantitative status by 2015, and the establishment of programmes of measures to reach the targets.

Regarding the ***Drinking Water Directive***, the Commission has in 2010 finalised its evaluation of a need for a revision of the Directive, assessing parameters and values, the coherence with other water-related legislation in particular the ***Water Framework Directive***, streamlining data exchange and reporting and risk-based approaches for a holistic protection of drinking water from the source to the tap of the consumer. The Commission will in 2011 publish its conclusions.

For the ***Marine Strategy Framework Directive***, the priority is to support actively a coherent policy development between Member States in taking forward their obligations, taking also into account cooperation within marine regions. Thus, as from 2012, Member States must

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[221] Report from the Commission to the Council and the European Parliament on implementation of Council Directive 91/676/EEC concerning the protection of waters against pollution caused by nitrates from agricultural sources based on Member States reports for the period 2004-2007.

elaborate comprehensive assessment, characteristics of good environmental status, targets and associated indicators. A priority to secure the success of these implementation milestones in the Directive is dependent on a successful integration of environmental concerns in a range of sectorial policies, such as the Common Fisheries Policy, the Integrated Maritime Policy, transport, energy, agriculture, regional policy, research and international cooperation.

For the ***Nitrates Directive***, priority will be given to the assessment of files from Member States that request for a derogation on the limit for land application of livestock manure and to continuing the follow up of implementation of the Directive in the Member States, in particular focusing on the fulfilment of obligations on the designation of "vulnerable zones" and the drawing up and updating of nitrates action programmes. Under the WISE umbrella, the Commission will continue its work on streamlining data management and updating the reporting guidelines for the next Member State reporting exercise in 2012.

8.4.3.2. Planned action (2011 and beyond)

Given that the preservation, improvement and restoration of water quality is so closely linked to the ***Water Framework Directive*** the Commission will focus on ensuring Member States fully meet their obligations, including in particular the adoption and implementation of appropriate River Basin Management Plans and programmes of measures for each river basin district and the development of national methods for assessing the ecological status of surface water bodies. Therefore, and in view of the above mentioned third report on the implementation of the Water Framework Directive, the following actions are planned:

- Enforcing the adoption of the 1st River Basin Management Plans and carrying out the compliance assessments of these plans, including checking the implementation of the Groundwater and the Environmental Quality Standards Directives.

- Supporting and enforcing the transposition of the Directives on Groundwater, Floods and Environmental Quality Standards, including starting conformity assessments.

- Continuing the development, together with the European Environmental Agency, of the Water Information System for Europe (WISE) in 2010 as a single platform for water information and reporting to simplify and reduce the overall administrative burden involved in reporting.

In addition, the Commission will launch, if necessary, appropriate legal enforcement action against Member States that fail to comply with the obligations set out in these Directives. In this respect, the Commission will continue to make use of the Common Implementation Strategy as an informal platform to foster better implementation and to exchange good practice.

As regards the ***Floods Directive***, the first stage of implementation was the identification and notification (in 2010), of units of management and competent authorities, if these are other than those in charge of the ***Water Framework Directive***, and 23 Member States reported new information. Compliance checking of the information is underway. The next implementation stages are the preliminary flood risk assessment by 2011, flood mapping by 2013 and flood risk management plans by 2015. For these stages, the development of reporting formats as well as information exchange between Member States is ongoing to support implementation

Planned new legislation includes the preparation of a proposal on priority substances

(amending annex X of the Water Framework Directive) and the establishment of related environmental quality standards. The list of priority substances and the environmental quality standards contained in that Directive are being reviewed as required by the ***Water Framework Directive*** and a Commission proposal is expected in 2011.

The Commission's work regarding the implementation of the ***Urban Waste Water, the Drinking and the Bathing Directives*** will be based on a twin-track approach. On the one hand, it will continue to promote the exchange of information, experience and cooperation at an informal level with Member States and stakeholders. On the other hand, the Commission will draw up and publish implementation reports, including a report an annual bathing water quality and also a tri-annual EU-wide synthesis report on drinking water quality; the next implementation report on the ***Urban Waste Water Directive*** is foreseen for 2011. In addition, the Commission will launch, if necessary, appropriate legal enforcement action against Member States that fail to comply with the obligations set out in these Directives. For the ***Urban Waste Water Directive***, this is likely to involve the first steps in legal action against some of the newer EU 12 Member States where extended deadlines for compliance in the Accession Treaties have elapsed. For these Member States the Commission will also continue to focus on tracking the availability of EU funds and the quality of the forward planning of these countries for compliance with future deadlines through focused bilateral contacts with the Member States and in contacts between the relevant Commission Directorate Generals.

The Nitrates Directive: The Commission's work to ensure compliant implementation will continue in 2011 on the basis of detailed assessments of the information provided by Member States in their 4-year implementation reports and via bilateral contacts. The assessments will focus on the main obligations of the Nitrates Directive, namely on water monitoring, the designation of "vulnerable zones" and the drawing up and updating of nitrates action programmes. It will then need to be decided whether these assessments need to be followed up with infringement action. The Commission will continue to organise meetings of the Nitrates Committee on Member States' derogation requests and to give Member States the opportunity to exchange information on implementation. The Commission published its 4 yearly report[221] on implementation in February 2010.

In relation to the ***Marine Strategy Framework Directive***, the planned action for 2011 and beyond will be the active organisation of the Common Implementation Strategy with Member States, to support a coherent policy development. In addition, increased participation will be required in Regional Sea Conventions. Future action will include increased efforts to integrate marine environment concerns in sectorial policies, such as for instance the reform of the Common Fisheries Policy and the design of the new Financial Perspectives (considering that the policy for the protection of the marine environment was adopted in the middle of the current cycle).

The new ***Bathing Waters Directive*** was required to be transposed into national law by 24 March 2008. In 2010, the Commission continued to verify whether the transposition is both correct and complete. In September 2010, the European Court of Justice ruled that the Czech Republic had failed to transpose the Directive (case C-481/09). The Commission will take further enforcement action where necessary.

8.4.4. **Sector summary**

Substantial progress regarding the implementation of EU water and marine law has been

observed in the past decade as a result of increased awareness among decision-makers of the critical importance of meeting water quality standards to preserve water and marine resources and the associated natural environment and to protect human health. Better implementation has often been driven by informal and formal cooperation between Member States, industries, non-governmental organisations, consumers and the Commission as well as by infringement procedures. However, more efforts need to be made to ensure full compliance with EU water Directives. In respect of the Nitrates Directive, the Commission has noted that several regions within the EU show worrying water quality trends for which reinforced action programmes will need to be developed. With regard to the Urban Waste Water Directive, Member States must ensure that it is fully applied, including in the new EU 12 Member States and in smaller towns for all 27 Member States. With regards to the Drinking Water Directive, targeted efforts by Member States will be required to ensure compliance for those smaller supplies currently delivering drinking water not fully complying with quality standards. The implementation of EU water and marine legislation and the enhancement, preservation and restoration of water quality will greatly depend on Member States meeting their obligation to take all required measures to guarantee the achievement by 2015 of the environmental objectives of "good chemical and ecological status" for surface water bodies and of "good chemical and quantitative status" for groundwaters set in the Water Framework Directive. In the case of the marine waters, the programmes of measures due by 2015 will have to include the necessary actions to achieve "good environmental status" by 2020.The Commission will continue to focus on the proper transposition of European water and marine legislation, including of the new Floods and Marine Strategy Directives and their implementation. The Commission will continue its efforts to ensure that Member States fulfil their obligation under these Directives and will assist them, when necessary, via formal and informal cooperation channels.

8.5. Air quality and environmental noise

8.5.1. Current position

8.5.1.1. General introduction

Ambient air quality

The new Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe is the key legal instrument in this sector[222]. The Directive entered into force on 11 June 2008 and merges four Directives[223] and one Council Decision[224] into a single air quality instrument. It introduces new objectives for fine particles ($PM_{2.5}$) but does not change existing air quality standards. Available evidence points to serious problems in complying with the air quality limit values in many European air quality zones; the new Directive does, however, give under certain conditions Member States

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222 OJ L 152, 11.6.2008, p. 1–44.

223 The four directives merged into the new directive are: Council Directive 96/62/EC of 27 September 1996 on ambient air quality assessment and management; Council Directive 1999/30/EC of 22 April 1999 relating to limit values for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead in ambient air; Directive 2000/69/EC of the European Parliament and of the Council relating to limit values for benzene and carbon monoxide in ambient air; and Directive 2002/3/EC of the European Parliament and of the Council relating to ozone in ambient air.

224 Council Decision 97/101/EC establishing a reciprocal exchange of information and data from networks and individual stations measuring ambient air pollution within the Member States.

greater flexibility in meeting some of these standards in areas where they have difficulty complying.

Under the new Directive 2008/50/EC Member States have the possibility to notify an exemption from the application of the limit values for PM_{10} (and to postpone the limit values for nitrogen dioxide (NO_2) which entered into effect in 2010) provided that certain conditions are satisfied. The Commission has nine months from the submission of a notification to assess it and to decide whether to raise objections or not. If no objections are raised, the notification will be tacitly approved at the expiry of the nine months assessment period.

Product regulation

There are several legal instruments regulating the composition of products which aim to prevent or reduce the emissions of certain air pollutants at source. These include Directive 98/70/EC relating to the quality of petrol and diesel fuels[225], Directive 1999/32/EC relating to a reduction in the sulphur content of certain liquid fuels[226] and the Paints Directive 2004/42/EC on the level of volatile organic compounds in paints, varnishes and vehicle refinishing products[227] .

Environmental noise

The Noise Directive[228] , 2002/49/EC, lays down a common approach to avoiding, preventing or reducing on a prioritised basis the harmful effects of exposure to environmental noise. It requires the assessment and mapping of ambient noise in large agglomerations and in the vicinity of major roads, railways and airports.

National emission ceilings

The National Emission Ceilings (NEC) Directive, 2001/81/EC[229], plays an important role in defining and limiting the total national emissions of certain air pollutants with the aim to reduce negative effects on human health and the environment, such as acidification, eutrophication and ground-level ozone. The NEC Directive covers air emissions of all economic sectors and sources within the national territories.

8.5.1.2. Report of work done in 2010

Ambient air quality

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225 Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC (OJ L 350, 28.12.1998, p. 58–68).

226 Council Directive 1999/32/EC of 26 April 1999 relating to a reduction in t he sulphur content of certain liquid fuels and amending Directive 93/12/EEC (OJ L 121, 11.5.1999, p. 13–18).

227 Directive 2004/42/EC of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC (OJ L 143, 30.4.2004, p. 87).

228 Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise (*OJ L 189, 18.7.2002, p. 12–25).*

229 Directive 2001/81/EC of the European Parliament and of the Council of 23 October 2001 on national emission ceilings for certain atmospheric pollutants (OJ L 309, 27.11.2001, p. 22).

Since 2005 when the PM_{10} limit values entered into force, a majority of Member States have reported as being in non-compliance. In 2008, around 280 zones in 22 Member States did not comply with these limits. The dilemma has been how to treat these breaches of existing EU law whilst recognising the explicit possibility for Member States to seek a time extension for compliance. The Commission's policy has been to launch infringement proceedings in respect of those situations which have not been the subject of a notification from the Member States or where the Commission has raised objections following a Member State notification. There are currently open infringement proceedings against 22 Member States in respect of PM_{10}.

Up until the end of December 2010, the Commission has adopted 29 Decisions on notifications coming from 19 Member States, concerning an exemption from the obligation to apply the PM_{10} limit values. As the daily and the annual PM10 limit value are assessed individually, a zone might get an exemption for the one but not the other limit value. For that reason the figures following might not always round up. For around 19 % of these, the Commission did not raise any objection, a further 40 % or so of the zones were already in compliance whilst objections were raised for approximately 70% of the zones covered by the notifications. Member States are free to re-notify for zones where objections have been raised but any exemption must expire before 11 June 2011.

Whilst closing some bad application infringement cases in 2010 (PM_{10} cases for Malta and Denmark, SO_2 cases for Spain, France and Czech Republic), the Commission also continued to pursue infringement procedures it had launched in previous years (PM_{10} cases for Belgium, Romania, Greece, UK, Slovakia, Poland, Austria, Germany, Hungary, Czech Republic, France, Slovenia, Sweden, Portugal, Italy, Spain, Cyprus, Latvia; SO_2 case for Bulgaria) and has started some others against two Member States (PM_{10} case for Bulgaria and SO_2 case for Romania) that have shown exceedances of the relevant limit values that have been in force since 1 January 2005. New exceedances were discovered in 2009 and reported to the Commission in 2010 as part of the formal reporting requirements. These excesses may also be the subject of further infringement proceedings in due course.

The deadline for transposing the Directive 2008/50/EC was on 11 June 2010. By that time only few Member States had transmitted to the Commission the national measures transposing the Directive into their national legal system. The Commission therefore launched infringement procedures against 21 Member States for non-communication of those national measures. In the course of 2010, 6 of those cases could, however, already be closed (Italy, Portugal, Austria, Bulgaria, Cyprus, Germany).

Product regulation

In 2010 the Commission's work focused on the preparation of the review of the Directive 1999/32/EC on the sulphur content of certain liquid fuels. The last amendment of the Directive in 2005 contains a review clause which requires the Commission to review a number of general and specific issues following its experience with the implementation of the Directive as well as progress made at the IMO level. Since 2005, revised IMO rules were agreed for SO_2 and for NO_x in October 2008. These rules are contained in Annex VI of the Marine Pollution Convention 73/78 (MARPOL Annex VI). In addition to the verification of the implementation of the Directive in Member States, a number of studies have been commissioned in order to assess the impact of a revised MARPOL Annex VI on the EU shipping industry. In addition, the Commission has regularly consulted stakeholders on the review of Directive 1999/32/EC, including an on-line public consultation (2010/2011)

addressed to all interested parties.

Environmental noise

Under the Noise Directive, the Member States had to send to the Commission by 30 December 2010 an update of the list of major roads, major railways and agglomerations. Most Member States delivered their reports on time, only Belgium and Italy have not reported yet. The reports are currently being assessed by the Commission.

The infringement case against Malta on the failure to draw up noise maps in accordance with Article 7(1) of the Directive has been referred to the Court in 2010.

NEC Directive

According to the NEC Directive, Member States shall prepare emission inventories and emission projections for certain air pollutants and shall submit this information to the Commission and the European Environmental Agency annually. The report due by 31 December 2010 had to include emission inventories for 2008 (final) and 2009 (provisional) and updated emission projections for 2010.

The analysis of the latest reports shows that a number of Member States are still projected to be above the ceilings for 2010. In a few cases the transgression is small and it is likely that the ceiling can be met in the course of the next years.

For eight Member States (Austria, Belgium, France, Germany, Greece, Ireland, Luxemburg, Spain) the transgression is substantial, ranging from 10 to 42% and these Member States would have to make significant additional efforts to comply with their ceilings.

The Commission is considering the most appropriate way to address these shortcomings and to ensure proper implementation of the Directive by the deadline of end 2010.

Petitions

In 2010 the Commission received 6 petitions related to air quality and environmental noise. 1 petition was closed during 2010. Many petitions started in previous years required additional Communications by the Commission in 2010. Very often the petitions do not address only ambient air quality but raise problems linked to an industrial installation or a planned construction which from the petitioners' point of view might also have an impact on the ambient air quality and/or the noise levels. Member States frequently concerned by petitions are Italy, Spain, Romania, Greece, Malta and Bulgaria as regards air quality and Germany as regards noise (petitions mainly relating to aircraft noise). The petitions did not lead to the start of infringement procedures as in most cases either the Commission could not identify a breach of the relevant EU legislation or an infringement procedure had already been launched.

8.5.2. **Evaluation based on the current situation**

Ambient air quality

There remain widespread non-compliance with air quality limit values and particularly those for PM_{10} which is probably the pollutant of most concern given its adverse impacts on health. The limits for nitrogen dioxide entered into force in 2010 and it is likely that there will also be

widespread non-compliance for this pollutant (the information on exceedances in 2010 will be available by the end of September 2011). This is due in part to a lack of preparedness by the Member States to undertake the necessary assessments of air quality and to put into place the necessary plans and actions to improve air quality in good time. The ongoing "time extension" exercise should improve the capacity of the Member State authorities to prepare plans and programmes. The Commission will also start the work of the review of the air quality Directive which is scheduled for 2013. Implementing measures in the pipeline for adoption on light and heavy duty vehicles will also help improve compliance.

Product regulation

The assessment of the implementation of Directive 1999/32/EC highlighted a number of problems. In particular, as regards the enforcement of the Directive, the reports on sulphur content of fuels submitted to the Commission by Member States varied significantly in structure and content, which rendered the assessment of the level of compliance with the Directive very difficult. Member States' reports also showed the low frequency of fuel samples taken, which was insufficient for a proper assessment of compliance with the Directive's requirements. Furthermore, following the adoption of the revised IMO's MARPOL Annex VI, there exist a discrepancy between the rules contained in the Directive 1999/32/EC and the IMO rules, which results in legal uncertainty for stakeholders. Similarly, several international technical standards to which the Directive refers have been amended. In addition, experience shows that the interpretation of certain provisions of the Directive caused problems in practice and stakeholders suggested they could be clarified.

Following a review of the Paints Directive 2004/42/EC as foreseen in Article 9 of that Directive, the Commission is preparing a report to the Council and the European Parliament which should be ready in 2011.

Environmental noise

The problems identified in last year's report still remain and have been confirmed by an extensive evaluation report[230] building on Member States responses finalised in 2010.

8.5.3. **Evaluation results**

8.5.3.1. Priorities

Ambient air quality

In the coming years, the Commission will continue to monitor closely the situation with regard to compliance with air quality limit values in all Member States. It will continue to follow its "horizontal approach", which allows air pollution problems to be addressed in a far higher number of places than would have been possible if it had only focused on individual cities or regions. Furthermore in the upcoming review a SWOT analysis will be done in order to analyse what is working and what is not and what could be further done in order to help Member States to reach compliance.

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230 Study report on the "Review of the Implementation of the Environmental Noise Directive 2002/49/EC" (see http://ec.europa.eu/environment/noise/home.htm)

Product regulation

The priority is to align the Directive 1999/32/EC with the revised MARPOL Annex VI as well as improve enforcement (monitoring and reporting) and compliance with the Directive 1999/32/EC.

Environmental noise

The first priority is to improve the consistency in the Member States' assessments of environmental noise and the usefulness of the reported information. A second priority is to improve the implementation of the Directive by the Member States by providing greater clarity and guidance.

8.5.3.2. Planned action (2011 and beyond)

Ambient air quality

Infringement procedures are to be continued against Member States in breach of the limit values for PM_{10} which did not apply for a time extension or did not meet the conditions for obtaining such extension. In addition, the Commission will start monitoring more closely the implementation of the limit values for NO_2 which entered into effect in 2010. As regards excessive SO_2, the Commission will continue to pursue the legal enforcement action against those Member States which are still exceeding the limit values.

Product regulation

The amendment of Directive 1999/32/EC is planned for the first half of 2011.

Environmental noise

In 2011, the Commission will present a more detailed implementation report on this directive which is currently under preparation.

In addition, the Commission intends to complete the work on the harmonised assessment methods which will be presented to the committee procedure later in 2011.

NEC directive

As described above, some Member States will probably fail to meet the national emission ceilings for 2010 for one or several pollutants mainly due to insufficient measures taken in order to reach compliance. The Commission will continue to closely monitor the situation and take action as appropriate. The possibility of launching infringement cases cannot be excluded.

In 2011 the Commission will also focus on assessing the quality of national transposition of the NEC Directive in all the Member States. The Commission will take appropriate measures to follow up with the Member States any potential deficiencies identified in the national transposition during this conformity-checking exercise.

8.5.4. **Sector summary**

In 2005 a set of legally binding EU air quality limit values became applicable, including limit values for particulate matter PM_{10}, pollutant with very important adverse impacts on health. A widespread non-compliance with PM_{10} limit values remains, partly due to challenging and complex nature of this pollutant and the lower and delayed impact of certain community measures. But the main reasons are serious delays in the implementation of the directives in a large number of Member States, mainly as regards the drawing up and implementation of the necessary plans to ensure that air quality is improved in good time. The capacity and awareness of the Member State authorities of the need to tackle air pollution at the source and to prepare plans and programmes should be increased through the procedure and conditions laid down in the new Directive 2008/50/EC on ambient air quality and cleaner air for Europe for extending the time required for achieving compliance with the limit values for PM_{10}, NO_2 and benzene, joined with coherent and timely enforcement where appropriate.

In the coming years, the Commission will continue to monitor closely the air quality situation in order to ensure long term and sustainable compliance with the limit values in all Member States. In particular, it will be a priority task to assess further time extension notifications (primarily for NO_2) or re-notifications (for PM_{10}) as well as to follow-up on the decisions adopted by the Commission. A further priority will be to ensure a timely and effective implementation of Directive 2008/50/EC. Dissemination of information to the public and cooperation between the Member States and the Commission in order to develop appropriate policies should continue.

As regards the air emissions of sulphur dioxide by ships, the focus will be on the improvement of enforcement of the limits on sulphur content of marine fuels, in particular by providing Member States with guidance on monitoring and reporting and on the alignment of the EU rules to the relevant international rules (MARPOL Annex VI).

8.6. Industrial installations

8.6.1. **Current position**

8.6.1.1. General introduction

The most important piece of legislation relating to industrial emissions is Directive 2008/1/EC (IPPC Directive, codified version of Directive 96/61/EC)[231]. This Directive sets out common permit rules for industrial installations in order to prevent and control emissions into air, water or soil. Installations covered by the IPPC Directive are required to operate under an integrated permit granted by the competent authorities of the Member States. The provisions of the directive were due to enter into effect either in October 1999 (for new installations) or before 30 October 2007 (for existing installations).

The Large Combustion Plants (or LCP) Directive, 2001/80/EC[232], aims to reduce emissions of sulphur dioxide, nitrogen oxides and dust from combustion plants whose rated thermal input

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231 Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control (OJ L 24, 29.1.2008, p. 8).

232 Directive 2001/80/EC of the European Parliament and of the Council of 23 October 2001 on the limitation of emissions of certain pollutants from large combustion plants (OJ L 309, 27.11.2001, p. 1)

is equal to or greater than 50 MW. The control of emissions from such plants contributes significantly to the Union's efforts to protect the health of EU citizens and the environment by combating acidification, eutrophication and ground-level ozone as part of the overall strategy to reduce air pollution (see also NEC Directive).

Further important legislation relating to industrial emissions (other than greenhouse gases) includes the Waste Incineration (WI) Directive, 2000/76/EC[233], the VOC Solvent Emissions (SE) Directive, 1999/13/EC[234] and the E-PRTR Regulation (EC) No 166/2006[235].

The Seveso II or Major Accident Hazards Directive, 96/82/EC[236], applies to establishments in which certain dangerous substances are present in sufficiently large quantities to create a major accident hazard. It contains obligations on both operators and Member State authorities to take measures aimed at preventing major accidents and limiting their consequences.

8.6.1.2. Report of work done in 2010

Revision of the existing legal framework

The Directive on Industrial Emissions (IED), which is a recast of seven directives (including the IPPC, LCP, WI and SE Directives) was adopted on 17 December 2010 and entered into force on 6 January 2011. Member States need to transpose the directive to national legislation by 6 January 2013.

Work on a review of the Seveso II Directive resulted in a Commission legislative proposal being adopted on 21 December 2010. Discussions on the proposal are currently ongoing.

Compliance promotion and legal enforcement work

In the course of 2010 the Commission continued to carry out implementation work concerning the IPPC Directive in line with the actions specified in its action plan which forms part of the 2007 Commission Communication "*Towards an improved policy on industrial emissions*"[237]

Transposition of the IPPC Directive

In 2010 out of the ongoing two non-conformity infringement procedures regarding the non-conform transposition of the IPPC Directive, the one against Lithuania was closed due to the adoption of legislative amendments addressing the shortcomings. One case against Estonia remains open, as the Commission awaits the confirmation from the Estonian authorities that the necessary legislative changes are carried out.

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233 Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste (OJ L 332, 28.12.2000, p. 91).

234 Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations (OJ L 85, 29.3.1999, p. 1).

235 Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 33, 4.2.2006, p. 1).

236 Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances OJ L 10, 14.1.1997, p. 13–33.

237 COM(2007) 843 final.

Transposition of the LCP and WI Directives

The Commission decided to channel the ongoing work regarding the transposition of the LCP and WI Directives in the transposition exercise of the Industrial Emissions Directive.

IPPC permits for existing installations under Article 5(1) of the Directive

By 30 October 2007, all existing IPPC installations had to obtain a permit issued in accordance with the requirements of the Directive. After the expiry of this deadline, the Commission launched eleven infringement procedures in 2008 against Belgium, Bulgaria, Denmark, Estonia, Greece, Spain, Ireland, Italy, The Netherlands, Portugal and Slovenia and in 2009 against Austria, France, Malta and Sweden. Out of these Member States, Belgium, Greece, Spain, Italy, Slovenia and Sweden have been referred to the Court of Justice of the European Union.

Implementation of the IPPC and WI Directives

Three-yearly implementation reports were to be sent by Member States to the Commission by 30 September 2009 (covering the period 2006-2008). The Commission has initiated an infringement procedure against Greece and Luxembourg who have not fulfilled this reporting obligation even after several reminders. As a result of these procedures, all reports are received and the Commission has set up a study for the assessment of the reports with the aim of publishing it in the course of 2011.

Implementation of the LCP Directive

For implementing the LCP Directive provisions for certain existing plants, eight Member States have chosen to apply a national emission reduction plan (NERP) instead of setting individual emission limit values: the Czech Republic, Greece, Finland, France, Ireland, Portugal, Spain and the United Kingdom.

The Commission has checked the compliance of these MS with the NERP ceilings but further communications with MS were necessary in order to validate the assessment. For those MS where breaches have been found, infringement procedures will be launched in the course of 2011.

The Accession Treaties of four Member States (Lithuania, Romania, Bulgaria and Poland) include transitional derogations for some provisions of the LCP Directive, which are conditional to meeting emission ceilings for all of the large combustion plants in the MS in certain specified years. The Commission has assessed the 2008 and 2009 LCP emissions in these MS against the Accession Treaty ceilings and has identified potential breaches for Bulgaria. Further communication with Bulgaria will be carried out in 2011 to evaluate the situation in view of possible infringement procedures.

Implementation of the VOC Solvents Directive

A summary report of the information submitted by Member States on their implementation of the SE Directive during the period 2005-2007 will be finalised in the course of 2011 in conjunction with the implementation report on the IPPC Directive 2008/1/EC.

Implementation of the E-PRTR Regulation

On 9 November 2009, the Commission and the European Environment Agency launched the new European pollutant release and transfer register (E-PRTR). The register contains information about the quantity and location of pollutants released to air, water and land by industrial facilities throughout Europe. It includes annual data for 91 substances and covers more than 24 000 facilities in 65 economic activities. It also provides additional information, such as the amount and types of waste transferred from facilities to waste handlers both inside and outside each country.

The Commission has been working on a questionnaire for the three-yearly implementation reports to be sent by Member States to the Commission, together with the information to be reported to the E-PRTR pursuant Article 7 of the Regulation by 31 March 2011.

Transposition of the Seveso II Directive

In 2010 the Commission pursued infringement procedures against a number of EU-12 Member States for non-conform transposition of Directive 96/82/EC and the amending Directive 2003/105/EC (the Seveso II Directive). During the course of the year several of those cases were closed. At the end of 2010, cases remained open against Poland and Lithuania. The Commission also closed several cases against EU-15 Member States. By the end of 2010, one case (Luxembourg) relating to non-conform transposition of amending Directive 2003/105/EC remained outstanding.

External Emergency Plans under the Seveso II Directive

The Commission also continued legal action before the Court against several Member States where external emergency plans for so-called upper-tier establishments were lacking in breach of the Seveso II Directive. During 2010 the Court issued a ruling against Spain (see below). Cases against Austria and Belgium were closed since the Member States concerned had taken steps to ensure that the necessary plans were in place. By the end of the year, two cases remained outstanding (failure of Portugal and Spain to comply with Court rulings).

Petitions

So far, the Commission received 4 new petitions related to industrial emissions with a reference year of 2010. These petitions raised issues concerning France, Germany, Greece and Italy. In addition, the Commission has been dealing with those petitions which were received in earlier years, but follow-up with the national authorities has proved necessary to enable sending updated information to the Parliament. Particular attention has been paid on cases where potential serious or persistent breach of EU law could have been identified.

Judgements of the Court of Justice of the European Union in 2010

In a judgement of 22 April 2010 (Case C-346/08), the Court found that by failing to apply the Large Combustion Plants Directive to the power plant operated by Rio Tinto Alcan Smelting and Power (UK) Ltd in Lynemouth, the United Kingdom had failed to fulfil its obligations under that directive.

In several judgements (Cases C-258/09, C-49/10, C-48/10, C-534/09, issued on 4 March 2010, 7 October 2010, 18 November 2010 and 2 December 2010 respectively), the Court found that by not issuing permits to all existing installations by the deadline of 30 October 2007, Belgium, Slovenia, Spain and Greece failed to fulfil their obligations under that

directive. A number of Member States are being referred to the Court for the issue in the case of which the judgment is still pending.

The Court also declared that Spain (Case C-392/08) was in breach of its obligations in relation to the drawing up of external emergency plans pursuant to Article 11.1 (c) of the Seveso II Directive (judgement of 25 March 2010).

8.6.2. **Evaluation based on the current situation**

IPPC Directive

The IPPC Directive still falls short of being fully applied and respected. The main problems relate to the important delays in issuing the IPPC permits, shortcomings in the implementation (in particular BAT), a need for increased clarity in the legislation, restrictions in its scope and insufficient enforcement of its application. While the new Directive on Industrial Emissions addresses the majority of these shortcomings, significant progress has already been achieved in terms of permitting, due to increased support to Member States, and due to the infringement procedures and the resulting judgements of the Court where necessary. The Commission is continuing its in-depth assessment of the implementation by Member States through the investigation of the permits and operational conditions of some specific installations. To this end, a new study was launched in 2010, which will also consider the implementation of some of the sectoral Directives (see below).

LCP Directive

The Commission has assessed the quality of national transposition of the LCP Directive in all the Member States. The results of this assessment have been communicated to the Member States with a request for further information and clarification on a number of transposition issues. As a result of this exercise, several MS have made commitments in terms of adopting new legislation to ensure full compliance with the Directive's provisions. The Commission will continue to monitor transposition of the relevant provisions within the framework of the transposition exercise of the Industrial Emissions Directive.

As set out under point 1.1.1.2, the Commission has identified issues concerning the application of the Directive in a number of Member States, in particular concerning compliance of the emissions with the ceilings defined under the NERP and with the ceilings under the Accession Treaty. In case of confirmation of the identified breaches, the Commission will launch infringement procedures in the course of 2011.

In addition, the correct application of the Directive at individual installations will be considered in the framework of the study mentioned in the context of the IPPC Directive.

Waste Incineration Directive and VOC Solvents Directive

The correct application of these Directives at individual installations will be considered in the framework of the study mentioned in the context of the IPPC Directive.

Seveso II Directive

Overall, the Directive is being satisfactorily applied and complied with. The level of transposition and implementation of the Directive has continued to improve, and the number

of outstanding legal proceedings has continued to fall. As noted above, a review of the Directive has recently been completed. This confirmed that overall the Directive is fit for purpose and that no major changes are required. The Commission proposal for a new Directive represents essentially a technical adaptation of the existing rules. The main change proposed is the adaptation of Annex 1 to the Directive, which defines its scope, to new international and Union rules on the classification of dangerous substances. Certain other amendments are proposed to update or clarify existing provisions to improve implementation and the existing high levels of protection.

8.6.3. **Evaluation results**

8.6.3.1. Priorities

Industrial emissions

Continued attention needs to be paid to improved respect for the existing provisions and to a strong follow-up on their full implementation.

Priority is therefore attached to:

- Providing assistance to Member States and ensuring full transposition of the relevant Community legislation regarding the recently adopted Industrial Emissions Directive;
- Increased assistance to Member States on implementation;
- Ensuring that Member States fulfil their reporting obligations;
- A more systematic approach concerning the breaches of the IPPC Directive and launching of infringement procedures;
- Annual reporting on progress in implementation of the Action Plan and its revision as part of the next Commission's report on IPPC implementation (in the course of 2011) (see further information below);
- Development of transposition checklist and interpretative guidance documents on the new IED to provide early support to Member States in transposition and implementation

On the basis of these priorities and the work programming set out below, it is hoped to improve substantially compliance with the existing provisions at the latest by 2012, by which time the focus of attention will move to the implementation of the new legislative framework.

Seveso II Directive

Regarding the Seveso II Directive, the main priority at present is to conclude the discussions on the legislative proposal as quickly as possible so that the new Directive can be adopted and transposed by Member States in good time to provide the necessary legal certainty before 2015, when the new Union rules on classification of dangerous substances become definitive. However importance also continues to be attached to ensuring the full transposition and implementation of the existing Directive.

8.6.3.2. Planned action (2011 and beyond)

The Commission will continue to prioritise work on its current collective infringement proceedings, covering a large number of deficiencies in several Member States. Infringement proceedings could also be opened against those Member States showing a significant delay in

fulfilling their reporting obligations.

The Commission will strengthen its monitoring and supporting mechanisms by revising and refocusing the previous IPPC Action Plan on Implementation for the time period 2008-2010 as set out below.

- Ensure full transposition of the legislation on industrial emissions

  The success of the existing legislation relies first of all on effective transposition by Member States in their national legal systems. In the course of 2011, the Commission will focus on providing assistance to Member States in order to ensure timely and full transposition of the Industrial Emissions Directive. Infringement proceedings to ensure full and correct transposition of the industrial emissions legislation will be considered only necessary if Member States fail to fully transpose the IED into national law (deadline for that exercise: 6 January 2013).

- Support Member States in their implementation of the legislation

  This will include enhanced information exchange, the development of guidance, visits to authorities and training. This support will continue throughout the introduction and implementation of the revised legislation.

- Enhanced monitoring and compliance checks

  The Commission will continue to monitor the number of IPPC permits issued and updated and, where required, investigate the system of monitoring and inspection at IPPC installations. Such investigation will cover specific industrial installations and sectors, the use of general binding rules, and the analysis of complaints.

- Improve data collection for the review of BREFs and BAT conclusions and create stronger links with the Research Framework Programme

  The Commission will continue to organise the exchange of information between experts from Member States, industry and environmental organisations resulting in the BAT Reference Documents (BREFs) and BAT conclusions.

Seveso II Directive

The Commission will continue to monitor implementation of the Seveso II Directive and take action as appropriate. Ongoing work in relation to the proposed new Directive will also continue in 2011 as necessary.

8.6.4. **Sector summary**

Both the transposition and the implementation of the legislation related to industrial installations and air emissions (in particular the IE, IPPC and the LCP Directives) pose difficulties for Member States. The Commission, while supporting Member States in different ways (transposition assistance, interpretational guidance, studies, workshops), carries out enforcement actions to ensure full compliance.

The capacity and awareness of competent authorities of the need to tackle pollution should be increased throughout the EU.

In the coming years, the Commission will continue to monitor closely the implementation of the existing legislation, giving priority to the transposition and preparation of the implementation of the incoming Directive on Industrial Emissions.

8.7. Chemicals and Biocides

8.7.1. Current position

8.7.1.1. General introduction

Chemicals

The REACH Regulation (1907/2006)238, which entered into force on 1 June 2007, is the cornerstone of the EU's new chemicals legislation. REACH, which is more far-reaching than previous legislation, deals with the registration, evaluation, authorisation and restriction of chemicals. Registration means the process by which information on the safety of chemicals is submitted for registration to a central database, managed by ECHA. Evaluation includes a quality check of the registration dossiers and an examination of testing proposals and this is also carried out by ECHA; it also includes a more thorough examination of specific substances, where Member States play an important role. Substances of very high concern will require authorisation for use and before being placed on the market. There is also a procedure for restriction of manufacturing, placing on the market or use of certain substances where there is an unacceptable risk to health or the environment, which needs to be addressed on a community wide basis.

Regulation (EC) No (1272/2008)239 on the Classification, Labelling and Packaging of Substances and Mixtures was adopted in 2008 and incorporates the UN GHS (United Nations Globally Harmonised System) into Community law and will replace, after a transitional period, certain provisions of the current directives related to the classification, packaging and labelling of dangerous substances (Directive 67/548/EEC240) and preparations (Directive 1999/45/EC241). Provisions of these Directives shall be repealed with effect from 1 June 2015.

Two other pieces of legislation should be mentioned here. Firstly, persistent organic pollutants ("POPs") are governed by Regulation (EC) No 850/2004242. This legislation implements the commitments to which the Community has signed up to under the 1998 UN-ECE Protocol on POPs and the UNEP Stockholm Convention on POPs. The Regulation contains requirements to eliminate and/or restrict POPs substances to a level equal to or stricter than foreseen under international agreements. The obligations from the two

238 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

239 OJ L 353, 31.12.2008, p. 1

240 OJ L 196, 16.08.1967, p. 1.

241 OJ L 200, 30.07.1999, p. 1.

242 OJ L 158, 30.4.2004, p. 7.

international agreements have thus been completely transported into Community Law and are, as such, enforceable according to these rules.

Secondly, basic provisions concerning the protection of laboratory animals used in experiments are contained in the newly adopted Directive 2010/63/EU, which updates the 1986 Directive 86/609/EEC on the protection of animals used for scientific purposes. The aim of the new Directive is to strengthen legislation, and improve the welfare of those animals still needed to be used, as well as to firmly anchor the principle of the 'Three Rs' - to Replace, Reduce and Refine the use of animals in EU legislation. The new Directive entered into force on 10 November 2010. The transposition of the Directive into national legislation is to be completed by 10 November 2012 and the Directive will take full effect on 1 January 2013.

Export and import of dangerous chemicals

Regulation (EC) 689/2008 of the European Parliament and the Council of 17 June 2008 concerning the export and import of dangerous chemicals implements the Rotterdam Convention on the Prior Informed Consent Procedure (PIC) for certain hazardous chemicals and pesticides in international trade. It establishes special rules for trade with third countries of certain chemicals with a view to protecting human health and the environment from potential harm and contributing to the environmentally sound use of such chemicals. By 10 February 2011 around 150 substances (pesticides and industrial chemicals) were listed in Annex I to the Regulation, including 40 substances that are subject to the PIC procedure under the Convention.

Biocides

Directive 98/8/EC of the European Parliament and of the Council regarding the placing of biocidal products on the market[243] (the Biocides Directive) concerns the authorisation and placing on the market of biocidal products in Member States, the mutual recognition of authorisations within the Union and the establishment at Union level of a list of active substances which may be used in biocidal products.

As of 1 February 2011, 40 active substances were listed in Annex I and 1 active substance in Annex IA. In accordance with Article 16(1) of the Directive, Member States are allowed to apply national rules and practices during the implementation of the review programme. The first three product authorisations and 31 mutual recognitions were granted in accordance with the Biocides Directive in 2009 and 2010.

8.7.1.2. Report of work done in 2010

This sector of EU environmental law is characterised by substantial new developments; however, legal enforcement action in these fields does not constitute a significant workload for the Commission.

Chemicals

REACH entered into force on 1 June 2007. This included the establishment of the European Chemicals Agency (ECHA) and the preparation of IT-systems to hold the new database.

243 OJ L 123, 24.4.1998, p. 1.

Registration of chemicals manufactured or imported in quantities of 1 tonne or more per year started on 1 June 2008. Between 1 June and 1 December 2008 manufacturers had the possibility to pre-register their phase-in substances. Pre-registration, as its name suggests, precedes full registration and provides for extended deadlines. Depending on the volumes and the hazardous properties of substances, these extended deadlines are 2010, 2013 or 2018. In 2008, ECHA received approximately 2.7 million pre-registration dossiers. If a company failed to pre-register by 1 December 2008 it can no longer place its phase-in substances on the market until it has completed registration. The first registration deadline, 30 November 2010, marked an important milestone for the new EU chemicals policy. This deadline applied to the most hazardous substances (e.g. those that are carcinogenic, mutagenic or toxic for reproduction) manufactured or imported in quantities of 1 tonne or more per year per company, substances very toxic to the aquatic environment manufactured or imported in quantities of 100 tonnes or more per year per company and substances manufactured or imported above 1000 tonnes per year.

24675 registration files for 4300 substances including nearly 3400 phase-in substances were submitted to ECHA by the November 2010 deadline. ECHA is proceeding with the checking of the files to ensure that all requirements have been met.

Six court cases were brought up before the ECJ in 2010, all of them by individual companies against ECHA and all of them seeking the annulment of the decision to include certain substances in the candidate list. Some of the cases might be joined by the Court due to their similarities and the admissibility of some of the applications have been questioned by ECHA and the Commission. The Commission is intervening in five of these cases.

Within the process of authorisation, the Commission has adopted a decision to add 6 chemicals to the list of substances subject to authorisation from the so called Candidate List. Companies that want to continue using these six chemicals have to submit requests for authorisation.

The Candidate List currently consists of 46 Substances of Very High Concern (SVHC). Inclusion of substances in the Candidate List triggers several legal obligations, for example, producers or importers of articles have to notify ECHA if their article contains a substance on the Candidate List; Suppliers of articles containing these substances must provide sufficient information to allow safe use by their customers or, upon request, to consumers. Similarly, suppliers of substances have to provide their customers with a safety data sheet.

Member States have notified the Commission of national provisions for penalties applicable for REACH infringements. A Commission study finalised in 2009, on the setting of penalties for the infringement of REACH provisions in national laws identified a number of differences between Member States´ approach to adopting penalties which are effective, proportionate and dissuasive. The Commission has, therefore, organised a workshop for Member States on penalties in order to discuss its findings. The results of the study, Member State's reports on the operation of REACH as well as work of the Forum for Exchange of Information on enforcement will provide the Commission with a broader picture as to the effectiveness of enforcement of the REACH Regulation across Member States and allow it to assess possible further steps.

The Forum for Exchange of Information on Enforcement, composed of members nominated by Member States, was set up within ECHA. The Forum coordinates a network of Member State authorities responsible for the enforcement of the Regulation. Its main tasks include:

proposing, coordinating and evaluating harmonised enforcement projects and joint inspections; identifying enforcement strategies, best practice in enforcement and examining proposals for restrictions with a view to advising on enforceability.

In 2009, the ECHA Forum developed inspection guidelines, in the form of minimum criteria to be applied as a common basis for the performance of REACH inspection activities within the MS. However, their provisions remain general and therefore it is useful to assess whether more specific and binding inspection criteria should be introduced in the REACH and CLP Regulation. At the end of 2010, the Commission launched a study which aims to assess whether and how the current enforcement requirements of REACH and CLP Regulations can potentially be reinforced.

Member States were obliged to notify the Commission of national provisions for penalties applicable for CLP infringements by 20 June 2010. A number of Member States did not fulfil this obligation and the Commission has reminded Member States of this obligation during the Competent Authorities meetings of REACH and CLP. The Commission is currently considering launching infringement procedures against those Member Sates who have still not complied.

In 2010, the Commission started the review of the scope of REACH mandated by Article 138(6), which calls on the Commission to assess by 1 June 2012 whether or not to amend the scope of REACH to avoid overlaps with other relevant provisions of EU law. On the basis of such a review, the Commission may if appropriate, present a legislative proposal. The Commission is being assisted by a contractor in the development of this work and has involved all its relevant services in the assessment of EU legislation. As part of the project, stakeholders were called to share any relevant experiences they may have gathered when facing the challenges of implementing REACH through a dedicated website www.reachscope.eu, which was operational from 10 March until 1 December 2010.

One of the aims of the CLP regulation is to improve the protection of human health and the environment by providing criteria for defining when a substance or mixture displays properties that lead to its classification as hazardous. The CLP regulation applies to manufacturers, importers, users or distributors of chemical substances or mixtures. They must classify, label and package any substance or mixture, regardless of its annual tonnage, in accordance with the Regulation. By 3 January 2011, industry had to notify ECHA of the classification and labelling of all chemical substances that are hazardous or subject to registration under the REACH regulation and placed on the EU market. ECHA received 3 114 835 notifications of 107,067 substances.

With regard to the CLP Regulation, two court cases challenged the classification of nickel and borates compounds listed in the 30th and 31st ATP of Directive 67/548/EEC and in the 1st ATP of CLP. The hearing took place on 20 January 2011.

In 2010 twenty non-communication cases were registered concerning the transposition of Directive 2008/112/EC[244] amending a number of Directives in order to adapt them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. More than a half of them were closed during 2010.

244 OJ L 345, 23.12.2008, p. 68.

In 2010 amendments were made to Regulation EC No 850/2004 to implement within the EU, restrictions on the 9 substances, which were included within the framework of the Stockholm Convention on POPS in 2009.

The Commission published the first report [245]on the application of Regulation (EC) No 850/2004 on persistent organic pollutants in accordance with Article 12(6) of the Regulation. Despite several reminders some Member States had not fulfilled the reporting obligations. In the report, the Commission concluded that "*Compliance with the reporting obligation is not satisfactory. A significant number of Member States have not respected their reporting obligations. The quality of information provided must improve*".

In 2010, the Commission finalised a study on mixture toxicity and adopted its final report which aimed to provide a 'state of the art' overview of the science and methodologies for assessing the hazardous effects arising from exposures to multiple chemicals from different sources and pathways. The final report has been made publicly available on the Environment website and was open for consultations to the interested parties. The Commission organised a workshop and consultations with Member States on the subject. This work coincided with an initiative taken in the Council in December 2009 requesting the Commission to assess how such effects arising from multiple exposures are covered in current legislation.

Export and import of dangerous chemicals

Two amendments of Regulation (EC) 689/2008 of the European Parliament and the Council of 17 June 2008 concerning the export and import of dangerous chemicals were favourably received by the regulatory committee in which the Member States are represented and are expected to be formally adopted and published in spring 2011. The amendments add further chemicals to the list of chemicals subject to certain requirements for their export (Annex I) and also to the list of chemicals that are banned for export (Annex V). The Commission drafted a guidance document on implementation of the Regulation, which was endorsed by the Member States and will be published in February.

Biocides

During 2008 the Commission followed the transposition of the Commission Directives amending Directive 98/8/EC concerning the placing of biocidal products on the market. The Commission has closed all of the open infringement cases.

In 2010 four non-communication cases were registered concerning Commission Directives 2009/85/EC[246], 2009/86/EC[247], 2009/87/EC[248], 2009/92/EC[249], 2009/93/EC[250] and 2009/99/EC[251], which all concern the inclusion of active substances in Annex I to Directive 98/8/EC. Furthermore, three non-communication cases were registered concerning Commission Directive 2009/94/EC[252] amending Directive 98/8/EC to include boric acid as an

245 COM(2010)514.
246 OJ L 198, 30.7.2009, p. 28.
247 OJ L 239, 6.9.2008, p. 9.
248 OJ L 198, 30.7.2009, p. 35.
249 OJ L 201, 1.8.2009, p. 43.
250 OJ L 201, 1.8.2009, p. 46.
251 OJ L 203, 5.8.2009, p. 62.
252 OJ L 201, 1.8.2009, p. 50.

active substance in Annex I thereto. Furthermore, two non-communication cases were registered concerning each of Commission Directives 2009/94/EC[253], 2009/95/EC[254] and 2009/98/EC[255]. All of the cases were closed during 2010.

The Commission adopted Decision 2009/244/EC concerning the placing on the market of a carnation (Dianthus caryophyllus L., line 123.8.12) genetically modified for flower colour, for the purpose of import, retailing and ornamental uses (not for cultivation or food/feed uses).

On biocides, as set out in the implementation report following Article 18 of the Directive published in 2008, the current progress rate of the review programme will not permit its completion by 14 May 2010 as planned. This is due mainly to the fact that, before any review could start (the second phase), it was necessary to establish an inventory of active substances used in biocidal products placed on the European market of biocidal products. In light of these findings, the Commission adopted Directive 2009/107/EC extending the deadline for completion of the review programme until 14 May 2014[256].

The Commission presented its proposal for a revision of the Biocides Directive in 2009. The proposal will take the form of a Biocides Regulation repealing and replacing the Biocides Directive. The main changes proposed by the Commission included an extension of the scope to articles treated with biocidal products, a possibility to have certain categories of products authorised at Union level, measures aimed at strengthening the mutual recognition, obligatory rules on data sharing of tests involving vertebrate animals and a partially harmonised fee structure. The European Parliament voted on the proposal in the first reading in September 2010. The Council reached a political agreement on the file in December 2010. The second reading will start in the second half of 2011. The proposed Regulation is expected to be applicable as of 2013.

Petitions

During 2010, there was one petition handled on strychnine hydrochloride.

8.7.2. **Evaluation based on the current situation**

Chemicals

The REACH Regulation entered into force on 1 June 2007. Its main obligations started applying on 1 June 2008. The first registration deadline was an important milestone. From now on the work of national enforcement authorities and Member States joined enforcement projects will become even more important. In order to ensure compliance, Member States should put in place effective monitoring and control measures. The Commission is concerned that Member States may not be able to make sufficient resources available to ensure compliance by economic operators.

Every five years Member States must submit a report to the Commission on the operation of the Regulation in their respective territories, including sections on evaluation and

253 OJ L 201, 1.8.2009, p. 50.
254 OJ L 201, 1.8.2009, p. 54.
255 OJ L 203, 5.8.2009, p. 58.
256 Directive 2009/107/EC of 16 September 2009 amending Directive 98/8/EC, OJ L262, 6.10.2009, p40

enforcement. The first reports were besubmitted in June 2010. The Commission is currently assessing the Member States reports and has in addition launched a contract for the in depth analysis of MS reporting. The results of the Member States reports, together with results from the ECHA reporting on the operation of REACH, on the joint submission of information, on the status of implementation and use of non-animal test methods, the results of several Commission studies related to enforcement of REACH and CLP as well as the work of the Forum for Exchange of Information on enforcement will provide the Commission with a broader picture as to the effectiveness of enforcement and implementation of the REACH Regulation across the Member States and allow it to assess possible further steps. With regard to the POPs Regulation, a possible reason for the delay in submitting annual reports could be that they are considered low priority by Member States, as the reporting format only sets out four questions which remain the same every year. As for the three annual reports, the reasons could be linked to non-ratification of the Stockholm Convention on POPs and/or the Protocol to the regional UNECE Convention on Long-Range Transboundary Air Pollution (CLRTAP) on POPs.

Biocides

In the biocides area the Commission undertook to monitor the progress made in the second phase of the Review Programme for biocides regulated by Commission Regulation (EC) No 1451/2007[257]. Serious delays and significant variations were found in the performance at all stages of the procedure between the Member States.

The reasons for the delays are, for example, the technical complexity of the work, insufficient human resources and lack of experience with dossier preparation (by participants) and dossier evaluation (by Member States). However, considerable time was also needed to develop appropriate testing methodologies and exposure scenarios or for defining harmonised approaches for the evaluations.

In reaction to the delays and variations in the performance, the Commission took a number of actions, for example prepared a note on the evaluation of multiple dossiers that should speed up and facilitate the evaluation of dossiers from several applicants by the competent authorities. At each meeting with the competent authorities, the Commission makes an overview of late dossiers and agrees further steps with the relevant competent authorities (see also section on 'Planned action').

The revised PIC Regulation was adopted in 2008 and requires the Commission to regularly compile a report on the operation of the procedures, which shall include reports from Member States. The Commission foresees that this report will be compiled in the course of 2012.

8.7.3. **Evaluation results**

8.7.3.1. Priorities

Chemicals

[257] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, OJ L 325, 11.12. 2007, p 3.

Effective implementation of REACH and CLP Regulations is the main priority in the chemicals sector. The Chemicals Agency is playing a key role in the effective implementation of REACH. It will coordinate, over a period of 11 years, the registration of some 30 000 chemical substances in use today.

Member States provided their first reports on the operation of REACH in June 2010 and ECHA will report by June 2011. On the basis of these reports, the Commission will prepare the first general report on the operation of REACH.

The priorities for POPs will be, firstly, to transpose the agreements reached in 2009 under the UNECE Protocol into the POPs regulation and secondly to develop proposals for new additions to the Convention.

Biocides

The first applications for authorisations and mutual recognitions in accordance with the Biocides Directive were received and processed in 2009/2010. Estimations showed that the number of applications for product authorisation and mutual recognition will exponentially increase in the future. In view of this, further action is needed to facilitate the implementation of the legal and practical requirements related to these procedures. The Product Authorisations & Mutual Recognition Facilitation Group, an informal group of Member States' authorities set up in 2007 in order to discuss procedural, regulatory and scientific issues arising during the course of product authorisation and mutual recognition, intensified its work in 2010. Several guidance documents were prepared and agreed by the Group (e.g. frame formulations, letters of access, changes to authorisations).

In addition the speeding up of the evaluation of biocidal active substances in the Review programme will be a main priority.

As concerns the PIC Regulation, it is planned to draft a proposal for an amendment that addresses changes resulting from Regulation (EC) 1272/2008 on classification, labelling and packaging of chemicals and to finalise the guidance documents for implementation of the Regulation.

8.7.3.2. Planned action (2011 and beyond)

Chemicals

The Commission will continue to work to enhance good cooperation, coordination and exchange of information with Member States and the European Chemicals Agency regarding enforcement so that the system established by the REACH and CLP Regulations can operate effectively. The Commission will work closely with the Forum for Exchange of Information on Enforcement in this regard.

Concerning the registration process there are two further registration deadlines in 2013 and 2018 for chemicals produced or imported in lower volumes. The Commission will examine the lessons learned from the first registration phase to allow as smooth a process as possible for future registration deadlines.

Most guidance documents necessary for industry preparedness for registration under REACH and notification to the Classification and Labelling inventory under the CLP Regulation have

been adopted, with some necessary updates underway. The remaining staggered deadlines for registration are 2013 and 2018. Equally a lot of work will be developed in 2011 to ensure the proper functioning of the evaluation and authorisation titles in REACH for which ECHA and Member States are responsible.

With regard to authorisation, following a recommendation from ECHA in December 2010, the Commission is taking steps to add a further 8 chemicals from the Candidate List to the list of substances subject to authorisation. The Candidate List currently consists of 46 Substances of Very High Concern (SVHC) but the Commission is committed to working together with Member States towards a target of including an additional 90 SVHC on the Candidate List by 2012 and to identify all relevant, currently known SVHCs in the Candidate List by 2020

REACH calls for the Commission to carry out a review of the scope of the Regulation by June 2012 to avoid overlaps with other relevant Community provisions and on the basis of this, a legislative proposal could be presented, if appropriate. The work to be undertaken has started and for this purpose the Commission has launched a study which will be further developed in 2011 with the view to assessing overlaps and gaps between REACH and other community legislation when regulating chemicals, but also identifying ways of increasing synergies between all relevant pieces of legislation.

In 2011 the Commission is pursuing the study which aims to assess whether the current enforcement requirements of REACH and CLP Regulations could potentially be reinforced and how.

With regard to the POPs Regulation, the Commission will continue to stress to Member States the importance of the continuity of the information provided by them. Furthermore the Commission intends to improve the reporting format with the aim to make it more user-friendly and less time consuming. This can be achieved by establishing links to the SEIS (Shared Environmental Information System) initiative. A SEIS Regulation is currently under preparation. The Commission will also remind Member States about their reporting obligations on the application of the POPs Regulation, followed by legal enforcement action where necessary.

Export and import of dangerous chemicals

The Commission will present to the Council and the European Parliament a proposal for a recast of Regulation (EC) 689/2008 concerning the export and import of dangerous chemicals which addresses changes stemming from the Treaty on the European Union and the Treaty on the Functioning of the European Union. The proposal will also align that Regulation with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures and it will transfer certain administrative, technical and scientific tasks to the European Chemicals Agency. In addition the proposal seeks to clarify some technical issues.

The fifth Conference of the Parties of the Rotterdam Convention will be held in June 2011 and requires a thorough preparation by the Commission, which began in 2010 and is a priority in 2011. The administrative work as well as the software of the European Database on Export and Import of dangerous chemicals, which is the central tool for implementation of the PIC Regulation, will undergo major changes that need to be implemented smoothly.

Biocides

With regard to biocides, the Commission will continue to carefully monitor that the obligations of the Member States under the biocides review programme, including the delivery of competent authority reports, are adequately met and will take action where this is not the case. During the meetings of the competent authorities for biocides, which are held four times a year, the Commission asks for an update on significantly delayed dossiers. Member States are invited to give their reasons in order to solve outstanding issues or collect expert views.

In view of the acceleration in the product authorisation stage, the Commission in consultation with the Member States will focus on the smooth implementation of the process and ensure the operation of the Register for Biocidal Products to be in line with the requirements.

8.7.4. **Sector summary**

The Chemicals and Biocides sector of EU environmental law is characterised by substantial new developments. In the chemicals sector, though the main obligations under REACH started to apply from June 2008, the majority of registrations came in by December 2010. The Industry Classification and Labelling inventory will be established during 2011. The available information on implementation is currently being assessed. Although full compliance has been achieved concerning introduction of penalties, the Commission is looking at the way forward for a more harmonised approach in relation to these penalties.

As regards biocides, the revision of the current legislative framework is expected to bring important improvements to implementation. In addition, the review programme for biocides requires close monitoring in order to avoid excessive delays and the start of the product authorisation stage is a key challenge which will require attention in the forthcoming years.

8.8. Governance

8.8.1. **Current position**

8.8.1.1. General introduction

Governance

Public access to environmental information has always been considered as a key issue to promote greater awareness of environmental matters, a free exchange of views and more effective participation by the public in environmental decision-making. The EU decided as long ago as 1990 to introduce specific legislation; however, new impetus was given by the UN-ECE Aarhus Convention. Directive 2003/4/EC[258] expanded the access granted under the previous legislation. The objectives of the Directive are: a) to guarantee the right of access to environmental information held by or for public authorities and to set out the basic terms and conditions of its exercise; and b) to ensure that, as a matter of course, environmental information is progressively available and disseminated to the public using in particular computer telecommunication or electronic technology. Both 'passive', i.e. upon request, and 'active' dissemination of environmental information are covered by the Directive. Its scope is

[258] Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC, OJ L 41, 14.2.2003.*p. 26–32*

broad due to the fact that 'environmental information' and 'public authority' are both given very wide definitions. The latter covers not only national, regional and local authorities, including public advisory bodies, but also private non-governmental bodies providing public services or performing public administrative functions in relation to the environment. The Directive makes provision for both administrative and judicial review. Directive 2003/4/EC had to be transposed by 14 February 2005.

Public access to environmental information is complemented by the second pillar of the Convention. This was implemented by Directive 2003/35/EC[259] in respect of certain plans and programmes relating to the environment, as provided for in Article 2. The scope of the instrument is further extended to environmental impact assessment (EIA) and integrated pollution prevention and control (IPPC). The main objective of this Directive is to ensure effective public participation in decision-making linked to certain projects. This aim is further strengthened by its integrated access to information and access to justice provisions. This Directive had to be transposed by 25 June 2005.

The third pillar of the Aarhus Convention is access to justice, which guarantees the effectiveness of the previous two pillars, was partially implemented by the previously mentioned two Directives and Directive 2004/35/EC and by Regulation 1367/2006[260].

Other activities pursued by the Commission to enhance access to justice can be summarised as compliance promotion, which ensures a dialogue with Member States on possible problems of implementing EU law at national level. Amongst others, access to justice constitutes an integrated element of the Cooperation with Judges programme that was started in 2008. Another initiative which contributes to enhance access to justice is the e-Justice portal launched by the European Commission, where environmental justice shall be gradually included.

8.8.1.2. Report of work done in 2010

Governance

Despite some delays, all the Member States have transposed Directive 2003/4/EC. The Commission contracted an external consultant to carry out studies dealing with the conformity of national implementing legislation with the requirements of the Directive. Further to the finalisation of these studies in 2008 and their examination, in 2009, letters were sent to most Member States inviting them to comment on the findings of the studies.

Only few petitions submitted to the European Parliament raised problems of the application of Directive 2003/4/EC in the Member States. On the basis of information available or supplementary documents supplied in the framework of the petitions, there was no evidence that public authorities applied the Directive incorrectly.

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259 Directive 2003/35/EC of 26 May 2003, OJ L 156, 25.06.2003, p. 17. Public participation and access to justice concerning Directives 85/337/EEC and 96/61/EC are dealt with the relevant sections of this Report.

260 See Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p. 13).

On 1.09.2010 a hearing took place before the Court in case C-204/09, reference for a preliminary ruling, Flachglas Torgau GmbH. Advocate-General's opinion and judgement have not been issued yet. The Federal Administrative Court of Germany asked several questions which concern interpretation of terms used in the Directive, i.e. bodies and institutions acting in a legislative capacity, public authority, confidentiality of proceedings.

On 22.12.2010 the Court delivered preliminary ruling in case C-524/09 Ville de Lyon following the French Tribunal Administrative de Paris reference on the applicability of Directive 2003/4/EC to information on the sale of emission quota and the scope of "environmental information". The Court concluded that the information requested comes under the specific rules governing public reporting and confidentiality under Directive 2003/87/EC and Regulation 2216/2005. According to Regulation 2216/2005 that information is confidential and subject to specific rules on its access.

On 16.12.2010 the Court made a judgement in case C-266/09 *Stichting Natuur en Milieu*. This concerns preliminary ruling reference from the Dutch Administrative College (College van beroep voor het bedrijfsleven) on the applicability of Directive 2003/4/EC and the scope of "environmental information". In agreement with the Advocate General, the Court concludes, first, that the Directive applies in the present case because the decision denying environmental information was taken after the transposition deadline of the Directive (while the request for environmental information was made before that). Second, the definition of environmental information has to be interpreted broadly and therefore includes information submitted by operators in the application process for a permit under the Plant Protection Products Directive (91/414/EEC). Third, protection of commercial information is limited where it relates to information on emissions into the environment or refusal to disclose is outweighed by public interest.

Despite some delays, all the Member States have transposed Article 2 of the Directive 2003/35/EC. By 25 June 2009 the Commission had to send a report on the application and effectiveness of the Directive to other institutions. National reports were not provided for by the Directive, however the Commission considered it important to have information from the Member States. The requested contributions were forwarded, in certain cases, with an important delay, preventing from the elaboration of the report by the deadline. On the basis of the received information, it appears that the effective application of Article 2 in the Member States was limited, notably due to the fact that in most cases the SEA procedure (see the section on the SEA) was followed. There is no evidence that it was applied incorrectly.

On 14 April 2010 the Commission adopted a report on the application and effectiveness of Directive 2003/35/EC[261] compiled pursuant to its Article 5. The report is limited to an examination of Article 2 of the Directive (public participation concerning plans and programmes), due to the fact that aspects dealing with Article 3 of the Directive (public participation and access to justice in EIA) were examined in a Commission Report of 23 July 2009[262] and those elements relating to Article 4 of the Directive (public participation and access to justice under IPPC) will be dealt with in the report to be compiled pursuant to Article 17(3) of Directive 2008/1/EC.

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261 (COM(2010)143).

262 (COM(2009)378).

In the interests of clarity, the recast of Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control took place in 2010.[263] Provisions were taken over from the previous version of the Directive, however the scope of public participation and access to justice has been broadened to cases of granting or updating of a permit for an installation where the competent authority may, in specific cases, set less strict emission limit values taking into account aspects of cost efficiency.

The Seveso II Proposal for a Directive of the European Parliament and of the Council on control of major-accident hazards involving dangerous substances was adopted by the Commission.[264] As a result of the review process, on 21 December 2010 the Commission adopted a proposal for a new Directive that would repeal and replace the current Seveso I Directive by 1 June 2015. In order to make the broadest possible use of the Aarhus tools in EU law access to information, public participation and access to justice provisions have been included in the text.

The Cooperation with Judges programme continued during the year 2010, starting with a seminar in Paris on Nature, followed by a London seminar discussing the same topic and in September a Lithuanian venue which all had the integrated element of access to justice in environmental matters.

The role of the Court of Justice of the European Union (ECJ) in interpreting access to justice provisions is outstanding and becoming more and more important in broadening this area. The Court delivered its first judgment on the topic in 2009 stating that Ireland has failed to transpose certain elements of Directive 2003/35, (case C-427/2007). By requiring the notion of prohibitive costs in judicial environmental cases to be explicitly transposed, the Court provided a better guarantee of effective access to justice for the public and NGOs. In a preliminary ruling concerning the Swedish national rules (case C-263/08) the Court ruled on NGOs standing, stipulating that the national rule setting a requirement that only an association with at least 2 000 members may bring an appeal against a decision adopted on an environmental matter is against the provisions and the objective of wide access to justice set out in Directive 85/337/EEC.

Ongoing cases before the Court of Justice of the European Union

Since last year there are several new court cases based on the preliminary references before the ECJ all concerning access to justice and public participation. One is a Belgian case, the Belgian Council of State has referred several questions (in Joined Cases C-12/09 to 131/09, 134/09 and 135/09) on the interpretation of the EIA Directive and also on its provisions as modified by Directive 2003/35/EC, including its provisions on access to justice.

Another Belgian case is brought to the Court by the Belgian Constitutional Court under C-182/10. The reference intends to receive clarification on topics such as the application of

263 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Text with EEA relevance OJ L 334, 17.12.2010, p. 17–119 (BG, ES, CS, DA, DE, ET, EL, EN, FR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV) .

264 Seveso II Proposal for a Directive of the European Parliament and of the Council on control of major-accident hazards involving dangerous substances was adopted by the Commission. /* COM/2010/0781 final - COD 2010/0377 */.

article 1 (5) of the EIA Directive and its relation to the Aarhus Convention regarding the applicability of legislative acts by virtue of which projects may be exempt from the scope of the Directive and possible links to access to justice. The Court requested clarification also on the legal status of the Aarhus Convention Implementation Guide. A further issue of interpretation was raised in relation to the requirement of EIA under Article 6(3) of Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora.

In another case, a German administrative court of appeals has referred several questions (in Case C-115/09) concerning the interpretation of Article 3.7 of Directive 2003/35/EC, with respect to the admissibility of actions brought by environmental NGOs, even if there are no subjective rights affected, and the standard of review to be followed by national courts under that provision. The hearing of the latter was held in June 2010, and following this, Advocate General Sharpston has delivered her opinion in December 2010 indicating that NGOs need to be given wide standing in order to meet the objective of wide access to justice set by the Directive. It should also be mentioned that there is a pending case on the same topic before the Aarhus Compliance Committee.

Direct effect of the Aarhus Convention (AC) was also the subject of a preliminary reference. Regarding Article 9 (3) AC the Supreme Court of the Slovak Republic referred several questions to the ECJ amongst which one seeks ECJ's position whether it is possible to recognise Article 9, and in particular Article 9(3) AC, which has become a part of EU law, as having the direct applicability or direct effect of EU law (Case C-240/09). Advocate General Sharpston has delivered her opinion in which she indicates that she does not find that there is direct effect of the provisions referred to. However, she does mention that even though not directly effective, Member States national courts have an obligation to take into account these provisions of the AC.

In Case C-165/09 regarding the interpretation of provisions of the IPPC Directive and Directive 2001/81/EC of the European Parliament and of the Council of 23 October 2001 on national emission ceilings for certain atmospheric pollutants Opinion of Advocate General Kokott has been released in December 2010. This also has an access to justice relevance, as she indicated that the individuals have the right to appeal before a national court by virtue of the IPPC access to justice provisions whenever the annual national emissions ceilings (based on Directive 2001/81) are endangered.

In Case C-416/10 a reference for a preliminary ruling from Najvyšší súd Slovenskej republiky (NSSR) was sent to the ECJ to answer five questions relating to the SK system of public participation in EIA and IPPC procedures. The preliminary reference deals with the temporal effect of the EIA Directive, the role of national judges when applying EU law and also relates to the question of effective access to justice including the applicability of injunctive relief even though there is no explicit provision on this in the EIA Directive (as modified by Directive 2003/35/EC).

Petitions

During 2010, there was one petition handled on access to justice with regard to Ireland.

Compliance promotion

Several studies were carried out during the years 2008-2010 in order to screen the

implementation status of Member States of Directive 2003/35/EC on public participation.

The Commission places a particular emphasis on implementing and monitoring the Member States' application of already adopted EU law, namely the Access to Information and Public Participation Directives' provisions on access to justice. On the basis of the above studies and judgements the Commission has started exchanges with the Member States in order to establish a clear picture on how they comply with the provisions of the Directive.

8.8.2. **Evaluation based on the current situation**

Governance

According to Directive 2003/4/EC, no later than 14 August 2009 Member States had to communicate to the Commission their national reports on the experience gained in its application to enable it to submit a report to other EU institutions. A Guidance Document for these reports was drawn up by the Commission, in co-operation with Member State experts, in 2007.

During 2009, the Commission reminded Member States of the need to submit these reports. By the end of 2009, the majority of the Member States had responded to the Commission's reminder, but it proved nonetheless necessary to prepare action under Article 258 of the Treaty for those Member States who had failed to submit a report.

Although the national reports had yet to be analysed at the end of the year, it appeared that, in general, public authorities at national and regional level have applied Directive 2003/4/EC correctly. However, given the Directive's wide scope, it was less clear whether, at local level, notably in small municipalities or entities, public access to environmental information is always provided according to the relevant standards.

In addition, requests for clarification to the Commission services show that public authorities need to make greater efforts to inform the public adequately of their rights under the Directive. This right includes the right to make an administrative or judicial challenge at national level to a refusal by a public authority to provide requested information. In general, the Commission considers that these rights should be exhausted before the Commission itself examines the justification for an individual instance of refusal of access to information. Moreover, it appears that public authorities need to pay further attention to the active dissemination of environmental information to the public, in particular, through the Internet.

On the basis of information available and national contributions, there was no evidence that public participation concerning plans and programmes, provided for in Article 2 of Directive 2003/35/EC was incorrectly applied by Member States.

The implementation of public participation provisions related to EIA and IPPC is still under assessment by the Commission, further action shall be taken in light of the findings.

The Cooperation with Judges programme is considered to be a useful tool in raising awareness of access to justice requirements at EU level amongst judges. This can be regarded as a very effective way of fulfilling the requirements of the Aarhus Convention on establishing a high level of access to justice and also ensuring the implementation of access to

justice provisions of the Treaty of Lisbon[265]. Regarding the case-law of the ECJ, there is a growing number of cases on the most important issues related to access to justice (such as the admissibility rules of the public in review procedures, and access to environmental information, in particular on the definition of 'environmental information' and the issue of prohibitive costs that can be regarded as barring effective access to justice) which have an indisputable positive effect on better application of the Directive and on access to justice. It can be seen that based also on the implementation activity of the Commission there is a growing number of cases linked to access to justice.

8.8.3. **Evaluation results**

8.8.3.1. Priorities

Governance

The priority for the Commission is to verify the conformity of national legislation with the requirements of Directives 2003/4/EC and 2003/35/EC to ensure that these are applied correctly in practice by public authorities at all levels. In 2011, the Commission will analyse Member State responses to the enquiries it sent and will ensure the necessary further follow-up. By monitoring Member States' implementation of existing provisions, drawing attention to possible non-compliance and engaging in interactive discussions the compliance promotion pursued by the Commission in access to justice issues is considered very effective.

The Cooperation Programme with Judges has a very important role of ensuring the high competence of Member States judges and a high level of awareness of the latest developments in EU law, not only as regards case-law, but also recent changes to the Treaties, international activity. This also gives the possibility of national training centres to take into account the material developed during these sessions. Six seminars were organized in the first phase of implementation of the programme: four seminars dedicated to EU nature law (in Sofia, Bulgaria, May 2009; in Paris, France, February 2010 and in London, United Kingdom, March 2010) and three seminars for EU waste law.

More than 100 judges (judges and prosecutors, from courts of first instance to Supreme Courts) from 20 Member States participated in these seminars. The content of the seminars, mixing front-teaching presentations with case-studies, proved to be very well adapted to the audience. It was considered as very useful, there was a high attendance rate with high quality expert debates amongst the different speakers and participants.

The creation of a European e-Justice portal, of which the first release was launched on 16 July 2010 is an important step in enhancing access to justice in Member States. The environmental access to justice provisions in Member States are envisaged to be incorporated into the site during the course of 2011-2012, which shall also contribute to the effectiveness the procedures at Member States level.

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[265] The Charter of Fundamental Rights of the European Union confirms the right to an effective remedy for everyone whose rights and freedoms guaranteed by the law of the European Union are violated Article 47(1). OJ, C 364 18.12.2000, p.1 This is further strengthened by Article 19(1) of the Treaty on European Union incorporating the principle of effective judicial protection, OJ C 306, 17.12.2007.

Identifying shortcomings in implementation and compliance promotion is a key aspect of ensuring a higher level of application of EU law. Given the constantly evolving nature of national legislation it is in some cases a considerable challenge to be up to date of national legislation in force. This is the reason the different stakeholder events, contact with civil society, cooperation with judges and conferences can contribute to receive up to date and valid information on application of EU law.

Thus, it is a key priority to ensure a constant exchange of information with different stakeholders on the application of EU law in national procedures and to ensure that effective legal protection is guaranteed in environmental procedures.

8.8.3.2. Planned action (2011 and beyond)

Governance

As mentioned above, in 2011 the Commission will ensure an appropriate follow-up to the dialogue it initiated with Member States in 2010 in order to address transposition of the Aarhus-related Directives or concrete difficulties encountered by public authorities in enforcement.

Compliance promotion in access to justice issues is envisaged to continue beyond 2010. The on-going Cooperation with Judges Programme shall ensure a constant dialogue with national judges on access to justice. The topic elaborated and presented through three regional workshops will be EIA including provisions implementing the Aarhus Convention on public participation and access to justice. Development of training modules in other sectors of EU environmental law (impact assessment studies, water, industrial emissions) is foreseen.

Cooperation with national authorities to ensure effective implementation is crucial. The Commission will liaise with counterparts in implementing EU law at Member States level.

It is also envisaged to start preparation for the inclusion of environmental access to justice provisions in the e-Justice portal described above.

As it was presented above, the ongoing activity of ensuring implementation of Aarhus provisions through compliance promotion, the Commission is exploring further the possibility to extend Aarhus provisions to other areas where projects and plans are involved in secondary EU law.

8.8.4. **Sector summary**

Overall, Member States appear to apply the Directive on access to environmental information correctly, but the existing practice indicates that public authorities of all levels, in particular lower ones, need to make greater efforts to inform and respect the right of the public under the Directive.

Full transposition of Directives 2003/4/EC and 2003/35/EC in the Member States is also a priority for the Commission and in 2011 the Commission will pursue the exchanges opened with Member States in 2010.

Based on the reports submitted by Member States, the Commission will also prepare a report on implementation of Directive 2003/4/EC.

A very important element of implementing the Aarhus Convention and secondary law is the developing case-law of the ECJ in the field. In view of the developing case-law of the ECJ, the Commission takes all the necessary measures to implement the findings in Member States.

8.9. Environmental Liability

8.9.1. Current position

8.9.1.1. General introduction

Directive 2004/35/EC of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage (Environmental Liability Directive)[266] establishes a framework for environmental liability based on the "polluter pays" principle, with a view to preventing and remedying environmental damage.

8.9.1.2. Report of work done in 2010

The Environmental Liability Directive (ELD) was to be transposed by 30 April 2007. Transposition was slow and finally only completed by mid 2010 when the last Member State completed its transposing legislation. The main reasons for the transposition delays were identified by the Commission as linked with (1) existing legal frameworks, particularly where Member States had already advanced liability rules on environmental issues, (2) challenging technical requirements of the directive, such as the need for economic valuation of environmental damage, different remediation types and techniques and damage to protected species and natural habitats, and (3) the framework character of the ELD which led to further delays as the broader range of options instigated relatively longer debates at national level.

With completion of transposition, the last non-communication cases launched by the Commission in 2007 were closed in 2010. Currently, there is only one case open on the ELD, and this one is related to the non-conformity of the national transposition. The Commission has assessed and is further assessing the transposition as well as the implementation of the ELD and has also started bilateral meetings with the Member States in this regard with the aim that both sides may address questions and potential problems in relation to transposition and implementation.

Apart from the seven ECJ judgements of 2008 and 2009 as to non-communication, the only substantial judgement so far on the ELD was given by the Court on 9 March 2010 in a combined Italian case upon a request for a preliminary ruling (C-378/08 combined with C-379/08 and C-380/08). In its ruling the Court decided that the polluter-pays principle is directed at action at EU level and can hence not be directly invoked by individuals without intermediate implementing legislation at EU level. The Court also decided that Member States have broad discretion in laying down national rules implementing the polluter-pays principle and in imposing remedial measures on the operator under the ELD when they have to establish a causal link between the activity and the environmental damage (for instance they may apply a presumption of causality which has to be based on plausible evidence such as vicinity between activity and pollution or correlation between the used substances and the pollutants). The competent authority may also alter remediation measures which have already

[266] OJ L 143, 30.4.2004, p. 56.

been partly or fully implemented if those are obviously ineffective and if certain conditions are met (operator and landowner heard, account taken of remediation criteria in the ELD, grounds stated in the decision).

After the Commission's studies of 2008 and 2009 and extensive consultations with national experts and relevant stakeholders, the Commission adopted on 12 October the report on the effectiveness of the ELD in terms of environmental remediation and the availability of financial security for the activities covered by the scope of strict liability of the ELD[267]. The ELD Report concludes that transposition of the Directive was slow due to the reasons outlined above, and that this lead to limited implementation and experience so far which – together with the very divergent application by Member States of implementation options offered by the Directive (e.g. on extension of the scope of biodiversity damage or on the optional incorporation of the permit and state of the art defences) - impacted negatively on the developments of financial security instruments and markets.

Petitions

During 2010, there were no petitions on this subject.

8.9.2. **Evaluation based on the current situation**

The abovementioned ELD Report concluded that insufficient availability of data on the effectiveness of the Directive in terms of remediation and insufficient developments of financial security instruments did not allow the Commission to draw reliable conclusions as to the core question whether mandatory financial security should be established at EU level. Developments in those Member States which have introduced or will introduce mandatory financial security at national level (around one third of the Member States) and also developments in relation with large scale accidents (the *Deepwater Horizon* incident in the Gulf of Mexico, the red mud accident at *Ajka* in Hungary) will have to be further monitored in order to draw reliable conclusions.

The Report has however identified some fields and measures for improving the implementation of the ELD: promoting information exchange and communication between key stakeholders, awareness raising of individual operators and financials security providers, development of interpretation guidance and establishment of records or registries of ELD cases.

Another, broader implementation report by the Commission will be due by April 2014, based on Member States application reports due by 2013. Besides several other questions, that report will have to revisit the same questions on effectiveness and financial security which had to be left unanswered in the report of 2010, then on the basis of the evidence gathered until 2013/2014.

Apart from the application of the significance criteria (Annex I of the Directive) and the application of the appropriate measures to ensure the remedying of environmental damage

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[267] Report from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions under Article 14(2) of Directive 2004/35/EC on the environmental liability with regard to the prevention and remedying of environmental damage, COM(2010) 581 final.

('primary', 'complementary' and 'compensatory' remediation according to Annex II of the Directive), the proper functioning of financial security instruments will be significant for the successful implementation of the ELD in the Member States in particular as regards effective remediation of environmental damage. Furthermore, the Commission continued to provide support to the Member States through interpretation of open questions in expert meetings and in particular through an EU supported research project developing a tool-kit on the remediation methods. The results of the research programme REMEDE were made available in 2008[268].

8.9.3. **Evaluation results**

8.9.3.1. Priorities

All Member States completed the transposition of the ELD and the Commission presented its report under Article 14(2) (COM(2010) 581 final). Therefore, the last horizontal non-communication case was closed in 2010. The next priority for the Commission is to ensure that the Environmental Liability Directive is correctly transposed in all Member States. Therefore the Commission started to assess the conformity of the domestic legislation with the ELD and has to conclude this exercise in cooperation with Member States in 2011 and 2012 and where necessary launch legal enforcement actions.

8.9.3.2. Planned action (2011 and beyond)

The Commission's efforts need to continue to ensure that the ELD is correctly transposed. Apart from continuing the examination of the conformity of the transposing legislation of the Member States and taking enforcement action as necessary, the Commission will continue to discuss questions of interpretation and application of the ELD with government experts in Commission organised meetings as well as in bilateral meetings.

The Commission will also strive to draw increasing attention to the areas identified in the ELD Report which deserve more efforts in order to improve the implementation of the ELD (information exchange, awareness raising, interpretative guidance, ELD-cases registries by the Member States).

8.9.4. **Sector summary**

Transposition of the ELD was finally completed in 2010, but its application still remains relatively limited. The Commission will have to promote the application and implementation of the ELD through measures identified in the ELD Report. It also works towards completing the conformity assessments and maintains dialogues with Member States on transposition and implementation. Finally, the Commission will further continue monitoring developments at national level, in particular with regard to financial security instruments and markets.

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[268] Available on the Internet at the official Website of Resource Equivalency Methods for Assessing Environmental Damage in the EU (REMEDE): <http://www.envliability.eu/>

9. INFORMATION SOCIETY AND MEDIA

9.1. General Overview

In *Information society and media* the regulatory framework for electronic communications continued to face a number of incorrect implementation issues, despite a decreasing number of open complaints and genuine efforts on the part of most Member States. Late transposition has generated non-communication cases in relation to the revised GSM Directive.

One key challenge in some Member States remains the independence of national regulatory authorities (NRA's), which is a prerequisite for ensuring fair and effective regulation of the sector. Moreover, the Commission had to intervene against some Member States that have imposed undue charges on operators. Finally, ensuring the effective implementation of consumer rights remained another key challenge for several Member States.

Commission guidance, such as the 2010 Recommendation on Regulated Access to Next Generation Access (NGA) networks, is intended to provide increased regulatory clarity to all market players, which is necessary to stimulate investment in fast and ultra-fast broadband.

Finally, in the run-up to the May 2011 deadline for transposing the revised regulatory framework for electronic communications, guidance papers have been provided to Member States, as well as bilateral assistance, on request.

In the audiovisual sector, in spite of preventive work with a view to ensuring timely and effective implementation of the Audiovisual Media Services Directive by the end of 2009, a sizeable number of infringements for non-communication of transposition measures were launched in 2010.

Regarding the Public Sector Information Directive, while a review is planned for 2012, a few Member States were still struggling with the correct implementation of the existing Directive, regarding for instance licensing and charging models that facilitate the availability and re-use of public information resources.

9.2. Electronic communications

9.2.1. Current position

9.2.1.1. General introduction

The EU **regulatory framework for electronic communications** came into force in 2002. Its five Directives are transposed into the national law of all 27 Member States[269]. The Framework Directive outlines the general principles, objectives, and procedures. The Authorisation Directive creates a regime of general authorisations for providers of communications services. The Access and Interconnection Directive sets out rules for a multi-carrier marketplace, ensuring, in particular, access to networks and services and interoperability. The Universal Service Directive guarantees basic rights for consumers and

[269] Directive 2002/21/EC (Framework Directive), Directive 2002/20/EC (Authorisation Directive), Directive 2002/19/EC (Access Directive), Directive 2002/22/EC (Universal Service Directive) and Directive 2002/58/EC on privacy and electronic communications (further referred to as the ePrivacy Directive).

minimum levels of availability and affordability. The e-Privacy Directive covers protection of privacy and personal data communicated over public networks.

Amendments to this regulatory framework, included in the **Better Regulation Directive**[270] and the **Citizens' Rights Directive**[271] were adopted in November 2009[272] and entered into force in December 2009. The aim of this telecoms reform is to consolidate a competitive internal market through more consistent national regulatory approaches, reinforce consumer protection and users' rights, and provide for more effective spectrum management and implementation. The new rules have to be transposed into national laws of all Member States by 25 May 2011. The new Regulation[273] establishing the new European Telecoms Authority called "Body of European Regulators for Electronic Communications (BEREC)" is directly applicable.

The **Roaming Regulation**[274] was introduced in 2007 because roaming charges were at excessive levels and constituted a barrier to the Internal Market. In June 2009, the Regulation was extended for a further three years up to June 2012 and to include SMS and data roaming services (at wholesale level only) in addition to voice[275].

The **Directive amending the GSM Directive** on the frequency bands to be reserved for the coordinated introduction of public pan-European cellular digital land-based mobile communications in the Community[276] came into force in November 2009. It provides for the introduction in the 900 MHz band of new wireless services, starting with UMTS services. The deadline for implementing the revised GSM Directive was 9 May 2010.

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270 Directive 2009/140/EC of the European Parliament and of the Council of 25 November 2009 Directives 2002/21/EC on a common regulatory framework for electronic communications networks and services, 2002/19/EC on access to, and interconnection of, electronic communications networks and associated facilities, and 2002/20/EC on the authorisation of electronic communications networks and services.

271 Directive 2009/136/EC of the European Parliament and of the Council of 25 November 2009 amending Directive 2002/22/EC on universal service and users' rights relating to electronic communications networks and services, Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector and Regulation (EC) No 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws

272 OJ L 337, 18.12.2009, p. 37; OJ L 337, 18.12.2009, p. 11.

273 Regulation (EC) No 1211/2009 of the European Parliament and of the Council of 25 November 2009 establishing the Body of European Regulators for Electronic Communications (BEREC) and the Office

274 Regulation (EC) No 717/2007 of the European Parliament and of the Council of 27 June 2007 on roaming on public mobile telephone networks within the Community and amending Directive 2002/21/EC, OJ L 171, 29.6.2007, p. 32.

275 Regulation (EC) No 544/2009 of the European Parliament and of the Council of 18 June 2009 amending Regulation (EC) No 717/2007 on roaming on public mobile telephone networks within the Community and Directive 2002/21/EC on a common regulatory framework for electronic communications networks and services http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:167:0012:0023:EN:PDF

276 OJ L 274, 20.10.2009, p. 25.

While most of the **radio spectrum harmonisation decisions** adopted until 2009[277] on the basis of the Radio Spectrum Decision 626/2002/EC[278] were implemented by the majority of Member States for some Decisions this was not yet the case. In particular, the Commission services were monitoring whether and how Commission Decision 2009/766/EC of 16 October 2009 on the harmonisation of the 900 MHz and 1 800 MHz frequency bands for terrestrial systems capable of providing pan-European electronic communications services in the Community had been implemented by Member States.

On the basis of the Decision No 626/2008/EC of 30 June 2008 of the European Parliament and of the Council of Decision on the **selection and authorisation of systems providing mobile satellite services (MSS)**[279], the Commission adopted on 13 May 2009 a Decision No 2009/449/EC selecting two operators of pan-European systems[280]. Implementation of the pan-European MSS framework has now been taken-over by the Member States. The Commission

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277 Commission Decision 2005/928/EC of 20 December 2005 on the harmonisation of the 169,4-169,8125 MHz frequency band in the Community (frequency band originally designated for the ERMES paging system); Commission Decision 2005/513/EC of 11 July 2005 on the harmonised use of radio spectrum in the 5 GHz frequency band for implementation of Wireless Access Systems including Radio Local Area Networks (WAS/RLANs); Commission Decision 2005/50/EC of 17 January 2005 on the harmonisation of the 24 GHz range radio spectrum band for the time-limited use by automotive short-range radar equipment in the Community; Commission Decision 2004/545/EC of 26 July 2004 on the harmonisation of radio spectrum in the 79 GHz range for the use of automotive short-range radar equipment in the Community; Commission Decision 2006/771/EC of 9 November 2006 on the harmonisation of the radio spectrum for use by short-range devices (SRD); Commission Decision 2006/804/EC of 23 November 2006 on harmonisation of the radio spectrum for radio frequency identification (RFID) devices operating in the ultra high frequency (UHF) band; Commission Decision 2007/90/EC of 12 February 2007 amending Decision 2005/513/EC of 11 July 2005 on 5 GHz WAS/RLAN; Commission Decision 2007/98/EC of 14 February 2007 on the harmonised use of radio spectrum in the 2 GHz frequency bands for the implementation of systems providing mobile satellite services (MSS); Commission Decision 2007/131/EC of 21 February 2007 on allowing the use of the radio spectrum for equipment using ultra-wideband technology in a harmonised manner in the Community (UWB); Commission Decision 2007/344/EC of 16 May 2007 on harmonised availability of information regarding spectrum use within the Community; Commission Decision 2008/294/EC of 7 April 2008 on harmonised conditions of spectrum use for the operation of mobile communication services on aircraft (MCA services) in the Community; Commission Decision 2008/411/EC of 21 May 2008 on the harmonisation of the 3400 - 3800 MHz frequency band for terrestrial systems capable of providing electronic communications services in the Community; Commission Decision 2008/432/EC of 23 May 2008 amending Decision 2006/771/EC on harmonisation of the radio spectrum for use by short-range devices (SRD); Decision 2008/477/EC of 13 June 2008 on the harmonisation of the 2500-2690 MHz frequency band for terrestrial systems capable of providing electronic communications services in the Community; Commission Decision 2008/671/EC of 5 August 2008 on the harmonised use of radio spectrum in the 5875 - 5905 MHz frequency band for safety related applications of Intelligent Transport Systems (ITS); Commission Decision 2008/673/EC of 13 August 2008 amending Decision 2005/928/EC on the harmonisation of the 169,4-169,8125 MHz frequency band in the Community; Commission Decision 2009/343/EC of 21 April 2009 amending Decision 2007/131/EC on allowing the use of the radio spectrum for equipment using ultra-wideband technology in a harmonised manner in the Community; Commission Decision 2009/381/EC of 13 May 2009 amending Decision 2006/771/EC on harmonisation of the radio spectrum for use by short-range devices and Commission Decision 2009/766/EC of 16 October 2009 on the harmonisation of the 900 MHz and 1 800 MHz frequency bands for terrestrial systems capable of providing pan-European electronic communications services in the Community.

278 Decision of the European Parliament and of the Council of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community (Radio Spectrum Decision), OJ L 108, 24.4.2002, p.1.

279 OJ L 172, 2.7.2008, p. 15.

280 OJ L 149, 12.6.2009, p. 65.

services closely monitor measures taken at national level, notably thanks to a dedicated working group of the Communications Committee on the implementation of Decision 2009/449/EC.

9.2.1.2. Report of work done in 2010

Enforcing effective implementation of the regulatory framework for electronic communications remained a priority in 2010. In line with the Commission Communication on better monitoring of the application of Community law[281], the Commission services have continued to avoid the need for recourse to infringement proceedings by making use of bilateral contacts with the relevant national authorities, including via the EU Pilot system. They also provided general guidance on implementation requirements via the Communications Committee (COCOM) and the Radio Spectrum Committee (RSC).

During 2010, in view of the implementation of the revised EU regulatory framework by May 2011, the Commission presented to Member States in COCOM several guidance documents on the interpretation of specific provisions, such as provisions on independence, universal service, network sharing, and privacy. In addition, the Commission continued to discuss with the Member States in COCOM the implementation of the European emergency number '112' and of the reserved '116' numbers for harmonised services of social value.

In addition to non-communication cases and cases of non-compliance with judgments of the Court of Justice in the area of electronic communications, infringement priorities in 2010 continued to focus in particular on structural issues and consumer protection.

Structural issues included in particular the functioning and the independence of the national regulatory authorities. As regards independence, the Commission has systematically monitored the requirement for independence of national regulatory authorities (NRAs), and has taken action when necessary. Firstly, clear rules regarding the formal establishment of the NRA structures should ensure the independence and impartiality of the NRA. The rules for dismissal of NRA management are fundamental in this regard. An infringement is still pending in Slovenia in this respect, while a Slovakian case and a Romanian could be closed following legislative amendments. Secondly, Member States must ensure that NRAs are legally distinct from and functionally independent of electronic communications networks and services providers ('effective structural separation'), not least when Member States retain ownership or control of electronic communications undertakings. Concerns remained in this regard in some Member States e.g., Romania, Latvia, and Lithuania. In the latter case, the Commission decide to refer Lithuania to the Court of Justice.

Attention was also being paid to the full application of the Community consultation procedure involving national regulatory authorities and the Commission which aims to consolidate the internal market for electronic communications (Article 7 procedure). A key principle of the regulatory framework for electronic communications is that undertakings should not be subject to economic *ex ante* regulation unless they have been found to be dominant in a relevant market, on the basis of a thorough market analysis by their national regulatory authority (NRA). Two infringement cases against Germany and Poland were pending, concerning the absence of communication to the Commission of mobile termination rates and

[281] COM(2002) 725, of 11 December 2002.

costing methodology, and wholesale broadband access rates and costing methodology respectively.

An increasing area of concern has been the imposition of specific telecom taxes on providers of electronic communications, in contradiction with the EU rules on administrative charges, under which charges can be levied on telecoms operators to cover only certain administrative and regulatory costs (mainly authorisations and regulatory functions). Reasoned opinions were sent to France and Spain in this regard.

A second priority concerned the **protection of consumer rights**. Consumer protection goes hand in hand with the growth and diversification of electronic communication services and a growing number of service providers. Infringement cases in this respect included: the functioning of the European emergency number 112 (Italy); the possibility to keep one's number when changing telecom operators, thereby allowing consumers to fully benefit from competition (Bulgaria); an effective mechanism to settle disputes between consumers and service providers that offers a more flexible, cheaper, and less formal alternative to court proceedings (Luxembourg); respect for consumer privacy (United Kingdom, Italy).

The general state of implementation of the regulatory framework, monitored in close contact with the national authorities and other stakeholders, is reflected inter alia in the Commission's sector specific annual Progress Report addressed to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions[282]. The Commission continued to monitor implementation of the Roaming Regulation, which, by means of its extensive six-monthly roaming data collection exercise, is providing a key input to the Commission's monitoring activities. The Commission services also closely monitor measures taken at national level to implement the initiative on mobile satellite services (MSS) following the selection of operators by the Commission, notably thanks to a dedicated working group of the Communications Committee on the implementation of Decision 2009/449/EC.

The Commission monitors the correct application of the provisions contained in the EU regulatory framework, also via contacts with stakeholders and complaints received from EU citizens. The online web tool **'EU Pilot'**, set up to provide quicker and better solutions to problems arising in the application of EU laws, has been increasingly used to facilitate contacts with the participating Member States on the implementation of the EU rules relating to electronic communications.

Management of infringements

As regards infringement proceedings, during 2010, the Commission opened 17 new cases, including seven cases for non communication of measures transposing the revised GSM Directive (concerning Spain, France, Italy, Cyprus, Hungary, Austria, and United Kingdom).

Seven cases were taken to the second phase with a reasoned opinion being sent to the Member States concerned on the following issues: the independence of the NRA – effective structural separation (Romania), fixed number portability (Bulgaria), rules on alternative dispute resolution (Luxembourg), the notification of mobile termination rates in accordance with

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282 "Progress Report on the Single European Electronic Communications Market - 2009 (15th Progress Report)", COM(2010)253 of 25 May 2010. The report covering 2010 is not yet available.

Article 7 of the Framework Directive (Germany), telecom wholesale price rules (Poland) and administrative charges (France, Spain).

The Commission decided to refer two cases to the Court of Justice under Article 258 TFEU: one concerning the independence of the NRA in Lithuania, and one on the implementation of rules on confidentiality of electronic communications in the United Kingdom.

At the same time, seven cases were closed following progress in Member States. As the definition of subscriber was amended in Polish law in line with the requirements of the Framework Directive, the relevant case was closed by the Commission. Following modifications of the national law, the Spanish case related to universal service, as well the Swedish case in relation to dispute resolution, have been closed. As calls to the European emergency number "112" in Italy became effectively handled, the relevant case has been closed as well. Other closed cases concerned the rules for dismissal of NRA management in Romania and Slovakia. Both cases could be closed following modifications of the national law. Finally, the case of non implementation of spectrum decisions concerning the 169 MHz frequency band in Bulgaria was closed following clarifications provided on the use of frequencies for security and defence purposes in line with the said Decisions.

On the other hand, not all the Member States have complied with the regulatory framework following infringement proceedings, and in 2010 the Court of Justice ruled on three cases [Poland (C-545/08), Belgium (C-222/08) and Portugal (C-154/09)]. The Commission was closely following whether the judgments of the Court of Justice were fully complied with. In particular, as Italy was not complying with the judgement concerning the availability of caller location information for 112 emergency number, it was decided to refer Italy to the Court of Justice under Article 260 TFEU which allows imposing financial sanctions on Member States that have not complied with a judgement of the Court of Justice. In view of the progress made by Italy to comply with the judgement, the Commission decided to suspend the application to the Court of Justice. At the same time, the Commission was able to close the case against Poland (with regard to a judgement C-492/07 delivered in 2009) as the issues were resolved.

In addition, the Commission was able to close 10 presumed infringements based on complaints. At the end of 2010, there were only two complaints pending. These complaints concerned the notification of mobile termination rates in Poland and the rules on confidentiality in Ireland in view of an alleged limited scope of the provisions implementing Article 5 of the ePrivacy Directive.

The Commission continues to frequently issue press releases on the opened proceedings. These press releases are available on the implementation and enforcement website dedicated to Information Society and Media sector[283] together with overview tables.

In November 2010, the European Law Academy ERA on behalf of the Commission organised the 5th seminar for national judges and the NRAs. The seminar topics have been further expanded. In 2009, the new package amended substantially the telecom framework and brought new challenges for all the players involved including national judges and regulators. Furthermore, a Digital Agenda for Europe, one of the key initiatives of the EU 2020 strategy, has been adopted in May 2010. The seminars were well received and participants indicated their strong interest in the continuation of such seminars, as such seminars contribute to

283 http://ec.europa.eu./information_society/policy/ecomm/implementation_enforcement/index_en.htm

creating a network of qualified judges applying EC telecom rules in a consistent and efficient manner.

Petitions

Six petitions on the regulatory framework were registered in 2010. These petitions concerned mainly Germany and Italy and involved consumer protection issues e.g. the quality of service, telecom prices including of national and international SMS services, as well as ePrivacy issues. All were answered without opening an infringement proceeding.

European Court of Justice

Finally, the European Court of Justice issued several important judgments on substance in the electronic communication area in 2010, both following infringement proceedings and requests for preliminary ruling under Article 267 of the TFEU Treaty. These covered among others universal service - providing special rates to certain categories of low-income or disadvantaged customers (C-222/08 - *Commission v Belgium*, C-389/08 – *Base and others*), designation of universal service provider (C-154/09 - *Commission v Portugal*), broadband retail regulation without prior market analysis (C-545/08 - *Commission v Poland*), out-of-court dispute resolution (C-317/08 – C-320/08 - *Alassini and others*), prohibition of combined sales (C-522/08 – *Telekomunikacja Polska S.A.*) or number portability – charges to subscribers (C-99/09 – *Polska Telefonia*).

Changes underway

On 20 September 2010, the Commission adopted three initiatives which are part of the **Digital Agenda for Europe**[284], one of the seven flagship initiatives of the Europe 2020 strategy for smart, sustainable and inclusive growth[285].

Firstly, the Commission adopted a Recommendation on Regulated Access to Next Generation Access (NGA) networks, which sets out a common regulatory approach for access to new high-speed fibre networks that requires national telecoms regulators to ensure an appropriate balance between the needs to encourage investment and to safeguard competition[286]. This is intended to provide increased regulatory clarity to all market players, which is necessary to stimulate investment in fast and ultra-fast broadband.

Secondly, the Commission made a proposal for a Decision of the European Parliament and of the Council to establish a five year policy programme to promote efficient radio spectrum management and, in particular, ensure that sufficient spectrum is made available for wireless broadband[287]. Efficient and competitive use of spectrum in the EU is expected to also support innovation in other policy areas and sectors such as transport and the environment.

Thirdly, the Commission adopted a Broadband Communication that sets out a coherent framework for meeting the Digital Agenda's broadband targets and, in particular, outlines how best to encourage public and private investment in fast and ultra-fast broadband networks[288].

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284 COM (2010)245.
285 COM (2010) 202.0
286 2010/572/EU, OJ L 251, 25.9.2010.
287 COM(2010) 471.
288 COM (2010)472.

It calls on EU Member States to introduce operational broadband plans for high and ultra high speed networks with concrete implementing measures, it provides guidance on how to cut investment costs and indicates how public authorities may support broadband investment, including making better use EU funds. It also announces plans by the European Commission and the European Investment Bank to bring forward broadband finance instruments.

In 2010, three spectrum harmonisation Decisions were adopted by the Commission: Decision 2010/166/EU of 19 March 2010 on harmonised conditions of use of radio spectrum for mobile communication services on board vessels, Decision 2010/368/EU of 30 June 2010 amending Decision 2006/771/EC on harmonisation of the radio spectrum for use by short-range devices and Decision 2010/267/EU of 6 May 2010 on harmonised technical conditions of use in the 790-862 MHz frequency band for terrestrial systems capable of providing electronic communications services. In addition, the Commission adopted a Recommendation on the authorisation of systems for mobile communication services on board vessels (MCV services)[289].

Volume of enquiries and priorities

While the 27 Member States have completed the formal transposition of the regulatory framework in 2007, there were still 27 proceedings for incorrect implementation pending at the end of 2010. The Commission was however able to close 10 presumed infringements based on complaints leaving only two complaints pending at the end of 2010.

In the light of complaints and issues raised by market players and national regulatory authorities, priorities remained the same as in the previous year: the functioning of the national regulatory authorities, the application of the Community consultation (Article 7) procedure, and consumer rights, including privacy. In addition, increasing attention was paid to administrative charges unduly imposed on telecom operators. Compliance with judgments of the Court of Justice continued to be an issue.

9.2.2. **Evaluation based on the current situation**

Overall, the implementation of the regulatory framework is working to bring competition to electronic communications markets, to the benefit of consumers in terms of prices and innovation. While examples of best practice are available across the range of regulatory and market issues, there continues to be considerable scope for further benefits to flow from a reinforced single market, strengthened competition and a reduction in inconsistent regulation.

A number of non-conformity and incorrect application issues remains, which require attention and appropriate follow-up with a continued focus on the functioning of the structural issues and consumer rights.

9.2.3. **Evaluation results: priorities and planned action (2011 and beyond)**

Specific attention will be paid in 2011 to the transposition of the revised regulatory framework for electronic communications, due by 25 May 2011. The swift and consistent implementation of the revised regulatory framework for electronic communications is an explicit priority of the Digital Agenda for Europe.

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289 2010/167/EC.

Priorities for 2011 regarding correct implementation are expected to remain similar to those of the reporting year. The number of cases is expected to remain about the same as in the reporting year.

In electronic communications, monitoring is expected to focus again on structural issues, such as the functioning and the independence of the national regulatory authorities. Independence of regulators is essential for the proper functioning of the electronic communications markets, and has been further strengthened in the revised framework. Attention will continue to be paid to the application of the Community consultation procedure involving national regulatory authorities and the Commission which aims to consolidate the internal market for electronic communications (Article 7 procedure). Attention will also be paid to undue administrative charges imposed on providers of electronic communications.

Another priority concerns the protection of consumer rights, including privacy. This issue is expected to remain a priority, not least as a result of the reinforcement of several consumer protection provisions in the revised regulatory framework. The Commission will continue to closely monitor the implementation of the Roaming Regulation which has ensured that consumers benefited from significant cost savings using mobile phones while in another Member State. Specific attention might also have to be devoted to the monitoring of spectrum refarming processes under the revised GSM Directive and to the full implementation in accordance with the Decision on mobile satellite systems.

9.3. The Audiovisual and Media

9.3.1. Current position

9.3.1.1. General introduction

The main instrument is the Audiovisual Media Services Directive[290] (hereafter the "AVMS Directive"). In March 2010, a codified version of Directive 89/552/EEC and its subsequent amendments were adopted[291]. It repealed all previous versions and renumbered the Audiovisual Media Services Directive as Directive 2010/13/EU. Non-binding measures include the Recommendation on Film Heritage[292] and the Recommendation on the protection of minors and human dignity in audiovisual and information services[293].

9.3.1.2. Report of work done in 2010

The activities focused mainly on the monitoring and assessment of the transposition of the Audiovisual Media Services Directive (Directive 2010/13/EU). In total, 25 infringement cases had to be opened for non-communication of measures transposing the AVMS Directive in

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290 Directive 89/552/EEC of the European Parliament and of the Council of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) as last amended by Directive 2007/65/EC of 11 December 2007, OJ L 332 of 18 December 2007.

291 OJ L 95, 15.4.2010, p. 1–24.

292 Recommendation of the European Parliament and of the Council of 16 November 2005 on film heritage and the competitiveness of related industrial activities, OJ L 323 of 9 December 2005, p. 57.

293 Recommendation of the European Parliament and of the Council of 20 December 2006 on the protection of minors and human dignity and on the right of reply in relation to the competitiveness of the European audiovisual and on-line information services industry, OJ L 378 of 27 December 2006, p. 72.

2010. In June, reasoned opinions were sent to 12 Member States while many cases were closed.

As regards correct implementation, a great deal of attention was devoted to the monitoring of the implementation of provisions governing commercial communications. The monitoring of advertising restrictions carried out by independent experts covered not only quantitative restrictions, but also qualitative aspects of TV advertising, e.g. the rules on the protection of minors. It addressed bother advertising and other forms of commercial communications such as product placement.

In September 2010, the Commission adopted its ninth report on the promotion and distribution of European works and independent production[294], and an accompanying staff working document[295]. In July 2010, the Commission adopted the Second Report on the challenges for European film heritage from the analogue and the digital era. In November 2010, the Council adopted Council Conclusions on film heritage, including the challenges of the digital era (17-18 November 2010). A study on challenges of the digital era for film heritage institutions was also launched.

Preparatory work for the first implementation report of the Audiovisual Media services Directive was also carried out. In June 2010, a study on the levels of Media Literacy in Member States was launched. In October 2010, a questionnaire was sent to the Member States regarding the implementation of the Audiovisual Media Services Directive and stricter rules adopted. In addition, a workshop on codes of conduct governing advertising in food high in fat, salt and sugar took place.

Changes underway

Questions faced by all Member States in the process of transposition of the AVMS Directive continued to be clarified at two meetings of the Contact Committee set up under Article 29 of the Directive as well as at one meeting of the Working Group of EU Regulatory Authorities. In 2010, priority has been given to a thorough examination of national implementing measures.

The AVMS Directive changed the number and order of subsidiary jurisdiction criteria for satellite (re)transmissions. In 2010, the Contact Committee completed an exercise to identify those audiovisual media services which would change jurisdiction at the end of the transposition period as a consequence of that reversal of criteria. In addition, questions concerning the practical application of the reporting obligation on European and independent works were discussed both at the Contact Committee and Regulators meetings. Finally, a call for tender for a study on the implementation of the provisions of the Audiovisual Media Services Directive concerning the promotion of European works in audiovisual media services was launched.

Volume of enquiries and priorities

In the light of complaints and parliamentary questions received so far, attention focused on the following areas: television advertising, protection of minors, prohibition of incitement to

294 COM (2010)450.
295 SEC(2010)995.

hatred, and freedom of expression. In addition, the issue of events of major importance for society, with the cases brought before the Court of Justice against the UK and Belgian measures, has been followed closely.

The number of complaints on alleged pornographic content transmitted during daytime and without encryption via satellite broadcasts decreased due to the cooperation procedure put in place under the aegis of the Commission between regulators as complaints about alleged pornographic content can be addressed directly to the regulator of the complainant's country for appropriate follow-up. Other issues arose concerning cross border gambling advertising and the concurrent application of the Audiovisual Media Service Directive and of the Authorisation Directive to digital terrestrial television services.

9.3.2. **Evaluation based on the current situation**

The transposition of the revised AVMS Directive has been delayed in many Member States. It is too early, therefore, to give a definitive view on the benefits of the review. At the same time, the number of complaints regarding pornographic content and alleged hate speech has decreased, in part thanks to cooperation between national regulators.

9.3.3. **Evaluation results: priorities and planned action (2011 and beyond)**

In general, the number of cases of infringements and petitions is expected to stay at the same level as in previous years. The correct implementation of the AVMS Directive is expected to be central. A first implementation report of the Audiovisual Media services Directive is expected to be adopted by the end of 2011. Monitoring of audiovisual commercial communication rules is expected to remain central.

9.4. Public Sector Information

9.4.1. **Current Position**

9.4.1.1. General introduction

Public Sector Information (PSI) is the single largest source of information in Europe (e.g. maps and satellite images, legislation, statistics and company registers) and is used as raw material for a variety of added-value products and services. **Directive 2003/98 on the re-use of public sector information** (PSI Directive) aims at enhancing an effective cross-border reuse of PSI and to limit distortions of competition on the EU market.

The Directive is built around two pillars of the internal market: transparency and fair competition. It contains provisions on transparency of conditions and non-discrimination, on prohibition of cross-subsidies and exclusive arrangements, on procedures regarding handling of re-use requests, on upper limits for charging, as well as on practical means to facilitate finding and using the material available for re-use. Ultimately, the Directive aims at a change of culture in the public sector, creating a favourable environment for the re-use of its information resources.

The Commission applies the principles of the PSI Directive also to its own documents through a Commission re-use policy. Commission Decision 2006/291/EC, Euratom goes beyond the Directive by applying charges based on (at most) marginal costs and by making all documents re-usable. Examples are EUROSTAT's statistical data, Commission translation

memories, the EU law database EUR-Lex and studies.

9.4.1.2. Report of work done in 2010

In 2010, the Commission completed the evaluation of national provisions implementing the PSI Directive and took appropriate steps against some Member States, who have not transposed the PSI Directive correctly. In June 2010, the Commission decided to refer Poland to the Court of Justice of the EU. In September 2010, the Commission closed infringement cases against Italy and Sweden after these Member States adopted new legislation correctly implementing the PSI Directive.

The Commission also analysed several complaints concerning incorrect application of the PSI Directive. In particular, the complaints against Denmark and Latvia have been successfully dealt with under the EU Pilot system. The exchange of views with national authorities has proved that there was no need to open infringements against the Member States concerned.

In conformity with the Commission Communication on better monitoring of the application of Community law (COM (2002)725), the Commission continued to pursue various accompanying measures in addition to formal infringement procedures. It has been closely monitoring the implementation process and providing technical assistance.

In particular, in June 2010 the Commission organised and chaired its annual PSI Group meeting for Member State experts and stakeholders with a view of providing assistance in implementation and facilitating the exchange of good practices. In addition, the Commission continued its deployment actions by participating in seminars and workshops organised in the Member States, networking across Europe and co-funding a project for promoting pan-European PSI re-use (European PSI platform). The objective of these actions is to stimulate developments of a stronger and more transparent environment for the PSI re-use markets.

In 2010, the Commission also carried out preparatory work for the 2012 review of the Directive as foreseen by the Commission's Communication on the application of the PSI Directive from 2009[296]. The Commission analysed the current situation and collected information in view of an Impact Assessment and possible legislative proposals. The Commission also organised an on-line stakeholders' consultation.

Moreover, the Commission undertook studies on PSI re-use. As foreseen by the 2009 Communication on the application of the PSI Directive, the Commission carried out a comprehensive study for monitoring the most important PSI markets and assessing the existence of possible exclusive agreements concluded by public sector bodies. Nine Member States were surveyed. The research has yielded a very few leads to potential exclusive agreements in the Member States and the overall results of the study are reassuring and positive.

Finally, the Commission also published a report on Economic Indicators and Case Studies on the PSI pricing models. Moreover, it launched calls for tenders on the assessment of the different models of supply and charging for public sector information, as well as on revised PSI market value for Europe. The results of these studies are expected to contribute to the review of the PSI Directive.

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296 COM(2009)212.

9.4.2. **Evaluation based on the current situation**

Directive 2003/98 on the re-use of public sector information is a first ever Directive in this area. A positive evolution and progress has taken place since the adoption of the Directive. At the time of the adoption of the PSI Directive, the issue of the re-use was barely known to the Member States and to other stakeholders. Seven years later, the PSI Directive is a well established legal instrument, which focuses the attention of governments, public sector holders and re-users. The online stakeholders' consultation conducted in autumn 2010 gathered around 600 replies showing a keen interest in the PSI Directive and in the re-use matters.

Yet, the full potential of the PSI Directive has no been unleashed. Barriers to re-use of public sector information still exist. The analysis of the current situation resulting from the state of implementation and application of the PSI Directive in the Member States as well as from various consultations and studies should indicate the most appropriate means for the Commission to propose in its revision of the PSI Directive.

9.4.3. **Evaluation results**

9.4.3.1. Priorities

The Digital Agenda for Europe lists the revision of the PSI Directive among its key actions. Accordingly, the Commission will focus on preparation of the Impact Assessment for the revision of the PSI Directive and will envisage possible legislative amendments. Besides, the Commission will continue its enforcement action as well as the relevant deployment measures.

9.4.3.2. Planned action (2011 and beyond)

In 2011, the Commission will focus on preparing the Impact Assessment with a view of a further revision of the PSI Directive, planned for 2012. Taking into account the progress made and the results of various studies, the Commission will consider, inter alia, the possibility of proposing legislative amendments to the PSI Directive.

The Commission will also continue to monitor closely implementation and application of the PSI Directive in the Member States. It will continue its enforcement action, by conducting ongoing infringement cases and launching new ones if appropriate.

The Commission will keep on working on its deployment actions by facilitating the exchange of good practices and by providing technical assistance through close administrative cooperation with the Member States, the PSI expert group, as well as through other measures such as the European PSI platform.

9.4.4. **Sector summary**

A positive evolution and progress has taken place. Governments can stimulate content markets by making public sector information available on transparent, effective and non-discriminatory terms. This is an important source of potential growth of innovative online services. However, the full potential of PSI re-use has not yet been unleashed. The ongoing works within the Impact Assessment for the review of the PSI Directive will show whether legislative amendments to the PSI Directive are necessary.

In the meantime, the Commission will continue to closely monitor implementation and application of the PSI Directive by facilitating the exchange of good practices and awareness-raising, and by launching infringement procedures where necessary.

More information on the re-use of public sector information:
http://ec.europa.eu/information_society/policy/psi/index_en.htm

9.5. Electronic Signatures

9.5.1. Current Position

9.5.1.1. General introduction

The principal instrument is **Directive 1999/93/EC on a community framework for electronic signatures**[297]. The implementing measures include the Commission Decision on the minimum criteria for the designated bodies[298] and the Commission Decision on the generally recognised standards for some electronic signatures products[299]. There were no infringement proceedings open. One complaint regarding the alleged discriminatory treatment of electronic signature solution providers established in other member states than Germany could be closed 2010.

9.5.1.2. Report of work done in 2010

Building on the Commission Action Plan on e-signatures and e-identification to facilitate the provision of cross-border public services in the Single Market[300], whose main objective is to promote the implementation of mutually recognised and interoperable electronic signatures and e-authentication solutions in Europe, Decision 2009/767/EC was adopted in 2009 and amended by Decision 2010/425/EU in July 2010. The Decision sets out measures facilitating the use of procedures by electronic means through the 'points of single contact' under Directive 2006/123/EC.

It also created an obligation for Member States to establish and publish by 28 December 2009 their trusted list of supervised/accredited certification service providers issuing qualified certificates to the public[301].

At the beginning of 2010, the Commission has mandated the European standardisation organisations to rationalise the current electronic signatures **standardisation framework**, which was expected to start at the beginning of 2011.

9.5.2. Evaluation based on the current situation

To address problems of mutual recognition and cross-border interoperability of electronic signature, standardisation work has been requested to the relevant European Standardisation

297 OJ L 13, 19.01.2000, p.12.
298 OJ L 298, 16.11.2000, p.42.
299 OJ L 45, 15.07.2003, p.45.
300 COM(2008)798.
301 See at: http://ec.europa.eu/information_society/policy/esignature/eu_legislation/trusted_lists

Organisation. In addition, in its "Digital Agenda for Europe" communication[302], the Commission has proposed a key action directed at the creation of a well functioning digital single market with a view to eliminate the current barriers to the use of e-signatures across Europe. Action focuses on the revision of the e-Signatures Directive with the aim to adapt existing legislation to the new technological and legal challenges of the digital world and to remove electronic barriers created by the Member States with the adoption of different legal and technical solutions.

9.5.3. Evaluation results: priorities and planned action (2011 and beyond)

In keeping with the above key action, the European Commission intended to launch a public consultation in early 2011 on how electronic signatures and electronic identification (eID) and authentication can help the development of the European Digital Single Market. The results of this consultation will feed into the Commission's review of the existing eSignature Directive.

10. MARITIME AFFAIRS AND FISHERIES

10.1. General introduction

With the Lisbon Treaty, fisheries have become one of the areas of shared competence between the Union and the Member States. However, the Treaty attributes exclusive competence the Union for the conservation of marine biological resources under the common fisheries policy. This means that only the Union can legislate in this latter field unless Member States have been explicitly empowered to do so by a legally binding Union act. The objectives for the common fisheries policy have been maintained unchanged in the new Treaty.

The main body of secondary legislation enacted in the field of fisheries to date, i.e. the conservation regime and the concomitant control framework, remain matters of exclusive Union competence. The full set of rules adopted under the Common Fisheries Policy can be found on the following website: http://ec.europa.eu/fisheries/index_en.htm.

The conservation regime in its current version is governed by the basic Council Regulation (EC) No 2371/2002 on the conservation and sustainable exploitation of fisheries resources under the common fisheries policy[303]. The control, inspection and enforcement system is circumscribed by the new Council Regulation (EC) No 1224/2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy[304]. As for external fisheries, Council Regulation (EC) No 1005/2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing[305] serves to ensure compliance with international conservation and management measures.

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[302] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions A Digital Agenda for Europe, COM(2010)245, 19.5.2010.

[303] OJ L 358, 31.12.2002, p. 59.

[304] OJ L 343, 22.12.2009.

[305] OJ L 286, 29.10.2008, p. 1.

10.2. Report of work done in 2010

Most provisions of the new Control Regulation (EC) No 1224/2009 have become applicable from 1 January 2010. In this context, work concentrated on the elaboration of the necessary implementing rules throughout the entire year 2010. Priority had also to be given to this process since some of the provisions of the said Regulation shall not apply until after the corresponding implementing rules have entered into force. In the meantime, this process has resulted in the adoption of Commission Implementing Regulation (EU) No 404/2011[306].

Another priority consisted of a sustained and, in the end, successful control campaign to protect the important bluefin tuna stocks in the Atlantic and the Mediterranean. The control campaign unfolded in most sensitive circumstances, namely the attempts to list bluefin tuna under the Convention on Trade in Endangered Species (CITES) in early 2010 and the identification of the Union under the Trade Measures Recommendation of the International Commission for the Conservation of Atlantic Tunas (ICCAT) for non-compliance with certain conservation and management measures established by that organisation. It served to secure compliance with the conservation measures for this fish stock and thus to attain the twofold objective of full respect of the catch quotas allocated to Member States and proper discharge of the Union's international obligations vis-à-vis ICCAT. The campaign resulted in the Commission's deciding early closures of the purse seine fisheries of France and Greece[307] and of Spain[308]. The closure now forms the subject matter of an action in annulment, which an operator brought before the General Court[309].

Priority was also given to the control of cod fisheries in the Baltic Sea in pursuance of the control action plan undertaken by Poland in the framework of Council Regulation (EC) No 338/2008 providing for the adaptation of cod fishing quotas to be allocated to Poland in the Baltic Sea from 2008 to 2011[310]. Action in this field has been addressed in the Report from the Commission to the Council on the implementation of the Polish National Action Plan in the framework of Council Regulation (EC) No 338/2008[311].

On 31 May 2010, transitional derogations to the minimum mesh size and minimum distance from the coast for the use of fishing gear under Council Regulation (EC) No 1967/2006 concerning management measures for the sustainable exploitation of fishery resources in the Mediterranean Sea[312] lapsed. This led to a sustained effort to induce Member States to ensure full compliance with the requirements of the said Regulation by their vessels and operators.

On 28 May 2010, the Commission adopted Regulation (EU) No 468/2010 establishing the EU list of vessels engaged in illegal, unreported and unregulated fishing[313]. This Regulation (together with the underlying basic Regulation (EC) No 1005/2008) has been attacked by way of an action in annulment brought before the General Court[314].

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[306] OJ L 112, 30.04.2011, p. 1.
[307] See Commission Regulation (EU) No 498/2010, OJ L 142, 10.06.2010, p. 1.
[308] See Commission Regulation (EU) No 508/2011, OJ L 149, 15.06.2010, p. 7.
[309] Case T-367/10, Bluefin Tuna Hellas Maritime Company vs. Commission.
[310] OJ L 107, 17.04.2008, p. 1.
[311] SEC(2010) 434 final 16.08.2010.
[312] OJ L 36, 08.02.2007, p. 6.
[313] OJ L 131, 29.05.2010, p. 22.
[314] Case T-337/10, Seatech International and Others vs. Council and Commission.

By way of its Decision of 12 November 2010, the Commission initiated the conduct by Malta of an "administrative inquiry" into irregularities that had become apparent in the Maltese scheme for the control and enforcement of conservation and management measures pertaining to bluefin tuna in the Mediterranean. This was the first case where the Commission had recourse to the novel compliance tools under the new Control Regulation (EC) No 1224/2009.

Furthermore, much work had to be devoted to the adaptations of the common fisheries policy to the novelties introduced by the Lisbon Treaty, e.g. the switch to co-decision as the ordinary legislative procedure, delegated powers and implementing powers as completely novel decision-making procedures, the handling of pending legislative procedures which had to be continued under the new Treaty provisions, the issue of implementation ("transposition") of international conservation and management measures established by Regional Fisheries Management Organisations and the alignment of existing basic acts on delegated powers.

Finally, the preparation of legislative proposals for the Reform of the Common Fisheries Policy entered its decisive phase in the second semester of 2010.

In this context, work mainly concentrated on those cases where infringement proceedings had already resulted in judgements of the Court, i.e. the driftnet cases against France[315] and Italy[316] and the case concerning the landing and marketing of undersized fish in Spain[317]. Regular contacts with Member States continued and inspection missions were conducted throughout the year 2010 in order to verify whether and to what extent the Member States concerned have complied with the respective judgments of the Court.

Apart from that, the policy of formally bringing each detected instance of non-compliance to the Member States' attention was continued and led to a consistent use of the EU Pilot.

10.3. Evaluation based on the current situation

Compliance with and enforcement of applicable rules is a cornerstone of the Common Fisheries Policy given that violations adversely affect the conservation and sustainable use of fisheries resources with possibly grave consequences in the longer term. Still, Member States' compliance records lack coherence.

There is also a link with the status of fish stocks and the endemic overcapacity of the Community fishing fleet. Where fishing opportunities decrease, Member States should step up their control and enforcement efforts.

The new Control Regulation (EC) No 1224/2009 has brought into focus that a credible conservation policy presupposes strict compliance with and enforcement of applicable rules. The new control system has introduced manifold novel compliance tools vis-à-vis both operators (e.g. a point system for serious infringements) as well as Member States (e.g. administrative inquiries and action plans, strengthened conditionality of financial assistance, closure of fisheries and or deduction of catch quotas for failures to comply with the objectives of the common fisheries policy and emergency measures).

[315] Judgement of 05.03.2009 in Case C-556/07, Commission vs. France.
[316] Judgement of 29.10.2009 in Case C-249/08, Commission vs. Italy.
[317] Judgement of 22.12.2008 in Case C-189/07, Commission vs. Spain.

Those new compliance tools will ensure that the Commission stays with its core activity of controlling and verifying the implementation of the rules of the Common Fisheries Policy by Member States. They strengthen the Commission's capacity to intervene proportionately to the level of non-compliance and, when applied properly either in separate procedures or, as the case may be, synchronised with infringement proceedings, they allow for a well-measured co-operative and at the same time decisive approach towards compliance failures on the side of Member States. It is expected that this will enhance compliance records at Union level, bring about a level playing field in this area and result in a genuine compliance culture eventually.

It is also expected that this will tackle one other feature of compliance failures in the fields of fisheries, namely the fact that, in most cases, non-compliance consists of administrative malpractice on the side of Member States. The new compliance tools will allow handling general and ongoing failures such that infringement proceedings can then be instituted in those cases which can make a difference.

10.4. Evaluation results

10.4.1. **Priorities**

The most tangible result was that a systematic approach to infringements could be upheld and that priority-setting and anticipatory planning has become the common denominator of all control activities carried out by DG MARE in 2010.

It was also decisive that the first case of recourse to the novel compliance tools under the new Control Regulation (EC) No 1224/2009, namely the administrative inquiry into the Maltese system for the control of conservation and management measures pertaining to the most sensitive bluefin tuna stock, was possible in 2010.

Furthermore, most of the pre-contentious cases opened in 2010 could be resolved in a satisfactory manner via the EU Pilot.

10.4.2. **Planned action (for 2011 and beyond)**

Conceptual work on the synchronisation of the novel compliance tools under the new Control Regulation (EC) No 1224/2009 and infringement proceedings will be completed in 2011 with due regard to the first experiences that can be gained in the application of those novel tools.

Ongoing infringement cases will be handled in such a way that the underlying compliance failures by Member States can be removed or, if ever Member States persevered, can result in appropriate operational follow-up (mainly in those cases where the Common Fisheries Policy is particularly put at risk, e.g. illegal driftnetting).

In the context of the reform of the Common Fisheries Policy, the Commission plans to present a proposal for a root-and-branch reform in the course of 2011, which will give priority to a long-term perspective and which will re-emphasise the decisive importance of compliance and of the rule of law as indispensable building blocks of the policy.

10.5. Summary

In the fields of *fisheries*, the finality of all preventive and repressive action is to ensure the

effectiveness of conservation and management measures adopted under the Common Fisheries Policy. Yet, Member States much too often favour short-term solutions when it comes to compliance with and the enforcement of applicable rules. The new Control Regulation (EC) No 1224/2009 has brought into focus that a credible conservation policy presupposes strict compliance with and enforcement of applicable rules.

The Common Fisheries Policy is based on the provisions of Article 3, 4 and 38 to 43 of TFEU. The full set of existing rules adopted under the Common Fisheries Policy can be found on the following website: http://ec.europa.eu/fisheries/index_en.htm .

11. INTERNAL MARKET AND SERVICES

11.1. Freedom to provide services and freedom of establishment (other than financial services)

Current position

General introduction

The relevant legal framework for this sector consists of Article 49 of the Treaty on the Functioning of the European Union (TFEU) on the freedom of establishment as well as of Article 56 of the TFEU on the freedom to provide services.

This framework is complemented by a number of Internal Market Directives which develop these freedoms as regards specific service activities or specific legal aspect (Postal Services Directive[318], the Directive on the legal protection of conditional access services[319] and the E-commerce Directive[320]).

It is also complemented by Directive 2006/123/CE on services in the Internal Market[321], a horizontal instrument adopted in December 2006 which had to be implemented by the Member States by the end of 2009. In addition to the two Comitology decisions already adopted in 2009[322], a Comitology decision has been adopted on the 28th of July 2010 regarding the establishment, maintenance and publication of trusted lists of certification service providers supervised/accredited by Member States.[323]

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318 Directive 2008/6/EC of the European Parliament and of the Council of 20 February 2008 amending Directive 97/67/EC with regard to the full accomplishment of the internal market of Community postal services, OJ L 52, 27.2.2008.

319 Directive 98/84/EC of the European Parliament and of the Council of 20 November 1998 on the legal protection of services based on, or consisting of, conditional access - OJ L 320, 28.11.1998, p. 54–57.

320 Directive 2003/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce), OJ L 178 of 17.7.2000, p. 1.

321 O.J. L 376/36 of 27.12.2006.

322 One on the use of the Internal Market Information System ("IMI") for the exchange of information between administrations as foreseen in the Services Directive (Commission Decision 2009/739/EC of 2 October 2009, OJ L 263 of 7 October 2009) and another one on practical arrangements concerning the use of electronic procedures in the Points of Single Contact (Commission Decision 2009/767/EC of 16 October 2009, OJ L 299 of 14 November2009).

323 Commission Decision 2010/425/EU amending Decision 7009/767/EC, OJ L 199 of 31 July 2010.

Report of work done in 2010

A. Management of legislation, including in committees and working groups

The Services Directive sets out a comprehensive modernisation programme for national administrations and is more than just a piece of European legislation to be implemented into national law. Until the end of 2010 Member States have adopted more than 1.000 implementing laws, some of which were "omnibus laws" containing dozens of changes to different pieces of legislation. At the same time, the Commission maintained its commitment from 2007 to provide assistance and guidance to Member States throughout the whole implementation process. As in 2009, bilateral meetings have been held with Member States as well as meetings of the "Expert Group on the implementation of the Services Directive" on specific questions of the implementation. The main aim of those meetings was to ensure a similar level of understanding by all Member States of the work required and the priorities for action.

An important and major part of the work carried out in 2010 concerned the "mutual evaluation" process, an innovative and evidence-based exercise of "peer review" foreseen by the Services Directive. By putting in place a structured dialogue between Member States it has created transparency as to the results of the implementation of the Services Directive and it has helped identify and promote good regulatory practices. Discussions have also helped to foster a habit of dialogue. Following the agreement in October 2009 of the High Level Group of the Competitiveness Council, the Commission and Member States on the methodology to use for what was to be a major exercise involving 30 countries[324] and covering close to 35.000 requirements, work started in 2010 with Member States meeting between January and March in "clusters" of five countries each to discuss the situation in those individual countries and prepare further discussions. It then continued between March and October with "plenary meetings" at which specific requirements and the main services sectors covered by the Directive were examined[325]. Interested parties were called upon to provide their views in a public consultation which was conducted between the end of June and mid September 2010.

Taking the results of the process of "mutual evaluation" of the Services Directive as a starting point, the Commission adopted a Communication[326] setting out an ambitious work programme that should improve and further develop the Single Market for services. [327]

As regards the Points of Single Contact (PSC), a so called "first generation" of PSC's is in place in 22 Member States. In five Member States (Greece, Italy, Romania, Slovenia and Slovakia) the electronic PSCs are not operational yet. Even if progress has been achieved with

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[324] The three EFTA countries part of the EEA Agreement - Iceland, Lichtenstein and Norway- also participated.

[325] The following services sectors were identified by Member States as a priority: construction and property related services, tourism and related services, food and beverage services, services of regulated professions, wholesale and retail services, business services and private education services. The Services Directive Committee was informed on the results of the process at its meeting of 15 October 2010.

[326] "Towards a better functioning Single Market for services – building on the results of the mutual evaluation process of the Services Directive" - Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, COM (2011)20.

[327] See below section on "Evaluation based on current position".

regard to the online completion of procedures though the PSC, difficulties remain as to their cross border use. Technical solutions for the identification and authentication of service providers, e-signatures and e-documents rely mostly on national means and their recognition and/or validation is not always ensured. In order to facilitate the cross-border use of e-procedures, and in particular the use of e-signatures, the Commission has so far adopted two Decisions (2009/767/EC and 2010/425/EU). The first Decision had in particular obliged Member States to establish so-called trusted lists (TLs) of their certification service providers (who issue qualified certificates) in order to facilitate verification of certificates for e-signatures. The second Decision (2010/425/EU) obliges Member States to provide machine processable forms of these TLs which means that applications can be created to automate their use. This greatly facilitates the cross-border validation of e-signatures. Given that the TLs can be used very widely, not limited to the use under the Services Directive, the impact of the Decision has been widely recognised by stakeholders, including commercial application builders who have already put in place some commercial services based on the TLs. The Commission has created a central list of Member States' TLs which further facilitates their use.

A number of Member States are also cooperating in the framework of the Competitiveness and Innovation Programme (CIP) Large Scale Pilot "Simple Procedures Online for Cross-border Services" (SPOCS)[328]. 16 Member States participate in SPOCS directly and the rest can rely on the results of SPOCS when they so wish. SPOCS should lead to additional technical solutions for more user friendly PSCs[329].

Enhanced PSCs, as fully fledged e-Government centres have also been highlighted as a priority in the recently adopted "Digital Agenda for Europe"[330]. Beyond the legal obligations foreseen by the Services Directive, Member States are encouraged to make available via their PSCs additional services that are vital for supporting/encouraging their use and that are strongly called for by the business community and the European Parliament, such as procedures relating to taxation (registration for VAT or income tax) or social security registration.[331] Another prerequisite to stimulate cross-border trade is the provision of information and forms in other EU languages through the PSCs. 11 Member States already provide translations to varying degrees (mostly in English and/or the language(s) of neighbouring countries). Most other Member States have plans to provide translated content of their PSCs in the near future.

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328 CIP pilots are financed half by the Commission (DG INFSO) and half by the consortium where in addition to Member States, academia, and industry is present. The involvement of industry is essential to ensure the practical take up of solutions developed.

329 SPOCS also enhances the PSCs with additional technical solutions for content syndication (to have the data on PSCs updated each time a change takes place for example at a relevant authority's webpage). It also foresees some assistance for businesses with mapping the documents that are required in Member States as some documents may exist in one Member State and not in another or they may have different names (like anti-maffia declarations which could be an extract of penal register in another one).

330 "A Digital Agenda for Europe", COM(2010) 245 final/2.

331 This is strongly called for by the European Parliament in its recently adopted report on the implementation of the Services Directive (2010/2053(INI). See: http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A7-2011-0012&language=EN

Concerning the use of IMI, the "Internal Market Information System"[332], the network of authorities registered in IMI for the purposes of administrative cooperation in the area of services is consolidating. End of 2010 there were around 5200 authorities which had been registered in the system across the Member States to deal with information exchanges on service providers. The number of registered authorities varies widely according to the Member States depending on their size, their administrative structure and their choice to organise their network of authorities in a more centralised or decentralised manner. In general, a solid structure for administrative cooperation appears to be in place in the large majority of Member States.

Article 20(2) of the Services Directive requires Member States to make sure that service recipients, in particular consumers, are not made subject to discriminatory requirements imposed by service providers on grounds of their nationality or place of residence. In 2010 the Commission has continued its work in order to ensure that this non-discrimination obligation is correctly implemented by Member States and enforced by national authorities and courts. In particular, building on the results of the study on business practices liable to fall under Article 20 carried out by an external contractor throughout 2009, the Commission has discussed the first experiences with the application of national legislation implementing this provision with Member States and consumer assistance bodies. Based on this work, the Commission intends to publish, by the end of 2011, guidelines to Member States aiming at facilitating the practical application of this provision.

Concerning the assistance for recipients of services as foreseen in Article 21 of the Services Directive, a meeting of national bodies providing assistance to recipients of services, business as well as consumers, when they want to have access to services from another Member State was held on 1st October 2010. First experiences of the network as well as members' experiences in cases of discrimination on the basis of nationality/place of residence have been discussed.

B. Management of Infringements

In order to ensure that work is speeded up in the Member States that had not yet finalised **implementation of the Services Directive**, the Commission sent in June 2010 a reasoned opinion for **non-communication** of the national transposition measures of the Services Directive to 12 Member States.[333]

The **control of the application of Articles 49 and 56 of TFEU** remains an important task. Infringement proceedings in 2010 concerned the various areas of the Internal Market.

As in previous years, a number of infringement procedures concerned health services:

- The Commission referred Germany to the Court of Justice[334] over its rules on reimbursement of cost of care services received in other Member States. The German rules on care insurance scheme ("*gesetzliche Pflegeversicherung*") provide that care services received during a temporary stay in another Member State will not be

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332 IMI is an electronic network which allows for direct communication and exchange of information between competent authorities in different Member States and thus facilitates the administrative cooperation required by the Services Directive.

333 Austria, Belgium, Cyprus, France, Germany, Greece, Ireland, Luxemburg, Portugal, Romania, Slovenia and the United Kingdom – see IP/10/821.

334 IP/10307.

reimbursed to the same level as care services received within Germany. On several occasions, the Court of Justice has recognised patients' rights to receive reimbursement of medical expenses incurred in other Member States through their health insurances. In the Commission's view, the same rule also applies in relation to care services received in other Member States.

- In another case concerning the reimbursement of medical expenses, Slovakia received a reasoned opinion[335] as under Slovak legislation, patients from Slovakia cannot be certain that they will be reimbursed for medical treatment received in other Member States in line with the principle of the freedom to provide services.
- Denmark received a reasoned opinion[336] because Danish law does not allow the recognition of medical prescriptions issued by a doctor in another Member State (except for Sweden and Finland). In the Commission's view, this is not justified by the public health reasons cited by the Danish authorities, especially given the fact that the medicines will be delivered on the basis of a medical prescription legally issued by a doctor in another Member State. Furthermore, Swedish and Finnish prescriptions have been recognised for some time without having produced the harmful effects claimed by the Danish authorities.

The Court delivered four decisions C-211/08 of 15.06.2010, C-173/09 of 5.10.2010 (preliminary ruling) C-512/08 of 5.10.2010 C-490/09 of 27.1.2011 relating to the issue of reimbursement of healthcare in another Member State, out of which three were actions for failure to fulfil obligations referred by the Commission.

According to the judgement of 15June 2010, patients who need to receive unscheduled healthcare because of their state of health during a temporary stay in another country will be reimbursed the amount that is reimbursable under the legislation of the Member State where the treatment is received. This is in line with the European Health Insurance card provided for by Regulation 1408/71 now 883/2004. However, in certain cases the reimbursed amount is lower than the amount which would have been reimbursed if the healthcare had been provided in the patient's home country. The Court considered that the restrictions to the freedom to provide hospital treatment services, tourist services or educational services (even in particular for the situation of elderly persons or of those suffering from chronic or pre-existing illness) alleged by the Commission were too uncertain and indirect. The Court considered that the mechanisms established by Regulation 1408/71 were based on the principle of overall compensation of risks and should be respected.

In its preliminary ruling of 5th October 2010, the Court confirmed its case-law regarding reimbursement of hospital care. The Court confirmed that Article 56 TFUE and Article 22 of Regulation 1408/71 could apply at the same time. Regarding Article 56 TFUE, the Court considered that national legislation which excludes, in all cases, reimbursement in respect of hospital treatment given in another Member State without prior authorisation amounts to an unjustified restriction to the freedom to provide services. The Court clarified that reimbursement of medical costs without the prior authorisation provided for by Article 22 (1)(c)(i) of Regulation 1408/71 can only be required within the limit of the cover provided by the sickness insurance scheme of the Member State of registration of the patient.

In a judgement also delivered on 5th October 2010, the Court considered that an authorisation may be required for the reimbursement of non hospital treatments when these treatments

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335 IP/10/505.

336 IP/10/505.

require the use of major medical equipment, such as the ones exhaustively listed in the national legislation at issue, which are especially onerous and therefore made subject of a planning policy and subsidies in the Member State of affiliation and subsidised by it.

Finally, in its judgement of 27th January 2010 , the Court declared that, by failing to provide a reimbursement mechanism regarding costs of laboratory analyses and tests carried out in another Member State, Luxembourg has failed to fulfil its obligations under Article 56 TFEU. By contrast, the Court considered that the Commission failed to place before the Court all the information needed to enable the Court to establish that the dispensing conditions for laboratory analyses and tests were incompatible with Article 56 TFUE.

Regarding the freedom of establishment, the Court delivered on 16 December 2010 a judgement relating to restrictions on the ownership by non-biologists of a stake in a firm operating biological analysis laboratories. Like in its judgments regarding "pharmacies", the Court stated that such restrictions were justified by the protection of public health, were appropriate for securing attainment of this objective and did not go beyond what is necessary for attaining that objective. By contrast, the Court considered that by prohibiting biologists from holding shares in more than two companies formed in order to operate jointly one or more biomedical analysis laboratories, the French Republic has failed to fulfil its obligations under Article 49 TFUE.

In other areas, the Commission has sent a reasoned opinion to the Netherlands[337], asking the Member State to review its rules on the **posting of workers** who do not (yet) enjoy free movement within the EU. Under Dutch rules, businesses must obtain work permits for certain staff members before they can be temporarily posted to the Netherlands to perform services. This applies to staff members from Bulgaria and Romania, as well as to staff members from non-EU countries who live and work legally in the Member State of their employer. The Commission considered that this work permit requirement constitutes a breach of the rules of the Treaty regarding the freedom to provide services.

The Commission has also decided to take action against Belgium before the Court of Justice[338] for failure to fulfil its European obligations by requiring self-employed service providers from other Member States to make a **prior declaration before being able to provide temporary services** in Belgium (so called 'Limosa' declaration). The fact that the Belgian authorities in a general way are making the exercise of a fundamental freedom subject to a prior administrative step is a serious restriction on the freedom to provide services. In order to be compatible with EU law, such a restriction must be justified and proportionate according to the consistent rulings of the Court. But the justifications cited by the Belgian authorities regarding self-employed workers have not convinced the Commission.

The Commission has also decided to refer Belgium to the Court of Justice[339] over its rules on **temporary employment agencies**. According to EU principles, any company providing a service in a Member State (in conformity with the national law in force) has the right to provide the same service without restrictions in all other Member States. However, Belgium imposed a number of requirements on temporary employment agencies established in other

337 IP/10/304.
338 IP/10/680.
339 IP/10/307

Member States that wish to provide their services in Belgium.[340] In particular, their scope was limited to activities related to human resources and they had to take on a specific legal form. In the Commission's view, these requirements were disproportionate and had the effect of limiting competition in this field. This situation was also likely to disadvantage employers and Belgian workers who used the services of these companies.

In the area of **patent agents,** Portugal was referred to the Court while Austria received a letter of formal notice requesting full information on its execution of the Court's ruling of 11 June 2009 (Case C-564/07). Despite its stated intention to change its rules in this area, Portugal still requires any patent agent established in a Member State who wishes to act before the Portuguese trademarks and patent office as a temporary service provider to be registered in advance with and be accredited by the Portuguese authorities. Furthermore, registration is subject to a prior check on professional qualifications. In the Commission's view, these requirements breach EU rules on the freedom to provide services and the recognition of professional qualifications.

A reasoned opinion was sent to Greece[341] asking for an amendment of its legislation on the **minimum prices** that lawyers should charge for their services. The Commission considered that these national rules have the effect of restricting lawyers from other Member States from operating in Greece and limiting the range of legal services on offer to Greek citizens.

The Court issued a ruling on 21 January 2010 in which it considered the bilateral agreement concluded between Germany and Poland on work contracts in Germany to be applied in a discriminatory way. Only German undertakings could call on Polish subcontractors for the performance of work contracts in Germany. Undertakings established in other Member States that were considering providing services in Germany could not benefit from the agreement and thus could not call on Polish subcontractors to provide their services. The Commission held the view that such an interpretation neither complied with EU Treaty rules on the freedom to provide services nor with the rules of the Treaty of Accession. Following the Court ruling, Germany accepted to modify the interpretation it had given so far of the provisions of the said agreement. Consequently the Commission closed its infringement proceedings against Germany.

In its ruling of 18 November 2010, the Court confirmed its case law on the temporary provision of services by condemning Portugal for its legislation relating to construction services which did not make any distinction between establishment and temporary provision of services.

The Commission decided on 18 March 2010 to close infringement proceedings against France concerning **restrictions on the establishment of retail stores** which were incompatible with Article 49 TFEU, following the adoption of a new legislation in 2008 and the application measures in 2009.

On **establishment of pharmacies,** the Court of Justice, on 1 June 2010, ruled in Joined Cases C-570/07 and C-571/07 that Article 49 TFEU, in principle, does not preclude national legislation that provides for a minimum distance between pharmacies of 250 metres and for a minimum number of 2800 inhabitants per pharmacy. Nevertheless, it considered that Article

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340 Certain of these restrictions have been lifted in 2010.

341 IP/10/498

49 TFEU precludes such national legislation in so far as the basic '2 800 inhabitants' and '250 metres' rules prevent, in any geographical area which has special demographic features, the establishment of a sufficient number of pharmacies to ensure adequate pharmaceutical services. It left it to the national court to ascertain this. Finally, the Court ruled that the Asturias provisions that benefited those applicants for a pharmacy licence with experience in Asturias are incompatible with Article 49 TFEU.

In July 2010, the Commission decided to refer Greece to the Court of Justice regarding restrictions on the **establishment of petrol stations**. The Commission challenged, in particular, the incoherence of the provisions relating to the location of new petrol stations' installations, the need to provide a fire safety study certified by a sworn expert registered in Greece and the minimum distances between petrol stations. The referral was suspended in September 2010 as the adoption of a new legislation was planned for November. The new Greek law was finally adopted on 7.12.2010. It is currently under examination.

As far as **Concessions** are concerned, the Commission challenged the Italian legislation concerning authorisations for the public domain (beaches), which granted a preference to the outgoing holder of the authorisation. Following the letter of formal notice, the Italian authorities amended the law, but the new provisions still foresee a restriction, notably the automatic renewal of the authorisation. A complementary letter of formal notice was sent in May 2010. In their reply, the Italian authorities notified a draft law abolishing the abovementioned restriction.

Concerning the question of **restrictions on land acquisition,** the European Commission sent on 28.6.2010 a reasoned opinion to Germany to ensure non-discriminatory treatment for EU citizens with regard to the sales of land by municipalities, as a number of them have introduced for the sale of land a special system aimed at favouring residents. The Commission considers that these provisions of German municipalities do not comply with the principles of non-discrimination, free movement of EU citizens, free movement of workers, freedom of establishment and free movement of capital. Germany replied to the reasoned opinion on 28.10.2010. The reply is currently under examination.

In the area of **gambling services,** the Commission services continued bilateral dialogue with Member States seeking to address issues raised in the infringement proceedings. The Commission decided on 5 May[342] and 24 November[343] to close infringement proceedings against Italy and France respectively following the adoption of new legislation in both Member States that allows for the cross border provision of on-line gambling services, with clear rules for the authorisation and the granting of licences to domestic and European operators. On 3 June 2010, the Court of Justice ruled[344] that Article 56 TFEU does not preclude legislation that gives a single operator exclusive rights to offer gambling services and prohibits any other operator from doing the same in the relevant territory. The Court ruled that the principle of equal treatment and the consequent obligation of transparency applies to procedures for the granting or renewing of a gambling licence to a single operator, if it is not given to a public operator whose management is subject to direct State supervision or a private operator whose activities are subject to strict control by the public authorities. The

342 IP/10/504.
343 IP/10/159.7
344 Case C-203/08, Sporting Exchange Ltd, trading as 'Betfair', v Minister van Justitie.

Court also ruled[345] that national legislation, which seeks to curb addiction and combat fraud, can be regarded as limiting betting activities in a consistent and systematic manner even where the holder(s) of an exclusive licence may introduce new games and advertise their supply of gambling services. In so far as an implementing measure is necessary to ensure the effectiveness of that legislation and does not include any additional restriction over and above that which arises from the legislation itself, national courts are not required to determine further, in each case, the suitability or proportionality of the measure to reach the stated objective.

On 8 July 2010[346] the Court of Justice ruled that Article 56 TFEU does not preclude prohibitions on advertising of gambling organised for the purposes of profit by private operators in other Member States. However, a Member State subjecting gambling to a system of exclusive rights cannot make promotion of gambling organised in another Member State subject to stricter penalties than the promotion of gambling operated on national territory without a licence.

In the first of three cases adopted on 8 September 2010[347] the Court declared that, by reason of the primacy of directly-applicable Union law, national legislation concerning a public monopoly for sports betting services which comprises restrictions that are incompatible with Articles 49 and 56 TFEU cannot continue to apply during a transitional period.

In the second case[348] the Court ruled that national authorities that seek to justify a public monopoly by an objective to combat gambling addiction and prevent incitement to squander money do not necessarily have to produce a study establishing the proportionality of the measure which is prior to its adoption. Moreover, the choice to use a monopoly, in the context of a non-exclusive legislative framework, may satisfy the requirement of proportionality, as regards the objective of a high level of consumer protection, if there is a legislative framework for the establishment of the monopoly suitable for ensuring it will be able to pursue this objective in a consistent and systematic manner. The fact that the competent national authorities may be confronted with difficulties in ensuring compliance with such a monopoly, due to the online offer of gambling services by operators established outside that Member State, is not capable of affecting the potential conformity of such a monopoly with the Treaty. The national court may consider that such a monopoly is not suitable to achieve the objective for which it was established if it finds that (a) a monopoly is seeking, through advertising, to increase participation in its other types of gambling services to maximise its revenue; (b) other gambling services are offered by licensed private operators; and (c) the competent authorities are conducting or tolerating policies of expanding supply of gambling services not covered by the monopoly, with a higher potential risk of addiction, again with a view to maximising revenues. Finally, an operator having an authorisation to offer gambling services in its Member State of establishment, does not prevent another Member State, while

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345 Case C-258/08, Ladbrokes Betting & Gaming Ltd/Ladbrokes International Ltd v Stichting de Nationale Sporttotalisator.

346 In Joined Cases C-447/08 and C-448/08, criminal proceedings against Otto Sjöberg (C-447/08) and Anders Gerdin (C-448/08).

347 Case C-409/06, Winner Wetten GmbH v Bürgermeisterin der Stadt Bergheim.

348 Joined Cases C-316/07, C-358/07 to C-360/07, C-409/07 and C-410/07,Markus Stoß (C-316/07),Avalon Service-Online-Dienste GmbH (C-409/07) and Olaf Amadeus Wilhelm Happel (C-410/07) v Wetteraukreis and Kulpa Automatenservice Asperg GmbH (C-358/07), SOBO Sport & Entertainment GmbH (C-359/07) and Andreas Kunert (C-360/07) v Land Baden-Württemberg.

complying with the requirements of European Union law, from making such operator subject to an authorisation issued by its own authorities.
In the third case[349], the Court ruled that an operator holding an authorisation to offer online sports betting services only to persons located outside the territory of its seat of establishment and wishing to offer services to such persons does not cease to fall within the scope Article 56 TFEU. The national court may legitimately be led to consider that a regional public gambling monopoly is not suitable to achieve the objective of reducing and limiting gambling opportunities in a consistent and systematic manner if that court at the same time establishes that: (a) other types of games of chance may be exploited by authorised private operators; and that (b) the competent authorities pursue policies of expanding supply of games of chance falling outside the said monopoly and which pose a higher risk of addiction than those subject to the monopoly, in particular with a view to maximising revenue. A system of prior authorisation for the supply of certain gambling services, which derogates from the freedom to provide services, may satisfy the requirements of Article 56 TFEU only if it is based on objective and non-discriminatory criteria known in advance, in such a way as to limit the discretion of national authorities so that it is not used arbitrarily. National legislation prohibiting the provision of on-line gambling services for the purposes of preventing the squandering of money on gambling, combating gambling addiction and protecting young persons may be regarded as suitable for pursuing such legitimate objectives, even if the offer of such games remains authorised through more traditional channels.

On 9 September, the Court of justice ruled that Article 49 TFEU must be interpreted as precluding national legislation under which only operators whose seat is in the territory of that Member State may offer gambling services in gambling establishments. Moreover, the obligation of transparency flowing from Articles 49 and 56 TFEU precludes the grant of concessions to operate gaming establishments without any competitive procedure[350].

Evaluation based on the current position

In 2010, the work continued on the control of the correct implementation of the Services Directive by Member States as well as on the carrying-out of the so called "*mutual evaluation process*". The main results of the mutual evaluation process were presented by the Commission in a communication of 27 January 2011.[351]As regards the implementation of the Services Directives most Member States have informed the Commission that they have completed their implementation work. However some Member States still need to finalise their work. In particular in two Member States the adoption of the horizontal legislation has accumulated serious delays.

Concerning infringement procedures, the Commission focused in particular on those areas which are not covered by the Services Directive.

Evaluation results

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349 Case C-46/08, Carmen Media Group Ltd v Land Schleswig-Holstein, Innenminister des Landes Schleswig-Holstein.

350 Case C-64/08, criminal proceedings against Ernst Engelmann.

351 "*Towards a better functioning Single Market for services – building on the results of the mutual evaluation process of the Services Directive*" - Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, COM (2011)20.

(a) Priorities

The overall assessment of the "mutual evaluation" process is very positive. It has allowed the drawing up of a detailed picture of the state of an important part of the Single Market for services. It has been the first time that Member States and the Commission have carried out together a thorough assessment of national rules affecting service activities. This concerned rules at national, regional and local level as well as rules set by professional associations with regulatory powers. In that respect, mutual evaluation has had an unprecedented "Single Market effect" within Member States as all levels of national administrations were called upon to critically assess their own rules and those existing in other Member States from a Single Market perspective. Finally, this process has also proven to be a valuable tool to identify remaining obstacles for the Single Market and to lay the basis for future policy actions in the service sector.

Concerning gambling services, the Directorate-General for Internal Market and Services held a Conference on 12 October 2010 jointly with the Belgian Presidency. It is expected that pro-active work on gambling services will be a priority in 2011 through the launch of a public consultation on online gambling in the Internal Market.

(b) Planned actions (2011 and beyond)

Based on the report on the results of the mutual evaluation process and as set out in the Communication "*Towards a better functioning Single Market for services – building on the results of the mutual evaluation process of the Services Directive*"[352], the Commission will continue and step up work with Member States on an individual basis so as to **achieve a complete and correct transposition and implementation of the Services Directive in all Member States**. A series of bilateral meetings with those Member States where there are strong indications of incorrect or incomplete implementation of the Services Directive will be held.

In parallel, a **first economic assessment** of the actual implementation of the Directive and of its impact on the functioning of the services markets will be carried out by the Commission in 2011.

The Commission, based on Member States' input as to the specific sectors that should be examined, will launch a so called **"performance check"** of the Single Market for services. The aim will be to assess the situation from the perspective of the users of the Single Market. The performance check should provide an assessment of how different pieces of EU legislation are applied and how they work on the ground. It should also allow the formulation of sector-specific conclusions on the functioning of the Single Market for services within one year in a report to the European Parliament and the Council and, where necessary, identify the need for other actions, including legislative intervention if required.

Targeted actions aimed at tackling remaining regulatory barriers unjustifiably hindering the potential of the Single Market for services will also be undertaken. There will be an assessment of the issue of **reserves of activity** focussing in particular on areas where the link with the professional qualification required warrants further discussion. This should be done in view of the need to achieve more integrated services markets offering high quality services

[352] idem.

as demanded by service recipients. Another assessment will be launched to better understand the manner in which restrictions on **capital ownership** and **legal form** affect certain services sectors and to gather evidence on the economic effects of these rules. In addition the difficulties for cross-border service providers resulting from **insurance requirements** will be examined first with stakeholders, including the insurance industry, with a view to finding practical solutions. On the basis of these assessments and the findings of the "performance check" the Commission will decide by 2012 on possible specific initiatives.

In order to ensure that the **freedom to provide services clause** in Article 16 of the Services Directive is applied properly and consistently in all Member States, the Commission will closely monitor its application and discuss its findings with all Member States. This process can be built upon the Services Directive itself, which already foresees that the Commission reports on the functioning of this clause. The monitoring should, to a large extent, be based on the collection of information and views from Member States and stakeholders. In this respect the Commission will issue its first annual guidance on the application by Member States of the freedom to provide services clause and the evolution of cross-border service provision in the Single Market by the end of 2011.

In 2011, the Commission will also work with Member States to consolidate the notification system in the Services Directive and to help providing guidance to national administrations as to its operation. By the end of 2012, the Commission will report on the functioning of the system and the need for a targeted extension of its scope of application.

And finally, in order to ensure that service providers, in particular SMEs, do not give up on testing markets across borders simply because it is made too difficult by regulatory barriers and in order to enforce their rights in the Single Market, the Commission will assess the effectiveness of means of redress available at national level to service providers for breach of their Single Market rights by national administrations and decide on next steps by the end of 2012.

As regards the **"Points of Single Contact"**, the Commission will continue to cooperate with Member States in order to improve the practical functioning of the existing PSCs with the aim to make them more user-friendly and useful for entrepreneurs, both as regards the availability/presentation of information and the availability and ease of the completion of procedures online both within a Member State and across borders. This work will be carried out through the so called "EUGO" network of national PSC experts (set up in 2010) to serve as a forum for the exchange of good practice, benchmarking of PSCs and development of common solutions at EU level. In 2011 the Commission will also carry out a large external benchmarking study to assess the usability of the PSCs from a business perspective and to identify the need for further action. The results of this study will be presented at a large conference, to take place in Brussels on 28 November 2011.

Furthermore the Commission will continue to work with Member States to further enhance the cross-border use of e-procedures via PSCs. A new Decision is to be adopted that should improve Member States' capacities to process e-signatures to facilitate the verification of documents signed electronically by public authorities. In order to assist Member States to implement the Decision, open source software for the creation/validation of common e-signature formats is being developed by an outside contractor for Member States' use at national level.

SPOCS Pilot will continue and start testing in real life the technical solutions put in place.

At a more horizontal level, interoperability of electronic tools, such as electronic signatures and electronic identification is to be enhanced via the forthcoming revision of the "e-signatures" Directive[353]. Such interoperability is a key priority in the context of the "Single Market Act".

Work will also continue in 2011,

- to monitor and improve the use of IMI for the administrative cooperation obligations under the Directive;
- to support the network of assistance to recipients of services and all other measures contained in the Directive to benefit consumers (e.g. obligation for business not to discriminate consumers because of their residence) and to improve the quality of services.

Concerning *infringement proceedings* and enquiries, the Commission will continue to use EU Pilot according to set priorities or alternative problem solutions mechanisms such as SOLVIT. The efficient use of resources has to be taken in account, notably due to the vast variety of restrictions concerning the Internal Market. As in previous years, the enforcement of the Treaty rules on the freedom to provide services and the freedom of establishment will continue to focus in particular on areas not covered by the Services Directive as well as on cases of clear discriminations or cases concerning entire categories of services providers. Considering the emphasis the Commission will put on the control of implementation of the Services Directive, infringement proceedings for incorrect implementation of this Directive will be treated as priority.

In the area of postal services and related logistics:

Current position

With the deadline for the implementation of the 3rd Postal Directive approaching, the main focus in 2010 was the continued provision of assistance to Member States in the run up to the complete implementation of the postal *acquis*.

As part of direct assistance to Member States, numerous bilateral meetings were held with ministries and national regulatory authorities; these meetings took place with all Member States that are in the first group to implement the 3rd Postal Directive and several of the second group. These meetings focused on delivering advice and guidance as well as providing preliminary evaluations of draft legislation under preparation by national authorities. In many instances, these meetings helped improve the quality of draft legislative texts.

With a view to ensuring the proper implementation of the Postal Directive, a wide range of transposition issues was also taken forward in the framework of a series of Working Groups convened under the auspices of the Postal Directive Committee.

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353 Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a EU framework for electronic signatures.

Building upon the recommendations of the sector study on the *Role of Regulators in a More Competitive Postal Market*[354] and following the activities already undertaken in 2009, the Commission established the European Regulators Group for postal services (ERGP)[355]. This expert advisory group should serve as a body for reflection, discussion and advice to the Commission in the postal services field.

It should facilitate consultation, coordination and cooperation between the independent national regulatory authorities in the Member States, and between those authorities and the Commission, with a view to consolidating the internal market for postal services and ensuring the consistent application in all Member States of the postal *acquis*.

Evaluation based on the current position

Two sector studies were delivered and presented to stakeholders at the end of September 2010.[356] The first study on *Main developments in the postal sector between 2008-2010,* provided a clear overview of the developments and changes underway in the postal sector and assessed the impact of recent market and regulatory developments on postal markets, especially in relation to the provision of universal service, employment in the postal sector and the impact of the VAT exemption on markets. The second study presented the external aspects of the EU postal *acquis,* especially in relation to the ongoing trade negotiations (multilateral and bilateral) and the acts of the Universal Postal Union.

The findings of sector studies, combined with complaints from stakeholders focusing on an incorrect interpretation and uneven application of the postal *acquis* by some Member States, are being used by the Commission to curtail bad market practices (e.g. predatory/excessive pricing), tackle and remove regulatory barriers to entry (e.g. excessive and burdensome licence conditions, access to the postal infrastructure) and ensure the timely and correct implementation of the postal *acquis*.

Market monitoring is being enhanced and supported also through the provision and publication of more comprehensive key data on postal markets in the EU (in close co-operation with EUROSTAT).

Evaluation results

(1) Priorities

Following its establishment in August 2010 and adoption of the Work Programme in December of the same year, the objectives of this Group are to ensure greater coherence in the operation of the postal regulatory model, exchanging best regulatory practices and "regulatory know how", notably with less well resourced national regulators, and contributing to the consolidation of the internal market for postal services. The priority for 2011 would therefore be to deliver on adopted work programme and to develop best regulatory practices in identified areas, which should contribute to the attainment of common objectives.

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354 Available at: http://ec.europa.eu/internal_market/post/doc/studies/2009-wik_regulators.pdf.

355 Commission Decision of 10 August2010 establishing the European Regulators Group for Postal Services (ERGP), OJ C 217.

356 Available at: http://ec.europa.eu/internal_market/post/doc/studies/2010-main-developments_en.pdf and http://ec.europa.eu/internal_market/post/doc/studies/2010-wik-external-dimension_en.pdf.

Another priority would be the assessment of the transposition measures concerning the 3rd postal directive (directive 2008/6/EC) for which the deadline for 16 Member States has expired on 31 December 2010.

(2) Planned action (2011 and beyond)

The European Commission and the Spanish Presidency co-hosted a High Level Conference on Postal Services in Valencia on 29-30 April 2010. The Conference provided a unique forum for informal discussion on the prerequisites for successful market opening, ensuring greater competitiveness across the postal sector and overcoming the challenges faced by regulatory bodies. Commission departments will follow up on the results of such conference and more in particular on the implementation of the postal reform which was recognised as the key issue.

11.2. Financial Services

The financial services sector includes three major areas for which similar European policies apply: **banking**, **insurance** and **securities**. The objective of the EU secondary legislation is to facilitate the establishment and the cross-border provision of services for financial institutions on the basis of the home country control principle. In addition to these main areas, financial services legislation covers **occupational pensions payments and retail financial services**.

11.2.1. **Banking**

Current position

General introduction

As regards infringement proceedings in the ***banking sector***, the Commission mainly dealt with non-communication cases. As regards the transposition of Directive 2007/44/EC which lays down the procedures and criteria for the prudential assessment of acquisitions and increase of holdings in the financial sector[357], seven infringement cases against Greece, Spain, Italy, the Netherlands, Poland, Portugal and the United Kingdom due to non-communication of the national transposition measures before the deadline of 21 March 2009, initiated in 2009, were still pending in 2010. Three cases were closed following to the notification of the implementing measures by the Member States concerned, while four cases – against Greece, Portugal, Poland and the Netherlands – were referred to the Court of Justice. Out of these cases, three were settled in Court further to the complete implementation of the directive, whereas the case against the Netherlands resulted in a Court's judgment establishing the failure of this country to transpose Directive 2007/44/EC in December 2010[358].

The Commission also launched infringement proceedings against seventeen Member States for non-communication of the implementing measures of Directive 2009/14/EC which has

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357 Directive 2007/44/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 92/49/EEC and Directives 2002/83/EC, 2004/39/EC, 2005/68/EC and 2006/48/EC as regards procedural rules and evaluation criteria for the prudential assessment of acquisitions and increase of holdings in the financial sector (OJ L 247, 21.9.2007, p. 1–16).

358 Judgment of the Court of 16 December 2010 in Case C-233/10, European Commission v Kingdom of The Netherlands.

amended the EU rules on deposit guarantee schemes[359]. 14 cases were already closed in 2009 and the remaining three cases in 2010 (against Slovenia, Finland and Greece).

In November 2010, 17 infringement proceedings were started against several Member States for failure to transpose Directive 2009/111/EC[360]. This Directive is part of the first package of changes to the Banking Directive 2006/48 (also known as "Capital Requirements Directive" or CRD) adopted in response to the financial crisis in order to strengthen prudential rules and supervision. The whole package of amendments had to be implemented in national law by the end of 2010. The other instruments of the package are two Commission Directives[361] which have made technical amendments to the Annexes of the CRD. Parallel infringement proceedings were also launched against the same 17 Member States for non-communication of the measures implementing these technical directives.

Report of work done in 2010

Further changes to the CRD to strengthen rules on bank capital regarding bank trading activities and on remuneration policies in the banking sector were adopted in December 2010[362].

A Directive improving depositor protection was proposed in July 2010 and is now being negotiated[363]. It follows Directive 2009/14/EC[364], which only dealt with selected issues to improve depositor confidence in the financial crisis. The new proposal marks a comprehensive revision and notably improves consumer protection and the financing of Deposit Guarantee Schemes.

In August, the Commission proposed a first revision of the Financial Conglomerates Directive[365], aimed at enabling supervisors to apply group related provisions in banking, insurance and supplementary conglomerates rules at the level of the ultimate parent undertaking, regardless of its legal statute.

In preparation of future legislative proposals, the Commission launched a public consultation regarding the putting in place of an EU framework for crisis resolution in the banking sector

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359 Directive 2009/14/EC of the European Parliament and of the Council of 11 March 2009 amending Directive 94/19/EC on deposit-guarantee schemes as regards the coverage level and the payout delay (OJ L 68, 13.3.2009, p. 3–7).

360 Directive 2009/111/EC of the European Parliament and of the Council of 16 September 2009 amending Directives 2006/48/EC, 2006/49/EC and 2007/64/EC as regards banks affiliated to central institutions, certain own funds items, large exposures, supervisory arrangements, and crisis management.

361 Commission Directive 2009/27/EC of 7 April 2009 amending certain Annexes to Directive 2006/49/EC of the European Parliament and of the Council as regards technical provisions concerning risk management (OJ L 94, 8.4.2009) and Commission Directive 2009/83/EC of 27 July 2009 amending certain Annexes to Directive 2006/48/EC of the European Parliament and of the Council as regards technical provisions concerning risk management (OJ L 196, 28.7.2009).

362 Directive 2010/76/EU of the European Parliament and of the Council of 24 November 2010 amending Directives 2006/48/EC and 2006/49/EC as regards capital requirements for the trading book and for re-securitisations, and the supervisory review of remuneration policies , OJ L329 of 14.12.2010.

363 COM 2010/368 and 369.

364 Directive 2009/14/EC of 11 March 2009 amending Directive 94/19/EC on deposit-guarantee schemes as regards the coverage level and the payout delay (OJ L 68, 13.3.2009).

365 COM(2010) 433 final.

and issued a communication on bank resolution funds. Consultations were also carried out in preparation of further proposed amendments to the CRD scheduled for 2011[366].

Evaluation results

The Commission's strategy to encourage early and consistent transposition in this area is to help Member States through the 'Capital Requirements Directive Transposition Group' (CRDTG). In 2010, the CRDTG has been busy providing clarifications, answering questions and assisting Member States in the transposition of new legislation. Currently about 400 answers are posted on its website[367].

(1) Priorities

The main priorities in the banking area concern the preparation of legislative proposals aimed at improving regulation, strengthening supervision and developing a regime for dealing effectively with bank crisis. Co-operation with Member States will continue to ensure good preparation and coherent implementation of the law, through Committee and working group discussions, including further work of the CRDTG.

(2) Planned action (2011 and beyond)

The Commission will continue to monitor the implementation and application of the banking legislation across the EU.

A further legislative proposal incorporating the new Basel III regulatory framework for banks in EU law is expected to be adopted by the Commission in July 2011. These proposals will significantly strengthen the prudential requirements for credit institutions and investment firms and such the overall financial stability. The proposal will also include measures related to the Commission's efforts to create a single rule book for banking in the EU. In this regard, a regulation appears to be the most efficient legal instrument to achieve such objective. Therefore, the legislative proposal will comprise two elements: a proposal for a new regulation in banking and a proposal amending the CRD.

A more comprehensive review of the Directive on Financial Conglomerates is planned in 2011. The Commission will launch a consultation about a more fundamental revision of this Directive, following up developments at G20 level regarding the supplementary supervision of groups with material activities in financial markets beyond one regulated sector.

Other legislative work is envisaged in 2011 to address the problem - surfaced during the financial crisis - of the absence of a coherent and comprehensive EU regime for dealing with cross-border bank crisis. The Commission intends to present a proposal for a new framework for bank recovery and resolution in September 2011.

11.2.2. **Insurance and occupational pensions**

Current position

366 The consultations are published at http://ec.europa.eu/internal_market/bank/regcapital/index_en.htm

367 http://ec.europa.eu/internal_market/bank/regcapital/transposition_en.htm

In 2010, 5 files related to insurance and occupational pensions were opened in EU Pilot,1 in SOLVIT,. 11 infringement cases were closed and one was referred to the Court. Bilateral contacts were held with the Member States either through package meetings, other (ad hoc) meetings or in the relevant sector committees.

As regards the non-communication cases launched in the insurance sector with regard to Directive 2005/68/EC (the reinsurance Directive), the only case still under examination was closed in 2010.

As regards motor insurance, the infringement case against the UK for non-communication of the transposing measures of Directive 2005/14/EC (judgement of 3.9.2009 in Case C-2008/457) was closed in 2010.

In 2010, the Court ruled that the Czech Republic had failed to transpose Directive 2003/41/EC on the institutions for occupational pension funds (Case C-343/08, judgement of 14 January 2010). The procedure under Article 260 TFEU was launched thereafter. Several other proceedings were launched concerning this Directive in 2010.

In 2010, the Court rendered its judgement in an important case concerning the Belgian sickness funds ("mutualités/ziekenfondsen"), which offer complementary health insurance without respecting the solvency rules of directives 73/239/EEC and 92/49/EEC (1st and 3rd non-life insurance Directives). In its ruling of 28 October 2010 (C-41/10), the Court found that Belgium had breached those Directives. The procedure under Article 260 TFEU was launched thereafter.

As regards petitions a total of 5 petitions were handled on insurance and pensions. They dealt inter alia with motor insurance, life assurance, non-life insurance (especially health insurance) and pension funds. About 168 queries of other nature concerned the insurance and pensions sector.

The key change and challenge ahead is the proposal for a directive called "Solvency II" Directive which was adopted in 2009 and is to be transposed by late 2012. The Directive provides for a transposition period of about 3 years so that implementing measures needed to make the new framework completely operational are adopted beforehand. Intensive work intended to prepare its transposition and proper application continued in 2010 and will continue through 2012. It is furthermore necessary to adapt this Directive to the changes brought by the new regulatory architecture for financial services and notably the Regulation which set the European Insurance and Occupational Pensions Authority (EIOPA) in December 2010. A key year is the one of 2011, when the Commission tables the Omnibus 2 Directive proposal, adapting Solvency II to the changes introduced by the EIOPA Regulation mentioned above, and the proposal of the Level 2 implementation measures. It is intended to modernise the evaluation and calculation of risks and therefore will provide for a new, prospective, and economic and risk based approach putting much greater emphasis on sound risk management and robust internal controls by insurance undertakings. In addition Solvency II will also profoundly influence the way in which supervision is carried out by the competent supervisory authorities. It also contains a new approach as regards insurance groups. It is far too early to anticipate what will be the effects and consequences of the new Directive.

Evaluation based on the current position

Conformity check of Directives transposed remains a key challenge. In the insurance

sector, comprehensive and updated concordance tables allow for the checking of the substantive conformity of the transposition.

The implementation of the Directive on *Reinsurance* (2005/68/EEC) was due by 10.12.2007, but not all Member States had completed their transposition process by that date. The checking of the completeness of the communication of the transposition of the said Directive has been completed. Focus has since shifted to a more in-depth and comprehensive look at the substance of the transposition measures.

In the insurance sector, breache of EU law have generally a considerable impact in economic terms and in terms of proper functioning of the relevant market both for undertakings and final users. A level playing field is particularly affected because breaches either limit the possibilities of competitors to stay on the market or allow national companies to offer services without fulfilling the obligations imposed by EU legislation. It also has consequences for the services and products that are offered to the consumers.

The number of complaints and infringement cases is likely to increase or at least remain broadly stable in 2011-2012 mainly due to increasing awareness of citizens of their rights in all 27 Member States. The economic/financial crisis may have repercussions on national measures and subsequently on complaints. Priority will be given to cases of non-communication of transposition measures, non-respect of Court judgments and cases that show a breach of a fundamental freedom or principle of the TFEU or a breach of a Directive which is blatant.

The main structural problems result from the complexity of the legislation adopted sometimes in several steps according to the Lamfalussy process. To tackle this problem, seminars explaining the legislation have already been organised and regular contact with Member States is maintained via the relevant Committees and their working groups and also by using the package meetings and other ad hoc meetings. For the Solvency II proposed Directive a longer transposition period (of around 3 years) is planned (with the so called "level 2" measures under the Lamfalussy process adopted around 1 year before the final implementation date). The same complexity creates problems in transposition which may also be of substance (problems of interpretation, for instance, or of misapplication, either in general or in specific individual cases).

Evaluation results

(1) Priorities

The main priority will be the ongoing work on the "level 2" measures as regards the Solvency

II Directive. The checking of recently to be transposed Directives, notably Directive

2005/68/EC on reinsurance, will be continued.

To ensure timely and effective problem solving, an efficient co-operation with the Member states as well as an efficient management of infringement proceedings will be pursued.

(2) Planned action (2011 and beyond)

As for **insurance legislation**, preliminary Guidance on the transposition of Solvency II has

started in close co-operation with the Member States and will continue through to 2012.

A detailed checking of the substance of the transposition of Directive 2005/68/EC by the

Member States will be continued and completed by the Commission services. Failure to fully implement these Directives prevents the creation of a level playing field and could conceivably affect reinsurance undertakings and the reinsurance market in a negative way.

The package meetings (and other meetings) with Member States, as well as the use of EU Pilot, will be continued in order to tackle problems in this respect.

11.2.3. **Securities**

Current position

(1) General introduction

'***Securities markets***' legislation includes the following (main) directives and regulations:

a. Directive on Markets in Financial Instruments 2004/39/EC[368] (MiFID) and its implementing provisions (Commission Directive 2006/73/EC[369] and Commission Regulation 1287/2006[370]), which regulate the provision of investment services and activities in the EU and for the trading activity, including the operation of regulated markets and multilateral trading facilities (MTF) and the rules applicable to systematic internalisers.
b. Investor Compensation Scheme Directive 1997/9/EC[371] (ICSD) introducing a compensation for investors having lost their assets as a result of the failure of an intermediary providing investment services.
c. Market Abuse Directive 2003/6/EC (MAD)[372] and its implementing texts (Commission Directive 2003/124/EC[373], Commission Directive 2003/125/EC[374],

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368 Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments amending Council Directives 85/611/EEC and 93/6/EEC and Directive 2000/12/EC of the European Parliament and of the Council and repealing Council Directive 93/22/EEC (OJ L 145, 30.4.2004, p. 1).

369 Directive 2006/73/EC of 10 August 2006 implementing Directive 2004/39/EC of the European Parliament and of the Council as regards organisational requirements and operating conditions for investment firms and defined terms for the purposes of that Directive (OJ L 241, 2.9.2006, p. 26).

370 Regulation (EC) No 1287/2006 of 10 August 2006 implementing Directive 2004/39/EC of the European Parliament and of the Council as regards record-keeping obligations for investment firms, transaction reporting, market transparency, admission of financial instruments to trading, and defined terms for the purposes of that Directive (OJ L 241, 2.9.2006, p. 1–25).

371 Directive 97/9/EC of the European Parliament and of the Council of 3 March 1997 on investor-compensation schemes (OJ L 84, 26.3.1997, p. 22–31).

372 Directive 2003/6/EC of the European Parliament and of the Council of 28 January 2003 on insider dealing and market manipulation (market abuse) (OJ L 96, 12.4.2003, p. 16–25).

373 Directive 2003/124/EC of 22 December 2003 implementing Directive 2003/6/EC of the European Parliament and of the Council as regards the definition and public disclosure of inside information and the definition of market manipulation (OJ L 339, 24.12.2003, p. 70–72).

374 Directive 2003/125/EC of 22 December 2003 implementing Directive 2003/6/EC of the European Parliament and of the Council as regards the fair presentation of investment recommendations and the disclosure of conflicts of interest (OJ L 339, 24.12.2003, p. 73–77).

Commission Regulation 2273/2003[375], Commission Directive 2004/72/EC[376]), whose aim is to prevent and to fight against insider dealing and market manipulation.

d. Prospectus Directive 2003/71/EC[377] and its implementing Regulation 809/2004[378] regulating the obligation to produce a prospectus and the content of the prospectus to be published when securities are offered to the public or admitted to trading in the EU.
e. Regulation (EC) No 1060/2009 of the European Parliament and of the Council on credit rating agencies

(2) Report of work done in 2010

Concerning the application of the *acquis*, in the area of ***securities markets***, the Commission service continued with the quality check of the implementation of the respective *acquis*. In this regards the following cases need to be mentioned:

Markets in Financial Instruments Directive (MiFID). Concerning Poland, the Polish authorities notified to the Commission the transposing law following a Court judgement in 2009 (case C-143/08), therefore the Commission services closed the two infringement proceedings opened for non communication and incorrect transposition of the MiFID and its implementing Directive 2006/73/EC. Thus, all non communication cases against Member States for MiFID and its implementing Directive 2006/73/EC have been closed.

Furthermore, the Commission service investigated two cases of incorrect transposition of the MiFID and its implementing Directive. The case against Austria was closed after having received satisfying explanation by the Austrian authorities. The case against Hungary is still under examination.

Moreover, the questions and answers database on MiFID (and meanwhile extended to other areas), launched by the Commission in 2007, continues providing all stakeholders with the possibility to clarify interpretational issues concerning MiFID.

Within the framework of the MiFID review, the Commission service organised a two-day public hearing which was held in Brussels in September 2010 and launched a public consultation on 8 December 2010 to help preparing the legislative proposal to amend the Directive by 2011.

Investor Compensation Scheme Directive (ICSD). On 12 July 2010 the Commission adopted a proposal to amend the ICSD.[379] The review of the ICSD is linked to evidence

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375 Regulation (EC) No 2273/2003 of 22 December 2003 implementing Directive 2003/6/EC of the European Parliament and of the Council as regards exemptions for buy-back programmes and stabilisation of financial instruments (OJ L 336, 23.12.2003, p. 33–38).

376 Directive 2004/72/EC of 29 April 2004 implementing Directive 2003/6/EC of the European Parliament and of the Council as regards accepted market practices, the definition of inside information in relation to derivatives on commodities, the drawing up of lists of insiders, the notification of managers' transactions and the notification of suspicious transactions (OJ L 162, 30.4.2004, p. 70–75).

377 Directive 2003/71/EC of the European Parliament and of the Council of 4 November 2003 on the prospectus to be published when securities are offered to the public or admitted to trading and amending Directive 2001/34/EC (OJ L 345, 31.12.2003, p. 64–89).

378 Regulation (EC) No 809/2004 of 29 April 2004 implementing Directive 2003/71/EC of the European Parliament and of the Council as regards information contained in prospectuses as well as the format, incorporation by reference and publication of such prospectuses and dissemination of advertisements (OJ L 149, 30.4.2004, p. 1–126).

received on problems in its practical implementation, divergences in its national application and to reflect changes in other legislative instruments, such as MiFID and the Deposit Guarantee Schemes Directive. The main elements of the review are the following: reinforce the funding requirements of the schemes and introduce a borrowing mechanism between national schemes as a last resort tool; reduce the considerable payout delays before the investor receives any compensation, requiring provisional payout of partial compensation if payout delays exceed a given time period; further specify the information requirements to clients; provide that investors have the right to be compensated by the scheme also in case of failure of a third party custodian resulting in the investment firm not being able to return the client's assets; extend coverage to provide for compensation to UCITS unit holders when there is a loss of assets due to the failure of the depositary of the UCITS scheme; increase the level of compensation to a fixed level of € 50 000; remove the requirement by which investors could bear a proportion of up to 10% of the loss within the compensation limit. Parallel reviews are also being conducted on other compensation schemes (the Deposit Guarantee Scheme Directive and a possible insurance scheme).

Market Abuse Directive (MAD). Two infringement proceedings, one against Luxembourg and one against the United Kingdom, had to be assessed. Both infringements concerned provisions on the powers of competent administrative authorities and administrative sanctions. Both Member States reacted by implementing a provision which tackles the issue sufficiently. Accordingly, both cases were closed in 2010.

The Commission issued a public consultation between June and July 2010 on the review of the MAD to receive feedback from competent authorities and market participants on future legislative proposal to review the MAD.

Short selling/CDS. The Commission adopted a proposal for a Regulation on short selling and credit-default swaps (CDS) in September 2010[380]. The proposal includes measures to increase transparency to regulators and the market about short selling positions in certain instruments; the marking or flagging of short orders for shares executed on trading venues; measures to reduce settlement and other risks of uncovered or naked short selling and powers to competent authorities and the European Markets and Securities Authority (ESMA) to take measures under exceptional circumstances.

OTC derivatives/central counterparties/trade repositories (EMIR). The Commission adopted a proposal for a Regulation on OTC derivatives, central counterparties and trade repositories in September 2010[381]. The Regulation introduces a reporting obligation for OTC derivatives, a clearing obligation for eligible OTC derivatives, measures to reduce counterparty credit risk and operational risk for bilaterally cleared OTC derivatives, common rules for central counterparties (CCPs) and for trade repositories, and rules on the establishment of interoperability between CCPs.

Prospectus Directive. The Commission service launched an infringement procedure against Poland on the incorrect transposition of the prospectus language requirements. Poland has

379 COM(2010) 371 final.
380 COM(2010) 482 final.
381 COM(2010) 484 final

adapted its regulatory framework and notified it to the Commission services which are analysing it.
Directive 2010/73/EU amending the Prospectus Directive was adopted by the European Parliament and the Council on 24 November[382].

Credit Rating Agencies. In June 2010 the Commission adopted a proposal to amend the Regulation No 1060/2009 on credit rating agencies (CRA Regulation)[383] to entrust ESMA with exclusive supervisory powers over CRAs, for which a political agreement was reached by the European Parliament and the Council in December 2010. In addition, the Commission adopted a decision on the recognition of the legal and supervisory framework of Japan as equivalent to the requirements of the CRA Regulation.[384]

The Commission services launched a public consultation in December 2010 on further issues linked to the use of credit ratings and the rating industry, such as the overreliance on ratings, the high concentration in the rating industry, the ratings of sovereign debt, the conflicts of interest linked to a specific bussines model and the civil liability of CRAs.

Evaluation based on the current situation

Secondary legislation is in permanent development in the ***financial services area***, although the main pillars have been already established following the Financial Services Action Plan launched in 1999.

The *acquis* requires a continuous and close monitoring of national measures to ensure timely and proper transposition. Further, some directives require the Commission to report on a number of key provisions that will allow to better evaluate their impact and to determine possible problems that need to be addressed. In this area the permanent dialogue within the various sectoral committees and the newly created European Supervisory Authorities[385] contributes to avoid deviations by Member States in the application of relevant EU law. Furthermore, convergence in the supervisory practices is also one of the key objectives in this area.

Particular attention has been and continues to be devoted to the observation and analysis of MiFID on securities markets, with the aim of assessing, in the perspective of the ongoing review, aspects such as investor protection, transparency, availability of data, fragmentation, and regulatory framework applicable to different venues. The Commission services have further followed closely, the phenomenon of high frequency trading, in the framework of the MiFID review. In addition, the G20 recommendations are taken into account in this review.

As to the ICSD, the review of the Directive was needed in order to solve problems raised by several complainants to the Commission concerning the application of the directive and to keep it aligned with other changes in the *acquis*.

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382 Directive 2010/73/EU amending Directives 2003/71/EC on the prospectus to be published when securities are offered to the public or admitted to trading and 2004/109/EC on the harmonisation of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market, OJ L327/1 of 11.12.2010.

383 OJ L 302, 17.11.2009, p.1.

384 OJ L 254, 29.9.2010, p. 46.

385 EBA in the banking sector, EIOPA in the insurance sector and ESMA in the securities sector.

On the Prospectus Directive, no particular problems were identified in the transposition check. However, some concerns were raised by plaintiffs regarding the way in which certain Member States implement additional requirements outside the Prospectus Directive. CESR updated in 2010 the common positions by its Members in the application of the Directive and continued to operate the Q&A database. CESR also worked on a mapping exercise leading into a peer review whose first results were presented in November 2010.[386] While CESR finds Member States broadly compliant with Prospectus Directive, the mapping showed existing divergences in practices and in the day-to-day application. ESMA will continue this work and the Commission services will closely follow the exercise.

Adopted in early 2003, MAD has introduced a comprehensive framework to tackle insider dealing and market manipulation practices. However, since its adoption in 2003 the financial and regulatory landscape has changed notably through the financial crisis and there are a number of areas where the Directive can be updated and improved. Furthermore, the necessity for improvement was confirmed lastly through two infringement procedures concerning the power of competent authorities and sanctions to be pronounced which were closed in 2010.

Evaluation results

(1) Priorities

In the area of ***financial services***, priority will be given to the review of MiFID, MAD and CRA Regulation and to the negotiation of the legislative proposals on ICSD and on short selling and CDS.

(2) Planned action (2011 and beyond)

The MiFID review is due in 2011. It will focus on issues that need to be revised and on a number of areas emerged from the first years of application in the EU. The review will tackle three principal issues: (i) ensure the directive is fully up-to-date concerning the latest technological and market developments in the interests of fair competition and efficient markets; (ii) bring into effect important G20 commitments in the field of derivatives and commodity market transparency and oversight; (iii) repair specific shortcomings revealed by the financial crisis, whether in the field of investor protection or enforcement and supervision.

The MAD review will aim at: (i) increasing the integrity of markets by widening the scope of the legislation to capture new markets (MTFs and other organised trading facilities) and instruments (OTC); (ii) increasing the protection of investors by strengthening the investigative and sanctioning powers of regulators; and (iii) clarifying certain key provisions and reducing administrative burdens where possible, especially for SMEs.

The review of the CRA Regulation will mainly focus on reducing the reliance on credit ratings, improving the transparency on sovereign debt ratings, increasing competition in the credit rating business, minimise any potential conflict of interest due to the business model and reinforce CRAs' civil liability.

The Commission services will further continue to assist Member States via ESC and ESMA in providing advice and answering questions emerging from the implementation of the *acquis*.

386 See CESR's executive summary of the report, Ref. CESR/10-123.

11.2.4. **Asset management**

Current position

(1) General introduction

In the area of asset management the Commission focussed on legislative action on the basis of commitments made in 2009:

1. The compromise text of the Directive on Alternative Investment Fund Managers (AIFMD) was approved by the European Parliament on 11 November. Its formal adoption and entry into force is expected to follow in early 2011. The AIFMD will then be transposed over a period of 2 years, becoming fully operational by early 2013;

2. Level 2 measures to the UCITS IV Directive were adopted on 1 July, in accordance with the set deadline, so that Member States could implement the whole UCITS IV package (Directive 2009/65/EC and its implementing measures) by 30 June 2011. These comprise 4 acts:

a) Commission Directive 2010/43/EU on organisational requirements, conduct of business rules, conflict of interests and content of the agreement between a management company and UCITS depositary;
b) Commission Directive 2010/44/EU on fund mergers, master-feeder structure and notification procedures;
c) Commission Regulation 583/2010 on key investor information; and
d) Commission Regulation 584/2010 on notification and supervisory co-operation.

The adoption of these measures completes the reform of the UCITS IV regulatory framework introduced by the UCITS IV Directive, ensuring the workability of the level I provisions.

3. Two consultation papers were issued announcing legislative changes:

a) on legislative steps for the Packaged Retail Investment Products initiative, and

b) on the UCITS depositary function and on the UCITS managers' remuneration. This followed the commitment made by the Commission in its communication on 2 June 2010 to publish proposals for appropriate legislative responses to issues revealed by the Madoff fraud and the Lehman Brothers default.

(2) Report of work done in 2010

In the asset management sector, the Commission pursued investigations against one Member State. This procedure concerns the national rules designed to counter the negative effects of the financial crisis. These measures empower the national authorities to take decisions which will allow certain UCITS to breach the minimum common rules set out in the UCITS Directive.

Concerning the UCITS IV package, during the second half of 2010, the Commission services provided assistance to Member States in their transposition efforts. A transposition workshop was organised in September 2010 to kick-off dialogue with Member States on the practical problems authorities are facing or may face in transposing the UCITS IV Package. The workshop showed the need for further discussion. This took place through the transposition network allowing for direct contact with experts involved in the transposition in national

authorities. The dialogue will continue in 2011 (transposition deadline – 30 June 2011).

2010 was marked by important actions affecting the asset management regulatory landscape:

AIFMD

In 2010 intensive negotiations of AIFM Directive, based on the Commission proposal of April 2009, has been completed. On 11 November the European Parliament approved the compromise text, thereby sealing a first reading agreement with the Council. Following the adoption of the AIFM Directive the Commission will continue its work on implementing measures required to give effect to the provisions of this Directive (over 90 implementing powers) In November 2010 the Commission issued a mandate to CESR / ESMA to develop technical advice on these measures.

Packaged Retail Investment Products (PRIPs)

Following the April 2009 Commission indicating the possible ways and means to improve regulatory protection for retailed investors and a technical workshop which allowed to gather views of relevant stakeholders, the Commission published a consultation paper on legislative steps for the Packaged Retail Investment Products initiative.

The consultation seeks feedback from stakeholders on the next steps to be taken in improving the European regulation of the retail investment market. The Commission committed in 2009 to developing legislative proposals for raising standards of investor protection and improving the consistency of existing measures across the different sectors making up the retail investment market.

Changes to UCITS IV Directive

Results of the public consultation of July 2009 showed the need to revise the UCITS depositary framework in order to strengthen investor protection. In the context of AIFMD negotiations the Commission also committed itself to introduce targeted changes to the depositary provisions in the UCITS Directive. These changes aim at: clarifying the UCITS depositary functions and ensuring consistency between the legislation applicable to the depositaries of UCITS and that applicable to the depositaries of AIF.

The financial crisis also revealed that the remuneration and incentive schemes commonly applied within financial institutions were themselves exacerbating the impact and scale of the crisis. Remuneration policies contributed to short-termism and incentivised excessive risk taking, thereby increasing levels of systemic risk. In the light of these systemic issues and commitments that were made at the G20 level to address them, the EU is taking coordinated steps across all financial services sectors to introduce consistent requirements governing the remuneration policy.

The purpose of the consultation paper published in December 2010 was to collect views and supporting evidence on the key options that are emerging in these two areas. The conclusions from this consultation will serve as a basis for the Commission to review the UCITS Directive in 2011.

Evaluation based on the current situation

Verification launched in 2009, on the basis of Member States responses to the administrative letter, showed the limited range of adopted, crisis-related legislative measures or administrative practice. Nevertheless, few questions still remain open, like the one concerning the possible scope of interpretation of the UCITS Directive by Member States in the context of the financial crisis, e.g. introduction of side pockets, or waivers of certain UCITS obligations. The reflections took place also in CESR and its dialogue with the Commission will continue in 2011.

It should be noted that concerns related to the depositary liability will be addressed in the legislative initiative resulting in the modification of UCITS rules on depositaries.

Evaluation results

Following the adoption of the AIFM Directive, the important work of adopting level 2 measures will start in 2011 for completion in 2012. In this context, particular efforts are needed from the Commission services to actively follow the work of ESMA on its technical advice.

In addition, the work on PRIPs initiative and revision of depositary rules and new requirements on remuneration policies within the UCITS Directive will enter in their decisive phases. Proposals are expected in the mid-2011.

As the deadline for Member States to transpose the UCITS IV Directive and its implementing directives expires on 30 June 2011, the Commission services will be attentive to the need to ensure that a maximum number of timely notifications from Member States are submitted. Soon afterwards, the process of transposition check should be launched.

Legislation

1. Council Directive 85/611/EEC of 20 December 1985 on the coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS) (OJ L 375, 31.12.1985, P. 3), as amended, available on the following website:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1985L0611:20080320:EN:HTML

2. The recast of the 85/611/EEC Directive (Directive 2009/65/EC) is available on the website:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:302:0032:01:EN:HTML

3. Implementing measures to Directive 2009/65/EC are available on the website:

- Commission Directive 2010/43/EU of 1 July 2010 implementing Directive 2009/65/EC of the European Parliament and of the Council as regards organisational requirements, conflicts of interest, conduct of business, risk management and content of the agreement between a depositary and a management company Text with EEA relevance

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:176:0042:01:EN:HTML

- Commission Directive 2010/44/EU of 1 July 2010 implementing Directive 2009/65/EC of the European Parliament and of the Council as regards certain

provisions concerning fund mergers, master-feeder structures and notification procedure Text with EEA relevance

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:176:0028:01:EN:HTML

- Commission Regulation (EU) No 583/2010 of 1 July 2010 implementing Directive 2009/65/EC of the European Parliament and of the Council as regards key investor information and conditions to be met when providing key investor information or the prospectus in a durable medium other than paper or by means of a website Text with EEA relevance

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:176:0001:01:EN:HTML

- Commission Regulation (EU) No 584/2010 of 1 July 2010 implementing Directive 2009/65/EC of the European Parliament and of the Council as regards the form and content of the standard notification letter and UCITS attestation, the use of electronic communication between competent authorities for the purpose of notification, and procedures for on-the-spot verifications and investigations and the exchange of information between competent authorities Text with EEA relevance

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:176:0016:01:EN:HTML

11.2.5. **Payments and retail financial services**

Current position

(1) General introduction

A proposal for a Regulation establishing technical requirements for credit transfers and direct debits in euros and amending Regulation (EC) No 924/2009, COM(2010)775 (hereby referred as "the SEPA migration end-dates Regulation") was adopted by the Commission and published in December 2010.

In order to ensure a timely and consistent transposition of the new E-Money Directive 2009/110/EC ((hereby referred to as 'the EMD') by end April 2011, the Commission services have continued to accompany Member States in their transposition process through transposition workshops, bilateral meetings and Q&A facility on the internet. The transposition of the Payment Services Directive 2007/64/EC (hereby referred to as 'the PSD') has been accomplished, with the sole exception of one Member State.

(2) Report of work done in 2010

The preparatory work on the end-date Regulation proposal (impact assessment, inter-service consultation, public consultations and public hearing in November) as well as the actual drafting of a highly technical legal text was the main focus of the Commission services attention in the area of payments. The proposal was adopted by the Commission on 16 December and transmitted to other EU institutions and the ECB. The main objective of the proposal is to accelerate the current slow rate of migration to pan-european credit transfers and direct debits by fixing technical requirements which must be respected by proposed migration end-dates. At the same time the proposal also provides clarity on the business

model for pan-european direct debits and reassures consumers when using such products by providing various mandate checking options.

An EMD Transposition Group (EMDTG), which has been set up a year before, met three times. The Group role was to address common transposition issues faced by Member States authorities and other stakeholders and to share responses with all interested parties. In total the Group collected around 100 questions from Member States concerning 24 articles of the EMD and provided written observations which served as a basis for reaching a common understanding. The web-based question-and answer tool, which has proved its effectiveness during the transposition of the PSD, has been also developed and used to answer individual questions on the EMD.

An *ad hoc* working group – the EMD Passporting Liaison Group – composed of representatives of a number of competent authorities in Member States responsible for the authorisation/supervision of e-money Directive Passport Notifications institutions has been set up and worked on the drafting of Guidelines on Electronic Money. These guidelines will be submitted afterwards to the Payments Committee for information and discussion. While the use of the Guidelines is voluntary, all competent authorities appointed under Directive 2009/110/EC will be strongly encouraged to use them for passport notification purposes. While the Commission services participated only as an observer in this working group, these Guidelines will be made available on the relevant area of the Commission's website for easy stakeholder access and transparency.

The Commission Communication *Reaping the benefits of e-invoicing for Europe* which was announced in the *Digital Agenda for Europe* was adopted on 2 December 2010. It aims at fostering the uptake of electronic invoicing within the EU. The Communication builds on the final report of the independent Expert Group on e-invoicing, and on a public consultation following this report. It is accompanied by a Decision which establishes a European E-invoicing Forum to be set up by June 2011.

The interpretative guideline concerning application of Article 8 of Regulation 924/2009 (on mandatory reachability for direct debits), which was much awaited by the payment industry, has been published in March. Another interpretative note, concerning the application of Article 3 of the same Regulation in the case of ATM withdrawals has been also drafted and published in January 2011.

In the field of payments, the number of petitions, questions and complaints remained relatively constant in comparison with previous years. Three petitions were received in 2010. The majority of the enquiries (around 200) concerned cross-border payment services and the application and interpretation of the two main legislative acts in this area – namely Regulation 924/2009 and the PSD.

Several infringement proceedings were launched during this period. Most of them concerned the late or non-transposition of the PSD. However, all of them, with the exception of the one involving Poland, were closed before summer following completion of transposition in all the Member States concerned. Poland was brought before the Court of Justice and the case is still pending, awaiting judgement. Another ongoing proceeding concerns Denmark and concerns discrimination of holders of payments cards issued in other Member States in breach of Articles 56 and 63(2) TFEU.

In the area of retail financial services, preparatory work (impact assessments, public consultations) continued on two legislative proposals concerning responsible lending and borrowing and the access to basic bank accounts.

Evaluation based on the current situation

The work on EMD transposition seems to be well advanced in almost all Member States, though no notifications of transpositions were received by the Commission by the end of 2010. The deadline for implementation was 30 April 2011. The actions covered by the EMD Transposition Plan have been praised by most of the Member States as being very helpful for ensuring a quick and consistent implementation. Other stakeholders have also expressed their support.

Late transposition of the PSD by Poland provokes legal uncertainty for both citizens and the payment industry. In addition, it undermines the SEPA project and, in particular, the possibility of offering SEPA Direct Debit in, from and to that Member State. Moreover, while most of the provisions on disclosure requirements and the rights and obligations of payment service providers and payment service users could be invoked directly by citizens before national courts, this is not the case for provisions regarding a positive action by Member States (e.g., setting-up of registers, designation of competent authorities, etc.). So delay in the transposition of these provisions exposes Poland to the risk of actions for compensation for losses related to the Member State's failure to implement the Directive in time.

The breach of Articles 56 and 63(2) TFEU by Denmark leads to the situation whereby holders of payment cards issued in other Member States are faced with disproportionate additional charges when using their cards in Denmark (including for internet transactions). On the other hand, holders of payment cards issued in Denmark are not subject to such charges. This constitutes a clear discrimination of customers from other Member States and, implicitly, could be treated as discrimination on the base of nationality, since holders of payment cards issued in Denmark are naturally, in the great majority of cases, Danish nationals.

The main challenges that could present themselves in the area of retail financial services include a possibility that consumers and businesses will not be motivated to seek out the benefits of the Single Market, in an environment of increasing national focus and even protectionism. This could lead to a magnification of the current problems of access to financial services for non-residents. Significant efforts will have to be made if citizens' confidence in the financial sector is to be restored.

Evaluation results

(1) Priorities

Priorities in the field of payment services will be evolving in the course of 2011, with a focus on the adoption of the proposal for a Regulation fixing SEPA migration end-dates. This legislation will mandate the migration euro credit transfers and direct debits to new common standards and rules, thus paving the way to establishing a true Single Market for euro payments in the EU.

The Commission services will maintain efforts and closely follow-up the transposition process (EMD) and support Member States' work with the aim of ensuring consistent application of the existing *acquis* (Regulation 924/2009, PSD and EMD) in Member States.

More priority will be given to monitoring the correct and consistent enforcement of the payment legal framework.

Preparatory steps will be also undertaken in view of the foreseen reviews of the EMD, the PSD and the Regulation 924/2009, scheduled for 2012. Particular regard will also be given to possible measures that support and facilitate operational migration to pan-european credit transfers and direct debits as set out in the proposed SEPA migration end-dates Regulation. For this purpose, tenders for studies on specific aspects of the PSD and Regulation 924/2009 will be launched in the course of 2011.

As for the activities carried out in the area of retail financial services, in the coming year, the Commission will bring forward proposals to promote responsible lending and borrowing as well as to facilitate access to basic bank accounts.

(2) Planned action (2011 and beyond)

Independently of whether the negotiations of the SEPA migration end-dates Regulation are completed in the course of 2011, the Commission services will continue to closely monitor the progress of migration to pan-European (SEPA) credit transfers and direct debits in the Member States and take a pro-active approach in identifying any potential barriers to that migration.

Where necessary and upon request, expert group or bilateral meetings will also be held to support legislative efforts, to closely monitor the implementation process and to spread best practice among Member States. Finally, a template for a concordance table will be provided by the Commission services facilitating the task of Member States to illustrate the correlation between the EMD provisions and the transposition measures adopted for incorporation into domestic law.

Summary

Based on the experience of the transposition of the PSD, we can conclude that a pro-active transposition approach has a positive impact and enhances consistent implementation by Member States. Therefore, a similar – although slightly lighter - approach has been applied for the implementation of the EMD. Legal and political pressure will be kept up on Member States which are late with the transposition of the PSD (Poland) or otherwise infringe EU payment services legislation and the TFEU (Denmark).

Legislation:

For detailed information on applicable legislation and work undertaken in the area of payments and retail financial services see the following web pages:

http://ec.europa.eu/internal_market/payments/index_en.htm

http://ec.europa.eu/internal_market/finservices-retail/index_en.htm

11.3. Free movement of capital (Articles 63 et seq. TFEU)

Current position

(1) General introduction

The relevant Treaty provisions governing the freedom of capital movements are enshrined in Articles 63 to 66 TFEU. In particular, Article 63 TFEU provides that "all restrictions on the movement of capital between Member States and between Member States and third countries shall be prohibited". A list of transactions that are to be considered as capital movements can be found in Annex I of Directive 88/361/EEC.[387] The legal framework governing this Treaty freedom can be found on the Europa website.[388]

(2) Report of work done in 2010

Work done in 2010 was again based on the priorities set in 2008, namely continuing the pro-active approach by way of monitoring, concentrating on more important cases, diversifying the range of restrictions to the free movement of capital which are being dealt with and addressing these restrictions at an early stage.

Since the last report, the number of opened formal infringement cases has considerably diminished[389]. The Commission services have engaged in a pro-active dialogue with Member States' authorities with the aim of exchanging views and, as *facilitator*, to closely liaise on topical matters and so avoid situations which could develop into infringements. EU Pilot also contributed significantly to the reduction in the number of formal infringement proceedings for those Member States which participated in this system. The implementation of a new registration system (CHAP –"Complaints Handling – Accueil des Plaignants has also facilitated the handling of complaints.

Of the number of cases that were open during the reporting period, those relating to privatisation and special rights of the State in privatised companies form the majority (about 60% of the total number of cases).

The other types of cases concerned bilateral investment law, real estate law, and financial services. The cases related to several specific sectors, the most common being the energy sector followed by real estate, telecoms, financial services and manufacturing. The energy sector cases concerned measures introduced by the Member States to secure their national interests (including protecting the security of supply) but which were potentially incompatible with the TFEU.

On the free movement of capital, the Court of Justice outlawed the Portuguese Government's special rights allocated in connection with the State's golden shares in Portugal Telecom[390], thus confirming many of the rules established in its earlier jurisprudence on special rights, namely:

- The free movement of capital includes both, 'direct' investments as well as 'portfolio' investments[391], and national measures must be regarded as restrictions to Article 63 TFEU if they are likely to prevent or limit the acquisition of shares in the undertakings concerned or to deter investors of other Member States from investing in their capital[392].

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387 OJ No L178, 8.7.1988.

388 http://ec.europa.eu/internal_market/capital/framework/index_en.htm

389 This was in part due to a decline in Merger and Acquisition activity.

390 Judgment in case C-171/08, Commission v Portugal, of 8/7/2010.

391 Case C-171/08, §49, see also e.g. joined cases C-282+283/04, Commission v the Netherlands, §19.

392 Case C-171/08, §50, see e.g. cases C-367/98, Commission v Portugal, §§45/46, C-483/99, Commission v France, §§40/41, C-463/00, Commission v Spain, §§61/62, C-174/04, Commission v Italy, §§30/31.

- The Court further clarified what constitutes a measure attributable to the State within the scope of Article 63 TFEU, in particular by contrasting these measures to situations resulting from a normal application of company law[393].
- The Court also reiterated that golden shares granting an influence which is not justified by the size of the State's shareholding are liable to discourage investors and thus represents a restriction[394]. And it further found that Article 345 TFEU does not have the effect of exempting the Member States' systems of property ownership from the fundamental rules of the Treaty and cannot, therefore, be relied on as justification for special rights[395].
- It found again in a different sector that special rights are not comparable to the rules concerning selling arrangements addressed in the *Keck and Mithouard* judgment, as they affect the position of a person acquiring a shareholding as such and, consequently, affect access to the market[396].
- The Court also held that an interest in ensuring the conditions of competition on a particular market cannot constitute valid justification for restricting the free movement of capital[397].
- And it pointed out that whilst ensuring the availability of the telecommunications network in case of crisis, war or terrorism may constitute a ground of public security in the sense of Article 65(1)(b) TFEU[398], such requirements must be interpreted strictly, so that their scope cannot be determined unilaterally by each Member State without any control by EU institutions and they may be relied on only if there is a genuine and sufficiently serious threat to a fundamental interest of society[399]. The Court again highlighted the difficulty for Member States to argue a connection between the holding or acquisition of shares and the safeguarding of public security[400].

On 11 November 2010 a further case on special rights in Energias de Portugal (EdP) was decided. The ruling in this case, as that in July 2010, found that, by maintaining special rights for the State and other public bodies in the company, Portugal had failed to fulfil its obligations under ECT Article 56 (freedom of capital movements - now Article 63 TFEU). The special rights involved included a right of veto for a number of important company decisions (e.g. disposal of assets, recourse to significant financing, opening or closing places of business, amendments to the Articles of Association, etc.) as well as the right to appoint a director. In addition, there was/is a restriction (which does not apply to the State) on the number of votes which could be cast by individual shareholders up to a limit of 5% of the share capital of EdP, regardless of the number of shares held.

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393 Case C-171/08, 54-56, confirming case C-112/05, Commission v Germany, §§45/46.

394 Case C-171/08, §60, see, inter alia, case C-112/05, Commission v Germany, §50.

395 Case C-171/08, §64 ("settled case law"), see e.g. cases C-463/00, Commission v Spain, §67, C-503/99, Commission v Belgium, §44, C- 483/99, Commission v France, §44.

396 Case C-171/08, §§65-67, confirming case C-98/01, Commission v the United Kingdom (BAA), §§45-47.

397 Case C-171/08, §70, see cases C-174/04, Commission v Italy, §§36/37, C-274/06, Commission v Spain, §44.

398 Case C-171/08, §72 building on an analogy with energy supply in case C-274/06, Commission v Spain, §38; see also e.g. cases C-326/07, Commission v Italy, §69 and C-463/00, Commission v Spain, §71.

399 Case C-171/08, §73, referring, inter alia, to case C-54/99, Église de scientology, §17.

400 Case C-171/08, §74; see also cases C-326/07, Commission v Italy, §48, C-207/07, Commission v Spain, §51.

Of special interest in the EdP ruling, was the Court's treatment of a claim from Portugal that it measures should only be examined under the **right of establishment** rather than the **freedom of capital movements**. Here Portugal relied on a ruling in a case against Italy (C-326/07 of 16/5/2009). In the EdP ruling, the Court rejects Portugal's arguments in some considerable detail (§§ 39-44). The Court refers to the Italian case but notes (§ 43): " *43 National legislation not intended to apply only to those shareholdings which enable the holder to have a definite influence on a company's decisions and to determine its activities but which applies irrespective of the size of the holding which the shareholder has in a company may fall within the ambit of both Article 43 EC and Article 56 EC (C-326/07 Commission v Italy, § 36)*". From that, the Court, in this case, concludes the following (§44): "*44 It must be stated that, in this action for failure to fulfil obligations, it is not inconceivable that the national provisions at issue affect all shareholders and potential investors and not only those shareholders capable of exerting a definite influence on the management and control of EdP. Consequently, the contested provisions must be examined in the light of both Articles 56 EC and 43 EC*." Later on, in §56-57 of the ruling, the Court notes why the veto rights affect all shareholders. It treats controlling shareholders in §56. However, importantly in §57, which considers portfolio investment, it states: "*57 Similarly, the right of veto at issue may have a deterrent effect on portfolio investment in EdP in so far as a possible refusal by the Portuguese State to approve and important decision, proposed by the organs of that company as being in the company's interest, is in fact liable to depress the value of that company and thus reduce the attractiveness of an investment in such shares….*"

Evaluation based on the current position

In 2010, eight infringement cases have been closed and two cases (restrictions on purchase of secondary residences in Cyprus and restrictions on acquisition of agricultural land in Tyrol (Austria)) have been opened.

The decisions to close eight cases were taken following satisfactory amendment or clarification of potentially discriminatory provisions in Member States. They were related to:

- special powers in certain strategic companies (Italy)
- an act conferring special powers in important national enterprises (Poland)
- privatisation agreements (two cases concerning Romania)
- investment restrictions for statutory pension funds (Slovakia)
- rental prices for apartments in restituted properties (Slovakia)
- limitation of voting rights of non-state shareholders (Greece)
- restrictions on acquisition of real estate in Tyrol (Austria).

Two cases are pending before the Court of Justice:

- the special rights in a privatised company (GALP) in Portugal and;
- investment restrictions for pension funds in Poland.

In seven other cases, following Court rulings, the Commission services are following the process for amending the discriminatory provisions and achieving compliance with Court rulings. Thus:

- C-112/05 Commission v Germany (Volkswagen);
- C-205/06 and C-249/06 Commission v Austria and Sweden (issues of EU rather than national competence with respect to third country Bilateral Investment Treaties);
- C-118/07 Commission v Finland (also a Bilateral Investment Treaty issue);

- C-207/07 Commission v Spain (powers in an energy company), and;
- C-171/08 Commission v Portugal (Telecom) as well as C-543/08 Portugal (EdP).

For a number of ongoing cases, Member States are in the process of removing provisions conflicting with the Treaty. The Commission services are closely following this process.

On the BITs outstanding issues, while it is important that protection is maintained for investors, it is all the more important that all investors be put in a position of legal certainty in compliance with EU law. The Court judgements concerned three Member States who must now remove the incompatibility found by the Court. However, many more Member States are likely to be in a similar situation (there are now, after recent accessions, around 300 other pre-accession BITs which were not subject to the Court rulings, since those countries were not Member States at that stage, but which contain identical provisions).

Evaluation results

(1) Priorities

During the period under review two procedures were engaged in respect to transitional provisions which had been granted to individual Member States.
With respect to Bulgaria and Romania the Accession Treaty laid down that the transitional period granted to these two countries with respect to the acquisition of agricultural and forestry land would be reviewed. The review was carried out in 2010 and the Commission reported the results of its analysis to the Council on 14 December 2010[401].

In the context of the enlargement of May 2004, several new Member States were granted a transitional period of 7 years (until 1 May 2011) for the acquisition of farming and forestry land[402]. There was an extreme possibility of a further extension of up to 3 years for certain of these new Member States. Poland was granted a transitional period of 12 years (until 1 May 2016) without a possibility to extend it. In September 2010 Hungary requested an extension. By Decision of 20 December 2010[403], in the light of the arguments presented by Hungary, the Commission granted an extension. In December 2010 Latvia also requested an extension. Other countries with a transitional period might follow.

(2) Planned action (2011 and beyond)

As regards foreign investment, the Commission will, where necessary, cooperate actively with Member States that have updated or are in the process of updating their legislation to cater for perfectly legitimate objectives as foreseen in EU law.

Summary

In the area of free movement of capital the priorities will remain enforcement action in important sectors (energy) as well as close and permanent monitoring activities related to

401 Report from the Commission to the Council on Review of the transitional measures regarding theacquisition of agricultural real estate foreseen in the Accession Treaty 2005; COM(2010)734 of 14/12/2010.

402 The Czech Republic, Slovakia, Hungary, Estonia, Latvia, Lithuania.

403 Decision 2010/792/EU of 20 December 2010.

strategic foreign investment control by Member States and to the unrolling of the specific measures taken in the context of the crisis. Increased activity related to Member States' bilateral investment treaties which involve agreements between Member States will also be required. A resolution to this question by mutual agreement or infringement procedures will be required, so that this long running issue may start to be resolved in 2011.

11.4. Public procurement

Current position

(1) General introduction

European public procurement provisions are based on the right of establishment and the freedom to provide services stemming from Articles 49 and 56 of the TFEU.

The secondary legislation in this field is three folds:

- First, there are two Directives on the coordination of procedures for the award of public works, supply and service contracts, Directives 2004/17/EC and 2004/18/EC adopted in April 2004 replacing the previous Directives 92/50/EEC, 93/36/EEC, 93/37/EEC and 93/38/EEC. Directive 2004/18/EC concerns award procedures carried out by public contracting authorities meeting certain value thresholds. Directive 2004/17/EC covers contract awards by entities operating in specific sectors (water, energy, transport, postal services).
- Secondly, there are two Directives concerning the legal protection of bidders participating in public procurement procedures, Directives 89/665/EEC and 92/13/EEC. These Directives have been modified by Directive 2007/66/EC which has been adopted in December 2007 and had to be implemented by Member States by December 2009.
- Thirdly, a special Directive for Defence and Sensitive Security procurement (Directive 2009/81/EC[404] of 13 July 2009) has been adopted in 2009. Member States have until August 2011 to transpose these new procurement rules into national law.

(2) Report on the work done in 2010

(a) New legislation in preparation or proposed and being adopted, impact assessments and implementation plans being developed in connection with new proposals, etc.

Substantial progress has been made in 2010 on an impact assessment on a Commission initiative on public procurement rules for **service concessions**, which was finalised at the beginning of 2011.

Article 30 of Directive 2004/17/EC provides that the Directive does not apply to contracts that are awarded for the pursuit of one of the covered activities if, in the Member State in which it is performed, the activity is directly exposed to competition on markets to which access is not restricted. In other words, the Directive does not apply if there has been a liberalisation resulting in such a level of competition that the discipline of the Directive is no

404 OJ L 216, 20.08.2009, p. 76.

longer needed. This exemption will be applicable where the Commission has adopted a formal Decision establishing that the conditions are met.

In 2010, four requests for exemption were submitted to the Commission concerning electricity generation and sale in Italy, exploration for and extraction of oil and gas in Italy and in Denmark, except Greenland and the Faroe Islands; exploration for and extraction of coal in the Czech Republic. Commission Decision 2010/142/EU of 3 March 2010 exempting certain services in the postal sector in Austria[405] ; Commission Decision 2010/292/EU of 29 March 2010 exempting exploration for and exploitation of oil and gas in England, Scotland and Wales[406] and Commission Decision 2010/403/EU of 14 July 2010 exempting the production and wholesale of electricity in Italy's Macro-zone North and the retail of electricity to end customers connected to the medium, high and very high voltage grid in Italy[407], were adopted in 2010. Decisions concerning the Italian, Danish and Czech requests must be adopted, respectively, by 19.4.2011, 28.2.2011 and 23.5.2011 at the latest.

(b) Preventive measures being taken in relation to recently adopted new legislation, transposition package meetings, development of guidelines, initiation of networking systems to manage the new legislation, etc.

A transposition plan including a number of initiatives aiming to accompany Member States in the transposition process was elaborated immediately after the adoption of **Directive 2009/81/EC on defence and sensitive security procurement**. During 2010 six workshops took place between January and July 2010 with national experts in charge of preparing measures to be taken at national level to transpose the said directive. The most sensitive or complex issues, both from implementation and legal perspective, were debated. The discussion resulted in a series of guidelines – essentially intended to national authorities – published on the Commission website.[408] The second half of the year has been dedicated to bilateral contacts with national authorities, where more detailed problems had to be analysed. Technical assistance will continue until the end of the transposition process and for those Member States which would not succeed in respecting the deadline also at the end of 2011.

Two guides on **social procurement** and procurement of social services of general interest have been updated in 2010 and were published in early 2011[409].

In addition, **package meetings** were held with four Member States (IT, DE, UK, EL) to discuss the most pertinent issues of the application of procurement law in the respective Member State, which allowed to solve a considerable number of infringement cases as well as to discuss the compliance of legislative developments in Member States with the EU legal framework.

Finally, the Commission invested in bilateral processes with Member States like the work on **structural reforms** in the public procurement system in Greece in the framework of the crisis support measures and Memorandum of Understanding.

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405 OJ L 056 , 06/03/2010, p. 8.
406 OJ L 84 of 31.3.2010, p. 52.
407 OJ L 186 of 20.7.2010, p. 44.
408 http://ec.europa.eu/internal_market/publicprocurement/dpp_en.htm
409 http://ec.europa.eu/internal_market/publicprocurement/other_aspects/index_en.htm#social

(c) Main actions being taken to control the correct application of the law - conformity assessments, reports on application of legislation, studies, etc.

Conformity of the national transposition measures for the Remedies Directive (Directive 2007/66/EC)) has been verified for the majority of Member States in 2010.

An in-depth evaluation process has been launched in 2010 aimed at assessing the application and effects of EU public procurement rules in the past, and several studies have been committed on various aspects, the results of which are due in the first half of 2011.

In addition, an intense cooperation is maintained between Commission services where the proper application of EU public procurement rules plays an essential role for the achievement of specific sectoral objectives. Namely funding programs establish that full respect of public procurement rules is a condition for EU financial support (regional and social funds, TEN programs). This cooperation takes place both prior and after the payment of funds.

(d) Management of the acquis through committees and expert groups

Exchange with the Member States on the public procurement legal framework is well established. The Commission regularly convenes Committees. First, the Advisory Committee on Public Contracts (ACPC), which consists of the representatives of Member States authorities, met five times in 2010. Specialised working groups of the ACPC also met in 2010, i.e. the Working Group on E-Procurement and the Economic and Statistical Working Group (two meetings each). The Commission also organises meetings of the Advisory Committee on the opening up of Public Procurement (CCO), which consists of public procurement and other technical experts.

In the context of the described Committees, discussions included the following topics:

- Evaluation of the EU *acquis* in public procurement and reform of Directives 2004/17/EC and 2004/18/EC

- A Commission initiative concerning European rules for the award of service concessions;

- The elaboration of a guidance document on the application of EU public procurement law to relations between contracting authorities;

- Electronic dimension of public procurement (i.e. PEPOL project, preparation of the Commission Green Paper on e-procurement; actions in favour of SMEs);

- Transposition of the 'Remedies' Directive 2007/66/EC (i.e. national time-schedules, problems met) and actions of the Commission in the transposition context (bilateral meetings with Member States to facilitate the transposition, launch of infringement procedures after implementation deadline, etc);

- Transposition of the "Defence" Directive 2009/81/EC of 13 July 2009 (i.e. national time-schedules, problems met) and actions of the Commission in the transposition context (i.e. bilateral meetings with Member States, etc);

- Discussion on actions to be taken by Member States to implement the European Code

of best practices facilitating access by SMEs to public procurement contracts;

- National recovery plans to overcome the economic crisis and phasing out of such measures;

- Information on various negotiations with third countries which contribute to reinforce the role of the European public procurement legislation (i.e. GPA negotiations);

- Compilation of indicators of public procurement subject to the EU Directives, processing of national statistical reports, and statistical analysis of various aspects of total public expenditure (breakdown of total expenditure, analysis of above and below threshold expenditure).

(e) Enquiries, problems and complaints management

In 2010, 226 new complaints have been registered by the Commission in the public procurement field. Countries most concerned were Germany, Italy, Greece, UK and Bulgaria. Enquiries and complaints in the field of public procurement have been increasingly treated within the EU Pilot system since the majority of Member States joined the system in the course of 2010. Public procurement files accounted for 50 % of the EU Pilot files in the internal market and services area.

(f) Petitions

In 2010 the sector of public procurement received four petitions concerning problems encountered in Spain, Italy and Romania.

(g) Management of infringements

In 2010, in 155 public procurement infringement files the Commission took relevant decisions to advance the files. Of these, 76 cases (49%) could be closed; 12 (approx. 7.5%) had to be referred to the Court.

In the public procurement field, 20 non-communication procedures had to be launched in 2010 concerning the Directive 2007/66/EC ("Remedies Directive"), which all could be closed except for one case due to compliance by the end of 2010. Two cases under Article 260 TFEU were opened and one brought before the Court.

Evaluation based on the current position

A comprehensive evaluation of the public procurement Directives 2004/17 and 2004/18 was set in motion in 2010. This essentially economic evaluation focuses on identifying the impact of the Directives, and assessing the effectiveness of the Directives in attaining their hoped-for objectives. The results of the evaluation – published in June 2011[410] – will, along with stakeholder responses to the Commission Green Paper on the modernisation of public procurement policy[411], constitute the basis for proposing relevant adjustments to the Directives. Without prejudging the outcome of this in-depth evaluation project, the following indications can be made.

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410 http://ec.europa.eu/internal_market/publicprocurement/modernising_rules/evaluation/index_en.htm

411 http://ec.europa.eu/internal_market/publicprocurement/modernising_rules/consultations/index_en.htm

Transposition of the EU *acquis* can be considered satisfactory by the end of 2010, although the delays in the transposition of the Remedies Directive (see reference to non-communication cases above) deprived aggrieved bidders of the improved measures for redress against decisions of contracting authorities for the period of delay.

As regards compliance of Member States with EU procurement rules, it has to be taken into account that more than 70.000 contracting authorities in the EU run procedures which have to respect EU rules on a daily basis. Any indicators such as the number of complaints have to be put into perspective against this background.

2010 saw a continued high level of caseload of public procurement infringement complaints. The increase in some countries may be explained by a more difficult economic situation, which sharpens competition among economic operators for a reduced number of public contracts in an environment of less private sector opportunities. However, the number of infringement complaints and cases indicates that compliance levels should be improved in a number of Member States. The Impact Assessment on a Commission initiative on concessions revealed an important level of non-compliance with EU procurement principles in the area of service concessions. It equally has to be recognised that the Commission regularly detects cases of non-respect of EU public procurement rules in the context of the disbursement of the Union's structural and social funds. Every tender procedure disregarding the EU procurement rules puts their objectives – best value for money, equal and fair opportunities for European business and fight against corruption – at risk.

Application of EU procurement rules lies exclusively with the Member States. The underlying reasons for cases of non-compliance at national level can include poor administrative capacity (contracting authorities subject to EU procurement rules include municipalities and other authorities at local level), complex and inefficient administrative procedures, insufficient awareness in contracting authorities, problems of corruption and conflicts of interest, unclear transposition in national rules as well as insufficient deterrent mechanisms for violations. While responsibility for corrective action therefore lies mainly with Member States, the Commission can contribute with support and legislative measures to remedy existing weaknesses.

Evaluation results

In terms of legislative actions, work will focus on

- Adoption of a proposal intended to modernise Directives 2004/17/EC and 2004/18/EC, including the development of a transposition plan at an early stage;
- Adoption and inter-institutional negotiation of a proposal for a Directive on service concessions;
- Adoption and inter-institutional negotiation of a proposal for an instrument transposing Member States' obligations under the GPA.

In terms of support measures, efforts will primarily be devoted to

- Ensuring smooth transposition of Directive 2009/81/EC in all Member States until the transposition deadline (21 August 2011) and verification of the quality of the national transposition measures;
- Finalising the verification of the quality of the national transposition measures of the Remedies Directive 2007/66/EC;

- Monitoring of the phasing out of national measures in the field of public procurement to overcome the economic crisis, and work on structural reforms in Member States mostly hit by the economic crisis.

Concerning infringement cases, in addition to the priority categories of non-communication cases and Article 260 cases, the following factors will determine the priority treatment of a case: high contract value and EU funding, problems of a horizontal nature affecting many procurements in a given Member State, cases raising important and/or new legal issues.

Legislation:

http://ec.europa.eu/internal_market/publicprocurement/legislation_en.htm

11.5. Professional qualifications

Current position

(1) General introduction

This sector deals with Member States' requirements for professional qualifications which lead to barriers to the free movement of qualified professionals in the Single market. To alleviate these barriers, Directive 2005/36/EC of the European Parliament and of the Council on the recognition of professional qualifications[412] implements Articles 45, 49 and 56 of the FEU Treaty for all regulated professions. Beneficiaries are all EU citizens holding a professional qualification. For lawyers, additional specific rules have been laid down at EU level (Directive 77/249/EC on the free provision of services of lawyers[413] and Directive 98/5/EC on the freedom of establishment of lawyers[414]).

(2) Report of work done in 2010

The work carried out in 2010 concentrated on the launch of the evaluation and on transposition, implementation and accompanying measures to Directive 2005/36/EC with a view to enabling citizens to make use of the new rights offered by the legislation (in particular the free provision of services and the mutual recognition under the so-called general system for cases which were previously only covered by the Treaty). The Commission also dealt with all kinds of difficulties reported by citizens when applying for recognition, such as undue delays in decision taking, compensatory measures required by the host Member State, negative decisions and requests for supplementary documentation, using all available means and in particular the network of national coordinators for Directive 2005/36/EC, EU Pilot and SOLVIT according to the nature of the problem, to find appropriate and EU law compliant solutions.

(a) Management of the acquis through committees and expert groups

The Commission held 7 meetings of its expert group composed of the national coordinators responsible for the application of Directive 2005/36/EC. The Group discussed the preparation

412 OJ L 255, 30.9.2005, p. 22.
413 OJ L 78, 26.3.1977, p. 17.
414 OJ L 77, 14.3.1998, p. 36.

of the evaluation of Directive 2035/36. The other main task has been to examine the compliance with Directive 2005/36/EC of new diplomas in architecture notified by Member States with a view to their insertion in the Annex to the Directive, granting the right to automatic recognition to the holders of these diplomas. In total, 33 diplomas and 4 certificates were examined. This work has allowed the achievement of a good level of mutual trust between Member States avoiding subsequent problems of bad application.

A network of Contact Points for Directive 2005/36/E, whose role is to inform and assist citizens, met once.

In addition, the regulatory committee of Directive 2005/36/EC met twice and voted on a Commission regulation amending Annex II (to upgrade some paramedical diplomas) and V (to add medical oncology and medical genetics to the list specialities to be recognized automatically) to the Directive. These meetings also allowed for peer pressure to accelerate the transposition of Directive 2005/36/EC for which some Member States were late.

(b) Enquiries, problems and complaints management:

Due to the large number of beneficiaries (all EU citizens holding a professional qualification and who wish to work in another Member State even temporarily), a large number of enquiries is received by the Commission which do not necessarily reveal a problem of application of EU law. In those cases the Commission refers citizens who wish to enquire about the situation in Member States to the national contact points under Directive 2005/36/EC whose task it is to give all information about regulated professions in their territory but also about procedural steps to be taken.

In the CHAP database approximately 88 inquiries and 82 complaints from citizens have been registered in 2010. As far as the complaints are concerned, roughly a half of these has already been closed.

When enquiries reveal a potential problem of application of EU law in individual cases, the Commission mostly refers citizens to the SOLVIT network and/or inserts their cases into the system with the citizen's consent.

Throughout 2010, 23 cases were introduced in EU Pilot for possible breaches of EU Law. 7 cases have been solved and 4 cases led to the opening of the infringement procedure.

(c) Management of infringements

The volume of infringements concerning restrictions in breach of Articles 45, 49 and 56 of the TFEU and the directives on the mutual recognition of professional qualifications which were dealt with, remained broadly rather stable in 2010. Approximately 31 decisions (to proceed with or to close a case) were taken by the Commission.

Concerning the infringement proceedings opened against Member States *for non-communication of national implementing measures*, the cases referred to in the previous report concerning Directive 2006/100/EC and Directive 2005/36/EC have been closed further to compliance by Member States.

The infringements cases opened against Bulgaria, the Czech Republic, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia and Slovenia because of the *nationality*

condition for notaries did not progress in 2010. This is due to the fact that almost all the Member States concerned intervened to support the Member States already referred to the Court of Justice (Germany, Austria, Belgium, France, Greece and Luxembourg). In these circumstances, it was considered necessary to examine and take into account all new arguments which might be brought forward by these Member States Estonia has abolished the condition of nationality but the Netherlands stopped the process of abolishing it waiting for the judgments of the Court. The Commission also referred Portugal to the Court on the same issue, because even though Portugal formally abolished the nationality condition previously in force for notaries, this condition thereafter appeared to still be applied.

Concerning the measures taken by Greece to comply with the judgment of the Court of 21 April 2005[415] regarding Greek legislation on the ownership, opening and operation of *opticians' shops* by companies, by judgment under Article 260 TFEU (ex-Article 228 EC) of 4 June 2009 in Case C-568/07 *Commission v. Greece*, the Court held that by failing to take, by the date on which the time-limit set in the reasoned opinion issued by the Commission expired, all the measures necessary to comply with the judgment of 21 April 2005 in Case C-140/03 *Commission v Greece*, Greece had failed to fulfil its obligations under Article 260 TFEU (ex-Article 228(1) EC), and condemned Greece to pay a lump sum. This having been done, the case has been closed in January.

In addition, under Article 260 TFEU (ex-article 228 EC), the Commission sent reasoned opinions to Greece for non-execution of the judgments of the Court of Justice in cases C-274/05 regarding the *recognition of professional qualifications of engineers* and C-84/07 regarding the *recognition of professional qualifications of opticians*. In particular, in both cases, Greece still refused to recognise diplomas awarded by competent authorities of other Member States under franchise agreements. Consequently, holders of such diplomas were still unable to practise their profession in Greece. The compliance to be achieved for those two judgments has been included in the Memorandum of Understanding with the Greek government for financing assistance in 2010.

(d) Petitions

In 2010, 13 petitions have been dealt with. These petitions in essence reflected the issues raised in enquiries and complaints which the Commission receives. Most cases concern complex individual situations.

(e) Preventive measures being taken in relation to recently adopted new legislation-conformity assessment of national transposition, transposition package meetings, development of guidelines, initiation of networking systems to manage the new legislation, etc.

In order to monitor the appropriate and smooth application of this Directive, the Code of Good Conduct which specifies the good national administrative practices competent authorities should follow when processing applications, adopted by the Group of Coordinators of Directive 2005/36/EC, has been published on the Europa website.

To enable citizens to make better use of the Directive, a document with frequently asked question has been published on the Europa website along with the "User's Guide".

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415 Judgment of 21.04.2005, Case C-140/03 *Commission v. Greece.*

To ensure legal certainty for professions benefiting from automatic recognition, whose corresponding national titles are listed in Annex V to Directive 2005/36/EC, the Commission published twice[416] the new titles and changes to existing titles notified by Member States on the basis of Article 21 (7) of Directive 2005/36/EC. These publications facilitate free movement as they give the right to the holders of the qualifications concerned to benefit from automatic recognition.

Evaluation based on the current position

Directive 2005/36/EC had to be transposed by Member States by 20.10.2007. The 7 Member States which did not yet completely transpose it by the end of 2009 achieved it in 2010. For Directive 2006/100/EC relating to accession of Bulgaria and Romania, which had to be transposed by 1.01.2007, the 3 Member States which had not completed transposition in 2009 did it in 2010. However, and as indicated in the previous report, due to the fact that Directive 2005/36/EC replaced 15 directives while maintaining their basic mechanisms of recognition, the non-transposition in due time by all Member States did not have a major negative impact on free movement and free establishment. In the large majority of cases, recognition of qualifications still took place on the basis of the national implementing measures adopted on the basis of the now repealed directives. The Commission services published a report on the transposition and the implementation of the Directive in 2010, which contains a first assessment of how the Directive has been transposed.

A second *scoreboard* was published in April 2010 offering an overview of where Member States stand in implementing Directive 2005/36/EC into national law. As stressed in the previous report, the main challenge related to this directive is represented by the enormous number of national measures needed to transpose it. By the end of 2010, around 1249 measures had been notified to the Commission.

The IMI system plays a key role in the smooth implementation of the Directive. It allows competent authorities from the host and home Member States to exchange information linked with an application for recognition where doubts are raised in relation to the professional. The number of information exchanges increased by another 30 %. It was extended to 4 additional professions (tour guides, psychologists, engineers and social workers) in October 2010, bringing the total number of professions covered to 35.

Evaluation results

(1) Priorities

As indicated in the previous report, the following are being identified as key issues: the new regime for providing services for professions falling under the general system of recognition because there was no specific regime for the provision of services for all the professions falling under the previous Directives 89/48/EEC and 92/51/EEC on the general system; the subsidiary application of the general regime, which did not exist either (recognition then fell under the Treaty) as well as principle questions under the Treaty such as partial access to a given profession.

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[416] Communication of 19 May 2010, OJ C 129 of 19.5.2009, p. 1 and Communication of 14 December 2010, OJ C 337, p. 10.

A transposition report and the experience reports of the national authorities have been published on our website. With professional organizations a meeting on the evaluation of the directive has been organized on 17 March and on 29 October.

(2) Planned action (2011 and beyond)

A public consultation will be launched in 2011. This consultation will aim at gathering stakeholders' (in particular professionals and consumers) views on a modernisation of the Professional Qualifications Directive (Directive 2005/36/EC), in particular as regards a professional card.

The final evaluation report and a Green Paper are foreseen for the autumn 2011 with a view to preparing a proposal for updating the Directive as announced in the Single Market Act.

Summary

Transposition of Directive 2005/36/EC has been completed in all Member States. The Commission therefore focussed on how Member States have implemented the Directive into their national regulations. The key challenges for the Commission have been first to ensure that Member States accurately transpose the Directive and second to evaluate how the Directive works and whether it delivers the effects compared to the objective of simplification. The evaluation could also take account of swiftly changing conditions, such as labour market, public health and others.

11.6. Company law, corporate governance and anti-money laundering

Current position

(1) General introduction

Directives in the fields of company law and anti-money laundering aimed at ensuring the stability and reputation of the financial sector (Anti-Money Laundering Directives, Directives 2005/60/EC and 2006/70/EC), harmonizing transparency requirements in regulated markets (Directives 2004/109/EC and 2007/14/EC), granting a transparent framework for takeover bids (Directive 2004/25/EC), ensuring shareholders' rights (Directive 2007/36/EC), strengthening rules on remuneration in the banking sector (Directive 2010/76/EC) and facilitating cross border mergers as well as easing administrative burden of companies by modernising and simplifying the current *acquis* (Directives 2003/58/EC, 2005/56/EC, 2006/68/EC, 2007/63/EC and 2009/109/EC). Taking into account the importance and impact of this *acquis*, the Commission established an Action Plan in 2008 to reduce transposition deficit and complete conformity assessments in the fields of company law and anti-money laundering.

(2) Report of work done in 2010

In the absence of communication of national transposition measures, 27 infringement cases were handled in 2010[417]. The Commission put particular emphasis on a straightforward management of infringement cases and identified priorities such as to ensure compliance with judgements of the European Court of Justice. Furthermore, the Commission continued to apply a number of complementary measures in order to reduce transposition deficit. It continued to publish scoreboards on state of play of transposition and package meetings were used to raise the issue of transposition. The Commission also kept up pressure on Member States through meetings of committees and national expert groups, in particular the Company Law Experts' Group and the Committee on the Prevention of Money Laundering by requesting delegations to justify their bad transposition record.

The Court of Justice issued one Court ruling for a non-communication case in this sector in 2010[418]. Furthermore, during 2010, the Commission dealt with seven infringement procedures based on Article 260 TFEU, all of them in the field of anti-money laundering. All the procedures could be closed before the formal referral to the Court of Justice of the European Union. As infringement procedures based on Article 260 TFEU aim at ensuring compliance with Court rulings, these cases have been treated as a priority and followed-up closely by the Commission.

The infringement procedures for non communication of national measures for Directive 2007/36/EC (the transposition deadline was 3 August 2009) were also followed up closely. Eight cases were referred to the Court of Justice. By the end of 2010, five cases remained pending before the Court. The Shareholder's Rights Directive aims at introducing minimum standards to ensure that shareholders of companies whose shares are traded on a regulated market have a timely access to the relevant information ahead of the general meeting and simple means to vote at a distance. It also abolishes share blocking and introduces minimum standards for the rights to ask questions, put items on the general meeting agenda and table resolutions. Late transposition might jeopardize the objective to enable shareholders of listed companies throughout the European Union to exercise their rights and have their say.

The Action Plan elaborated in 2008 also included the monitoring of the national legislation implementing directives in the fields of company law and anti-money laundering. Conformity checks were therefore given all attention in 2010. The first phase of conformity checks, i.e. the technical conformity assessments, was concluded for a high volume of national transposition measures. Taking into account the high number of Directives adopted and transposed in the previous years, the absence of concordance tables and the fact that the assessment of long and comprehensive national instruments (for example Civil and Commercial Codes) have significant implications in terms of resources, the Commission outsourced a part of the first phase of conformity checks in the course of 2009. The work related to seven different directives in the fields of company law and anti-money laundering[419] and consisted in the substantial analysis and the reporting of the relevant transposition

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417 More than 140 procedures had been handled in 2009, out of which only 0.7% of the cases were non-conformity cases in the fields of company law and anti-money laundering. In 2010, only 18.50% of the procedures handled were non-conformity cases.

418 Decision of the Court of Justice of the European Union of 24 June 2010, in case C-2009/478.

419 Directives 2004/109/EC and 2007/14/EC (Transparency Directives), Directive 2003/58/EC (modification to the 1st Company Law Directive), Directive 2005/56/EC (Cross-Border Mergers Directive), Directive 2007/36/EC (Shareholders' Rights Directives) and Directives 2005/60/EC and 2006/70/EC (Anti-Money Laundering Directives).

measures[420]. The second phase of the conformity checks (i.e. the analysis of the technical assessment and, when required, the launching of formal infringement procedures for non conformity) will be carried out as from 2011.

Although only one case for non compliance with the EU *acquis* was opened in 2010 (the case was opened *ex officio*), five non conformity cases were examined in 2010 in the fields of company law and anti-money laundering. All of them were at an early stage in the formal procedure. In parallel, contacts with national authorities were privileged to come to acceptable solutions. Although this approach will also be followed in 2011, the non conformity cases will be pursued in the absence of effective action with a view to putting an end to the relevant infringements.

As regards external submissions in the fields of company law and anti-money laundering the number of enquiries, petitions and complaints has increased; four petitions were received in 2010. Two cases were registered in EU Pilot in 2010. Furthermore, fourteen complaints were registered in CHAP.

One new Directive which deals also with issues related to company law (remuneration policies in the banking sector) has been adopted in 2010: Directive 2010/76/EC of the European Parliament and of the Council of 24 November 2010 amending Directives 2006/48/EC and 2006/49/EC as regards capital requirements for the trading book and for re-securitisations, and the supervisory review of remuneration policies.

Evaluation based on the current position

Through the rigorous action and the comprehensive range of initiatives taken by the Commission in accordance with its Action Plan, positive results have been achieved. The most significant success in 2010 in the fields of company law and anti-money laundering were the completion of national transposition of three Directives[421] and the conformity assessment of 57 national measures for seven directives.

81% of the infringement cases for non communication recorded at the beginning of 2010 had been closed by the end of the year and the transposition of three Directives could be completed. Furthermore, all the cases in relation to which the transposition deadline had expired before 2010 had been referred to the Court.

Completing the transposition of the Third Anti-Money Laundering Directive and its implementing measures[422] was essential since they aim at boosting the fight against financial crime as well as preventing damage to the stability and reputation of the financial sector and the single market. Moreover, delayed implementation could create difficulties for the banking sector in terms of costs related to the different rules in force in Member States. For its part, the implementation of the Directive simplifying the rules for merger or division of public limited liability companies as regards the requirement of an independent expert's report[423] grants more flexibility to European companies. This had a particular importance in the context of the financial crisis.

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420 In the context of the outsourcing, 8,500 pages have been translated and analysed.
421 Directive 2005/60/EC, Directive 2006/70/EC and Directive 2007/63/EC.
422 Directives 2005/60/EC and 2007/60/EC.
423 Directive 2007/63/EC.

The Commission drew up conclusions on the high effectiveness of the measures taken on the basis of the Action Plan in relation to the completion of the national transposition of Directives in the fields of company law and anti-money laundering. However, a number of Member States proved to have still problems by being late with implementation. While in the fields of company law, Belgium, France, Greece, Luxembourg, Spain and Sweden[424] had difficulties to transpose on time, anti-money laundering rules were implemented late by Belgium, France, Ireland and Spain[425]. Although the Commission has kept and will keep up the pressure on the Member States which are late with transposition, there are 22 Member States which had no transposition deficit anymore at the end of 2010.

The technical assessment of national transposition measures in the fields of company law and anti-money laundering was also a major success. The assessment included a reference to the relevant articles of the national implementing measures in the light of the corresponding articles of the concerned Directive (all in both the concerned Member State's official language and in English) and an indication of the technical assessment of conformity.

Evaluation results

(1) Priorities

Priorities in the fields of company law and money laundering will not change substantially in 2011. The Commission will endeavour to reduce further the transposition deficit, keep up pressure on Member States to ensure compliance with Court rulings, follow up closely non-communication cases and continue with the conformity checks of national transposition measures. Two new transposition deadlines will expire in 2011. The transposition of Directive 2010/76/EC[426] is due for 1st January 2011 for issues related to remuneration policies in the banking sector. And the transposition deadline of Directive 2009/109/EC[427], simplifying reporting and documentation requirements in the case of mergers and divisions, is 30 June 2011. A particular emphasis will be put on the four cases of late transposition of the Directive on Shareholders' Rights that were referred to the Court in June 2010[428].

(2) Planned action (2011 and beyond)

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424 At the beginning of 2010, Belgium and Greece were late with the transposition of the Directive simplifying the 3rd and the 6th Company Law Directives (2007/63/EC). Both Member States notified implementing measures in 2010. The score of the transposition of the Shareholders' Rights Directive (2007/36/EC) improved throughout 2010, and by the end of the year, only five out of the 14 infringement cases existing at the beginning of the year remained open (Belgium, France, Luxembourg, Spain and Sweden).

425 At the beginning of 2010, Belgium, France, Ireland and Spain had not implemented Anti-Money Laundering Directives (2005/60/EC and 2006/70/EC) and were pursued in the context of Article 260 of the TFEU. These four Member States transposed the directives in 2010 before the relevant cases were referred to the Court to ask for a penalty.

426 Directive 2010/76/EC of the European Parliament and of the Council of 24 November 2010 amending Directives 2006/48/EC and 2006/49/EC as regards capital requirements for the trading book and for re-securitisations, and the supervisory review of remuneration policies.

427 Directive 2009/109/EC of the European Parliament and of the Council of 16 September 2009 amending Council Directives 77/91/EEC, 78/855/EEC and 82/891/EEC, and Directive 2005/56/EC as regards reporting and documentation requirements in the case of mergers and divisions.

428 France notified measures transposing Directive 2007/36/EC at the beginning of 2011.

As complementary instruments included in the Action Plan had successfully reduced the transposition deficit in the fields of company law and anti-money laundering, they will be applied in the future. Concerning non-communication cases, Member States will be requested to provide detailed information on the state of play of transposition at relevant committee and experts' meetings. A scoreboard in the fields of company law and anti-money laundering will be published on a quarterly basis and as required, package meetings will be used as well. In the case of Directive 2007/36/EC, procedures under Article 260 TFEU would be accelerated as soon as the relevant Court Decisions will have been delivered.

Remaining technical conformity assessments will be continued in the course of 2011. Given the high number of measures to be considered, the risk-based approach will be pursued. The second phase of the conformity checks (i.e. the analysis of the technical assessment and, when required, the launching of formal infringement procedures for non conformity) will be carried out as from 2011.

Summary

In the fields of company law and anti-money laundering, the focus remained on reducing the transposition deficit, on ensuring compliance with Court rulings and on assessing the conformity of national measures. The Action Plan established in 2008 has brought very positive results. The actions and instruments identified in it will therefore be applied in 2011, too. In order to overcome the remaining difficulties related to conformity checks, risk-based assessments will be continued. Infringements will be followed up strictly against Member States which are late with transposition.

11.7. Auditing – statutory audits

Current position

(1) Report of work done in 2010

In the field of auditing, in 2010 the Commission carried on its work on the correct implementation of the Directive 2006/43/EC on statutory audits of annual accounts and consolidated accounts of 17 May 2006[429] ("the Directive"), which transposition was due on 29 June 2008.

In 2009, six Member States (Austria, Estonia, Ireland, Italy, Spain and Luxemburg) were referred to the Court of Justice for non communication of the transposition measures for the Directive 2006/43/EC. However, all theses cases were closed by September 2010, the Member States having communicated their national transposition measures.

To facilitate the establishment of auditor public oversight bodies in Member States, as required by the Statutory Audit Directive, and to help the existing ones become operational, the group of national experts "European Group of Auditors' Oversight Bodies" (EGAOB) continued its work on exchanging good practices on the establishment of those systems. Three

[429] OJ L 157, 9.6.2006, p.87.

EGAOB meetings – including one *ad hoc* EGAOB on the Green Paper on Audit Policy[430] - were organized in 2010.

Within the EGAOB, the sub-group on Cooperation which became the sub-group on Third Countries held three meetings in 2010. At these meetings, issues related to the equivalence assessment of third countries audit regulatory systems under Article 46 of the Directive, the adequacy assessment under Article 47 of the Directive, and the extension of the transitional regime for certain third countries were discussed.

Another sub-group established within the EGAOB, the sub-group on Inspections held four meetings in 2010. The issues discussed at the meeting of this sub-group related to, among others, the inspections procedures among the Member States, inspections of network firms, PCAOB joint inspections.

Under the Directive, the Commission services may also adopt various implementing measures using the comitology procedure; whereby the Commission services are assisted by the Audit Regulatory Committee (AuRC) composed of representative of the Member States. In 2010, six AuRC meetings were held; issues discussed include the transposition of the Directive, the equivalence and adequacy assessments, the cooperation between EU public oversight authorities.

In the area of adequacy, Article 47 of this Directive requires the Commission to assess the adequacy of the third country auditor oversight competent authorities that wish to cooperate with the Member States' auditor public oversight authorities on the exchange of audit working papers, in cooperation with the Member States.

The Commission adopted a Decision on 5 February 2010 recognising the adequacy of the auditor oversight system of the competent authorities of Canada, Japan and Switzerland [431] and another Decision on 1 September 2010 on the adequacy of the competent authorities of Australia and the United States of America[432]. These Decisions enable the exchanges of audit working papers between the EU Member State's oversight authorities and their counterparts in the above mentioned third countries.

In the area of equivalence, the Commission also used the means under Article 46 of the Directive 2006/43/EC to assess the equivalence of third country auditor oversight, external quality assurance, investigations and penalties systems. A draft Decision on the equivalence of certain third country public oversight systems for auditors and a transitional period for audit activities of certain third country auditors in the European Union[433] was submitted to the AuRC for its consideration in 2010. The draft Decision received a favourable vote from the AuRC at its meeting of 8 November 2010. This draft recognises the equivalence of the audit oversight systems in ten countries: Australia, Canada, China, Croatia, Japan, Singapore, South Africa, South Korea, Switzerland, and the United States of America. It also grants a transitional period to auditors from twenty countries: Abu Dhabi, Bermuda, Brazil, the Cayman Islands, The Dubai International Financial Centre, Egypt, Guernsey, Hong Kong, India, Indonesia, the Isle of Man, Israel, Jersey, Malaysia, Mauritius, New Zealand, Russia,

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430 COM (2010) 561 final.
431 OJ L 35, 6.2.2010, p. 15.
432 OJ L 240, 11.9.2010, p.6.
433 OJ L 15, 20.1.2011, p. 12.

Taiwan, Thailand and Turkey. Following the adoption of this Decision, auditors from these third countries will be able to continue their audit activities in the European Union while further assessments are carried out. After the exercise of the European Parliament's right of scrutiny which ended on 11 December 2010, the formal adoption of the draft Decision by the Commission and its publication in the Official Journal eventually took place in January 2011.

(2) Changes underway in 2011

The Commission published a Green Paper on audit policy on the 13th of October 2010 seeking views from stakeholders and the broader public on a broad range of issues related to statutory audit; the consultation closed on the 8th of December 2010, although responses continued to be filed after that date. In all, almost 700 responses were received. The objective of this Green Paper was to initiate a debate on the role and governance of auditor; it covered issues encompassing the concentration of the audit market and its potential implications on financial stability, the need respond to the specific needs of small and medium size practitioners, the audit of SMEs and international standards on auditing. This debate would continue at a Conference organised in February 2011. The conclusions of this debate may lead to a decision on the need to propose amendments to the current *acquis* in the area of audit.

Furthermore, the European Commission, following a competitive tendering procedure, awarded in 2010 a contract for undertaking an external study on the effects of the implementation of the *acquis* on statutory audit of annual and consolidated accounts including the consequences on the audit market. The study will also provide up to date data on the European audit market. The results of this study should be available in autumn 2011.

Evaluation based on current position

The transposition deadline for the Directive 2006/43/EC was 29 June 2008. Amongst the remaining six Member States which did not transpose the Directive in 2009, all of them finally implemented the Directive in 2010.

The obligation for Member States to establish independent competent authorities to ensure a public oversight, external quality assurance, investigations and penalties of statutory auditors and audit firms is now completed in twenty-six Member States (most of these authorities became operational in 2009). As of end 2010, only one Member State (Cyprus), had not established in practice an effective auditor public oversight body, even if it has adopted the relevant legislation to set up such an oversight body. On 6 April 2011, a reasoned opinion was sent to the Cypriot authorities because of its failure to set up a public oversight system for statutory auditors and audit firms under national law in accordance with the Directive 2006/43. Following that, the Commission services received information that an effective oversight body was established in Cyprus and the case was thus closed.

(1) Priorities

The main priority concerns the reshaping of the audit policy at European level through the Green Paper, and the aftermath of its public consultation on the *acquis* in this domain.

Another priority is ensuring that auditors' public oversight bodies pursuant to the Directive are operational in the Member States and cooperate with each other and work towards the reinforcement of the supervision of audit firms at European level.

(2) Planned action (2011 and beyond)

The transposition scoreboard will continue to be updated regularly and to be published on the Commission website.

The expert group "European Group of Auditors' Oversight Bodies" (EGAOB) will also continue its work on facilitating co-operation between public oversight bodies established by the Member States pursuant to Directive 2006/43/EC.

11.8. Accounting

Current position

(1) Report of work done in 2010

In the field of accounting, 9 Directives were in force in 2010. Two of them had not yet, in 2010, been transposed in all Member States: Directive 2006/46/EC, which transposition deadline expired on 5 September 2008 (the last transposition was completed in January 2011), and Directive 2009/49/EC which transposition deadline expired on 1 January 2011. The Commission services control the application of the relevant EU law by the means of infringement procedures and discussions in meetings with the Member States.

The majority of infringement cases and the petitions received stem from the non-communication/non-adoption of national transposing measures. Five infringements procedures have been closed in 2010. The Court had given a ruling on 2 cases. The Commission services have been encouraging the Member States to complete a swift transposition. As regards transposition of Directive 2009/49, which transposition deadline was 1 January 2011, 17 Member States notified complete transposition; they are under examination by the services. For the 10 Member States which did not notify full transposition, several reminders have been sent before and after the transposition deadline to national authorities.

(2) Changes underway

The Commission services are working on a larger simplification and modernisation proposal to review the 4th and 7th Company Law Directives which is expected to be adopted by the Commission in 2011.

Evaluation based on the current position

At the beginning of 2010, the transposition deficit in the accounting field was rather low (6 infringement procedures were open) and were all closed in the course of the year, except for one which was closed in January 2011. The delay in transposition was not due to political difficulties but rather to administrative delays in the Member States' legislative procedures.

(1) Priorities

The main priority in the field of accounting remains to ensure the timely transposition of adopted Directives. Furthermore, as mentioned above, the Services are working on a general

comprehensive overhaul of the accounting *acquis* (4th and 7th Company Law Directives).

(2) Planned action (2011 and beyond)

In the case of the Directive whose transposition deadline expired, the Commission Services are closely monitoring the transposition status by pursuing infringement cases. In the case of future Directives, the Commission services will continue to use complementary measures such as possible transposition workshops, bilateral meetings and discussions within the Accounting Regulatory Committee.

As regards the planned overhaul of the 4th and 7th Company Law Directives, the Commission services are pursuing a public consultation, meetings with stakeholders, targeted questionnaires, an external study aimed at evaluation of the cost burden reduction potential of certain proposed simplification measures, in order to be able to present the amending proposal accompanied by a corresponding Impact Assessment.

11.9. Protection of rights

Current position

Patents

On 30 June 2010, the European Commission proposed a Council Regulation on the translation arrangements for the EU patent[434]. The Commission's proposal was the subject of extensive discussions in the Council. Subsequently, the Presidency proposed a compromise based on the Commission's proposal with some extra elements addressing the concerns of several Member States. Despite strong support of a large majority of Member States for the Presidency compromise, it was not possible to achieve unanimous agreement among the 27 EU Member States.

Following the failure of the Council to agree on translation arrangements for the EU patent on the basis of the compromise by the Presidency, twelve Member States sent a request to the Commission to propose enhanced cooperation in the area of the creation of unitary patent protection. Furthermore, a number of other Member States were also favourable to enhanced cooperation and signalled their wish to participate.

On 14 December, the Commission adopted a proposal for a Council decision authorising enhanced cooperation in the area of the creation of unitary patent protection indicating the scope and objectives of enhanced cooperation.

In 2010, discussions on creation of a unified patent litigation system have been suspended since the European Court of Justice was still considering a request for an opinion submitted by the Council[435] regarding the compatibility with the EU Treaties of the draft Agreement to establish the European and EU Patents Court.

Trademarks

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434 COM(2010) 350 final.

435 Opinion 1/09. OJ C 220, 12.9.2009, p. 15–15.

The process of comprehensive evaluation of the trade mark system in Europe continued throughout 2010. The major, but not the only, element of the evaluation is a study on the overall functioning of the European trade mark system, commissioned to the Max Planck Institute on 16 October 2009, which will serve as a basis for the revision of the Council Regulation (EC) No 207/2009 on the Community trade mark and of the Directive 2008/95/EC approximating the laws of the Member States relating to trade marks.

The Council adopted on 25 May 2010 conclusions on the future revision of the Trade Mark system in the European Union[436]. The Conclusions identified the key points to which the Council would like to draw the Commission's attention in designing the future revision. The Conclusions called on the Commission to present proposals for the revision of the Community Trade Mark Regulation and the Trade Mark Directive.

In the area of the enforcement of *intellectual property rights*, the monitoring of the transposition of Directive 2004/48/EC was done. The Directive had to be implemented by Member States by 29 April 2006. All Member States have notified their national implementing measures. According to Article 18 of the Directive, Member States were requested to submit a national report on the implementation and impact of the Directive. Based of these reports, the Commission adopted in December 2010 a Communication on the Application of the Directive. This Report was complemented with a Staff Working Document.

The Commission continued the work of the European Observatory for Counterfeiting and Piracy. Subsequently, the Commission organised in February 2010, the second meeting of private stakeholders and in June the first Joint Plenary meeting with public and private sectors. In addition, the Commission in June organised, jointly with the European Parliament, the award ceremony for the competition addressed to schools. Finally, the Legal sub-group of the Observatory has produced three different reports regarding the legal framework and in particular comparative analysis and recommendations on the implementation of the Directive 2004/48/EC.

The Commission continued also the work of the stakeholders' dialogue on the sale of counterfeit goods over the internet and on the similar dialogue for the illegal down loading and illegal up loading. The objective of these dialogues is to foster voluntary inter-industry agreements between the relevant stakeholders; such agreements, given the quick development in the digital economy, often provide for quicker and more flexible solutions than legislation.

A study on a possibility to establish an electronic exchange system on counterfeit goods has been concluded in November.

Evaluation based on current position

In the context of a highly political area and due to the complex nature of the Directive 2004/48/EC, the main problem encountered by the Commission was the late transposition by some Member States. This has impacted directly the sending of national reports on the implementation of the Directive. The monitoring was done through a constant dialogue with the Member States not having sent its report. The latest reports have been submitted only in October. Subsequently, the Commission has not been able, in its report, to engage in a critical

[436] OJ C 140, 29.5.2010, p. 22–23.

economic analysis of the effects that this Directive may have had on innovation and the development of the information society.

As far as the follow up of the European Counterfeiting and Piracy Observatory is concerned, in addition to the three working groups that have been set up and which meet on regular basis (one working group on statistics, one on legal framework and one on public awareness), a reflection has been launched on a possible future sustainable structure of the Observatory.

As far as the stakeholders' dialogues are concerned, several meetings have taken place. A drafting of a Memorandum of Understanding between participants has been almost completed for the stakeholders' dialogue on the sale of counterfeit goods over the internet.

Concerning trademarks, the Community Trade Mark Regulation and the Trade Mark Directive have stood well the test of delivering an efficient and effective trade mark registration system. However, given the considerable time passed since their adoption, a revision process has been launched, in order to consider any necessary updates.

As regards Patents, failure to reach an agreement on the translation issue and thus to break an impasse over a single EU patent prompt some Member States to resort to enhanced cooperation under which at least nine EU countries can go ahead while others may join at any time at a later stage.

(1) Priorities

The priorities identified in the 2009 Annual Report were the same also for the year 2010. The monitoring of the Directive 2004/48/EC and the planning for the enhancement of administrative cooperation were duly performed. Priorities in 2010 included also the comprehensive evaluation of the European trade mark system the creation of a single EU patent and the establishment of a unified patent litigation system in the EU.

(2) Planned action (2011 and beyond)

On December 2010, the Commission adopted a report on the conformity of the national measures with the provisions of the Directive 2004/48/EC. This report will be followed-up by a public consultation and a deep impact assessment. If a modification of Directive appears necessary a proposal may be submitted by the end of 2011 or beginning 2012. Meetings with the Council on the Commission Communication will be organised during the year.

Following the creation of the European Counterfeiting and Piracy Observatory, a tender on the methodology for the collection of statistics is expected to be delivered in the course of next year. A proposal regarding its future structure and, in particular, its transfer to the Office for Harmonisation in the Internal Market (OHIM) is expected this year.

As far the stakeholders' dialogue the Commission will keep working with the stakeholders on a possible adoption of the Memorandum of Understanding.

In addition the Commission will follow-up the study on how to set up an information system for the rapid exchange of information on counterfeit goods.

Concerning Trademarks, in March 2011, the final report of the study on the overall functioning of the trade mark system was submitted to the Commission.

The Commission will come up with proposals for revision of the Community Trade Mark Regulation (EC) 207/2009 and the Trade Mark Directive 2008/95/EC in the 1st quarter of 2012. The objective is to modernise the trade mark system both at EU and national levels by making it more effective, efficient and consistent as a whole, including enhancing the complementarity between the EU and national systems by facilitating cooperation between the OHIM and national trade mark offices.

As far as Patents are concerned, the creation of unitary patent protection is foreseen under the mechanism of enhanced cooperation. In March 2011, the Council authorised the launch of the enhanced cooperation among 25 Member States (Italy and Spain do not take part). Discussions in the Council and the European Parliament will continue throughout 2011 on the proposals for regulations implementing enhanced cooperation in the area of unitary patent protection. Their adoption is envisaged in 2012.

As regards the unified patents court, discussions were re-launched in the Council as the Court of Justice delivered its opinion on the compatibility of the draft agreement creating the unified patent court with the EU Treaties in March 2011. Discussions on the way forward will continue throughout 2011. It is envisaged that the draft agreement will be signed by the Member States in a diplomatic conference convened in 2012.

12. REGIONAL POLICY

12.1. Current situation

12.1.1. General introduction

According to Article 174 TFEU, European regional policy aims to reduce disparities between the levels of development of the various regions and the backwardness of the least favoured regions by actions supported by the Structural Funds[437] (the European Regional Development Fund[438], ERDF, and the European Social Fund[439], ESF) and the Cohesion Fund[440] (CF). ERDF and CF are under the responsibility of the Directorate General for Regional Policy, while ESF is under the responsibility of the Directorate General for Employment, Social Affairs and Equal Opportunities. These Funds are managed by the Commission and the Member States under shared management arrangements, as are similar programmes under the

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437 Council Regulation (EC) No 1083/2006 of 11 July 2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and repealing Regulation (EC) No 1260/1999 (OJ L 210, 31.7.2006, p. 25).

438 Regulation (EC) No 1080/2006 of the European Parliament and of the Council of 5 July 2006 laying down general provisions on the European Regional Development Fund and repealing Regulation (EC) No 1783/1999 (OJ L 210, 31.7.2006, p. 1).

439 Regulation (EC) No 1081/2006 of the European Parliament and of the Council of 5 July 2006 laying down general provisions on the European Social Fund and repealing Regulation (EC) No 1784/1999 (OJ L 210, 31.7.2006, p. 12).

440 Regulation (EC) No 1084/2006 of the European Parliament and of the Council of 5 July 2006 laying down general provisions on the Cohesion Fund and repealing Regulation (EC) No 1164/94 (OJ L 210, 31.7.2006, p. 79).

European Agricultural Fund for Rural Development[441] and the fisheries sector[442]. In addition, Directorate General for Regional Policy is responsible for programmes under the Instrument for Pre-Accession Assistance (IPA)[443]. Rules covering the programming period 2007-2013 were adopted in 2006. All 317 operational programmes financed by the ERDF and CF were negotiated in partnership and adopted by the Commission in 2007 or early 2008[444]. The new programmes of the Member States overlap with those of the period 2000-2006, for which the final eligibility date for expenditure was the end of 2008 or 30 June 2009. Closure is now under way for the 2000-2006 programmes and projects.

In accordance with EU law[445], assistance under the Funds is provided according to an approach of complementarity and partnership between the Commission and the Member States, with due regard to their respective powers. In this context, implementation on the ground is the responsibility of the Member States, meaning in particular that the Commission is normally not responsible for the selection of individual projects (exceptions being the approval of CF projects for the 2000-2006 period and of major projects within ERDF programmes), as this comes under the competence of the national authorities.

To be eligible for co-financing from the EU budget, projects must be selected and implemented in accordance with the principles laid down in the programming documents adopted by the Commission, and must comply with the specific legislation governing Cohesion Policy expenditure and generally applicable law (public procurement, state aid, the environment, etc.) and also with relevant national rules. The management and control system put in place by the Member States seeks to ensure the regularity of all expenditure and the Commission supervises its effective functioning. When the rules are found to have been breached, making expenditure ineligible, the irregular expenditure has to be excluded by means of "financial corrections". If the Member States fail to correct irregular expenditure or to remedy deficiencies in the management and control system, the Commission itself may impose financial corrections or require improvements in the control system. In the event of serious deficiencies, the Commission can interrupt or suspend its interim payments to a programme until the weaknesses are corrected.

Most complaints tend to arise when an economic operator or member of the public considers that individual projects do not (fully) respect relevant EU and/or national rules and prefers to address the complaint to the Commission rather than to his/her national authorities. Such complaints can only be resolved with considerable support from the national authorities. Last year, the number of complaints dealt with by the Directorate General for Regional Policy increased significantly (from 141 to 227). Nevertheless, they do not normally lead to infringement procedures, but are resolved by application of the normal control and financial correction provisions specific to Cohesion Policy.

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441 Council Regulation (EC) No 1698/2005 of 20 September 2005 on support for rural development by the European Agricultural Fund for Rural Development (OJ L 277, 21.10.2005, p. 1).

442 Council Regulation (EC) No 1198/2006 of 27 July 2006 on the European Fisheries Fund; (OJ L 223, 15.8.2006, p. 1).

443 Council Regulation (EC) No 1085/2006 of 17 July 2006 establishing an Instrument for Pre-Accession Assistance (IPA) (OJ L 210, 31.7.2006, p. 82).

444 In addition 17 programmes under IPA were adopted. The following is focussed on ERDF and CF programmes.

445 Article 9 of Regulation (EC) No 1083/2006.

12.1.2. **Report of work done in 2010**

12.1.2.1. New legislation

Simplification of existing legislation is in itself an additional means to promote a reduction in errors and irregularities while reducing administrative burdens.

After a first wave of simplification in 2009, new regulations were adopted in 2010[446] with a set of measures amending two Council Regulations and proposing further simplification of the rules governing the financial management of the Structural Funds, in the context of efforts to provide more support in face of the international financial crisis and to improve the effectiveness of the delivery system of cohesion policy.

A regulation was also adopted allowing the extension of financial support from the ERDF for housing interventions for extremely poor and marginalised communities, including many Roma communities[447]. The aim is to promote the inclusion of Roma and other marginalised people by providing them with acceptable housing conditions.

12.1.2.2. Preventive measures taken (Comitology and cooperation with Member States)

In 2010, eight documents providing technical guidance in order to facilitate the implementation of operational programmes and to encourage good practice(s) were prepared by the Commission and then presented, discussed and finalised during the nine meetings of the Committee for the Coordination of the Funds (COCOF)[448].

12.1.2.3. Main actions being taken to control the correct application

Financial corrections

Financial corrections by the Member States themselves[449] and by the Commission[450] are applied where expenditure for a project is irregular or where there are serious deficiencies in

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446 Regulation (EU) No 539/2010 of the European Parliament and of the Council of 16 June 2010 amending Council Regulation (EC) No 1083/2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund as regards simplification of certain requirements and as regards certain provisions relating to financial management - (OJ L 158, 24.6.2010).
Commission Regulation (EU) No 832/2010 of 17 September 2010 amending Regulation (EC) No 1828/2006 setting out rules for the implementation of Council Regulation (EC) No 1083/2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and of Regulation (EC) No 1080/2006 of the European Parliament and of the Council on the European Regional Development Fund. (OJ L 248, 22.9.2010).

447 Regulation (EU) No 437/2010 of the European Parliament and of the Council of 19 May 2010 amending Regulation (EC) No 1080/2006 on the European Regional Development Fund as regards the eligibility of housing interventions in favour of marginalised communities (OJ L 132, 29.5.2010)

448 Article 103 of Regulation (EC) No 1083/2006.

449 Article 23 of Regulation (EEC) No 4253/88 for the 1994-1999 periods; Article 39(1) of Regulation (EC) No 1260/1999 for the 2000-2006 period; Article 98 of Regulation (EC) No 1083/2006 for the 2007-2013 period.

450 Article 24 of Regulation (EEC) No 4253/88 for the 1994-1999 period; Article 39(3) of Regulation (EC) No 1260/1999 for the 2000-2006 period; Articles 99 to 100 of Regulation (EC) No 1083/2006 for the 2007-2013 period.

the management and control system of the operational programme (under the Member States' responsibility) which has put at risk the Union contribution paid to the programme. In 2010, total financial corrections carried out by the Member States (accepted at Commission request) and by the Commission (through a formal Commission decision), following Commission audit work (ERDF and CF; periods 1994-1999 and 2000-2006) amounted to approximately EUR 755 million. This amount is in addition to the EUR 288 million corrected in 2007, the EUR 1 billion corrected in 2008 and the 2 billion corrected in 2009, reaching thus a total of EUR 4, 1 billion in the years 2007-2010. The corrections reflect the completion of the follow-up of previous audit work and an acceleration of financial correction procedures under the "Action plan to strengthen the Commission's supervisory role under shared management of structural actions"[451] (hereinafter referred to as "Action Plan").

Compliance assessment

In order to improve the management and control of the 317 programmes for the 2007-2013 period, the Member State authorities have to undertake at the beginning of the period an assessment of the description of the national management and control system per programme accompanied, by an independent report giving an opinion on their compliance with the regulatory requirements to be submitted before the first interim payment can be made. This compliance assessment is a new element[452] seeking to ensure that the set up of management and control systems are in conformity with applicable rules. By the end of 2010, all compliance assessment reports (except one) regarding national systems had been received by the Commission, of which 313 (more than 98% of those received) were judged acceptable as of 31 December 2010.

Audits

In 2010, the Commission carried out 13 on-the-spot audit missions for the 2000-2006 period and 94 for the 2007-2013 period concerning ERDF and Cohesion Fund in 21 Member States (and some cross-border programmes). They focussed on the remaining risks in management and control systems, the review of bodies responsible for the closure of the 2000-2006 programmes, audits of operations on a representative sample of projects for the 2007-2013 period and review of the work of the audit authorities for the 2007-2013 period. There were also 4 IPA/ISPA audit missions in Croatia, Macedonia and Turkey. Deficiencies uncovered typically concerned organisational problems in the systems themselves or breaches in public procurement or eligibility rules. The outcome of these audits may take the form of action plans to improve performance, and possibly also suspension and interruptions of payments or the launch of financial corrections procedures, where necessary.

12.1.2.4. Management of the *acquis* through committees and expert groups

Beyond the development of guidelines presented to the COCOF committee, no other committees or expert group meetings linked to the legality of the expenditure of the Funds have been organised.

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451 COM (2008)97 of 19 February 2008.

452 Articles 71 and 72 of Regulation (EC) No 1083/2006.

12.1.2.5. Enquiries, problems and complaints management

135 complaints have been registered. The complaints concerning Regional Policy did not lead to an infringement procedure in 2010.

A first category of complaints concerns the selection process of individual projects under the different programmes. The principal motivation for complaints was the rejection of the complainant's application for financial support. As indicated above, under shared management, such complaints are examined by the competent national administrative or judicial authorities. A second category of complaints concerns alleged non-compliance of individual projects with EU law, mostly relating to environmental law or public procurement law. A third category of complaints concerns the alleged defects in selected projects (examples include allegations that a particular infrastructure project is not in the right place (e.g. roads), does not work properly (water sewage treatment plants) or constitutes poor value for the European tax-payer's money. In such cases, there is generally no specific allegation of a breach of EU law.

As indicated in previous reports, concerning the new Council Regulation on a European Grouping of Territorial Cooperation (EGTC)[453], which entered into force on 1 August 2006, Member States have been required to adopt national rules to ensure the effective application of the Regulation and to inform the Commission of these rules. By the end of 2010, only two Member States had not completely adopted national rules due to their particular constitutional set-up. These results were achieved through political dialogue and cooperation with the national authorities without recourse to infringement procedures.

12.1.2.6. Petitions

Directorate-General for Regional Policy has treated as a lead service 11 petitions involving projects possibly co-financed by the Funds and has been associated or consulted on 20 petitions, mostly led by Directorate-General for Environment. In general, petitions concern the misuse of EU funding, deterioration of environment linked to the construction of infrastructure projects, or other alleged infringements of Union law.

12.2. Evaluation based on the current situation

12.2.1. Assessment of the current situation (satisfactory or problematic nature of the current situation)

In January 2005, the Commission made it a strategic objective to strive for a positive statement of assurance (DAS) from the European Court of Auditors. To make progress towards this goal, it introduced an Action Plan towards an Integrated Internal Control Framework[454]. In 2008, the Commission adopted a specific Action Plan[455] to strengthen its supervisory role in the structural actions area, in order to address the European Parliament's concerns arising from the weaknesses identified by the Court of Auditors in its 2006 Annual Report. The structural actions Action Plan addressed both the causes and effects of the high

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453 Regulation (EC) No 1082/2006 of the European Parliament and of the Council on a European Grouping of territorial cooperation (OJ L 210, 31.7.2006, p. 19).

454 COM (2006) 9 and SEC (2006) 49.

455 "Action Plan" (COM (2008)97 of 19 February 2008).

rate of error found by the European Court of Auditors in structural actions expenditure. The Commission's focus has been on increasing the effectiveness of the controls undertaken by the Member States and of its own supervisory activity, in order to ensure that by the time the 2000-2006 programmes and projects are closed, most of the irregular expenditure is corrected and the residual risk of error is as low as possible. For the 2007-2013 period, the Commission's preventive actions aim to ensure that the Member States' management and control systems function effectively from the beginning of the programme implementation and that deficiencies are detected as early as possible.

12.2.2. **Importance of the impact of the identified problems on the objectives of the *acquis***

Achieving the aims of cohesion policy in reducing geographical disparities of the programmes depends on effective implementation and requires that projects are selected and implemented correctly. The planned actions set out below contribute to this overall priority.

12.2.3. **Underlying reasons for problematic areas**

Under shared management (see following section), according to Article 317 of the Treaty, *"the Commission shall implement the budget in cooperation with the Member States, in accordance with the provisions of the regulations made pursuant to Article 322, on its own responsibility (...), having regard to the principles of sound financial management. Member States shall cooperate with the Commission to ensure that the appropriations are used in accordance with the principles of sound financial management"*. Consequently, any item of expenditure co-funded from the Funds shall comply with the provisions of the Treaty and of acts adopted under it[456]. Compliance with the *acquis* on matters as diverse as single market rules (EU Directives on public procurement), competition (state aid rules), environment, research, transport or energy poses a complex task for Member States when implementing operations on the ground together with a huge number of public or private final beneficiaries spending the contribution from the Funds.

12.2.4. **Responsibility for the problems and their correction**

Under shared management, the Commission is responsible for the execution of the Union budget, but the Member States are responsible for the implementation of the individual projects. Errors and irregularities (which in practice contain very few cases of fraudulent behaviour) concerning the projects are matters outside the direct control of the Commission. Member States are responsible in the first instance to correct these errors (mainly by financial corrections on project level). The Commission seeks to ensure, through its supervisory role that the management and control systems set up by the Member States are effective and, in cases where the systems are dysfunctional or where the corrections undertaken by Member States are not sufficient, applies financial corrections on programme or - in the case of CF for the 2000-2006 period – on project level.

12.2.5. **Corrective action required (priority character, timing and scale)**

From the different actions carried out in 2010, it is evident that the respect of the regional policy *acquis* requires actions of a different nature: corrective (financial corrections, action

[456] Article 9(5) of Regulation (EC) No 1083/2006.

plans, and infringement and complaints procedures), preventive (simplification of the *acquis*, compliance assessment, audits and controls, guidance notes, seminars) and informal/political (comitology, direct dialogue).

The implementation of the Action Plan and the Joint Audit Strategy of the Directorates-General in charge of Cohesion Policy, which focus on measures to strengthen the supervision of the correct implementation of the programmes and projects, further simplification and the finalizing of the compliance assessment, have been key elements to reduce as far as possible errors linked to the closure of the 2000-2006 programmes and to avoid errors under the new programming exercise.

12.3. Evaluation results

12.3.1. Priorities

As indicated in its "Annual Management Plan 2011" (21 December 2010) one of the specific objectives identified[457] is to seek reasonable assurance that the management and control systems in the Member States and beneficiary countries comply with the requirements of the EU regulations and are functioning effectively, so as to prevent and detect errors and irregularities and assure the legality and regularity of the expenditure declared to the Commission. To this end, the Directorate General for Regional Policy will seek to ensure through its supervisory role that Member States and regions have established the appropriate structures for management and control and will advise on measures to tackle weaknesses in administrative capacity for delivery, as well as provide appropriate support for setting up a sufficient stock of projects.

12.3.2. Planned action (2011 and beyond)

12.3.2.1. New legislation in preparation

The informal preparation of the new legislation concerning the 2014 to 2020 programming period has been intensified in 2010, but formal proposals will be sent to the legislator in 2011, including on the EGTC instrument.

12.3.2.2. Preventive measures taken (Comitology and cooperation with Member States)

In order to help the national and regional authorities with implementation, many guidance notes were presented in the years 2007 to 2010. Two are planned to be presented to the Committee for the Coordination of the Funds (COCOF) in 2011. Due to the amendments to the legislation adopted in 2009 and 2010, some guidance notes will have to be revised accordingly.

12.3.2.3. Main actions being taken to control the correct application

Interruptions of payments

As a preventive measure, in addition and as a possible first step to the suspension of payments decided by the Commission, Authorizing Officers by Delegation are empowered by Article 91

[457] See section 5.2.

of Regulation (EC) No 1083/2006) to interrupt payment deadlines of Structural funds and Cohesion fund applications for payments of the 2007/13 programming period if (a) in a report of a national or Community audit body there is evidence to suggest a significant deficiency in the functioning of the management and control systems or (b) he has to carry out additional verifications following information coming to his/her attention alerting that expenditure in a certified statement of expenditure is linked to a serious irregularity which has not been corrected. These interruptions are valid for a maximum period of 6 months and lifted as soon as the remedy measures have been undertaken by the national authorities. In 2010, 41 applications for interim payments have been interrupted (corresponding to a total amount of EUR 2.155.582.086,26), most of which having been lifted, to date.

Financial corrections

The current estimate of potential financial corrections likely to result from the financial correction procedures underway at the end of 2010 is approximately EUR 459 million (it was 600 million at the end 2009). Due to the audit work executed (see below section 1.3.2.3.3), financial corrections through formal Commission decisions are necessary only in cases that recommendations for remedial actions for deficiencies identified in the systems or detected irregularities have not been taken up by the Member States.

Compliance assessment

Concerning the 2007-2013 period, the compliance assessment exercise has been almost completed.

Audits

In terms of audit and control activities, the Directorate General for Regional Policy will maintain the momentum generated by the Action Plan to strengthen the Commission's supervisory role under shared management of structural actions and continue rigorous actions in 2011 under its multi-annual audit strategy. Overall, it will continue to seek to make progress towards a positive declaration of assurance (DAS) on expenditure under Cohesion policy through preventive and corrective measures focused on the closure of the programmes for 2000-2006, and the start up and functioning of the programmes for the 2007-2013 period. Concerning the 2000-2006 period, the completion of financial corrections, the completion of the follow-up of the review of bodies responsible for the closure of the 2000-2006 programmes and the review of closure declarations has been the main priority in 2010. Concerning the 2007-2013 period, audits will continue to be focused on the work of the audit authorities to obtain assurance on the reliability of their work and on the functioning of the management and control systems in the Member States.

13. TAXATION AND CUSTOMS UNION

13.1. Situation in the sector of CUSTOMS

13.1.1. Current position

13.1.1.1. General introduction

In continuation with previous years, the strategy was to put the emphasis on the prevention of

the infringements, fully in line with the Communication[458] on a strategic review of better regulation in the European Union, and moreover with the Communication[459] on a better monitoring of the application of EU law, the attention is devoted to a better and simplified legal environment. Due to its responsibilities in the area of the EU legislation, the Commission continued its efforts aiming at enhancing the correct and uniform application of the customs EU legislation.

Member States are fully committed to apply correctly EU customs rules, helped in this crucial task by a close cooperation with the Commission. The key element of this process is the priority given to preventive approach aimed at involving all parties concerned. To enable a comprehensible approach, the multi-annual programme of monitoring the compliance of Customs legislation in different Member States has been satisfactorily continued and developed. This pro-active strategy follows a planning process, targeting a selection of legislative sectors presenting, according to the risk criteria, actual or potential risk of incorrect or non uniform application, thus damaging main interests of Trade and of financial importance.

13.1.1.2.*Existing measures in force: see Annex I*Report of work done in 2010

In 2010 22 judgments related to customs were delivered, while 23 judgments were delivered in 2009.

Most of the Court's judgments in this area concerned references for preliminary rulings.

The most relevant judgment in 2010 was C-386/08 Brita GmbH v Hauptzollamt Hamburg-Hafen: Brita, a German company wished to import into Germany goods supplied by Soda-Club, a company based in the West Bank to the east of Jerusalem. This company sought preferential treatment for these products under the EC/MS-Israel Association Agreement while Germany suspected the products to have been produced in the occupied territories.

The judgment ruled that the assertion made by the Israeli authorities that products manufactured in the occupied territories qualify for the preferential treatment granted for Israeli goods is not binding upon the customs authorities of the territorial application of the Association agreement with Israel and the territory of the State of Israel, must be interpreted as meaning that products originating in the West Bank do not fall within the territorial scope of that agreement and therefore do not qualify for preferential treatment under the Association agreement with Israel. Goods which originate in the West Bank cannot benefit from preferential treatment unless origin certificates have been produced by Palestinian competent authorities.

Regarding parliamentary questions, nine have been treated, while one petition has been registered.

As regards customs, the Commission opened no own investigations regarding presumed infringements, and three files on the basis of complaints.

Besides, twenty three requests that constitute potential infringements have been received.

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458 COM(2006)689 of 14.11.2006.
459 COM(2002)725 of 16.05.2003.

No reasoned opinion (under Article 258 TFEU) has been sent. Thus, the total number of infringement cases (three) is lower than in 2009 (four) and is also the same for reasoned opinions (0 in 2009).

During 2010, two infringement cases were closed after the Member States concerned modified their legislation to comply with EU Law.

Most of enquiries and complaints in this area relate to the application of Customs legislation in general. No prioritisation was necessary to deal with the cases as regards clear and serious infringements of EU legislation.

13.1.2. **Evaluation based on the current situation**

In the customs field, EU legislation is mainly adopted in the form of Regulations. The correct and uniform application of EU customs law is consequently a clear obligation for the Member States.

The policy on infringements should be envisaged in a larger framework. The control of the correct application of EU legislation should be seen as one of the instruments of a wider policy of the harmonisation of Member States legislation and the implementation of EU legislation (committees, working groups, soft law, comitology, proposing a modifying act).

This is clear in the area of customs, where the main EU legislative instrument is the regulation and where a correct application of EU law and a common application of EU rules are dependent on both clear and accurate legislation and strong cooperation between the Member States. The practical application of EU legislation to individual cases is particularly important, which accounts for the high volume of requests made by national courts to the ECJ for preliminary rulings that become a major guarantee of the uniform application of the EU law.

There has been no significant increase in the number of infringements over recent years. The overall situation in the area of customs remains stable and this tendency is expected to continue.

Another way of improving the correct application of customs legislation is through increased use of informatics. Thus, in recent years, Customs authorities have developed and introduced the extensive application of electronic instruments, through the package called 'E-Customs'. The introduction of this computerisation involves both a harmonisation and standardisation of data and procedures that should contribute to improved application.

13.1.3. **Evaluation results**

13.1.3.1.Priorities

As far as Customs are concerned, the situation has not clearly changed regarding infringements but the number of references to the Court has increased. Consequently, priorities set for 2010 remain unchanged for 2011. Considering that, on the one hand, the global volume of infringements and complaints remains stable, and on the other hand, this trend is likely to be stable in 2011, no specific action regarding prioritization should be envisaged.

13.1.3.2.Planned action (2011 and beyond)

Taking into consideration the evaluation of the current situation, a specific planning is not required. Nonetheless, it should be noticed that a decrease of volume does not necessarily mean that the situation is fully satisfactory and that legislation is evenly and correctly applied. As in previous years, economic operators or citizens might face problems when they have to comply with measures in the short term, but they do not always report to Commission services. This is why a pro-active and horizontal approach has been preferred to continuing to target individual, isolated infringements approach.

In line with COM(2006) 689, attention has been put on helping Member States to ensure correct and uniform application of EU customs legislation. The strategy is built on close cooperation with Member States oriented towards new tools enabling improved monitoring of the application of EU Customs law. Consequently multi-annual programme of monitoring the compliance of Customs legislation in the whole EU territory has been introduced and developed since 2008.

13.1.4. **Sector summary**

During the year 2010 in the area of **CUSTOMS**, the volume of enquiries, complaints and references for preliminary rulings has been stable compared to the other years. Taking in consideration the likeliness of this tendency to continue, there is no need for any specific urgent action to be launched.

Like previously, the strategic emphasis targeted the prevention of the infringements in order to act *ex ante* instead of increasing the intervention at the downstream level, through the infringements process.

Existing measures in force: see Annex I

13.2. Situation in the sector of INDIRECT TAXATION

13.2.1. **Current position**

13.2.1.1. General introduction

Establishing an Internal Market supposes the application of legislation on indirect taxation that neither distorts competition nor free movement of goods and services.

Therefore it is necessary to achieve harmonisation of legislation in line with the changes in the economy by means of proposals for new directives although achieving that objective is often compromised by the rule of unanimity.

For this reason a coordinated infringement policy is necessary to ensure the proper functioning of the free market and to avoid distortions where there is no harmonisation.

13.2.1.2. *Existing measures in force (situation on 31/12/2010): see Annex I* Report of the work done in 2010

a) New legislation in preparation or already proposed and in the course of being adopted, impact assessments and implementation plans being developed in connection with new proposals, etc.

Value added tax (VAT)

Measures for a consistent response to carousel fraud in certain sectors

In order to allow Member States to take rapid action against carousel fraud, the Commission adopted on 29 September 2009 a proposal for a Directive allowing the application of a reverse charge mechanism on the supply of five categories of particularly fraud sensitive goods and services, namely: computer chips, mobile phones, precious metals, perfumes and greenhouse gas emission allowances.

The possibility for all Member States to opt for the application of reverse charging under the same conditions to a limited list of goods and services provides Member States with the necessary tool to tackle worrying fraud phenomena in a flexible manner while ensuring consistency in the response Member States give to carousel fraud and avoid fraud relocation. The aim was also to provide valuable experience for evaluating the efficiency of such a measure.

On 16 March 2010 the Council adopted the part of this proposal relating to greenhouse gas emission allowances (Council Directive 2010/23/EU).

The remaining part of the proposal is still on the table of the Council.

Invoicing

On 13 July 2010, the Council adopted a directive related to invoicing rules (Council Directive 2010/45/EU). The aim of the directive is to simplify VAT invoicing requirements, and in particular to facilitate the use of electronic invoicing by removing unnecessary conditions and, thereby, to create the conditions for equal treatment with paper invoicing. The directive also simplifies, modernises and harmonises other VAT invoicing rules. This measure will reduce burdens on business, support small and medium sized enterprises (SMEs) and help Member States to tackle fraud. While the Commission's initial proposal would also have led to a set of simplified rules on invoicing, the Council could not reach agreement on the removal of the many options available under the current rules.

The directive is a key element of the EU commitment to reduce burdens on business by 25% by 2012.

Improvement of the functioning of the cross-border refund directive

The new VAT Refund Directive (Council Directive 2008/9/EC) replaced on 1 January 2010 a previous Directive from 1979 providing for a paper procedure by which taxpayers established within the EU had to send original invoices to all Member States in which they incurred VAT in order to receive a refund. The new Directive introduces an electronic system by which the taxable person submits his application to the Member State of refund via a web portal developed by the Member State in which he is established. Member States were obliged to make this web portal available on 1 January 2010. The deadline for submission of the refund application in the Member State of establishment was set for 30 September of the calendar year following the refund period.

However, some Member States were late in launching their web portals (mid-May for the last one), whilst others have had a number of technical problems, both leading to a situation in

which taxable persons have not been able to submit their refund applications. Additionally, divergences in the technical details relating to Member State web portals led to several difficulties.

Therefore the Commission made a proposal to prolong the deadline applicable to 2009 requests until 31 March 2011 as well as granting the Commission the necessary comitology powers to adopt the technical measures that are necessary for such a pan-European refund scheme to function properly[460].

The Council adopted on 14 October 2010 the first part of the proposal relating to the extension of the deadline (Council Directive 2010/66/EU). The second part relating to the use of comitology to adopt technical implementing measures is however still before the Council.

VAT on postal services

The ECOFIN Council of 7 December 2010 discussed the way forward on the 2003 Commission proposal on VAT on postal services and acknowledged that it will not be possible, at this stage, to make progress.

In the absence of progress at this stage, the status quo, based on the current provisions of the VAT Directive and the case law from the Court of Justice will remain.

VAT standard rate

Following the Commission's proposal (COM(2010) 331) of 24 June 2010, the Council adopted on 7 December 2010 Directive 2010/88/EU maintaining the current minimum standard rate of VAT at 15% until 31 December 2015.

Future of VAT

On 1 December 2010, the Commission adopted a Green Paper on the future of VAT (COM(2010) 695) - "Towards a simpler, more robust and efficient VAT system", by which it launched a wide public consultation on how the EU VAT system can be strengthened and improved, to the benefit of citizens, businesses and Member States.

In the same month a Communication on "Removing cross-border tax obstacles for EU citizens"[461] was also adopted. The Communication outlines the most serious tax problems that EU citizens face in cross-border situations (e.g. double taxation, difficulties in claiming tax refunds or obtaining information on foreign tax rules) and announces plans for solutions in some areas such as e-Commerce.

Recast – Council Regulation (EU) N° 904/2010

In the context of the fight against VAT fraud, the Commission worked on its proposal for a Council Regulation on administrative cooperation and combating fraud in the field of Value

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460 Proposal for a Council Directive amending Directive 2008/9/EC laying down detailed rules for the refund of value added tax, provided for in Directive 2006/112/EC, to taxable persons not established in the Member State of refund but established in another Member State (COM(2010)381final).

461 COM(2010)769 of 20 December 2010

Added Tax (Recast) (COM (2009) 427 final), a proposal that was adopted by the Commission 18 August 2009. The aim of this proposal is to give Member States the means to combat cross-border VAT fraud more effectively and to provide for a legal basis for Eurofisc. The Council reached a political agreement on 8 June 2010. The proposal was formally adopted by the Council on 7 October 2010 (Council Regulation (EU) N° 904/2010). It was published in the Official Journal of EU on 10 October 2010 and the major part will enter into force on 1/1/2012.

Mutual recovery assistance

The Council adopted Directive 2010/24/EU concerning mutual recovery assistance on 16 March 2010 (OJ L 84 of 31.3.2010). This directive is based on Commission proposal COM(2009)28 of 2 February 2009. Member States have to transpose this Directive by 31 December 2011.

Outermost regions

The Commission adopted on 14 December a Report on the functioning of Council Decision 2004/162/EC of 10 February 2004 concerning the dock dues tax arrangements in the French overseas departments and a proposal for a Council decision amending Decision 2004/162/EC as regards the products that may benefit from exemption from or a reduction in dock dues. The proposal should be adopted during spring 2011 after the Parliament has given its opinion.

Excise duties

In the area of excise duties, Council Directive 2010/12/EU of 16 February 2010 amending Directives 92/79/EEC, 92/80/EEC and 95/59/EC on the structure and rates of excise duty applied on manufactured tobacco and Directive 2008/118/EC, was adopted. This new Directive has a two fold objective: 1) to achieve greater convergence between the tax levels and closer approximation of the retail prices of manufactured tobacco products applied in the Member States and by this means improve the functioning of the Internal Market; and 2) to ensure a higher level of health protection by increasing the level of taxation, and consequently the level of price of tobacco products, which in turn influences consumers to reduce tobacco consumption.

b) Preventive measures being taken in relation to recently adopted new legislation – conformity assessment of national transposition, transposition package meetings, development of guidelines, initiation of networking systems to manage the new legislation, etc.

Implementation of the "VAT Package"

From 1 January 2010, the new "VAT Package", i.e. Directives 2008/8/EC of 12 February 2008 amending Directive 2006/112/EC as regards the place of supply of services and 2008/9/EC of the same date laying down detailed rules for the refund of value added tax to taxable persons not established in the Member State of refund but established in another Member State, entered into force across the EU. Those directives included new provisions which resulted in the payment of VAT for most business-to-business services in the country of the customer rather than in the country where the supplier is located, while for business-to-consumer services, VAT continued to be paid in the Member State in which the supplier is established. On the same date, a new electronic procedure was put in place in order to allow

taxable persons to claim back the VAT they paid in another Member State.

Implementing regulation

In preparation for the entry into force of the new rules on supply of services and in order to further assure, at the EU level, the smooth and coordinated transition to the new system, the Commission adopted on 17 December 2009 a proposal on implementing measures for the VAT Directive 2006/112/EC (COM(2009) 672 final). The proposal included a number of measures related to the VAT Package, in particular with a view to prevent situations of double taxation that could arise as a result of diverging interpretations of the new rules. For example, there are guidelines for suppliers on establishing the location and tax status of the customer, as this will determine the rate of VAT that must be paid. Other guidelines focus on the provisions within the VAT Package which complement or provide exceptions to these general new rules. This proposal was based on work undertaken by the VAT Committee in 2009.

The proposal has been extensively discussed in 2010 by the Council (11 meetings were organised). The preparation of, and subsequent discussions on, this proposal allowed for further clarification of numerous concepts and rules adopted in Directive 2008/8/EC so that Member States could, if they so wished, take them into account in their national implementing measures. Political agreement was reached on 18 January 2011, allowing for the adoption of the Implementing Regulation early 2011.

Refund directive

As regards the new VAT Refund Directive, the Commission held a large number of meetings with stakeholders and businesses in view of monitoring the concrete implementation of the new scheme. In addition to the technical problems reported, it appeared that several Member States do not always apply correctly the provisions of the directive.

Specifically, these cases relate to restrictions on the right of access of the web portal, in particular to agents who are not established in the same Member State as the applicant; the late opening of web portals (or more recently to major disruptions in the functioning of national systems); the absence of any confirmation by the Member State of establishment that a request has been submitted; the limitation of the number of invoices which can be claimed in one application; and the identification of VAT groups with multiple VAT numbers.

Preventive measures have been taken through discussions in the relevant committee (SCAC).

Studies in the field of VAT

In 2010 the Commission launched several expert studies aimed at an assessment of various fields of the current EU VAT system and proposals for further developments on:

– the impact of different medium-term options relating to import VAT collection under centralised customs clearance;

– the impact of the current VAT rules applied to the public sector and to activities in the public interest, whose aim is to identify options for legislative actions and assess their respective impact;

– the feasibility of alternative methods for improving and simplifying the collection of VAT through means of modern technologies and/or financial intermediaries;

– supplies on board means of transport with an aim to identify eventual options for new legislative actions.

Implementation of Regulation 904/2010

The new provisions incorporated in recently adopted Regulation 904/2020 enter into force in 2012. Several practical details need to be further developed and approved by the Standing Committee on Administrative Cooperation (SCAC).For this purpose several project groups will be set up early 2011 under the Fiscalis program. The outcome of these project groups and the decisions taken by SCAC will then need to be reflected in a Commission implementing Regulation amending and completing Regulation 1925/2004, that is planned to be adopted by the end of 2011.

The specific provisions providing a legal base for Eurofisc entered into force already shortly after the publication of the 2010 Regulation in the Official Journal of EU. A first meeting of the Eurofisc Group has already been held, where the rules of procedure were adopted, the working fields were identified, the chairperson chosen and shortly after also the working field coordinators were elected. In the beginning of 2011 each working field will start its activities.

Automated access by competent authorities to certain types of information will enter into force only by 1/1/2013 but, as this will require changes to the Member State IT systems, preparatory works will also start early in 2011.

c) Main actions being taken to control the correct application of the law – conformity assessments, reports on the application of legislation, studies, etc

Value added tax (VAT)

The Commission has checked the correct implementation by Member States of the Council Directive 2009/69/EC of 25 June 2009 regarding tax evasion linked to imports. This process has not yet been completed as not all Member States have notified their transposition measures.

Article 2 of the Council Directive 2008/117/EC of 16 December 2008 provides that the Commission shall, on the basis of information provided by the Member States, present, no later than30 June 2011, a report assessing the impact of Article 263(1) of Directive 2006/112/EC on Member States' ability to fight against VAT fraud connected with intra-EU supplies of goods and services as well as the usefulness of the options provided for in Article 263(1a) to (1c), as well as, depending on the conclusions of the report, any appropriate proposals. Due to the fact that not all Member States have implemented the above mentioned Directive by 1/1/2010 and in order to have a complete picture of the impact of the new rules in all Member States, the Commission has decided to present the report by the end of 2011, rather than on 30 June 2011.

VAT Package

As the VAT Package brought about a fundamental change to the VAT system, after 31 December 2009, with the new rules on the place of supply of services and the refund of VAT

to non-established EU VAT traders, it has been inevitable that a number of monitoring tools had to be implemented at an early stage by the Commission services.

The Commission has checked thoroughly the transposition of national legislation of Member States to conform to the EU VAT Package rules –as a priority task identified in 2010 based on the Commission's risk-based approach to some monitoring actions.

Those monitoring actions were initiated in 2008-2009 (preparatory stage *prior* to the entry into force of the new legislation) and continued in 2009-2010 (first monitoring stage). They included the following steps in the facilitation and control of this transposition:

– Organisation of Fiscalis seminars on the new place of supply and refund rules.

– Preparation of Working Papers and chairing discussions with national delegations on the new place of supply and refund rules in the VAT Committee and the SCAC.

– Internal monitoring of the implementation of new measures in each Member State.

– Analysis of the notifications of national provisions to the Commission by Member States, followed by the Commission's analysis of Member States' measures.

– Analysis of the correctness of the transposition for each Member State, based on Member State notifications and detailed questionnaires on the place of supply and refund rules prepared by the Commission services in order to facilitate the check to be conducted internally by the Commission staff.

Excises

Twice a year, the Commission asks Member States to update the **excise duty** tables containing detailed information on the rates and tax reductions or exemptions applied by Member States on excise goods subject to EU legislation (energy products and electricity; alcohol and alcoholic beverages; manufactured tobacco). In doing so, the Commission controls the respect by Member States of the minimum levels of taxation and of the correct application of tax reductions or exemptions.

d) Management of the acquis through committees and expert groups

VAT Committee

As regards management of the EU VAT legislation, the VAT Committee, an advisory committee set up by Article 398 of the VAT Directive 2006/112/EC of 28 November 2006, has competence to examine questions raised by the Commission or the representatives of the Member States, which concern the application of EU provisions on VAT. At least twice a year, the VAT Committee examines questions raised on the interpretation and application of the existing EU VAT legislation.

The VAT Committee in 2010 had 2 meetings discussing issues arising from the new rules on the place of taxation of supplies of services. It resulted, amongst other, in common guidelines on the admission to events which could be included by the Council in the proposal for a recast of implementing measures for the VAT Directive 2006/112 (COM(2009) 672 final) under discussion.

There were also discussions on the scope of the exemption applicable to the supply of postal services and the supply of goods incidental thereto, leading to the agreement of guidelines as a follow-up to the Court's judgement in the TNT-case (Case C-357/07 *TNT Post UK Limited*).

Business Expert Group

The Business Expert Group on the smooth functioning of VAT in the EU was set up in 2010. The Group had 3 meetings of one day each to discuss various topics concerning the EU VAT legislation with a view to strengthen and improve the EU VAT system.

The group focuses on ways in which the relationship between tax payers and tax administrations could result in a smoother functioning of the present VAT system. Day-to-day practical problems arising from managing the VAT system are to be discussed, as well as suggestions for possible solutions. The aim is to offer a platform at EU level where information on practical bottlenecks in the management of the VAT system can be shared, discussed and solutions found in order to smoothen the functioning of the system and for the benefit of both the tax administrations and the business.

Administrative cooperation in the field of VAT and the fight against VAT fraud

As regards administrative cooperation in the field of VAT and the fight against VAT fraud, several expert groups, funded through the Fiscalis 2013 budget, discussed specific problems that are either related to specific fraud problems or targeted at exchanging best practises or enhancing cross border administrative cooperation. These groups dealt with multilateral controls, e-auditing, internet monitoring, new means of transport (cars and yachts), risk management and e-learning.

In 2011 some new project groups will be set up under Fiscalis in order to assist the Commission with the implementing Regulation for Regulation 904/2010. These groups will discuss forms, feedback, statement of best practises, statistics, etc.

Eurofisc has also started its activities in 2010 and the different working fields will report to the Eurofisc Group that will annually report to SCAC.

Through SCAC the Commission will continue to monitor the use Member States make of the tools on administrative cooperation and the fight against VAT fraud offered to Member States by this new legislation.

Mutual recovery assistance

Several expert project groups, funded through the Fiscalis 2013 budget, discussed specific problems to prepare the implementation of the new Council Directive (dealing with the development of the request forms, the uniform recovery instruments, and the organisation of the new communication structure).

Through the Recovery Committee, the Commission monitors the use Member States make of the tools on mutual tax recovery assistance.

e) Enquiries, problems and complaints management

Within the area of **indirect taxation**, the prioritisation criteria were fixed in line with the

2007 Communication of the Commission on 'A Europe of results'. The Commission continued with its efforts to ensure alignment of Member States' indirect tax legislation with the requirements of primary and secondary EU law, by intensifying its infringement actions following the adoption of new Directives and by pursuing a more targeted infringement approach in support of ongoing policy initiatives such as the Commission's initiative on tax policy coordination. Inter alia in the area of VAT grouping, the Commission issued a Communication[462] and has opened infringement procedures against Member States violating the VAT Directive. Other priorities concerned procedures affecting the EU's own resources and also procedures related to VAT on postal services, with interpretation of the VAT Directive provided by the Court in the case TNT Post UK Limited. Travel agencies and reduced VAT rates were likewise launched in this context.

In the 2007 Communication[463], the Commission decided on the introduction of an arrangement for monthly decision-taking to allow for the quicker progress of infringement cases which have to be referred to the Court. The results of this new decisional method were particularly significant within this domain where considerable efforts were made to achieve this objective. A significant number of cases is currently awaiting a ruling from the Court of Justice.

In the field of indirect taxation the Commission receives an increasing number of complaints. They are registered in CHAP (an internal registration system operating since 2009) and their treatment is tracked in each step. There were 124 open complaints in December 2010, the processing of which the Commission is trying to accelerate despite the complexity of the cases.

The year 2010 is characterized by an unusually high number of preliminary questions (52 cases). The role of the Commission, to suggest an interpretation of EU law to the Court, is particularly important in this area as most of the judgments of the Court of Justice in this area are delivered on the basis of preliminary questions.

The Commission also continued with the EU Pilot project to test and improve working methods between Commission services and Member States on information exchange and problem solving.

SOLVIT will also remain an important problem solving tool in cross-border cases involving Internal Market issues.

f) Petitions

Regarding the petitions treated in the area of indirect taxation, the most recurrent issues reminded in the area of taxation of cars. It should be noted that the majority of petitions related to already open infringement cases by the Commission.

g) Management of infringements

462 COM(2009)325.
463 COM(2007)502.

Within the area of indirect taxation, 2010 was another year with a considerable number of infringement cases closed after Member States brought their legislation into conformity with EU law during the different steps of the procedure.

The following Court cases merit extra attention:

In the joint cases *Commission v. France*[464], *Austria*[465] *and Ireland*[466] the Court decided that by adopting and maintaining in force a system of minimum prices for the retail sale of cigarettes released for consumption and a prohibition on selling tobacco products 'at a promotional price which is contrary to public health objectives', the concerned Member States (France, Austria and Ireland) have failed to fulfill their obligations.

In the judgment in the case *Commission v. France*[467] the Court decided that France in applying a reduced rate of value added tax to the supply of services by 'avocats', 'avocats' of the Council of State ('Conseil d'État') and the Court of Cassation ('Cour de cassation'), for which they are paid in full or in part by the State under the legal aid scheme, violated provisions of EU law.

In the judgment in the case *Commission v. Poland*[468] the Court decided that Poland by applying a reduced value added tax rate to supplies, import and intra-EU acquisition of clothing and clothing accessories for babies and of children's footwear, the Republic of Poland has failed to fulfill its obligations resulting from the VAT directive.

Finally the judgment in the case *Commission v. Austria*[469] the Court decided that by inclusion of the standard fuel consumption tax (SFCT), which essentially consists of a single registration tax, in the basis of assessment of the value added tax on the delivery of a motor vehicle Austria violated the EU law.

13.2.2. **Evaluation based on the current situation**

It is important to recall again that unanimity is and will remain the rule for the adoption (and thus the adjustment of the principles as of 1979 in the area of VAT) of the texts towards harmonization in the field of taxation. This situation makes harmonization through legislation more complex.

The overall situation in the area of indirect taxation is changing as infringement action and references to the Court have steadily increased in recent years and this trend is likely to continue. The key challenges will be to achieve correct application of EU law within acceptable deadlines. This needs to be monitored continuously.

Hence, infringement policy simplifies the situation for taxpayers by contributing significantly to more uniform application of EU rules in this area.

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464 Judgment of 4 March 2010, case C-197/08.
465 Judgment of 4 March 2010, case C-198/08.
466 Judgment of 4 March 2010, case C-221/08.
467 Judgment of 17 June 2010, case C-492/08.
468 Judgment of 28 October 2010, case C-49/09.
469 Judgment of 22 November 2010, case C-433/09.

A number of measures have already been taken to improve the situation and to rationalize action. These include a more strategic approach to infringement action by focusing on specific priorities and adopting a more horizontal approach to similar infringements in different Member States. In addition, a lot of emphasis is put on prevention by better co-ordinating the preparation of national legislation transposing EU legislation into national law.

The Commission's approach can be illustrated by following examples:

- In the field of postal services, three solutions adopted by the Member States were analysed (taxation, exemption, partial taxation) in order to propose a solution before the Court, and then after the judgment in the TNT Post case the national legislation of all Member States was monitored.

- In the field of VAT grouping, after a communication, all Member States not complying with the EU law were invited to change their legislation. In those cases where legislation was not changed, a referral to the Court is envisaged.- Regarding travel agencies, infringement proceedings were suspended to give the Member States the possibility to adapt the text of the Directive. After three successive EU presidencies without progress, the Commission announced to the concerned Member States that the cases will be referred to the Court in order to prevent distortions of competition.

The new system of complaints registration (CHAP)introduced in 2009 to simplify the registration and treatment of complaints continued to be used and tested.

Finally, it is welcomed that during 2010, 69 infringement cases have been closed because the Member States concerned brought their legislation into conformity with EU law without the need for any referral to the Court of Justice. These figures reveal clearly that the alignment of Member State legislation with EU law is being achieved through the work done by the Commission and Member States in the context of infringement proceedings following the adoption of new directives. As stated in its 2007 Communication, the Commission has started to work with Member States to try to ensure quicker results without recourse to infringement proceedings always being necessary.

13.2.3. **Evaluation results**

13.2.3.1.Priorities

The existing pro-active infringement policy and prioritisation of specific issues has been maintained and further developed as a strategy in order to persuade Member States to approve ongoing legislative proposals. Unfortunately, this policy has not always attained the goal (e.g. travel agencies and postal services).

On the control of the implementation of Directives, the national implementing provisions were checked systematically by the Commission services in charge. In this regard, correlation tables is recognised as a useful preventive tool for the Commission, national administrations and stakeholders as they ensure transparency and facilitate the complex work related to transposition of directives.

A second priority concerns the EU own resources. Those resources within the area of indirect taxation include those accruing from VAT and are obtained through the application of a uniform rate of tax to a tax base determined in a uniform manner and in accordance with EU

rules. Cases detected through own investigation with a possible impact on own resources continue to be initiated by the Commission. For example the Commission has initiated several procedures concerning the correct application of VAT exemptions according to Article 137 of the VAT Directive. Their purpose is to ensure the equal treatment of Member States' contributions to EU own resources.

Last but not least, in the field of car taxation, object of many complaints and petitions, the Commission, in accordance with is using Article 110 of the TFEU as interpreted by the Court of Justice, ensures that the Member States do not tax in a discriminatory way, at the time of registration, second-hand vehicles bought in the other Member States.

Cases of registration and use of leasing cars and company cars in the Member State of the residence of an employee or manager other than Member State where the company is based constitute a new field of the control of application of EU law.

For **indirect taxation** issues, Directorate-General for Taxation and Customs Union opened 80 new infringement cases: 46 of which related to VAT, 22 related to excise duties and 12 regarding car, energy and environmental taxation.69 infringement cases were closed after Member States modified their legislation and therefore complied with EU Law; mostly after referral to the Court of Justice before compliance was achieved.

The infringement policy of the Commission was reflected both in a considerable number of infringement cases and a considerable number of observations made in the context of references for preliminary rulings to the Court. The Court of Justice delivered 51 judgments related to indirect taxation (45 in the domain of VAT and 6 regarding other indirect tax issues), mostly judgments in consequence of a preliminary question in pursuance of which the Commission has given its interpretation.

The volume of petitions in the different sectors falling within the competences of Directorate-General for Taxation and Customs Union is relatively moderate and stable (33 new petitions have been introduced in 2010).

Finally the number references for preliminary ruling increased significantly (52 in 2010 comparing with 36 in 2009)

13.2.3.2. Planned action (2011 and beyond)

One of the specific objectives planned for the mid-term is to create a simpler and transparent tax environment for individuals, SME's and other businesses in cross-border transactions through the control of the application of EU law, modernisation, better coordination and harmonisation of tax systems in the Internal Market.

Since VAT has been identified as causing a high level of administrative burden for business, the Commission is seeking how to simplify and rationalise the VAT legislation.

The Commission will focus in the field of indirect taxation on taxation of leasing and use of company cars, particular aspects of VAT grouping and follow up of VAT-package-check results.

13.2.4. Sector summary

In the field of **INDIRECT TAXATION**, the number of enquiries, complaints and references for preliminary rulings in this year continued to increase. The Commission focused its efforts to ensure alignment of Member States' indirect tax legislation with the requirements of primary and secondary EU law, by pursuing a more targeted infringement approach. Infringement procedures affecting the EU own resources and specific infringement procedures related to VAT on postal services, VAT grouping, travel agents and reduced VAT rates were followed up. Despite the good figures for notification regarding the transposition of the existing secondary EU Law, the existing pro-active infringement policy and prioritisation of specific issues should be maintained, particularly concerning the implementation of new legislation (e.g. VAT package). In 2010, 69 infringements proceedings have been closed after Member States modified their legislation in line with EU law, and 80 new infringement cases were opened.

Existing measures in force: see Annex I

13.3. Situation in the sector of DIRECT TAXATION

13.3.1. **Current position**

13.3.1.1. General Introduction

There is very little harmonisation in the area of direct taxation. As a consequence, the relevant Treaty provisions constitute the main part of the legal framework.

Existing measures in force: see Annex I.

13.3.1.2.Report of work done in 2010

a) New legislation in preparation or already proposed and in the course of being adopted, impact assessments and implementation plans being developed in connection with new proposals, etc.

On 7 December 2010 political agreement was reached in the Council on the proposal for a **Council Directive on administrative cooperation in the field of taxation**. It is based on a proposal of 2009[470] and aims to create a legal instrument of high quality enhancing administrative cooperation in the field of taxation in order to allow the smooth functioning of the Internal Market by providing effective means to combat tax evasion. The Directive ensures that the EU standards for the exchange of information on request are aligned on international standards. In particular, it provides that Member States can no longer rely on bank secrecy to refuse the exchange of information.

Several **proposals for Directives** were also on the agenda during 2010:

- In the interest of clarity and legal certainty, a **Proposal for a Council Directive on the common system of taxation applicable in the case of parent companies and subsidiaries of different Member States** was put on the table aiming at transforming the

[470] (COM (2009)29).

planned codification of Directive 90/435/EEC into a recast in order to incorporate the necessary amendment;

- Negotiations are ongoing on the amendment to the **Savings Taxation Directive** (2003/48/EC). Adoption by Council in 2011 would require substantial transposition work.

Several **public consultations** were launched during 2010, which aim to gather information in areas of importance for the Internal Market and EU citizens, such as:

- Consultation on Taxation of cross border interest and royalty payments between associated companies;

- Consultation on possible approaches to tackling cross-border inheritance tax obstacles within the EU;

- Consultation on Double Tax Conventions and the Internal Market: factual examples of double taxation cases.

Separately, **the Council Resolution** of 8 June 2010 on coordination of the Controlled Foreign Corporation (CFC) and thin capitalisation rules within the European Union (2010/C 156/01) addressed the question of how far the Member States are allowed to go in applying anti-abuse measures while preserving the fundamental freedoms as applied by the Court of Justice.

b) Main actions being taken to control the correct application of the law – conformity assessments, reports on the application of legislation, studies, etc.

In December 2010 the Commission launched an external study covering all 27 Member States aiming to identify the most common obstacles in the direct tax area that cross-border workers encounter when they decide to exercise their fundamental freedoms. The results of the study will be used as a basis for initiating infringement procedures.

c) Management of the acquis through committees and experts groups

The **Working Group for Administrative Cooperation in the field of Direct Taxes** (WG ACDT) examines matters concerning the application of the Directive on mutual assistance in direct tax matters and insurance premiums (Directive 77/799/EEC) and the application of the Directive on the taxation of savings income in the form of interest payments (Directive 2003/48/EC). Three meetings have been held in 2010.

In addition, a sub group of the WG ACDT devoted to the design and IT development of common forms for exchange of information met four times in 2010.

The eForms for exchange of information on request, spontaneous exchanges and for feedback have been released for entry into production at the end of 2010.

d) Enquiries, problems and complaints management

Considering that there is little secondary EU legislation in the area of **direct taxation**, almost all of the enquiries and complaints in this area (*a sizable volume of 145 well-founded enquiries and complaints*) relate to the application of the fundamental Treaty freedoms in respect of differential treatment of domestic and cross-border situations. They therefore fall mainly in the following category of the 2007 Communication 'A Europe of results' –

"breaches of EU law, raising issues of principle or having particularly far-reaching negative impact for citizens, such as those concerning the application of Treaty principles (..)".

As in previous years, the main focus in 2010 were infringement actions targeted at areas where the Commission sees scope for co-ordination of Member States' direct tax systems, as highlighted in the 2006 Communication on Co-ordinating Member States' direct tax systems in the Internal Market. Particular emphasis was given to infringement cases in respect of taxation of dividend payments and dividend payments to pension funds.

e) Petitions and parliamentary questions

Most of the **petitions** in the direct tax area relate to possible infringements of Treaty freedoms and instances of double taxation due to the simultaneous application of different Member States' tax legislation. The volume of petitions in the direct tax area is relatively moderate (10 petitions in 2010).

In addition, the direct tax area has been of significant interest for the Honourable Members of the European Parliament as indicated by the significant number of **parliamentary questions** on the subject.

f) Management of infringements

In the wake of the financial crisis and the need for Member States' to preserve and expand their tax revenues, the external interest in the area of **direct taxation** remains substantial. The stable number of well-founded enquiries and complaints and the increased number of referrals for preliminary rulings from the Court are a clear indication of this trend. This trend is likely to increase and intensify over the coming years.

In the area of **direct taxation**, the Commission opened a smaller number of infringements than in 2009. This was partly due to more Member States joining EU Pilot and an increased use of this tool in order to find solutions compatible with EU law without the need to open a formal infringement procedure (*32 such cases*).

A special emphasis has been given to those cases which reveal serious infringements of EU law that prevent EU citizens and enterprises from exercising their rights to establish themselves or invest in other Member States. Moreover, particular attention has been paid to those areas where the Commission sees scope for co-ordination of Member States' direct tax systems, as highlighted in the 2006 Communication on Co-ordinating Member States' direct tax systems in the Internal Market[471] and the subsequent specific communications on cross-border losses, exit taxes and anti-abuse rules. In addition, work on the priority areas of cross-border dividend payments and cross-border pensions continued. Finally, two new priority areas are being addressed relating to inheritance tax and eliminating the direct tax obstacles encountered by cross-border workers.

In the area of **direct taxation,** 2010 was once again a year with a considerable number of infringement files closed after Member States changed their legislation in order to conform to EU law as a direct result of the Commission initiating procedures under Article 258 TFEU. Namely, 68 infringement procedures were closed after the Member States concerned modified their legislation.

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471 COM(2006)823 of 19.12.2006.

Likewise, the number of decisions by the Commission to refer Member States to the Court of Justice for incompatible direct tax legislation remained relatively stable (*10 such decisions*).

In 2010 the Court of Justice delivered 15 judgments related to direct taxation. Most of the Court's judgments in this area (13) concerned references for preliminary rulings. The following cases were of particular relevance:

In *SGI*[472] the Court held that Belgian transfer pricing rules applicable only to cross-border situations are a restriction of the freedom of establishment. However they are justified by the need to prevent abuse and safeguard the balanced allocation of taxing powers between Member States. The Court concluded that the rules were, subject to verification to be carried out by the referring court, proportionate.

In *X-Holding*[473] the Court held that the Netherlands restricted the freedom of establishment by not allowing cross-border group taxation for foreign subsidiaries. However, it found the restriction justified by the need to safeguard the balanced allocation of taxing powers, even where the risk of double loss relief or tax avoidance was very limited.

In *Gielen*[474] the Court ruled that the Netherlands infringed the freedom of establishment by discriminating non-resident business operators by not taking into account the hours that they worked in their foreign business when calculating a deduction for self-employed persons and that the option for non-residents to be taxed as residents did not justify this discrimination.

In *Commission v. Spain*[475] the Court ruled that Spain infringed the freedom of capital movement by taxing outbound dividends paid to companies in other EU Member States, while dividends paid to Spanish companies were exempt from any taxation. The ruling confirms the legal analysis of the Commission's Dividend Taxation Communication of 19 December 2003.

In *Commission v. Portugal*[476] (Case C-105/08), the Court rejected the action as it found that the Commission had not proven that the Portuguese tax legislation leads in certain situations to a higher taxation of non-resident financial institutions on the interest they receive on loans made to Portuguese borrowers.

13.3.2. **Evaluation based on current situation**

The situation in the **direct tax** area continues to be challenging as the number of infringement actions stabilised while the number of references to the Court has increased in recent years. It remains to be seen whether this trend will continue.

The key challenges ahead are to manage the high level of activity in the area without an increase in resources while achieving equal surveillance and uniform application across Member States of EU law in this largely non harmonised area.

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472 Ruling of the Court of Justice in case C- 311/08, Société de Gestion Industrielle SGI of 21.01.2010.
473 Ruling of the Court of Justice in case C-337/08, X Holding v. Staatssecr. van Fin. of 25.02.2010.
474 Ruling of the Court of Justice in case C- 440/08, Gielen v. Staatssecr. van Fin of 18.03.2010.
475 Ruling of the Court of Justice in case C-487/08, Commission v. Spain of 03.06.2010.
476 Ruling of the Court of Justice in case C-105/08, Commission v. Portugal of 17.06.2010.

A number of measures have already been undertaken to improve the situation. This includes a more strategic approach to infringement action and adopting a more horizontal approach to similar infringements in different Member States.

Moreover, the Commission is encouraging Member States to take a more pro-active approach to removing existing tax obstacles by examining the scope for co-ordination of Member States' direct tax systems. As outlined in the 2006 Communication on Co-ordinating Member States' direct tax systems in the Internal Market[477], the aim of this initiative is to ensure that national tax systems comply with EU law and interact coherently with each other. The initiative seeks to remove discrimination and double taxation for the benefit of individuals and business while preventing tax abuse and erosion of the tax base. Coordinated solutions could help to remove discrimination and further eliminate the tax obstacles to cross-border activity and thus help to reverse the trend of increased litigation by taxpayers in national courts and the ECJ.

13.3.3. **Evaluation results**

13.3.3.1. Priorities

As far as direct taxation is concerned, the priorities set for 2010 remain unchanged for 2011. Two new areas will also be addressed with priority: inheritance tax and eliminating the direct tax obstacles encountered by cross-border workers.

13.3.3.2. Planned action (2011 and beyond)

Given the evaluation of the current situation, continued and intensified infringement action is envisaged in the direct tax area.

Common Consolidated Corporate Tax Base (CCCTB)

In 2011, adoption by the Council of the planned legislative proposal for a Common Consolidated Corporate Tax Base (CCCTB) would require substantial implementation/ transposition by Member States and conformity assessment by the Commission possibly combined with expert group/ committee meetings to manage the application of the measure. Once adopted and implemented, CCCTB would reduce the scope for cross-border restrictions and thus result in a decrease in infringements in the corporate tax area.

Amendment Savings Directive[478]

The Commission on 13 November 2008 adopted an amending proposal to the Savings Taxation Directive, with a view to closing existing loopholes and better preventing tax evasion. The Commission proposal seeks to improve the Directive, so as to better ensure the taxation of interest payments which are channelled through intermediate tax-exempted structures. It is also proposed to extend the scope of the Directive to income equivalent to interest obtained through investments in some innovative financial products as well as in certain life insurance products. Adoption by the Council would require substantial

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477 COM(2006)823 of 19.12.2006.

478 Directive 2003/48/EC on taxation of income from savings (OJ L 157 p 38 of 26.06.2003).

implementation by Member States and conformity assessment by the Commission combined with committee meetings to manage the correct application of the measure.

Financial Transaction Tax

On 7 September 2010, the Council held an exchange of views on the options regarding financial industry contributions in the wake of the financial crisis. Discussions covered the coordination of levies on banks and other financial institutions and the possible introduction of a financial transaction tax.

On 7 October 2010, the Commission set out its ideas for the future taxation of the financial sector. Working on the basis that the financial sector needs to make a fair contribution to public finances, and that governments urgently need new sources of revenue in the current economic climate, the Commission put forward a two pronged approach. At global level, the Commission supports the idea of a Financial Transactions Tax (FTT), which could help fund international challenges such as development or climate change. At EU level, the Commission recommends that a Financial Activities Tax (FAT) would be the preferable option. If carefully designed and implemented, an EU FAT could generate significant revenues and help to ensure greater stability of financial markets, without posing undue risk to EU competitiveness.

The Commission has lunched an in-depth Impact Assessment to further examine the ideas it has set out in its Communication. The Impact Assessment is planned to be ready by summer 2011. If appropriate, legislative proposals will follow before the end of the year.

Inheritance taxes

It appears that Member States' inheritance tax rules as applied in cross-border situations may hinder EU citizens from benefiting fully from their right to move and operate freely across borders within the Internal Market and create difficulties for the transfer of small businesses on the death of owners. First, such individuals may be exposed to tax discrimination. Second, there is the risk of taxation of a single inheritance by several Member States with no comprehensive relief for the double taxation.

The Commission has worked on several different fronts to obtain more evidence of the extent of any such cross-border inheritance tax problems within the EU and to find solutions to the problems identified. In this regard, a public consultation was launched in 2010 on cross-border inheritance tax obstacles within the EU and possible approaches to tackling these issues. As a reference document to this consultation, the Commission published a study by external consultants on "inheritance taxes in EU Member States and possible mechanisms to resolve problems of double inheritance taxation in the EU". The Commission has also been preparing an impact assessment, on the basis of which it will decide on the best solution and it aims to adopt an initiative along these lines in 2011.

13.3.4. **Sector summary**

As there is very little secondary EU legislation in the area of **DIRECT TAXATION**, the main focus is on the application of the fundamental Treaty freedoms in respect of differential treatment of domestic and cross-border situations.

The number of well-founded enquiries and complaints remain stable while the referrals for preliminary rulings from the Court of Justice have increased, therefore the interest

remains just as high as in previous years.

In order to manage the workload in the direct taxation area, the Commission will continue to pursue a strategic approach to infringement action by focusing on specific priorities and by looking more horizontally at similar infringements in different Member States. Moreover, as outlined in the 2006 Communication on Co-ordinating Member States' direct tax systems in the Internal Market, the Commission is encouraging Member States to be more pro-active in removing existing tax obstacles by examining the scope for co-ordination in this area. Such co-ordinated action can help to remove discrimination and promote compliance with EU law. The previous priorities established in this area remain unchanged for 2011. In addition, two new areas will be addressed with priority: inheritance tax and eliminating the direct tax obstacles encountered by cross-border workers.

14. EDUCATION AND CULTURE

14.1. Current position

14.1.1. General introduction

14.1.1.1. Education and training

The continuing challenge in the field of education and training is to ensure the application of the principle of free movement for students, a fundamental objective of EU action in accordance with Article 165 TFEU. Students in the different types and levels of education and training should not be treated less favourably because they have exercised their mobility to another country for all or a part of their studies. This problem is particularly manifest in the case of recognition of diplomas awarded in another country[479].

The Commission believes that learning mobility plays a key role both in the personal and skills development of the individual student and in promoting greater labour market flexibility after the studies. It is also an important component for creating a Europe of citizens, one of the key objectives of the Union. The obstacles to mobility should therefore be removed as far as possible. Despite the relative lack of specific, binding provisions in EU primary and secondary law in this area, the Commission took action to protect the principle of free movement. The obstacles encountered relate mainly to the equality of tuition and registration fees, to some benefits directly related to student status, to the recognition of periods of study and diplomas acquired in other Member States and to the scholarships and/or student loans offered. Infringement procedures begun in 2009 on areas such as discrimination in access to distance learning provided from a Member State other than the Member State of residence and discrimination in access to reduced fares for students on public transport, have been continued in 2010.

The main Treaty articles and other legal provisions applicable are:

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479 When the diploma or the professional qualifications in itself would be sufficient to exercise the profession in the Member State of origin, the terminology used is "recognition of professional qualifications"; that is the responsibility of the Directorate General for Internal Market and recognition in this case is regulated by binding provisions (notably Directive 2005/36/EC). When the citizen is mainly interested in the recognition of the diploma itself, especially for continuing studies, this is called academic recognition (TFEU, Article 165, par. 2, second indent).

- Article 18 TFEU, establishing the principle of prohibition of any discrimination on grounds of nationality within the scope of application of the Treaty[480].

- Article 20 TFEU, establishing citizenship of the Union and ensuring citizens of the Union enjoy the rights conferred by the Treaty.

- Article 21 TFEU, which is the main provision on the right of every citizen of the Union – and therefore every student or person undergoing a training, and every teacher as well – to move and reside freely within the territory of the Member States.

- Articles 165 TFEU, related to education. In paragraph 2, the objectives of the EU institutions' action in the field of education are set out. Among those objectives are "encouraging mobility of students and teachers, by encouraging inter alia, the academic recognition of diplomas and periods of study" and "encouraging the development of distance education". Similar provisions are contained in Article 166, related to vocational training.

- Directive 2004/38/EC, on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States. This Directive contains several provisions concerning students and persons under vocational training. Indeed, students are an important category of citizens moving between Member States and the Directive contains key provisions related to students on, for example, rights of residence for students legally enrolled in education or vocational training, and on equal treatment of EU citizens with specific rules on social assistance and maintenance grants.

Directives and other EU legal acts containing provisions related to education or vocational training[481] are not adopted on the basis of Articles 165 and 166 TFEU, because the harmonisation of the laws and regulations of the Member States for the achievement of the objectives referred to in these Articles is excluded by the Treaty (see paragraph 4 of Articles 165 and 166). EU action based on these articles may only encourage, support and supplement Member States' action, while fully respecting their responsibility for the content of teaching and vocational training and for the organisation of education and training systems.

Nevertheless, Article 165 paragraph 2, taken together with the abovementioned Articles 18, 20 and 21 and Directives, provides a clear structure for the legal framework on the free movement of students. On that basis, a student who moves from his Member State of origin to another to carry out all or part of his/her studies, is protected not only against discrimination on grounds of nationality in the second Member State, but also against prejudicial treatment in his/her Member State of origin on grounds (directly or indirectly) related to the fact that s/he

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480 The Court of Justice has held that the field of education is among those included in the scope of the Treaty under Article 12. Inter alia, see the judgment of 11 July 2002 in the case C-224/98, *D'Hoop*, grounds 29 to 32; judgment of 15 March 2005 in the case C-209/03, *Bidar*, operative part. Article 12 (Article 18 TFEU) must be read in conjunction with the provisions of the Treaty on citizenship of the Union, i.e. articles 17 (Article 20 TFEU) and 18 (Article 21 TFEU).

481 Another example is Council Directive 2000/78/EC of 27 November 2000 establishing a general framework for equal treatment in employment and occupation. This Directive, which lays down a general framework for combating discrimination on the grounds of religion or belief, disability, age or sexual orientation, may apply in some questions related to education and vocational training.Directive.

has studied abroad. This new standard finds its application, e.g., when a student asks his/her own Member State to recognize a diploma acquired in another Member State or when s/he asks for the portability of a grant or scholarship in order to continue studying in another Member State[482].

In that light, the refusal to recognize a diploma without a proper justification or the application of disproportionately long or costly procedures could be interpreted as penalising a European citizen for having exercised his or her right to free movement and having followed studies in another Member State. Such practices could, therefore, also constitute violations of EU law.

Finally, it is useful here to show the methodology used by the Commission in the exercise of its tasks for the classification of the issues pertaining to education and training. The categories are:

(1) Access to educational institutions in a Member State for students from other Member States. The principle of non discrimination (18 CE) is the main rule here. Among seven cases handled by Directorate-General for Education and Culture in 2010, the cases against Austria and Belgium concerning access to their universities, principally for medical and related studies, by candidates from Germany and France respectively, remain suspended for five years (until 2012). The Commission is closely monitoring the impact of the conditions imposed by those Member States, requiring them to submit to the Commission statistical data[483] which will enable a judgement to be drawn on whether the measures are necessary and proportionate. Moreover, in the preliminary case C-73/08, *Bressol*, related to the Belgian case of access to university (mainly for veterinary studies) the Court of Justice pronounced its judgment on 13 April 2010 and then ruled that Articles 18 and 21 TFEU preclude national legislation, such as that at issue in the main proceedings, which limits the number of students not regarded as resident in Belgium who may enrol for the first time in medical and paramedical courses at higher education establishments, unless the referring court, having assessed all the relevant evidence submitted by the competent authorities, finds that that legislation is justified in the light of the objective of protection of public health. Therefore, in order to evaluate the impact of that judgment on the handling of the Belgian infringement (and perhaps on the Austrian infringement as well), the Commission must wait for the judgment of the Constitutional Court of Belgium.

(2) The conditions for awarding grants, either to cover tuition and registration fees, or to cover living expenses. This issue is examined both in connection with the host country, where it concerns students from other Member States, and in relation to the country of departure, which, under certain conditions (Case C-11-06, *Morgan*), is obliged to award grants to students who decide to go to another country for all or part of their studies.

(3) Other rights of students in the host country during their studies, in order to ensure equal treatment with domestic students. To this category belongs the issue of of equality of treatment with national students in relation to transport fares. On this issue,

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482 Judgment of the Court of 23 October 2007 in the joint cases C-11/06 and C-12/06, *Morgan* and *Bucher*.

483 A second annual set of statistics was provided by Austria in December 2009 and a third one in November 2010.

the Commission in 2010 decided to refer to the Court of Justice the case against one Member State (Austria) and to issue a reasoned opinion in another case (the Netherlands).[484].

(4) The academic recognition of diplomas. The Commission receives a lot of correspondence on this issue, relating particularly to excessive delays in recognising diplomas or periods of study, exceeding a reasonable cost for such recognition, not permitting appeals against negative decisions or not presenting justifications for such decisions.

Apart from the binding provisions of EU law in this sector, the role of "soft law", consisting principally of Recommendations of the European Parliament and of the Council, is particularly important in providing a framework in which the difficulties encountered by citizens can be resolved. In this context, the European Qualifications Framework, due to be implemented by all Member States by 2012, is beginning to have an impact. Valuable results are also often obtained in this area by the ENIC-NARIC network (European Network of Information Centres, National Academic Recognition Information Centres)[485].

14.1.1.2.Sport

In the area of sport, it is established case-law of the Court of Justice that sport federations and regulations must respect the fundamental rights guaranteed by the Treaty, and in particular the principle of non-discrimination on grounds of nationality[486]. The same case law has recognised that this principle does not apply to rules which have a purely sporting interest (i.e. rules which fall into the definition of the specific nature of sport), such as the selection of athletes for national teams. In this context, the principle of proportionality applies.

The entry into force of the Lisbon Treaty introduced a new Article 165 TFEU extending the competence of the European Union in the area of sport. Following a combined reading of Articles 18, 21 and 165 TFEU, the Commission considers that the general EU principle of prohibition of any discrimination on grounds of nationality applies to sport for all EU citizens who have used their right to free movement. As a consequence, sport activities as a whole fall into the scope of EU law, including therefore amateur as well as professional sport, while the latter also falls more specifically under the provisions related to internal market freedoms, in so far as the sport activities under consideration constitute an economic activity.

Moreover, the Commission considers amateur sport to be a social advantage in the context of the free movement of workers. According to Article 7(2) of Regulation (EEC) 1612/68[487],

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484 To the same category (student rights toward the country of destination) could be classified the issue of entry and residence permit for students. As for the movement of students between Member States, the issue was addressed initially by Directive 93/96/EC and recently by Directive 2004/38/EC. As for the movement of students between a EU country and a third country to which extends the application of Union programmes, the problems are often resolved by the provisions governing the programme (mandatory or not). In cases of other third countries, the solutions are given either by the provisions of mutual agreements or by other instruments of the Union, which are the responsibility of the Directorate General for Justice, Liberty and Security.

485 http://www.enic-naric.net/

486 See the Court of Justice's cases C-36/74 *Walrave*; C-13/76 *Donà*; C-415/93 *Bosman.*

487 Regulation (EEC) 1612/68 of the Council of 15 October 1968 on freedom of movement for workers within the Community.

migrant workers have to be treated equally with nationals of the host country concerning access to employment, as well as working conditions and social advantages. The Court has held that these cover also non financial advantages, in particular those which would facilitate integration into the host Member State.

Additionally, the Commission takes into account the recent ECJ case law[488] which considers that Union citizenship is destined to be the fundamental status of nationals of the Member States. In that regard, the Commission considers that the exercise of the right to move and reside freely in another Member State is enhanced if citizens of the EU are able to practice sport as amateurs on the same footing as its nationals. Consequently, in exercising that right in another Member State, persons are in principle entitled, pursuant to Article 18 TFUE, to treatment no less favourable than that accorded to nationals of the host State.

In applying Union law to amateur sport, the Commission takes into account the specific characteristics of sport, as set out in Article 165 TFEU and in the Commission's White Paper on sport[489].

14.1.2. **Report of work done in 2010**

14.1.2.1. Education and training

The Commission services have intensified their activity in this area, through infringement cases, replies to parliamentary questions, petitions to Parliament, citizens' inquiries and complaints, and by the application of new tools (EU Pilot, CHAP) for the implementation of EU law.

The Commission had opened, in 2009, infringement proceedings under Articles 18, 20, 21 and 165 of the Treaty and Article 24 Directive 2004/38 about discrimination of students by the host country, regarding fares on public transport. On 2010, the procedures have reached the stage of reasoned opinion for one Member State (the Netherlands), and the referral to the Court for another Member State (Austria). The Commission believes that students who perform some or all of their studies in a Member State should have access to public transport of that State under the same conditions as domestic students.

The Commission had also opened in 2009 infringement proceedings against two Member States relating to fees and grants for distance learning. The Commission believes that students, who study in a Member State other than the one where the university providing the distance learning is situated, should not pay higher tuition fees than students from that country nor receive a lower maintenance grant than if the university was situated in the Member State of residence. Significant improvements of the situation in one of the Member States concerned (UK), which meant compliance with EU law, enabled the Commission to close this case early in 2011, although the other one (Germany) remained open at the end of 2010.

In an infringement file concerning tuition fees in higher education (Poland), compliance has been achieved following approaches from the Commission services. Therefore the file has been closed.

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488 See Cases C-184/99 *Grzelczyk*, paragraphs 31 to 33; C-85/96, *Martinez Sala*, paragraph 63; C-158/07 *Förster*, paragraphs 37 to 43.

489 White paper on sport, 11 July 2007, COM (2007) 391 final.

In response to a petition to the European Parliament, the Commission services opened an infringement file for possible discrimination in access to compulsory education based on the language spoken by the child at home. Such a criterion risks constituting indirect discrimination based on nationality. Clarification of the situation in the Member State concerned (Belgium) enabled the Commission to close this case early in 2011.

14.1.2.2.Sport

The Commission received a significant number of complaints in 2010 relating to discrimination on grounds of nationality, concerning access to competitions, obstacles to mobility and transfer or administrative fees. The Commission's concern is to ensure that rights to free movement and equal treatment are respected, taking into account the specific characteristics of sport. A study launched by the Commission addressing the specific issue of access to individual competitions has been published in December 2010 and the conclusions and recommendations contained therein help provide better guidance in this area.

The complaints concerned access to both individual and collective competitions in various sports such as football, handball, basketball, squash or shooting. Infringement proceedings started in 2009 were pursued concerning discrimination on grounds of nationality in individual judo competitions (BE) and basketball regulations (Luxembourg). The former was closed in 2010 following modifications of national regulations that brought them in line with EU law. Two requests were dealt through EU PILOT related to nationality quota in squash and restrictions on the free movement of young football players between clubs. The Commission continued its dialogue with sport associations as foreseen in the White Paper on Sport.

14.2. Evaluation based on the current situation

14.2.1. Education and training

The observations are similar to those of the previous report. The level of compliance of Member States with the *acquis* can be considered generally satisfactory. However, the number of complaints and petitions of citizens, especially on the recognition of diplomas and periods of study, reveals that the obstacles to free movement are still widespread in practice. On 2010, in an issue of recognition of professional qualifications, in which the Commission decided to initiate infringement proceedings (Greece), some problems of recognition of academic qualifications were also the subject of the proceedings.

Finally, the Commission has published the guidance announced in a previous Report on monitoring the application of EU law, for public authorities and stakeholders in the Member States, drawing out the key implications of the case law established by the Court thus far, on education and training. This guidance covers issues such as access to educational institutions, recognition of diplomas, the portability of grants, and other rights of students in the host country or in the country of origin. It should help to establish the rights of students to free movement as a clear area of EU law, underpinning the trend already established by the Court. In doing so, it would contribute to the Union’s objective of achieving a substantial increase in

the level of mobility among students in higher education. This guidance has been published in the framework of the Commission initiative *Youth on the Move*[490].

14.2.2. **Sport**

In the area of amateur sport, sport regulations concerning various collective and individual sports, could reportedly contravene to EU law. The Union *acquis* concerning collective sports enables the Commission to act against discrimination on grounds of nationality and obstacles to free movement. The Staff Working Document on Sport and Free movement (January 2011) accompanying the Communication on Developing the European Dimension in Sport (COM(2011)12) should provide guidance for a better understanding of these issues. Other areas of sport challenging EU law and not yet covered by the Court's case law, such as access to individual competitions destined to select national athletes or award national titles, medals or records, need legal certainty. In that light, the study on equal treatment in individual sports competitions launched by the Commission and published at the end of 2010 provides for a better guidance in this area and a better definition of the specific characteristics of the concerned sports.

14.3. Evaluation results

14.3.1. **Priorities**

14.3.1.1.Education and training

The priority area remains the mobility of students within the European Union, where the current obstacles prevent the Union from realising its full economic and social benefits. In this context, the academic recognition of diplomas is probably the most difficult issue to deal with.

14.3.1.2.Sport

The priorities set in the previous Annual Reports are unchanged. The Commission will continue to ensure that rights to free movement and equal treatment are respected, taking into account the specific characteristics of sport.

14.3.2. **Planned action (2011 and beyond)**

14.3.2.1.Education and training

Noting that the area of education is a separate chapter of the Union's *acquis*, the Commission intends to support its implementation by:

- Opening formal proceedings in cases which, in the Commission's view, represent clear infringements of EU law;
- Participation in significant preliminary references to the Court, when matters relating to education and sport are involved;

490 http://ec.europa.eu/education/yom/wpguidance_en.pdf

- The supervision of application of the abovementioned guidance to Member State administrations, students and other stakeholders.

14.3.2.2. Sport

The planned actions for 2011 are to:

- Continue the enforcement of EU law, relying on the new provisions of Article 165 TFEU;

- Continue dialogue with sport associations in a preventive perspective;

- Continue to monitor closely the activities of the national and international governing bodies for sport;

- Provide guidance and better explain the existing rules to Member States and sport stakeholders so as to help them address possible legal difficulties stemming from actions or rules in the field of sport.

15. HEALTH AND CONSUMERS

15.1. Introduction

The mission of Directorate-General Health and Consumers is to improve the health, safety and confidence of European Citizens. Its policies and laws touch the daily lives of citizens. Consumers can be confident that their food is safe and that the safety of their food is protected by strict enforcement of controls. Patients can rest assured that a high protection of public health. Citizens benefit from action at EU level against animal and plant diseases and pests that is far more efficient and cost effective than individual efforts of Member States. Consumers expect throughout the EU an equally high level of protection in consumer markets that are more competitive, open, transparent and fair. Directorate-General Health and Consumers provides European Citizens with an improved regulatory framework that maintains its capacity to manage and communicate on risk, especially during times of crisis.

To accomplish the above Treaty powers are used to the fullest extent possible while overcoming any obstacles in the application of *acquis* in this domain. Directorate-General Health and Consumers ensures that EU laws are fully and consistently enforced and seeks to engage society at large in its implementation efforts. Delivering effective policies requires close cooperation with Member States so that lawmaking maximises benefits and minimizes burdens to society. The food, consumer and health policies are part of a globalised system where we should take every opportunity to show that as international partners we expect to trade in safe products.

Member States are key partners because they have the primary responsibility for ensuring implementation of EU law. But equally better cooperation between national enforcement agencies and the Commission will result in more uniform application of legislation in this area. In addition, the Commission sought during the course of 2010 to empower citizens, consumers and patients through information and education to enable them to support implementation efforts of Member States and the Commission.

At the beginning of 2010, an internal reorganisation of competencies took place between

Commission departments. Pharmaceuticals (including the European Medicine Agency), medical devices and cosmetics policy areas were transferred from the domain of "Enterprise and industry" to the domain of "Health and Consumers", and policy areas of genetically modified organisms (GMO) and of sustainable use of pesticides, were transferred from the domain of "Environment" to the domain of "Health and Consumers", while policy areas "Consumer Contract" and "Marketing law" became the responsibility of Commission departments in the domain of "Justice".

The legislation in the health and consumers areas is often technical and requires some guidance to Member States for better implementation. For the implementation of this *acquis* prevention often works better than legal action. Although infringement proceedings remain an important instrument, prevention of an infringement is often a more optimal use of the resources and nurtures better working relations with Member States.

Although most of the *acquis* in this domain is stable, evaluation of the existing legislation is being continued to ensure that it meets its policy goals without creating unnecessary burden to business and national enforcers.

15.2. Public health

15.2.1. Blood and tissues

15.2.1.1. Current Position

General Introduction

The legislative framework for substances of human origin consists of:

- Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components;

- Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells; and

- Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation.

The legislative framework on blood and blood components is completed by the following implementing measures: Commission Directive 2004/33/EC as regards certain technical requirements for blood and blood components, Directive 2005/61/EC as regards traceability requirements and notification of serious adverse events and reactions and Directive 2005/62/EC as regards EU standards and specifications relating to a quality system for blood establishments.

With regards to tissues and cells, two implementing Directives complete the legislative framework: Directive 2006/17/EC as regards technical requirements for the donation, procurement and testing of human tissues and cells, and Directive 2006/86/EC as regards traceability requirements for the coding, processing, preservation, storage and distribution of human tissues and cells. Finally, Commission Decision 2010/453/EU of 3 August 2010

establishes guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials, in the field of human tissues and cells.

One of the main challenges of 2010 was the completion of the EU's efforts to ensure common quality and safety standards for the procurement, transport, characterisation, transplantation and use of organs across the EU. The added value of this initiative was to reduce the risks to patients across Europe, maximise the benefits of transplantation for the EU citizens, increase trust in transplantation systems, facilitate exchanges of organs and finally ensure high quality transplantation for all Europeans. This was achieved through the adoption of Directive 2010/53/EU of the European Parliament and of the Council on 7 July 2010 and the Commission Action Plan on organ donation and transplantation (2009-2015) that accompanies the Directive.

15.2.1.2.Report of work done in 2010

With respect to the blood Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC, the Commission continued checking whether Member States have transposed them adequately into their national legislation on the basis of checklist tables which were sent out to the Member States in 2009. At the beginning of the year a number of Member States had not yet sent to the Commission their responses. During the meeting with the competent authorities in April, the Commission asked those Member States that had not yet provided the relevant information to do so. Consequently a number of Member States responded to the request, whilst the Commission continues to follow up the situation with the remaining Member States that sent either no information at all or sent insufficient information concerning their national legislation transposing the blood directives.

As regards Directives in the field of tissues and cells the transposition rate is satisfactory. Only one infringement procedure is pending for incomplete transposition into national law of Directives 2004/23/EC, 2006/17/EC and 2006/86/EC with respect to reproductive cells, foetal tissues and cells, and adult and foetal stem cells.

Following the completion of the notification of Member State's transposition, a questionnaire is being prepared addressing the most important aspects of the three tissues and cells Directives which will be sent to the Member States during 2011 for completion. With this exercise the Commission aims to monitor the adequacy of the transposition measures into the national law of the Member States.

In addition to the transposition checks, two reports on the implementation of the Directives on blood[491] and on tissues and cells[492] have been developed during 2009. Both were published in January 2010. The reports show that the implementation of both Directives is satisfactory although further efforts are needed:

1. in the blood sector regarding the finalisation of the accreditation/designation/authorisation/licensing process in respect of each

[491] COM(2010)0003 final. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0003:FIN:EN:PDF

[492] COM (2009) 0708 final. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0708:FIN:EN:PDF

individual blood establishment; the performance of inspections and the submission of the annual report on vigilance to the Commission;

2. in the tissue and cell sector regarding the finalisation of the accreditation/designation/authorisation/licensing process in respect of each individual tissue and cell establishment; development of inspection systems; monitoring of import/export measures; registry of tissue establishments, and fulfilment of different reporting requirements.

A common approach for setting up a vigilance and traceability system for tissues and cells at EU level is currently being developed.

In both sectors there are differences concerning how Member States apply the principle of voluntary unpaid donation. These issues will be further addressed in the relevant reports focusing on this principle which are being finalised and will be transmitted to the European Parliament and the Council in 2011.

In 2010, the Commission adopted Decision 2010/453/EC establishing guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials, in the field of human tissues and cells provided for in Directive 2004/23/EC of the European Parliament and of the Council.

On blood, a technical amendment to Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life has been presented to and got a favourable opinion by the regulatory committee on blood and blood components. The draft directive is expected to be adopted in first semester of 2011.

With regard to organs, the European Parliament and the Council adopted on 7 July 2010, in first reading, Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation.

Work for the preparation of the implementing measures and delegated acts in accordance with Directive 2010/53/EC has been initiated in 2010.

In addition to Directive 2010/53/EU, the Action Plan on Organ Donation and Transplantation (2009-2015) aims at 1) increasing organ availability, 2) enhancing the efficiency and accessibility of transplantation systems and 3) improving quality and safety, through the creation of several technical working groups and Projects funded by the Health Programme.

Significant progress has been achieved in 2010 with regard to several priority actions of the Action plan.

15.2.1.3.Evaluation, Priorities & Perspectives

The Commission continues to ensure that legislation on organs, blood, tissues and cells is fully and consistently implemented by competent authorities. Member States are called upon to take full responsibility for ensuring implementation of the EU legislation in this field and promote cooperation between the Commission and national competent authorities. The Commission holds bi-annual meetings with the Competent Authorities for Blood and Tissues/Cells to exchange information, expertise and experience on the implementation of the Directives. The first Competent Authority meeting for Organs was held in September 2010. In

addition implementation of the organs Directive 2010/53/EU and of the Action Plan (mid-term and final review – 2012 and 2015 respectively) remain a priority.

15.2.2. **Tobacco**

The main pieces of legislation in the area of tobacco control are Directive 2001/37/EC concerning the manufacture, presentation and sale of tobacco products and Directive 2003/33/EC relating to the advertising and sponsorship of tobacco products.

The two existing Directives in the area of tobacco control are well implemented in Member States.

Member States have, in general, wider advertising and sponsorship bans than the cross-border bans required by the Tobacco Advertising Directive (2003/33/EC). However, certain cases of tobacco advertising at the point of sale, on billboards, in airports and advertising in the context of on-line marketing occur. Advertising in the form of promotional campaigns outside the EU is displayed on the internet. This is a challenge not only for the EU but requires a global solution. Cross-border internet sales of cigarettes continue to be an issue which involves tax evasion and illegal tobacco advertising and promotion.

As regards the Tobacco Products Directive (2001/37/EC), the second report on its implementation[493] identified several areas which should be improved. In a resolution from October 2007, the European Parliament called on the Commission to present a proposal for amendments to the Tobacco Products Directive.

Currently, an Impact Assessment is ongoing for a review of the legislation in order to update it in relation to scientific progress, market and international developments. The considerations include: extending the scope to cover e.g. novel forms of oral tobacco, herbal cigarettes and electronic nicotine delivery systems; regulating all non combustible (smokeless) tobacco products in a consistent way; improving consumer information for example by making picture warnings bigger and mandatory and by making packaging more neutral (plain packaging); dealing with the reporting, registration and regulation of ingredients; regulating the access to tobacco products in a way that does not induce people to smoking.

Based on the outcome of the Impact Assessment, the Commission will work on the legislative text that is expected to be finalised by the end 2011.

The Commission is also looking at the renewal of text warnings and corresponding pictures. This is done by Comitology procedure and does not require a change in the Directive. New warnings could be adopted towards the end of 2011.

As regards the Council Recommendation on smoke-free environments[494] the Commission will support and encourage its implementation by the Member States. A meeting of the National Focal Points on smoke free environments is planned for 2011.

In 2010 the fourth Conference of the Parties of the Framework Convention on Tobacco Control (FCTC) took place. The EU as Party to the FCTC contributed significantly to the

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493 COM(2007) 754 final.

494 2009/C 296/02.

progress in international tobacco control as regards the protocol on illicit trade and the guidelines on tobacco product regulation and disclosure; on education and communication; and on tobacco cessation.

15.2.3. **Pharmaceuticals**

15.2.3.1. Current position

Currently the level of harmonisation in the pharmaceutical is very well advanced; many aspects concerning safe, effective and high-quality medicinal products are regulated in EU legislation. In this regard the pharmaceutical *acquis* focuses on harmonised authorisation requirements for human and veterinary medicinal products by establishing common procedures and streamlining the scientific assessment. Additionally, surrounding aspects such as clinical trials, orphan medicines, paediatric medicines and advanced therapies are covered. Legislation is mainly based on the internal market competence of EU (Article 114 TFEU), but partly also on health competencies (Article 168 TFEU).

In general, compliance with the pharmaceutical *acquis* is high. One reason for that is an established and sustained dialogue between the Commission, the Member States and the competent agencies on regulatory matters in the pharmaceutical sector. Working parties dealing with the general interpretation of European pharmaceutical legislation, such as the Pharmaceutical Committee, habitually discuss transposition and implementation matters. Coordination groups in the human and in the veterinary sector are in place to examine questions in relation to marketing authorisations in two or more Member States. Additionally, the "Notice to applicants" group publishes guidance documents intended for stakeholders. If needed chapters of the guidelines interpreting requirements for applications for marketing authorisations are updated at regular intervals. These working parties are an important tool to find pro-active solutions outside or in parallel with infringement procedures under Article 258 TFEU.

Nevertheless, these instruments cannot totally replace the formal dialogue with Member States within the framework of an infringement procedure. Eleven procedures had to be opened in 2010, for example for the non-timely transposition of Directive 2009/120/EC. However, by end of 2010, all but one was closed.

Additionally, the Commission continues to receive complaints from stakeholders or initiates investigations on its own on certain aspects of implementation of pharmaceutical legislation. In 2010 an increase in the number of complaints was observed. In parallel, certain rulings of the Court of Justice contributed valuable clarifications to the implementation of the pharmaceutical *acquis*. In 2010 the Court of Justice delivered for example the following judgments:

- In cases C-350/08 and C-385/08 the Court clarified based on infringement procedures initiated by the Commission accession related questions concerning the "phasing in" of national marketing authorisations granted prior to accession in the new Member States in order to guarantee that all valid marketing authorisations in the EU comply with the high standards of the *acquis*.

- In case C-62/09 the Court provided guidance as to the borderline between prohibited promotion for medicinal products on the one side (covered by

Directive 2001/83/EC) and financial incentives granted by public health authorities for prescribing named generics on the other (not-covered by Directive 2001/83/EC).

As regards legislative developments, the adoption of parts of the pharmaceutical package and the implementing regulation for maximum residue limits took place in 2010. In December 2010 Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency as well as Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance Directive 2001/83/EC on the Community code relating to medicinal products for human use, were published in the Official Journals. These new rules strengthen pharmacovigilance by establishing clear standards, while at the same time rationalising and simplifying obligations for all actors involved.

Other parts of the "package" are being discussed within the co-decision procedure:

- Two legislative proposals on information to patients involving amendments of Directive 2001/83/EC and Regulation (EC) No 726/2004;

- A legislative proposal on falsified medicines involving amendments of Directive 2001/83/EC. A compromise agreement was reached between the three institutions at the end of 2010.

Additionally, the Commission published several guidance documents in the area of clinical trials and herbal medicines.

Finally, some groundwork was done to consider the necessity for future policy action in the pharmaceutical sector. Public consultations on the functioning of the Clinical Trial Directive 2001/20/EC and the review of the veterinary medicinal legislation were held. Moreover, the Commission received in 2010 the final report on the evaluation of the European Medicines Agency.

15.2.3.2.Evaluation based on the current situation

The pharmaceutical sector remains a highly dynamic sector, which is subject to frequent change because of innovation. In such an environment questions of timely and correct implementation of EU law are crucial to achieve the public health goals of the *acquis* and to guarantee a level-playing field for the actors involved. In this respect the priorities remain unchanged.

The experience of the past years shows that in general the legal framework is well respected. Hence, implementation and compliance by Member States with the *acquis* can be considered satisfactory. An important contributor in this regard are the various working groups, committees and networks which exists in the pharmaceutical sector and which provide useful forums for raising and discussing relevant questions. At the same time they may give impetus for tightening or clarifying the *acquis*, where necessary.

15.2.4. **Medical devices**

The role of medical devices in healthcare is essential. The diversity and innovativeness of this sector contribute significantly to enhanced quality and efficacy of healthcare.

Covering a wide range of products, from simple bandages to the most sophisticated life-supporting products, the medical devices sector plays a crucial role in the diagnosis, prevention, monitoring, and treatment of diseases and the improvement of the quality of life of people suffering from disabilities.

The involvement of Directorate-General Health and Consumers concerns mainly the regulatory framework for market access, international trade relations and regulatory convergence, all aiming to ensure the highest level of patient safety while promoting the innovation and the competitiveness of this sector.

Rules relating to the safety and performance of medical devices were harmonised in the EU with Council Directive 90/385/EEC relating to active implantable medical devices, Directive 93/42/EEC concerning medical devices and Directive 98/79/EC on in vitro diagnostic medical devices.

15.2.4.1.Report of work done in 2010

European databank for medical devices

Patient's safety will increase in Europe as a direct result of the development of the new European databank for medical devices called 'Eudamed'.

A Commission Decision adopted on 19 April 2010 obliges EU Member States, as from May 2011, to enter and share data on medical devices in this secure web-based databank.

Essential data for safety, such as certificates (including those which are withdrawn or suspended) and incident reports will be rapidly accessible to the Authorities in charge of market surveillance and therefore risks for patients will be reduced.

Reprocessing of single use medical devices, a complex issue

The current EU law (the Medical Devices Directive) distinguishes between reusable medical devices and medical devices intended for single use:

- Some medical devices, such as many of the surgical instruments, are intended by their manufacturers to be reused. In this case, the legislation sets specific requirements that the manufacturer must fulfil in order to allow safe reuse.

- Other medical devices, such as syringes, needles and catheters, are intended to be used once only for a single patient. Such devices are defined as single-use medical devices.

The issue of the reprocessing of single use medical devices, such as catheters, was discussed in the context of the last revision of the medical devices Directives, especially at the request of the European Parliament, but it was not possible to solve such a complex issue during this negotiation.

To ensure a follow up of these discussions, the Parliament asked the Commission to prepare a report on this issue and to put forward appropriate measures.

The reprocessing practice of single-use medical devices is not regulated at European level and the situation diverges in the Member States, with the consequence that patients are treated with reprocessed single-use medical devices in some Member States - without knowing it - when it is not the case in some other Member States.

On the basis of a scientific opinion of the Scientific Committee on Emerging and Newly Health Risks (SCENIHR), the Commission adopted on 27 August 2010 a report which examines public health, ethical, liability, economic and environmental considerations. In the light of the findings of this report, the Commission will assess which measures are to be put forward as part of the forthcoming review of the medical devices Directives to ensure a high level of protection for patients.

Improved control and safety for the future in vitro diagnostic medical devices for variant Creutzfeldt–Jakob disease (vCJD)

In vitro diagnostic medical devices for vCJD are not yet on the EU market.

However, to pave the way for such tests and ensure an appropriate regulatory framework, two Comitology measures have been prepared which are planned to be adopted in 2011:

The first measure will submit vCJD blood screening, diagnostic and confirmation assays to the control of notified bodies (instead of a manufacturer's control only) before such tests can be placed on the market;

The second measure will establish performance criteria for vCJD blood screening assays. Performance criteria will be established for the two other categories of vCJD tests as soon as science will have sufficiently evolved.

Possibility to provide instructions for use on electronic way for medical devices

Work has progressed well on the preparation of another Comitology measure which will allow that, for certain categories of devices, the instructions for use may be provided in electronic rather than paper form. In order to ensure at least an equivalent protection of patient safety the modalities of delivering such electronic instructions need to be specified. The measure is expected to be adopted during 2011.

Improved governance for GMDN (Global Medical Device Nomenclature) Agency

Work was ongoing to improve the governance of the GMDN Agency, to find a new funding mechanism and to achieve international acceptance of the GMDN nomenclature. Use of a single nomenclature for medical devices will greatly facilitate communication on devices. A representative of Directorate-General Health and Consumers holds the Chair of the Policy Advisory Group to the Agency. Work is ongoing on the translation of GMDN into 20 EU languages.

Screening of the national law transposing Directive 2007/47/EC

The screening of national legislation transposing Directive 2007/47/EC, started in 2008 and

was completed in 2010. Several deficiencies of the national law of Member States were identified and discussed with the respective Member State. The screening also helped to identify issues in which the Member States are ahead of EU law. These issues are examined in order to enhance better understanding of the regulatory landscape in a view of the next revision of medical devices directives.

Screening of standards

The screening of standards providing presumption of conformity with legal requirements of directives prevented some of these standards to deviate from the directives on medical devices. The screening led to several informal interventions and the first Commission driven formal objection against several standards.

Support for and supervision of Member States authorities

Mostly in a supportive role, but also partly in a supervisory role, the Commission followed the application of the medical devices directives by the Member States. Numerous interpretative questions have been clarified together with the authorities. Some of these interpretative questions were dealt with in guidance documents. The Commission services offered advice to authorities in individual cases, mainly in the field of market surveillance, and co-ordinated Member States' actions with regard to incidents (so-called vigilance cases). The screening of Member States' designations of Notified Bodies led to numerous restrictions of the scope of designations. Cases of insufficient performance of Notified Bodies were investigated.

International regulatory cooperation

1. At bilateral level, the main issues to mention are the following:

- **USA**: in the context of a confidentiality arrangement, sharing of information took place on the revision of both legislations (for example, on the rules on in vitro diagnostic medical devices – IVD). On specific products, the exchange focused primarily on the adoption of corrective actions to improve the safety and performance of infusion pumps and to avoid the recurrence of serious vigilance cases.

- **China**: the following major events took place in 2010: China International Medical Device Forum in September in Beijing, High Level Forum on Standardization with SFDA, Regulatory dialogue on Medical devices in October in Beijing.

- **India**: a workshop took place in June 2010, in view of regulatory developments, in order to provide EU expertise.

- **Turkey**: several legal obligations were clarified in order to ensure the free movement of medical devices within the Custom Union.

Following the development of several **WHO's programs** in the field of medical devices, direct contacts have been established with this organisation in order to enhance bilateral exchange of information.

2. At multilateral level, the main results are the following:

- In the context of GHTF (Global Harmonization Task Force), a first discussion took place on a strategy for the future of GHTF and the EU will have to define its position in this context.

- On a more technical side, the work has progressed in the study groups through guidance on clinical evidence for IVD and on labelling and essential requirements for IVD and MD. Such guidance will be useful in the context of the recast of the medical devices Directives.

- An international ad hoc working group, chaired by a Commission representative, has prepared a draft guidance document on a commonly agreed traceability system, based on a unique device identifier (UDI). This paper was published for public consultation in November 2010. Comments were received until April 2011 and are being analysed. This work is reflected at European level: this issue was discussed under the Spanish Presidency in a Competent Authorities meeting, and a small working group chaired by Directorate-General Health and Consumers held its first meeting in June, composed of representatives of some Member States, to which will be added representatives of industry, hospitals and patients. The aim of this group of volunteers is to provide concrete answers in view of an impact assessment of the implementation of a UDI mechanism at the European level, which will improve market surveillance and contribute to fighting against counterfeiting.

- An international regulators ad hoc Task Force on combination products, composed of the Members of the GHTF for medical devices and of representatives of ICH (International Conference on Harmonization) for the pharmaceutical products explored the possible way forward in converging the regulatory frameworks of combination products internationally and produced a draft report on the preliminary scoping of objectives, issues and process.

15.2.4.2.Evaluation, Priorities & Perspectives

Experience indicates that the current system does not always offer a uniform level of protection of public health in the EU. New and emerging technologies have challenged the current framework, highlighting gaps and pointing to a certain scarcity of expertise. In addition, in recognition that the medical devices market is a global one, to keep European industry competitive, the EU regime needs to further converge on the 'global model'. And finally, the legal system has been criticised as being too fragmented and difficult to follow and fraught with national variation.

The Commission is considering a revision of the legal framework for Medical Devices in order to improve and strengthen this framework and to meet the growing expectations of European citizens since the last technical revision brought about by Directive 2007/47/EC.

The initiative to undertake a systemic revision of the three medical devices directives took off with a public consultation in 2008. In 2010 it was complemented by an additional public consultation concerning specific aspects related to in vitro diagnostic medical devices (IVD).

The drivers for the proposed revision are the simplification programme 2005, the "revised New Approach", legal gaps regarding products falling outside any specific EU legislation and weaknesses of the current directives (lack of coordination and unequal level of enforcement).

The initiative to "recast" the three medical devices directives shall contribute to a high level of safety for the patient and user, delivering a transparent system whereby citizens can be confident in the safety of medical devices. Its objective is also to ensure a simple and easily-understandable regulatory environment for medical devices to ensure the efficient functioning of the Internal Market.

A lot of contacts have also taken place with the stakeholders, the work on the impact assessment has begun and the roadmap was finalized in October 2010. A high level conference will be organised in March 2011 on research and innovation in the field of medical devices and the revision of the regulatory framework.

At the same time, the implementation of the current medical devices directives will be ongoing in 2011 to support their effective and coherent application throughout the EU, in particular as regards:

- the maintenance of IT tools for the database Eudamed;
- the coordination of the treatment of vigilance cases and market surveillances activities;
- the elaboration of new and the revision of existing guidance documents (MEDDEVs), in particular in the field of combined medical devices/pharmaceuticals;
- the supervision of the designation of Notified Bodies by the Member States.

15.3. Consumers

There are now some 500 million consumers in Europe and their expenditure represents over half of the EU's gross domestic product (GDP). Consumers are essential to economic growth and job creation in a large market of products and services.

The Commission's Consumer Policy supports the aims laid out in Articles 169 and 114 TFEU, which promote the interests, health and safety of European consumers. It is designed to ensure that the internal market is open, fair and transparent and products sold are safe, allowing consumers to exercise real choices, whilst excluding rogue traders.

With so many new products and brands and increasingly sophisticated financial services, European consumers are having a hard time getting their bearings. They are not comfortable with the idea of buying something in another Member State: only one out of five people have done so over the past twelve months. Yet, the EU single market offers many possibilities for competition and for buying at a lower price.

15.3.1. **Report of work done in 2010**

Consumer credit

Directive 2008/48/EC of 23 April 2008 on credit agreements for consumers had to be implemented by Member States on 11 June 2010. By the end of 2010, 23 Member States have already notified their implementing measures, although some of them have done it partially. Four Member States have not yet notified any implementing measure.

The Commission sent a Reasoned Opinion for non-communication on 24 November 2010 to Spain, Luxemburg, the Netherlands, Poland and Sweden. Sweden notified its implementing measure on 22 December 2010. Moreover, a Reasoned Opinion has also been issued on 24 November 2010 against Belgium and France for partial transposition. In addition, the Commission launched on 24 November 2010 infringement procedures for incorrect transposition against Belgium, UK and Romania.

EU-Sweeps

In 2010 the fourth EU "Sweep" was carried out, involving systematic and simultaneous checks in different Member States to investigate potential breaches of consumer protection rules in the tickets for cultural and sporting events sector. This Sweep looked into 414 websites, of which 60% were flagged for further investigation in the enforcement phase. The exercise was carried out by all the EU Member States, as well as by Norway and Iceland. The most common breaches detected in the 2010 Sweep were related to missing, incomplete or misleading information about the price (e.g. hidden taxes or handling charges), 74% of the problems; unfair terms and conditions (e.g. ticket delivery was not guaranteed on time or a refund was excluded in the event of cancellation), 73% of the problems; and missing, incomplete or misleading information about the trader (e.g. missing geographical address and e-mail or falsely presenting himself as authorised by the promoter), 48% of the problems. The results of the enforcement phase are planned to be presented during the second half of 2011.

The final report on the follow-up of the 2009 Sweep related to websites selling electronic goods was published in 2010. In 2009 the Sweep on electronic goods looked at 369 websites of which 55% were flagged for further investigation. At the end of the enforcement phase, 84% of the websites flagged were compliant with EU laws.

Consumer empowerment

Through the European Consumer Consultative Group (ECCG), the Commission pursued its dialogue with consumer organisations and consulted them on initiatives having an effect on consumers. ECCG members also shared their views regarding the application of EU legislation. Following the revision of the Commission Decision setting up the ECCG[495] aimed at further improving the efficiency and representativeness of the group; the group has met 4 times under its new composition.

The European Consumer Centres Network (ECC-Net)

In 2010, the European Consumer Centres Network (ECC-Net) handled over 71000 contacts with consumers who turned to them for advice about their rights or for help with problems in the course of cross-border shopping.

[495] Commission Decision 2009/705/EC, OJ L 244, 16.9.2009, p. 21–24.

The work of the centres shows that, in 2010, as it was already the case in 2009, European consumers' biggest problems were related to transport, recreation and culture and accommodation services.

The ECCs also helped consumers to reach agreements on complaints with traders using out-of-court dispute resolution mechanisms.

In addition, the ECCs have carried out joint projects analysing consumer complaints and concerns on key issues such as Alternative Dispute resolution mechanisms in Europe and a pan European survey on ski resorts.

The ECCs participated actively in the European Consumer Summit 2010 in the workshop dedicated to car hire that looked at problem areas in existing practices and tried to raise standards for consumers in the car hire sector.

Education and training activities

In 2010, an information campaign raising awareness of EU-wide consumer rights was launched in Bulgaria. The campaign contributes to the better enforcement of consumer law by informing consumers about specific rights they have at home and in other EU countries, and by increasing awareness of associations and institutions that provide further information and advice, such as consumer associations, government institutions and European Consumer Centres.

In 2010 the Commission carried out a series of training courses designed to help build the capacity of European consumer organisations, aiming at providing a better understanding of the consumer *acquis* and thereby preventing infringements. The Commission also distributed 3.275.500 copies of the Europa Diary containing consumer education materials to over 21.000 EU schools and developed its consumer education website: www.dolceta.eu.

Consumer Protection Cooperation (CPC)

The CPC Network was established by the Consumer Protection Cooperation (CPC) Regulation[496] in December 2006 to stop intra-Union infringements of EU consumer laws in cross-border situations. It links some 250 enforcement authorities in Member States to form an EU-wide enforcement network.

In 2010 the Network recorded a total of 222 new mutual assistance requests[497] (compared to 319 the year before) which include 37 alerts concerning suspected or confirmed intra-Union infringements (compared to 43 in 2009). As every year since the Network started operating, a joint market surveillance and enforcement exercise was carried out in the form of an EU-sweep (for more details see above under "EU sweeps"). Other joint activities that started in 2010 include a project on strengthening the Network's internet enforcement capacities by establishing new means of sharing best practice and that takes forward some of the work carried out in the context of a first common CPC activity in 2007. The latter had established among other things a common methodology for the EU-sweeps ("sweepers' manual").

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496 Regulation (EC) No 2006/2004 of the European Parliament and of the Council of 27 October 2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws, OJ L 364 dates 9.12.2004.

497 Data extracted from the IT-tool used by the Network as of 30 November 2010.

A second project focuses on the visibility of the Network's activities and will seek to develop a common (internal and external) communication strategy for the Network. Both projects will continue in 2011. The Commission pursued its efforts to address, in close partnership with the Member States, the shortcomings in the Network's operations as described in the first Commission biennial assessment of the application of Regulation (EC) No 2006/2004[498]. Building on the work already initiated in 2009, operating guidelines were endorsed by the CPC committee in June 2010 and a number of initiatives were taken to enhance the IT-tool used by the Network. Finally, as some issues required adjusting partially some of the cooperation rules applied by the Network, an amendment to the rules implementing the Regulation was discussed with the Member States and is planned to be adopted by the Commission in 2011. Training on the IT-tool continued with the assistance of the Trainers Network established in 2009.

Drawing from the experience learnt in 2009, the Commission organised two workshops on subjects of relevance to the CPC-Network: the outcome of the workshops on applicable law and sanctions were taken forward in a follow-up discussion end of 2010 and a workshop on consumer issues in the area of financial services prepared the ground for future Network activities in 2011.

Product safety

In 2010 the Commission presented the key elements and envisaged actions of the consultation on the revision of the General Product Safety Directive. Streamlined procedures to get European standards of safe products and alignment with other market surveillance rules are in the core of the intended improvements. As the stakeholder consultation confirmed, consumer confidence and level playing field for business indeed require that the product safety framework and its enforcement are modern and effective and that benchmarks are fully shared.

Commission Decision 2010/9/EU on the safety requirements for bath rings, bathing aids and bath tubs and stands for babies and young children

On 6 January 2010 the Commission adopted Decision 2010/9/EU[499] setting the safety requirements for products used to assist parents and caregivers to bath their babies. The Decision, based on Article 4 (1) of Directive 2001/95/EC, lays down the essential requirements to ensure that bath rings, bathing aids and bath tubs are safe. There are no European safety standards for these products which if not used adequately expose the babies to drowning. Also, requirements are needed to eliminate additional risks such as entrapment and injuries. Standardisation work follows to make this decision effective.

Commission Decision 2010/11/EU on the safety requirements for child-resistant locks for window and balcony doors

On 7 January 2010, the Commission adopted Decision2010/11/EU[500] setting the safety requirements for **child-resistant locks for windows and balcony doors**. This Decision, based on Article 4(1) of Directive 2001/95/EC lays down the requirements that European

498 COM (2009) 336 final.
499 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:003:0023:0029:EN:PDF
500 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:004:0091:0093:EN:PDF

standards will have to meet to ensure that these locks are safe. Accidental falls of children from windows and balconies are a leading cause of death or permanent damages to children below the age of 5 in Europe. There are no European standards for these products. The safety requirements will ensure that the locks cannot be disengaged by children, resist wear and tear and weather conditions and are moreover provided with the necessary instructions to be installed by consumers. Standardisation work follows to make this decision effective.

Commission Decision 2010/376/EU on the safety requirements for some products in the sleeping environment of babies and young children

On 2 July 2010 the Commission adopted Decision 2010/376/EU[501] setting safety requirements for 5 products commonly used in the **sleep environment of babies and young children**. The products concerned are cot mattresses, cot bumpers, sleeping bags for babies, suspended baby beds, duvets for babies. The Decision, based on Article 4 (1) of Directive 2001/95, lays down the requirements that European standards will have to meet to ensure that these products are safe. At the moment there are no safety standards for these products, which can pose serious risks to babies and young children, such as entrapment, suffocation, strangulation and injuries. Standardisation work follows to make this decision effective.

Commission Decision 2010/153/EU prolonging the ban of dimethyl fumarate in all consumer products

The Commission adopted Decision 2010/153/EU on 11 March 2010 on the basis of Article 13(4) of the General Product Safety Directive (GPSD). The Decision concerns dimethyl fumarate (DMF), a biocide preventing moulds which is strongly sensitising and can cause severe skin reactions. The Decision requires Member States to ensure that all consumer products containing DMF are withdrawn from the market and recalled from consumers. Since the Decision can only be valid for one year at a time, it will be prolonged for further periods until a permanent measure is put in place in EU legislation. Such a measure is currently under preparation under REACH.

Commission Decision 2010/157/EU on child-resistant lighters

On 12 March 2010, the Commission adopted Decision 2010/157/EU, extending for the fourth time – until 11 May 2011 – Decision 2006/502/EC requiring Member States to take measures to ensure that only lighters which are child-resistant are placed on the market and to prohibit the placing on the market of so-called novelty lighters. Upon a mandate from the Commission, CEN is currently revising the relevant standard (EN 13869:2002 ‘Lighters — Child-resistance for lighters — Safety requirements and test methods’).

RAPEX system

RAPEX is the EU Rapid Information System for dangerous non-food products which operates under the General Product Safety Directive and the Regulation No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (hereinafter the 'Regulation 765/2008'). The Member States, EFTA/EEA countries and the Commission use RAPEX to rapidly exchange

501 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:170:0039:0048:EN:PDF

information about dangerous non-food products found on and consequently withdrawn from the European market.

RAPEX operations improved again in 2010, when in total 2 244 notifications were exchanged through the system by participating countries and the Commission. This constitutes an increase of 13% compared to 2009. Half of the countries participating in the system further enhanced their activities and submitted more notifications on dangerous products than in the previous years. As RAPEX notifications sent by the Member States in 2010 were of the better quality, the number of notifications distributed for information purpose decreased by 14% compared to 2009 (243 notifications distributed in 2010 compared to 283 notifications in 2009).

Clothing and textiles, toys, motor vehicles, electrical appliances and childcare articles were still among the most often notified products through the system. These categories of products accounted for almost 80% of all products notified in 2010. It should be noted that since 2009, there has been a significant increase in the number of RAPEX notifications on clothing and textiles (in 2009: 395 notifications, 23% of the total and in 2010: 625 notifications, 32%) which results mainly from the enhanced market surveillance activities undertaken by national authorities following, in particular, the launch of the joint market surveillance action on cords and drawstrings in children's clothing and the adoption of the Commission Decision 2009/251/EC banning dimethyl fumarate in all consumer products. This proves that risk-focused EU-level measures and joint prioritisation of certain types of products in the surveillance actions taken by Member States result in well spent resources in terms of finding dangerous products that could be harmful to consumers.

The number of notifications with an unidentified country of origin increased slightly compared with 2009 (from 7% in 2009 to 10% in 2010). It should, however, be stressed that it is one of the big improvements of the system, as in 2004 23% of notifications contained no information about the country of origin. This is an indicator that the market surveillance authorities in Europe are increasingly aware of the importance of (a) taking the incriminated product off the shelves in their country but also (b) of the importance of traceability data for authorities in other countries and ultimately in the country of origin of the product. The number of dangerous products of Chinese and European origin notified through RAPEX was maintained at the level of respectively 58% and 17% of all notifications (i.e. 1 134 and 338 notifications). These results are similar to previous year's results.

Extension of the scope of RAPEX

On 1 January 2010, following the entry into force of the Regulation 765/2008, the scope of the RAPEX system was extended. As of that day, RAPEX applies to both consumer and professional products which pose serious risks to various public interests, such as health and safety of consumers, environment, energy efficiency, public security, etc.

Risk Assessment Application

Following Decision 2010/15/EU laying down the new guidelines for the management of the EU Rapid Information System ‘RAPEX’ established under Article 12 and the notification procedure established under Article 11 of Directive 2001/95/EC, improved risk assessment method started to be applied. In December 2010, the Commission made available an online system called "*Risk Assessment Guidelines application*". The application was established to

simplify the preparation of risk assessments according to the new RAPEX Guidelines. The application makes it possible to easily estimate and document the risk of consumer products, while giving the risk assessor the necessary freedom to make the appropriate assumptions as described in the Guidelines.

Joint Actions on market surveillance activities

To support the Member States in their cross-border activities, in 2010 the Commission awarded a financial contribution of EUR 1.4 million to a single joint market surveillance action, covering 4 different product groups including; children's fancy dresses, laser pointers, ladders and high visibility clothing. To further strengthen cooperation between the Member States on consumer product safety, the Commission will continue joint actions in 2011 and will financially contribute to the best proposals suggested by Member States.

International cooperation

The Commission further strengthened collaboration with its international partners in the product safety area. The main aim is to share information about emerging product safety risks, provide updates on legislative and normative developments and prevent dangerous products from finding their way onto the EU market. More particularly, in October 2010, Commissioner Dalli participated in the EU-US-China Trilateral Summit on Product Safety, which took place in Shanghai, China. The meeting agreed a joint statement on points of consensus regarding international product safety cooperation and committed to develop specific actions to further their implementation. Negotiations with the United States for an agreement on cooperation and information exchange in the area of consumer product safety and consumer protection cooperation made progress but will continue in 2011.

In 2010 the collaboration with the People's Republic of China's General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) continued and the Commission continued to make available on the Internet the analyses of the quarterly follow-up reports to the RAPEX notifications sent to China.

COSMETICS

Cosmetic products are important consumer products with an essential role in everyone's life: apart from "traditional" cosmetic products, such as make-up and perfumes, it also includes products for personal hygiene, for example tooth-care products, shampoos and soaps.

Today's cosmetic market is driven by innovation including new colour pallets, treatments targeted to specific skin types and unique formulas concentrating on different needs. Most cosmetics products have a lifespan of less than five years and manufacturers reformulate 25% of their products every year. They need to improve products constantly in order to stay ahead in a highly competitive market where more choice and ever greater efficacy are expected by the consumer.

The European cosmetics industry is a world leader and dominant cosmetics exporter, a highly innovative sector and a significant employer in Europe. The EU's involvement concerns mainly the regulatory framework for market access, international trade relations and regulatory convergence, all aiming to ensure the highest level of consumer safety while promoting the innovation and the competitiveness of this sector.

Technical adaptations to the current Cosmetics Directive

Until 2013 the work continues under the current Cosmetics Directive and following opinions of the Scientific Committee on Consumer Safety (SCCS), two technical adaptation directives were adopted in 2010 (one of them is important for the safety of hair-dyes) while two other are in preparation (one of them concerning zinc oxide used as UV filter in sunscreens).

A technical adaptation on tooth whitening products was submitted to the Member States for a vote, but did not receive an opinion. The file should be transmitted to the Council, and discussions are ongoing to try to get Member States on board.

Animal testing

The Commission has to prepare annual reports on this issue, explaining the evolution of the situation (number of animals used, validation of alternative methods, international situation). The 2008 Report was adopted in September 2010.

In 2011 the Commission will inform the European Parliament and the Council if the alternative methods will not be developed and validated before 2013 for three complex end-points: repeated-dose toxicity, reproductive toxicity and toxicokinetics.

In order to establish the perspectives for the availability of alternative methods for these three end-points, the Commission has set up a working group of independent experts proposed by different stakeholders. This group has elaborated a draft technical report which was available for public consultation until October 2010 and is now being finalized. The results so far clearly indicate that - while important progress has been made – full replacement of animal tests will not be possible by 2013 and for some end-points it is not likely to become a reality in the coming 10 years.

In parallel to this technical exercise, an impact assessment will be carried out on the basis of the hypothesis that alternative methods are not available. Options to be analysed in order to define the Commission's position include keeping the 2013 deadline, a further extension of the deadline and considering other mechanisms. A targeted stakeholder consultation was launched in December 2010.

International regulatory cooperation

At bilateral level, the main results are the following:

- a first meeting took place in June with **Indonesia** with the aim to convince this country to adopt the Asean cosmetics Directive, based on the model of the EU legislation. Indonesia agreed to start implementing the requirements of the Asean cosmetics Directive as from 2011 and expressed the wish to further increase the regulatory cooperation with the EU;

- an **Asean Cosmetic meeting** took place in June during which Unit B2 presented the new cosmetics Regulation to the Asean countries in view of an increased EU-Asean cooperation in the area of convergence of cosmetics regulations;

- a Consumer Thematic Day took place in **Shanghai** in October, and the EU-China Cosmetics Safety Assessment Seminar and the regulatory dialogue on cosmetics

at the same period in **Beijing**;

- attention has been drawn by industry on important difficulties encountered to **export cosmetic products to China.** After signalling the problem in writing, bilateral meetings were convened in the autumn with the Chinese Authorities in charge of the registration of new cosmetics in order to speed up the resolution of the backlog of imported cosmetics which could not be put on the Chinese market.

At multilateral level, Directorate-General Health and Consumers took the chair in July 2010 of **ICCR** (International Cooperation on Cosmetics Regulation), for which five teleconferences were held with regulators from US, Canada and Japan, as well as a face-to-face meeting in Toronto in July 2010. This led to significant progress towards regulatory convergence and, in particular, to the joint support by the ICCR jurisdictions of a document on criteria for the identification of nanomaterials in cosmetics.

15.3.2. **Evaluation, Priorities & Perspectives**

On 13 March 2007 the Commission adopted a Consumer Policy Strategy for 2007-2013. The strategy sets out the challenges, role, priorities and actions of EU consumer policy for this period. The overall objectives of the Strategy are to empower consumers, to enhance their welfare and to protect them effectively. The Commission's vision is to achieve by 2013 a single, simple set of rules for the benefit of consumers and retailers alike.

Given the progress achieved on the review and development of the consumer *acquis*, effective enforcement will play an important role. This will include, from the Commission's point of view, continued efforts in accompanying the transposition process in the Member States and supervising the transposition and application of directives by the Member States.

As part of a larger exercise to monitor how well the internal market functions for consumers, Commission services and the Member States developed in 2009 a framework for regular collection of enforcement indicators to measure the effectiveness of enforcement at national level. National policies and institutions related to enforcement play a key role in making the Internal Market function for consumers: free circulation of safe products and the protection of consumers from rogue traders depend on the effectiveness of enforcement and market surveillance in all Member States. An expert group composed of members of the CPC (Consumer Protection Cooperation) and GPSD (General Product Safety Directive) committees identified the most appropriate indicators, taking account of differences between national enforcement systems.

The Commission carried out in 2010 a mid-term evaluation of the 2007-2013 Consumer Policy Strategy and of the 2007-2013 Programme of Community Action (as well as an ex-post evaluation of the Programme of Community Action 2004-2006). The results of this evaluation will feed into the preparation in 2011 of the next (post 2013) Consumer Policy Strategy and Programme of Community Action. The new Strategy and Programme will also integrate the results of separate evaluations which will be conducted in 2011 on consumer education tools.

The Commission plans to open a period of joint reflection with the Member States on the future role of ECC-Net. In parallel, an evaluation of the Network is foreseen five years after the merger of the two previous networks into ECC-Net. This evaluation started in 2010.

One of the key initiatives is the implementation of the new Cosmetics Regulation. Main issues are the Cosmetics Products Notification Portal, a centralized notification database which will be managed by the Commission, guidelines on the cosmetics product safety report, guidelines on common criteria in order to use specific claims, "cosmetovigilance", CMR substances and nanotechnologies. Other key issues will be the availability of alternative methods to animals and the EU Chair of ICCR until July 2011 when the ICCR-5 meeting takes place in Europe.

15.3.3. **Summary of the Consumer activities' field**

The challenge in this sector in the near future is to increase EU-wide consumer confidence in the Internal Market through clearer, simplified and harmonised rules that are uniformly enforced by national authorities. Another challenge is to further engage consumers in enforcement efforts because the Commission cannot deliver effective application of EU consumer law alone, without the Member States and consumers themselves playing their full role. To do so the Commission will seek increased transparency of enforcement action and output to ensure that Member States' role is not only crucial in ensuring proper transposition of Directives but also in effectively deploying the resources and mechanisms needed to ensure compliance.

15.4. Food safety and animal health and welfare

15.4.1. **General Introduction**

For consumers, safety is the most important ingredient of their food. Consumer confidence is an essential outcome of a successful food policy and is therefore a primary goal of EU action in this area. The central goal of the Commission's food safety policy is to ensure a high level of protection of human health and consumers' interests in relation to food, taking into account diversity, including traditional products, whilst ensuring the effective functioning of the internal market.

The Commission's guiding principle is to apply an integrated approach from farm to table covering all sectors of the food chain, including feed production, primary production, food processing, storage, transport and retail sale. The credibility and legitimacy of the Commission's actions depend on how effectively the food safety policy is implemented and results delivered. Greater transparency at all levels of food safety policy is the thread running through the Commission's integrated approach and will contribute fundamentally to enhancing consumer confidence in Europe's food safety policy.

Legislation applicable to the various components of the food chain includes, in addition to the food and feed law, rules applicable to animal and plant health and to the welfare of animals. There have been enormous developments in the past decades, both in the methods of food production and processing, and the controls required to ensure that acceptable safety standards are being met. Legislation will be reviewed and amended as necessary in order to make it more coherent, comprehensive and up-to-date. Enforcement of this legislation at all levels will be promoted. Member States are key partners in ensuring adequate and uniform application of Europe's food safety legislation.

15.4.1.1.Report of work done in 2010

Work is ongoing on the modernisation and simplification of the legislation applicable to food and feed safety, animal and plant health, and animal welfare. The aim is to achieve better

enforceability of existing rules, whilst providing for a state of the art legislative framework.

Both the Animal Health Strategy[502] and the recently launched work towards a Plant Health Strategy[503] include the objective of providing the EU with a more coherent and directly enforceable set of rules in these areas in order to replace a vast amount of Directives adopted in the course of the last decades (the food safety *acquis* is one of the largest, numbering more than 500 Directives).

In more general terms, the Commission through an internal reorganisation in 2009 has integrated the issue of enforcement throughout the EU food safety policy area. This has mainly resulted in a systematic analysis of all issues related to implementation of EU legislation and emerging from in-house information, including the more than 200 inspection reports produced yearly by the Food and Veterinary Office (FVO) of the Commission, or from information received from Member States or stakeholders. For each of them an appropriate action is decided upon in cooperation with the responsible Units and a continuous follow-up is ensured until the issue has been resolved.

The issues related to transposition highlighted in the previous report have been specifically followed-up during 2009 and 2010, and all of them have now been closed due to the fact that transposition has taken place.

FVO inspections

At EU level, valuable information regarding the application of EU legislation along the food chain is provided by the inspection activities of the Commission's FVO. Information collected by the FVO during recent years was carefully screened during the course of 2009 to provide an overview of potential shortcomings in relation to transposition problems of some Directives or inadequate application of legislation throughout the food chain.

The Commission services are in contact with the Member States concerned to address these issues through an array of approaches. The FVO continues to screen Directives with the purpose of identifying any significant transposition problems. In a similar vein, the Commission services are considering the most efficient and effective enforcement action with respect to issues other than transposition that have been identified by the FVO.

The Court delivered in the framework of three infringement proceedings judgments condemning Greece to have failed to correctly apply EU law:

- The FVO missions have highlighted since 1998 fundamental systemic shortcomings in the performance of the Greek authorities' official controls in the area of food safety, animal health and animal welfare. These shortcomings are mainly attributable to the shortage of human resources in the Greek veterinary services. Because of these shortages both in central administration as well as in the decentralised authorities, there was a failure to carry out the official controls in

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502 Communication from the Commission to the Council, the European Parliament, the European Economic and social committee and the Committee of the Regions on a new Animal Health Strategy for the European Union (2007-2013) where "Prevention is better than cure". COM(2007) 539 final.

503 The Council called on the Commission to evaluate the current plant health *acquis* and to consider possible modifications to it, and subsequently present a proposal for a Community plant health strategy. The Commission has launched the evaluation, and is preparing a study.

an effective and substantial way. The Court concluded that the results of the efforts made by the Greek authorities to solve these problems were unsatisfactory[504].

- FVO missions provided evidence of systemic deficiencies in the management of animal by-products. The Court concluded that Greece failed to correctly apply key provisions of Regulation (EC) No 1774/2002 laying down health rules concerning animal by-products not intended for human consumption[505].

- Also on the basis of evidence gathered during FVO inspections, the Court of Justice condemned Greece for failure to apply in a satisfactory way EU legislation relating to the protection of animals during transport and in slaughterhouses[506].

All three cases show the need to give priority to initiatives that aim at engaging fully Member States' enforcement actors in discussions and actions to address the optimal use of finite enforcement resources.

15.4.2. **Enforcement of the rules applicable to the food chain**

15.4.2.1.Current Situation

Sustained attention to and coordination of enforcement action remains a priority in all areas related to food and feed safety, plant health and animal welfare.

Consideration will continue the strengthening of cooperation on enforcement matters with and among Member States' competent authorities and to a more transparent use and efficient handling of the vast amount of enforcement related data which is available to the Commission and to Member States.

Information contained in several reports from the FVO audits carried out in 2010 indicate that in some Member States the recent economic crisis might have had an impact on the availability of resources allocated for official controls to verify compliance with the food chain *acquis* (food and feed law, animal and plant health and animal welfare rules). Lack of resources is not a valid justification for non compliance with EU rules, and cases where insufficient controls result in a violation of EU law will be dealt with accordingly.

The finite nature (and sometimes the scarcity) of control resources is however a fact which deserves attention. The Commission has therefore started a review of the rules on the financing of official controls, as set out in Regulation (EC) No. 882/2004, with a view to improving the mechanisms with the intention to ensure appropriate resourcing of control activities at national level and ultimately to promote a more efficient use of available resources.

Legislative changes underway

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504 Judgment of the Court of Justice of 23.4.2009 in case C-331/07.
505 Judgment of the Court of Justice of 17.12.2009 in case C-248/08.
506 Judgment of the Court of Justice of 10.9.2009 in case C-416/07.

The impact assessment on the mentioned review on the legislation on the financing of official controls has started and it is planned to be finalised during early 2012. It will include extensive consultation with the Member States and other stakeholders in order to assess the advantages and disadvantages of the different options available for change. The related data will be acquired in the course of the consultation or, where needed, through specific surveys. A proposal for change, if required, can therefore be expected in 2012 (further details can be found at the following web address:

http://europa.eu/food/food/controls/inspection_fees/index_en.htm).

The review of the specific rules laid down in Council Directive 96/23/EC will be continued in order to fully integrate the related provisions within the framework of Regulation (EC) No. 882/2004 to provide Competent Authorities, operators and exporting countries with a simpler and more transparent framework for controls on residues of veterinary medicines.

15.4.3. **GMO Food and Feed**

15.4.3.1.Current position

Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified (GM) food and feed sets out a comprehensive set of rules governing the authorisation process for GM food and feed, while ensuring a high level of protection of human and animal health, of the environment and of consumers.

The Regulation provides for a single EU procedure for the authorisation of all food and feed containing, consisting or produced from a genetically modified organism. This authorisation, valid throughout the EU, is granted subject to a single risk assessment process under the responsibility of the European Food and Safety Authority (EFSA) and a single risk management process involving the Commission and the Member States through the examination procedure.

Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms (GMOs) outlines the principles for, and regulates, experimental releases and the placing on the market of GMOs in the EU for uses other than food and feed. The Directive provides for a notification procedure for the placing on the market according to which the applicant notifies the Member State where it wishes to cultivate. The Member State in question conducts an assessment report and decides whether to grant consent or not to the applicant in consultation with the other Member States and the Commission. Once the consent for placing on the market is granted the product may be used throughout the EU.

The Regulation provides for a single authorisation procedure, “one door - one key”, for all food and feed containing GMOs. The operator can submit his application in accordance with this Regulation or else he can split this application and have it dealt with under this Regulation and under Directive 2001/18/EC on the deliberate release of GMOs into the environment.

15.4.3.2.Report of work done in 2010

In line with its obligations deriving from Regulation (EC) No 1829/2003 and Directive 2001/18/EC, the Commission implemented the EU legislation on GM food and feed mainly in

the two following areas:

Authorisations were granted to those GM food and feed complying with all the conditions set out in the basic legislation:

- On 02 March 2010 the Commission adopted Decision 2010/141/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON863xNK603 (MON-ØØ863-5xMON-ØØ6Ø3-6);

- On 03 October 2010 the Commission adopted Decision 2010/140/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON863xMON810 (MON-ØØ863-5xMON-ØØ81Ø-6);

- On 02 March 2010 the Commission adopted Decision 2010/139/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON863xMON810xNK603 (MON-ØØ863-5xMON-ØØ81Ø-6xMON- ØØ6Ø3-6);

- On 02 March 2010 the Commission adopted Decision 2010/136/EU authorising the placing on the market of feed produced from the genetically modified potato EH92- 527-1 (BPS-25271-9) and the adventitious or technically unavoidable presence of the potato in food and other feed products;

- On 28 July 2010 the Commission adopted Decision 2010/432/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507x59122 (DAS-Ø15Ø7-1xDAS-59122-7);

- On 28 July 2010 the Commission adopted Decision 2010/428/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122x1507xNK603 (DAS-59122-7xDAS-Ø15Ø7xMON-ØØ6Ø3-6);

- On 28 July 2010 the Commission adopted Decision 2010/429/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 x MON 810 (MON-88Ø17-3 x MON-ØØ81Ø-6);

- On 28 July 2010 the Commission adopted Decision 2010/420/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034xNK603 (MON-89Ø34-3xMON-ØØ6Ø3-6);

- On 28 July 2010 the Commission adopted Decision 2010/426/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xGA21 (SYN-BTØ11-1xMON-ØØØ21-9).

Authorisations were granted to the following GM for cultivation complying with all the conditions set out in the basic legislation:

- On 2 March 2010 the Commission adopted Decision 2010/135/EU authorising the placing on the market of a potato product (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch.

- The Commission monitored the situation as regards the risk of non-authorised GM food and feed in products imported from third countries being placed on the EU market. This was in particular the case concerning emergency measures regarding the presence of the unauthorised genetically modified organism Bt 63 in rice products coming from China and regarding the non-authorised genetically modified organism LL RICE 601 in rice products originating from the United States for which an emergency withdrawal measure was adopted. In addition, a protocol of sampling and testing on linseed has been agreed with the Canadian authorities in order to prevent the import of the non authorised linseed FP 967 and its functioning has been audited by FVO inspections to Canada.

15.4.3.3.Evaluation based on the current situation

The Commission launched in June 2009 two evaluations in parallel, one on genetically modified food and feed and one on the cultivation of GMOs, with a view to assess to what extent the EU legislative framework and its objectives in this sector are still in line with the needs of EU society.

The primary objective of these evaluations is to assess the implementation of the major aspects of the legislative framework and to present possible policy options.

Both evaluations have been concluded in 2010 and the results will be assessed in 2011.

15.4.3.4.Priorities and planned action

Priorities

On 13 July 2010 the Commission proposed to confer to Member States the freedom to allow, restrict or ban the cultivation of GMOs on part or all of their territory. While keeping unchanged the EU's science-based GM authorisation system, the proposed package consists of a Communication, a new Recommendation on the co-existence of GM crops with conventional and/or organic crops, and a draft Regulation proposing a change to the GMO legislation. The new Recommendation on co-existence allows more flexibility to Member States taking into account their local, regional and national conditions when adopting co-existence measures. The proposed regulation amends Directive 2001/18/EC to allow Member States to restrict or prohibit the cultivation of GMOs in their territory.

The priority for 2011 is to obtain the endorsement by the European Parliament and the Council of the draft Regulation.

Additionally, the Commission drafted and presented to the Member States, with a view for adoption in 2011, a Commission proposal for a Regulation which would harmonise the methods of sampling and analysis for the official control of feed as regards presence of GMOs for which an authorisation procedure is pending ("Low Level Presence" proposal – LLP).

Another priority is the adoption of the report on socio-economic implications of the

cultivation of GMOs. The report will be transmitted to Council and Parliament in 2011.

Planned action

The Commission will continue to decide on applications for authorisations of GMOs for food and feed and cultivation and with the implementation of the current legislative framework.

The guidelines on GM food and feed have reached an advanced stage and will be presented for adoption to the Member States representatives in 2011.

Discussion with the Member States on the updated guidance on the Environmental Risk Assessment (ERA) of GMOs, as published by EFSA on 12 November, will take place in 2011, in order to allow the Member States to take greater ownership of the scientific content and data requirements in this regard.

15.4.3.5.Summary

As an overview, in 2010, some key authorisation decisions have been treated as expeditiously as allowed by procedures. A draft text on LLP has been completed and presented to the Member States whilst the cultivation package as adopted by the Commission and presented to both the European Parliament and Council is currently under discussion. The evaluation of the legislation has been completed and the results will be assessed in 2011. The ERA guidelines will be discussed with the Member States in 2011 whereas the guidelines for GM food and feed will be presented for adoption in 2011. Finally, the report on socio-economic implications of the cultivation of GMOs will be transmitted to Council and Parliament at the beginning of 2011.

Food hygiene

15.4.3.6.Rapid Alert System for Feed and Food

The Rapid Alert System established by Regulation (EC) No 178/2002 (Article 50) is a tool for exchange of information between competent authorities on consignments of food and feed in cases where a risk to human health has been identified and measures have been taken, such as withholding, recalling, seizure or rejection of the products concerned. This quick exchange of information allows all Member States to verify immediately whether they are also affected by the problem. Whenever the product is already on the market and should not be consumed, the Member States' authorities are then in a position to take all urgent measures, including giving direct information to the public, if necessary.

A Commission Regulation implementing Article 50 of Regulation (EC) No 178/2002 is scheduled for adoption in 2011. These measures concern in particular the specific conditions and procedures applicable to the transmission of notifications and supplementary information. This Regulation was discussed with the Member States and the stakeholders before its adoption.

15.4.3.7.Food hygiene legislation

The EU Food "Hygiene package" is composed of three Regulations consolidating, updating and simplifying the EU legislation on food hygiene:

- Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs;

- Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin; and

- Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

Those rules are based on the principles of a risk-based approach to a comprehensive and integrated food chain and the separation of responsibilities of food business operators and the competent authorities. Food business operators are primarily responsible for the (food) safety of their products.

- **Flexibility**: the new rules incorporated the principle of flexibility that enables *inter alia* the continued use of traditional methods of production, processing and distribution of food. In 2010, a Commission Staff Working Document on the Understanding of certain provisions on flexibility provided in the Hygiene Package was presented to give guidance to the food business operators and another one to provide guidance to the competent authorities of the Member States. The aim is to better explain the possibilities for flexibility so they are correctly used.

- **Composite products:** A Regulation laying down requirements for the certification for imports into and transit through the EU of certain composite products has been adopted in 2010. Regulation (EC) No 853/2004 provides that food business operators importing food containing both products of plant origin and processed products of animal origin (composite products) are to ensure that the processed products of animal origin contained in such food satisfy certain public health requirements laid down therein. In addition, food business operators must be able to demonstrate that they have done so, for example through appropriate documentation or certification. The application of such measures would have presented practical difficulties in certain cases. Commission Regulation (EC) No 2076/2005 therefore provided a transitional measure derogating from that obligation. This transitional period was prolonged until 31 December 2013 by Regulation (EC) No 1162/2009.

- **Mechanically Separated Meat (MSM):** In accordance with Article 9 of Regulation (EC) No 999/2001, the Commission is required to present a communication to the European Parliament and the Council on the future necessity and use of MSM in the EU, including the information policy towards consumers. On 2 December 2010, the Commission adopted a Communication presenting an overview of the specific hygiene and labelling requirements in the EU legislation and their implementation, an overview of the production and use of MSM, information concerning the future necessity of production and use of MSM and the perception of consumers concerning the use of MSM and the preferred information policy from the side of consumers.

- **Review of meat inspection:** In the Council Conclusions on the Hygiene report of

20 November 2009, the Commission has been requested to reflect on a new approach to meat inspection taking into account trends of hazards over the last decades. The Commission organised on 18 May 2010 a first Round Table on meat inspection with all relevant parties (Member States Authorities, stakeholders, EFSA, international organisations (Codex) and representatives of third countries) to review the effectiveness of current sanitary inspection in slaughterhouses. Sessions were included on current provisions on meat inspection, the risk-based approach and the international context. A second conference focussed on pig meat inspection was organised on 25 October 2010.

- **Derogations granted to Romania and Bulgaria:** In order to give certain establishments in Romania and Bulgaria enough time to adapt to the EU legal framework, the Commission granted them derogation from certain structural requirements of Regulations (EC) Nos 852/2004 and 853/2004. Commission Decision 2010/89/EU lays down transitional measures concerning the application of certain structural requirements of to establishments for meat, egg products, fishery products and cold stores in Romania. Commission Decision 2009/861/EC, amended in 2010 by Commission Decision 2010/653/EU grants a derogation from Regulation (EC) No 853/2004 to allow the processing of compliant and non-compliant milk with or without separate production lines. As long as these establishments are covered by transitional measures, products originating from them may only be placed on the domestic market.

- **Biotoxins:** The mouse bioassay is the official reference method for the detection of certain marine biotoxins. In July 2006 the Commission requested EFSA to provide a scientific opinion to assess the current EU limits and methods of analysis with regard to human health for various marine biotoxins as established in EU legislation, including new emerging toxins. The last opinion was published on 24 July 2009. EFSA noted that this bioassay has shortcomings and is not considered an appropriate tool for control purposes because of the high variability in results, the insufficient detection capability and the limited specificity. Recently developed alternatives to the biological methods for the determination of the marine biotoxins have successfully been tested in pre-validation studies. Consequently, Regulation (EC) No 15/2011 was adopted and establishes that a technique such as liquid chromatography (LC) mass spectrometry (MS) should be applied as the reference method for the detection of lipophilic toxins and used as matter of routine, both for the purposes of official controls at any stage of the food chain and own-checks by food business operators.

Following the report from the Commission to the Council and the European Parliament on the experience gained from the application of the hygiene Regulations, adopted in 2009, the Commission will draft a proposal amending these Regulations. This will concern the review of meat inspection and revision of certain articles. The procedure will start in 2011 with the aim to achieve a result by 1 January 2014.

15.4.3.8.Better training for Safer Food

Regulation (EC) No 882/2004 provides the legal base for the initiative "Better Training for Safer Food (BTSF)". It aims at training official safety control staff in the Member States and third countries on food, veterinary and plant health issues. This initiative keeps control staff

up to date with EU rules and guarantee uniform and efficient controls. This helps ensure respect for EU legislation and contribute to providing safer food and feed.

In 2010, 120 events gathering 6000 people took place in the Member States and in third countries.

In the Member States, the programme covered the following subjects:

- HACCP
- Animal By Products
- Food Hygiene and Control
- Animal Health Controls (Aquaculture)
- Animal Health Controls (bees and Exotic zoo animals)
- Plant Health Control
- BIPs Seaport/roads/rail
- Zoonoses and microbiological criteria
- Animal Welfare
- Plant Protection Products
- Feed law
- Food Contact Materials
- TSE
- Import controls of food of non-animal origin

The third country programme concerned:

- RASFF/TRACES
- Avian Influenza
- EU food import standards
- GMO Analysis
- Food testing on SPS issues
- BTSF Africa

In 2011, 130 events will be organised for approximately 6300 participants. The 2010

programmes will continue on:

- HACCP
- Animal By Products
- Food Hygiene and Control (3 modules)
- Animal Health Controls (Aquaculture)
- Animal Health Controls (bees/exotic zoo animals)
- Plant Health Control (2 modules)
- Feed Law
- Animal Welfare
- Plant Protection Products
- Veterinary/food safety controls in BIPs
- Prevention, control, eradication of TSE
- Microbiological criteria/zoonoses
- Controls on feed/food of non-animal origin

New programmes will be launched on:

- Quality schemes (organic farming/geographical indications)
- TRACES
- Audit systems/internal auditing
- FVO Pool of EU inspectors

15.4.4. **Transmissible spongiform encephalopathies**

Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. The success of the EU's efforts in combating Transmissible Spongiform Encephalopathies (TSEs), such as Bovine Spongiform Encephalopathy (BSE) in cattle or scrapie in sheep and goats, allows the EU to contemplate changes in some of its rules. On 16 July 2010, the Commission adopted a Communication to the European Parliament and the Council, which outlines areas where future possible changes to EU TSE-related measures could be made. The document "The TSE Road Map 2 – A strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015" underlines that any amendment should maintain the EU's high level of protection of human and animal health and of food safety and should be backed up by solid science. The Road Map is a reflection paper that opens up dialogue on the issue.

15.4.5. **Food additives**

15.4.5.1. Current position

General introduction presenting the legislation

Council Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption has been repealed by Regulation (EC) No 1333/2008 on food additives which applies since 20 January 2010.

The new regulation required a review of all current additives authorisations for their compliance with their general conditions of use by 20 January 2011 and transfer of these provisions in the Annex of this Regulation. Until that transfer was completed, the Annexes to Directives 94/35/EC, 94/36/EC and 95/2/EC continued to apply. In addition, powers to adopt implementing measures were conferred to the Commission to amend the annexes to Directives 94/35/EC, 94/36/EC and 95/2/EC until the establishment of the EU list of food additives in the Annex of Regulation (EC) No 1333/2008.

Regulation (EC) No 1333/2008 required furthermore the adoption of a programme for the re-evaluation of food additives by 20 January 2010 and a regulation adopting specifications of the authorised food additives. It requires the establishment of new lists of food additives used in food additives, enzymes and nutrients (Annex III, parts 2, 3 and 5).

Regulation (EC) No 1331/2008 established as well that a common authorisation procedure for food additives, food enzymes and food flavourings should be adopted by end 2010.

Report of work done in 2010

In 2010 the Commission adopted:

- Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

- Commission Directive 2010/69/EU of 22 October 2010 amending the Annexes to European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners.

- Commission Directive 2010/37/EU of 17 June 2010 amending Directive 2008/60/EC laying down specific purity criteria on sweeteners (neotame).

- Commission Directive 2010/67/EU of 20 October 2010 amending Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners.

15.4.5.2. Evaluation based on the current situation

In the framework of the regulatory procedure with scrutiny, the European Parliament adopted a resolution against the food additives which required a re-submission addressing the

concerns of the resolution. This delayed however the adoption of all other parts of the text. In future, closer and earlier contacts with European Parliament and more specific drafts are to be prepared.

The adoption of an implementing measure for Regulation (EC) No 1331/2008 is slightly delayed. A Commission proposal will be ready for vote at the Standing Committee on the Food Chain and Animal Health in 2011.

The Commission Regulations establishing the Union lists of food additives and the regulation adopting specifications of the authorised food additives are in a final stage of preparation. The procedure for their adoption will be launched in 2011.

15.4.5.3. Priorities and planned action

Priorities

The adoption of following acts is prioritised:

1. Commission Regulation implementing Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

2. Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives.

3. Commission Regulation amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing. a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients.

4. Commission Regulation laying down specifications of the approved food additives.

5. Commission Directive amending Directive 2008/128/EC laying down specific purity criteria concerning colours for use in foodstuffs (lycopene).

6. Commission Regulations amending the Annexes to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

Planned actions

Actions 1, 2, 3, 4 and 5 are in a final stage and will be presented for vote at the Standing Committee during 2011, except for action 5, which is expected to be adopted in January 2011.

The Commission Regulations amending the Annexes to Regulation (EC) No 1333/2008, will be presented for vote at the Standing Committee during the second half of 2011 following consultation with Member State experts and stakeholders, and the Union list of food additives needs to be established first.

15.4.5.4. Summary of food additives

The application of the EU law in the area of food additives is ongoing as planned. The adoption of the Commission regulations establishing the Union lists of food additives during the first half 2011 will receive highest priority. The Commission Regulation on an implementing measure for Regulation (EC) No 1331/2008 will allow an efficient management of the Union lists. Amendments to these lists will be necessary to take into account possible safety concern raised in the opinions of EFSA and to allow authorisations of new additives.

15.4.6. **Food enzymes**

15.4.6.1.Current Situation

General introduction presenting the legislation

The new Regulation (EC) No 1332/2008 on food enzymes harmonises for the first time the use of food enzymes, both as food additives and processing aids.

This Regulation has already entered into force, with the exception of Article 4 which shall apply from the date of application of the Union list.

The Union list of food enzymes shall be drawn up on the basis of applications made pursuant to the requirements of Article 17 of the above Regulation. The deadline for submitting such applications from interested parties is 24 months after the date of applications of the implementing measures to be laid down in accordance with Article 9(1) of Regulation (EC) No 1331/2008.

The Commission shall establish a Register of all food enzymes to be considered for inclusion in the Union list in respect of which an application complying with the validity criteria laid down in the implementing measure has been submitted following the requirements of Regulation on food enzymes.

The establishment of the Union list will take place in a single step procedure after the EFSA has expressed opinions on all products for which sufficient information has been submitted during the 24-month period. This is, however, a lengthy process which will take several years.

Report of work done in 2010

When drafting Regulation on implementing measure which concerns the content, drafting and presentation of the applications to update the Union lists on food additives, food enzymes and flavourings, the arrangements for checking the validity of applications and the type of information that must be included in the opinion of the EFSA, a number of meetings have taken place with Member States experts and with stakeholders. EFSA was also consulted. The Commission is currently finalising this implementing measure which should be adopted in the first half of 2011.

As far as food enzymes are concerned, a couple of trial dossiers were submitted in April and July 2010 by the Association of Manufacturers and Formulators of Enzyme Products (AMFEP) to the Panel on food contact materials, enzymes, flavourings and processing aids (CEF Panel) to be tested under the published guidelines. This is a simulated evaluation to give indications to EFSA about the type of dossiers that they will get and info to applicants on how to prepare the application, notably concerning grouping of dossiers. As a result of this exercise, which has taken place in December 2010, EFSA will update its guidelines with more

practical advice.

15.4.6.2.Evaluation based on the current situation

It is not yet possible to fully appreciate the enforcement of Regulation (EC) No 1332/2008. However, significant improvements are expected (in particular by food businesses) from the simplification of the legislative framework.

15.4.6.3.Priorities and planned action

Priorities

The Regulation on implementing measure was planned to be adopted in the first half of 2011 and a number of applications were expected to be submitted from interested parties to the Commission. A data base for food enzymes will be established in order to handle these applications. This database will be used for establishing a Register of all food enzymes which will be made available to the public. This Register will be established in 2012.

Planned action

The Commission is responsible for verifying whether an application falls within the scope of the enzyme Regulation and whether an application is valid. Once the application is valid it will be submitted to EFSA for its risk assessment.

Meetings with Member States, stakeholders and EFSA are also foreseen during 2011 to follow the requirements of this set of legislation.

15.4.6.4.Summary

Although there is a new Regulation on food enzymes which harmonises for the first time the use of food enzymes it is not yet possible to fully appreciate the enforcement of this provision.

An important number of dossiers are expected to be submitted in the two-year initial period of submission which will start at the date of application of the implementing measures. A couple of trial dossiers have been tested by the CEF panel and a new database will be established.

15.4.7. **Food flavourings**

15.4.7.1.Current position

General introduction presenting the legislation

The general framework for food flavourings in the EU was established by Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production. This Directive lays down general requirements for safe use of flavourings in food and provides definitions for different types of flavourings. It also establishes maximum levels for certain substances that are naturally present in flavourings and in food ingredients with flavouring properties, but which may raise concern for human health.

Commission Directive 91/71/EEC of 16 January 1991 completing Council Directive

88/388/EEC sets out labelling rules on flavourings.

It was necessary to update these Directives in the light of technical and scientific developments. Therefore, the Commission proposed on 28 July 2006 a new Regulation on flavourings and certain food ingredients with flavouring properties.

The new Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods was adopted on 16 December 2008. It repealed Council Directive 88/388/EEC and Commission Directive 91/71/EEC as from 20 January 2011.

Similar to the previous legislation, the Regulation lays down general requirements for safe use of flavourings and provides definitions for different types of flavourings. The Regulation sets out flavourings and source materials for which an evaluation and approval is required. The Regulation prohibits the addition of certain substances as such to food and lays down maximum levels for certain substances, which are naturally present in flavourings and in food ingredients with flavourings properties, but which may raise concern for human health. The Regulation also sets out the rules for labelling of flavourings from business to business and for sale to the final consumers. It also describes the specific requirements for use of the term "natural".

Currently, Regulation (EC) No 2232/96 sets out the basic rules for the use of flavouring substances in or on foodstuffs and lays down a procedure for the establishment of an EU list of flavouring substances. The Regulation will become obsolete after the establishment of the EU list provided for in Regulation (EC) No 1334/2008, when only those flavouring substances listed will be allowed to be added to foods.

The European Parliament and the Council Regulation (EC) No 2065/2003 on smoke flavourings used or intended for use in or on foods establishes an EU procedure for the safety assessment and the authorisation of smoke flavourings in order to ensure a high level of protection of human health and protection of consumers' interests, as well as to ensure fair trade practices.

In addition, a separate Regulation (EC) No 1331/2008 establishes an effective, expedient and transparent common authorisation procedure for food additives, food enzymes and food flavourings.

Report of work done in 2010

Several working group meetings were organised with the governmental experts on flavourings to discuss the EU list on flavouring substances (around 2600 substances). The list will form part of the Regulation (EC) No1334/2008 and was scheduled to be adopted in the by the end of the year. However, the evaluations of flavouring substances by EFSA is still on-going, therefore, no list could be adopted yet.

The EU list on smoke flavourings was discussed twice in the Standing Committee on Food Chain and Animal health, in several working group meetings of governmental experts on flavourings and with the stakeholders in the working group if the Advisory Group on the Food Chain, Animal and Plant Health. However, no conclusion on the authorised substances was reached so far.

15.4.7.2.Evaluation results based on the current situation

The use of flavourings continues to be regulated by general requirements laid down in the framework measures. The use of flavourings substances is not yet harmonised in the EU. Those smoke flavouring primary products for which a valid application was submitted by 30 June 2005 in accordance with Regulation (EC) No 2065/2003 and for which applications have not been withdrawn, continue to be traded in and used.

15.4.7.3.Priorities and planned action

Priorities

Priority for 2011 is to adopt the EU list of flavourings substances and the EU list on smoke flavouring primary products.

Planned action

Although the evaluations of flavourings substance are on-going, the work on the EU list of flavouring substances will continue and the intention is to establish the list in the first half of 2011.

The EU list of smoke flavouring primary products was expected to be established in the first half of 2011 as EFSA was reviewing new scientific data in 2011 related to already evaluated smoke flavourings.

15.4.7.4.Summary by sector

The new framework Regulation applies from 20 January 2011. New rules, for example on categorising flavourings, on the labelling and on the maximum levels for certain substances, which are naturally present in flavourings and in food ingredients with flavourings properties, will apply. Work is on-going to harmonise the use of flavouring substances and smoke flavouring primary products in the EU.

15.4.8. **Residues of veterinary medicinal products**

15.4.8.1.Current position

General introduction presenting the legislation

During their lifetime animals may have to be treated with medicines for prevention or cure of diseases. In food producing animals such as cattle, pigs, poultry and fish this may lead to residues of the substances used for the treatment in the food products derived from these animals (e.g. meat, milk, eggs). The residues should not however be harmful to the consumer.

EU legislation requires that the toxicity of potential residues is evaluated before the use of a medicinal substance in food producing animals is authorised. If considered necessary, maximum residue limits (MRLs) are established and in some cases the use of the relevant substance is prohibited. The evaluation procedure is laid out in Regulation (EC) No 470/2009 of 6 May 2009. This Regulation also sets out procedures to establish and review reference points for action (RPAs) to be used in case residues of non authorised substances are detected. Such RPAs are currently established by Commission Decision 2005/34/EC. Finally, due to

the health risks for consumers, the use of certain groups of veterinary medicinal products (such as substances having a hormonal or thyrostatic action and beta-agonists) in stockfarming is banned by Directive 96/22/EC.

To guarantee a high level of consumer protection, an EU-wide monitoring of certain substances and residues is implemented by the Member States. Provisions on frequencies and level of sampling, groups of substances to be controlled for each food commodity, drafting and approval of annual national residue monitoring plans (NRCPs) are laid down in Directive 96/23/EC and Commission Decision 97/747/EC. The principal objective of Directive 96/23/EC is to detect illegal use of substances in animal production and the misuse of authorised veterinary medicinal products and to ensure the implementation of appropriate actions to minimise recurrence of all such residues in food of animal origin. Detailed rules for official sampling procedures and official treatment of samples until they reach the laboratory responsible for analysis are laid down in Commission Decision 98/179/EC. Laboratory accreditation and validation of methods used is established in Commission Decision 2002/657/EC.

Residue monitoring requirements for third countries wishing to export food of animal origin to the EU are outlined in Directive 96/23/EC: such third countries must submit a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances. The guarantees must have an effect at least equivalent to those provided for in the Directive for Member States.

Report of work done in 2010

The annual approval of the NRCPs of the Member States and third countries assures a uniform basis for residue monitoring in the EU and provides for the necessary guarantees regarding residues of veterinary medicinal products in food of animal origin, both produced in the EU and imported from third countries. The drafting of the annual report on the residue monitoring exercise of the previous year, based on more than 750.000 analytical results, consolidates the efforts regarding residue monitoring within the EU. Finally, the shortcomings detected during the FVO missions carried out both in Member States and third countries are closely monitored.

Several topics related to residue monitoring were discussed during working group meetings: accreditation of laboratories and validation of methods, interpretation of results, control measure to apply in case of non compliance. The future steps in residue monitoring, including control measures, reduction of administrative burden, new implementing measures were presented to the Member States.

15.4.8.2.Evaluation based on the current situation

The current legal framework related to residues of veterinary medicinal products seems to be achieving its goals through correct enforcement. No complaints have been received regarding the bad application of the relevant legislation by the Member States.

15.4.8.3.Priorities and planned action

Priorities

The administrative procedure laid down in Directive 96/23/EC in relation to the approval of the NRCPs is rather heavy and the outcome offers little flexibility to adapt the NRCPs, once approved, in a risk based manner to changes in risk profile. Reporting on monitoring is limited to compliance/non-compliance and follow-up measures on non-compliant samples. Data concerning residues below MRLs available at Member State level are not available at EU level, reducing information related to the percentage of animals treated and consumer exposure.

Since Regulation (EC) No 470/2009 now offers the necessary legal basis, priorities regarding control measures will relate to residues following cascade use (use in non target species, defined in Directive 2001/82/EC) and residues of non authorised substances. Regarding this last issue, it is important to clarify how the existing RPAs under Commission Decision 2005/34/EC relate to the provisions in Regulation (EC) No 470/2009.

Planned action

The general objectives of the review of Directive 96/23/EC are the optimisation and simplification of the overall legislative framework, the consistency with Regulation (EC) No 882/2004 allowing for the introduction of risks assessment criteria and an increased flexibility. This review will be continued starting with the impact assessment with the involvement of Member States and other stakeholders.

On the establishment and review of RPAs, a mandate will be sent to EFSA to request and opinion on scientific methods and methodological principles to be taken into account in this context. Following discussion with the Member States, the Opinion will be used as a basis for the implementing measures. The next step will include the transfer (including possible review) of the existing RPAs to this new implementing measure. In parallel, the actions to be taken in case of repeated confirmed presence below RPA and the MRLs to be considered for control purposes for foodstuffs derived from animals which have been treated under the cascade system will be discussed at working group level.

15.4.8.4.Summary by sector

The legislative framework on monitoring of residues of veterinary medicinal products in food of animal origin is effective but the administrative burden is high, both for the Commission and the Member States.

Possibilities for implementing measures laid down in Regulation 470/2009 relating to control issues will be fully explored in the near future.

15.4.9. **Contaminants in food**

15.4.9.1.Current position

General introduction presenting the legislation

The EU harmonisation of legislation on contaminants in food fulfils two essential objectives: the protection of public health and the removal of internal barriers to trade.

Council Regulation (EEC) No 315/93 of 8 February 1993, laying down community procedures for contaminants in food, constitutes the framework for the EU action on

contaminants.

The Regulation provides that:

- Food containing a contaminant in an amount which is unacceptable from the public health viewpoint shall not be placed on the market;
- Contaminant levels shall be kept as low as can reasonably be achieved by following good practices at all stages of the production chain;
- In order to protect public health, maximum levels for specific contaminants shall be established where necessary (by comitology); and
- The consultation of EFSA for all provisions which may have an effect upon public health is mandatory.

Based on this framework Regulation, maximum levels for the following specific contaminants in foodstuffs have been established by Commission Regulation (EC) No 1881/2006 of 19 December 2006; such as nitrate, aflatoxins, ochratoxin A, fusarium-toxins, and patulin (mycotoxins); lead, cadmium, mercury (heavy metals); dioxins and PCBs; 3-MCPD; inorganic tin; benzo(a)pyrene (as marker substance for the group of PAH).

In addition, several Regulations have been adopted containing provisions as regards the sampling and methods of analysis to be used for official control of the compliance with the maximum levels established on contaminants, in order to ensure a harmonised enforcement approach:

- Commission Regulation (EC) No 1882/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs;
- Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of dioxins and dioxin-like PCBs in certain foodstuffs;
- Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs;
- Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs.

Following safeguard measures as regards mineral oil, melamine and aflatoxins are in place:

- Commission Regulation (EC) No 1135/2009 of 25 November 2009 imposing special conditions governing the import of products originating in or consigned from China, and repealing Commission Decision 2008/798/EC.
- Commission Regulation (EC) No 1151/2009 of 27 November 2009 imposing special conditions governing the import of sunflower oil originating in or

consigned from Ukraine due to contamination risks by mineral oil and repealing Decision 2008/433/EC.

- Commission Regulation (EC) No 1152/2009 of 27 November 2009 imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC.

Report of work done in 2010

The provisions on maximum levels and sampling for aflatoxins in food were updated, including the alignment of EU legislation with Codex decisions as regards maximum levels and sampling for aflatoxins in almonds, hazelnuts and pistachios (Commission Regulation (EU) No 165/2010 of 26 February 2010 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins and Commission Regulation (EU) No 178/2010 of 2 March 2010 amending Regulation (EC) No 401/2006 as regards groundnuts (peanuts), other oilseeds, tree nuts, apricot kernels, liquorice and vegetable oil).

Taking into account the outcome of EFSA scientific opinion on ochratoxin A in food, new provisions on maximum levels for ochratoxin A in spices and liquorice were adopted (Commission Regulation (EU) No 105/2010 of 5 February 2010 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards ochratoxin A).

An amendment of Regulation (EC) No. 1881/2006 containing clarifications and updates of the existing provisions (e.g. with regard to the portion to be analysed for cadmium in crabs), was finalised in 2010. Adoption and entry into force is foreseen for 2011. Additionally, an Information Note containing guidance for national authorities to issue consumer advice on cadmium in crabs, was prepared and will be put on the Directorate-General Health and Consumers' webpage when the Regulation enters into force.

Following the outcome of the FVO inspection mission in October 2009, Commission Regulation (EU) 258/2010 of 25 March 2010 imposing special conditions on the imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins, and repealing Decision 2008/352/EC, was adopted.

Two recommendations on acrylamide were finalised in 2010. The first, a recommendation extending the existing monitoring programme, was adopted early 2010. The second, a recommendation for Member States to carry out further investigations on acrylamide, was finalised at the end of 2010, and adoption was planned for 2011.

Data is being collected on a number of other contaminants, such as brominated flame retardants (polybrominated diphenyl ethers (PBDE's) etc), furan, ethylcarbamate, perfluorooctane sulfonates/acids (PFOS/A).

15.4.9.2.Evaluation based on the current situation

Much attention is paid to the effective and uniform enforcement of the legislation on contaminants and of related safeguard measures. Consideration is given to enforcement issues from the very first stages of the discussions on new measures, in order to ensure optimal

uniform enforcement across the EU.

Enforcement issues are discussed in the Standing Committee on the Food Chain and Animal Health and in relevant expert groups thereof. These discussions result in some cases in guidance documents for the control of the legislation, publicly available and published on the Directorate-General Health and Consumers' web pages:

- Guidance document for competent authorities for the control of compliance with EU legislation on aflatoxins[507] (available in all EU languages);
- Guidelines for the enforcement of provisions on dioxins in the event of non-compliance with the maximum levels for dioxins in food[508];
- Guidance on sampling of whole fishes of different size and/or weight[509];
- Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation, with particular reference to the contaminants legislation[510].

15.4.9.3. Priorities and planned action

Initiatives for possible changes to the contaminant legislation include the development of proposals to limit the presence in food of other contaminants (T-2 toxin, HT-2 toxin, arsenic and PCBs) and to review some existing provisions (heavy metals, polycyclic aromatic hydrocarbons (PAHs) and dioxins). Alongside the review of maximum levels for PAHs, Regulation (EC) No 333/2007 laying down methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs, will be amended to reflect the changes in legislation.

In the contaminants area new and emerging risks are difficult to predict, but require continuous attention to protect public health.

15.4.9.4. Summary by sector

Existing maximum levels for contaminants are continuously reviewed and updated in the light of new scientific evidence and technological progress. New maximum levels are established where this is necessary to protect public health. Furthermore, much attention is paid to the effective and uniform enforcement of the legislation on contaminants and of related safeguard measures.

507 http://ec.europa.eu/food/food/chemicalsafety/contaminants/aflatoxin_guidance0309_en.pdf
508 http://ec.europa.eu/food/food/chemicalsafety/contaminants/guidelines-july_2004_en.pdf
509 http://ec.europa.eu/food/food/chemicalsafety/contaminants/guidance-sampling%20-whole-fish-with%20exemples-dec2006.pdf
510 http://ec.europa.eu/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf

15.4.10. **Plant Protection Products – Pesticide Residues**

15.4.10.1. Current position

The legislation in this area regulates the placing on the market and use of plant protection products (Directive 91/414/EEC and Regulation (EC) No 1107/2009), the sustainable use of pesticides (Directive 2009/128/EC) and the maximum residue levels (MRLs) of pesticides that can be found in or on food and feed (Regulation (EC) No 396/2005).

The evaluation, marketing and use of plant protection products in the EU are regulated under Council Directive 91/414/EEC. This Directive lays out a comprehensive risk assessment and authorisation procedure for active substances and products containing these substances. Each active substance has to be proven safe in terms of human health, including residues in the food chain, animal health and the environment, in order to be allowed to be marketed. It is the responsibility of industry to provide the data showing that a substance can be used safely with respect to human health and the environment.

The rules for the placing on the market and use of plant protection products provide that persons or companies wishing to secure the inclusion of active substances in the positive list of Annex I of Directive 91/414/EEC, submit by a certain date a dossier meeting the requirements of the Directive in order to demonstrate that it may be expected that plant protection products containing those active substances are sufficiently safe for human or animal health or for the environment.

In 2010 the Commission's activity in this area was mainly focussed on active substances previously not included in Annex I of Directive 91/414/EEC and for which a new dossier was re-submitted. 18 Commission proposals were finalised in 2010. This work will continue in 2011, when some 60 active substances will have to be evaluated by the Commission. In addition, several other decisions were taken for 1) the approval or renewal of the approval for 12 active substances; 2) the amendment of the conditions for approval of 15 substances, including new provisions to protect honeybees for certain insecticides; 3) the establishment of a work programme in view of the future renewal of 31 active substances.

In 2010 the Commission started working on the implementation of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. This Regulation will enter into force in June 2011 and will repeal Council Directive 91/414/EEC. The work carried out in 2010 was mainly devoted to the creation of the conditions for the correct implementation of the authorisation system in 3 zones (zonal system) and to the transfer of the existing data requirements under Directive 91/414/EEC into Regulation (EC) No 1107/2009.

As regards Regulation (EC) No 396/2005, in 2010 the Commission adopted 5 Regulations to set several new maximum residue levels (MRLs), following the EFSA evaluation of new MRLs applications by manufacturers, as well as third countries. The Commission finalised 4 other proposals for Regulations expected to be published in the first half of 2011, including a proposal to reduce the MRLs of 13 pesticides no longer approved in the EU. In addition, the Commission also adopted a Regulation to amend the list of commodities to which MRLs apply (Reg. (EU) No 600/2010), and a Regulation on a coordinated multi-annual control programme of the EU on pesticide residues (Reg. (EU) 915/2010).

15.4.10.2. Evaluation based on the current situation

Although this policy area is characterised by complex technical issues, the enforcement of the legislation seems to be adequate.

As regards the new Regulation on the placing on the market of plant protection products and the Directive on the sustainable use of pesticides, it will not be possible to appreciate the situation comprehensively until the legislation is fully applicable and implementing measures have been in force for some time.

The implementation of Regulation (EC) No 396/2005, which since September 2008 harmonises the setting of MRLs in the EU, resulted in significant improvements (in particular for food business operators) due the simplification of the regulatory system and to the removal of national MRLs. However, this area needs to be further improved, with particular regard to the time needed from the submission of an application from a third party to the publication of the MRLs in the EU Official Journal. Furthermore, the provisions of this Regulation need also to be aligned to the timelines and procedures of Regulation (EC) No 1107/2009.

Commission Decisions not to include active substances in the positive list of active substances that may be used in plant protection products (Annex I of Directive 91/414/EEC) are regularly challenged before the Court. As in 2009, the General Court and the Court of Justice continued in 2010 to dismiss such applications[511]. In addition, one case was withdrawn from the Court. Those judgments confirm the correct application by the Commission of EU law when assessing and deciding on active substances.

15.4.10.3. Priorities and planned action

In 2011 the Commission's activity will be aimed mainly at the implementation of Regulation (EC) No 1107/2009 and of Directive 2009/128/EC. This will include, among other things, the adoption of new data requirements for the dossiers to be submitted by industry on active substances and plant protection products and the adoption of several implementing Regulations, required by 14 June 2011. By 14 December 2011 the Commission will present a report to the European Parliament and to the Council on the establishment of a European fund on minor uses.

In parallel, the activity under Directive 91/414/EEC will continue, with a special focus on the dossiers submitted by several manufacturers under Regulation (EC) No 33/2008. This Regulation lays down rules concerning the re-submission of dossiers regarding substances previously not included in the positive list of Directive 91/414/EEC (Annex I). About 60 dossiers are expected to be finalised in 2011.

The work in the area of pesticides residues will increase in 2011, due to the need to review existing MRLs for a) substances approved before 1 September 2008 and b) substances both approved and not approved after 1 September 2008. This MRLs review programme is based on the provisions of Article 12 of Reg. (EC) No 396/2005 and is expected to involve about 80 active substances per year. In parallel, the normal MRL setting process will also continue, as required by Reg. (EC) No 396/2005.

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511 Cases C-77/99 Gowan Comercio v; Commission, C-517/08P Makhteshim-Agan Holding v. Commission.

15.4.10.4. Summary by sector

Placing on the market of plant protection products

Activity in 2010 was mainly devoted to 1) the decision for active substances previously not approved and for which new dossiers were resubmitted and 2) the preparation of a number of implementing measures for Reg. (EC) No 1107/2009. In 2011 the Commission will continue the work started in 2010 both for resubmitted substances and for the implementation of the new Regulation (EC) No 1107/2009 and also of Directive 2009/128/EC. Important achievements are expected to take place in both directions, as the Commission should finalise the decision-making for around 60 substances and ensure the smooth implementation of the new legislation. This will involve the adoption of several implementing Regulations in 2011, the update of the data requirements for the dossiers and the submission of a report on a European fund on minor uses.

Pesticide residues

The Commission's activity in 2010 focused mainly on the setting of new MRLs for about 100 MRLs applications. The Commission has also worked to reduce the MRLs for 13 old pesticides and to adapt the list of commodities by including several new crops. In 2011 more work is expected in this area, due to the need to review existing MRLs for several substances according to Article 12 of Reg. (EC) No 396/2005.

15.4.11. **Extraction Solvents**

15.4.11.1. Current position

General introduction presenting the legislation

Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 applies to extraction solvents used or intended for use in the production of foodstuffs or food ingredients.

This Directive establishes the list the above mentioned extraction solvents as well as maximum residual amounts, where appropriate.

Report of work done in 2010

The European Food Safety Authority evaluated the safety of dimethyl ether as an extraction solvent to remove fat from animal protein raw materials. On the basis of the proposed uses, it was considered appropriate to permit the use of this extraction solvent.

The conditions of use for methanol and propane-2-ol were too strict for the production of flavourings. Specific conditions for this use were therefore needed. The proposed conditions of use for the production of flavourings should be introduced in Part III of the annex to the Directive.

For the above mentioned reasons the following act was adopted:

- Commission Directive 2010/59/EU of 26 August 2010 amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation

of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

15.4.12. **Food Labelling**

15.4.12.1. Current position

General Introduction

EU legislation on food labelling includes general provisions on the labelling of foodstuffs to be delivered to the consumer, as laid down in Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. This Directive sets out harmonised rules to enable European consumers to get comprehensive information on the content and the composition of food products. Nutrition labelling on foods is regulated by Directive 90/496/EEC. At the moment, under EU legislation, nutrition labelling is optional, although it becomes compulsory when a nutrition or health claim is made in the labelling, presentation or advertising of a foodstuff or when vitamins or minerals are voluntarily added to foods.

Report of work done in 2010

EU legislation on food labelling is currently under revision. The Commission adopted, on 30 January 2008, a proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers. This proposal combines Directive 2000/13/EC with Council Directive 90/496/EEC on nutrition labelling for foodstuffs into one instrument. In addition, the proposal is in line with the simplification process in the context of Better Regulation as it simplifies the structure of the horizontal food labelling legislation in Directive 2000/13/EC, by recasting and replacing provisions already in place under this Directive.

In 2010 there was progress in the negotiations between the European Parliament and the Council. The European Parliament adopted on 16 June 2010 its first reading position on the Commission's proposal. The Employment, Social Policy, Health and Consumer Affairs Council of 7 December 2010 reached a political agreement on the Council position on the Commission's proposal.

The labelling *acquis* is managed through the Standing Committee on the Food Chain and Animal Health (SCFCAH). The Committee plays a key role in exchange of views between the Member States and the Commission regarding the application of the labelling provisions and the increasing number of draft measures notified by the Member States (on the basis of Article 19 of Directive 2000/13/EC). In 2010, the Commission dealt with the assessment of the following notified draft national measures:

- **Italy:** draft measure providing, *inter alia*, for additional warnings for the labelling of certain herbal extracts (completion of the assessment carried out in 2009).

- **France**: draft measure laying down the conditions and labelling requirements for the use of virgin linseed oil for human consumption (completion of the assessment carried out in 2009).

- **Spain**: draft Decree laying down that labelling or documentation of all the meat

intended for human consumption which is obtained from animals slaughtered according to religious rites shall indicate the following wording “obtained through the stunning special exemption”.

• **Germany**: Second Order amending the Order on fruit juice and other regulations under food law providing for the mandatory health warnings on energy drinks.

• **Belgium**: draft measure requiring *inter alia* compulsory warning to be provided on the labelling of a number of plants.

• **Spain**: draft Royal Decree providing *inter alia* for mandatory labelling requirements for candied fruit as well as for 'dragées' or 'confits' made of dried fruit.

• **Latvia**: draft Regulation requiring *inter alia* mandatory labelling requirements for dairy products, composite dairy products or preparations of dairy products to which other foodstuffs or ingredients, whatever piece-like or not, and flavouring have been added; as well as labelling requirements for cheese and other specific dairy products and preparations of dairy products.

Of the draft measures above, only the Spanish draft Decree concerning candied fruit and 'dragées' or 'confits' made of dried fruit was accepted by the Commission. The assessment of the Belgian draft measure is still ongoing.

15.4.12.2. Evaluation based on the current situation

During 2010 discussions on the Commission's proposal for a Regulation on the provision of food information to consumers continued with the European Parliament and the Council. The controversial discussions demonstrated the difficulties in striking a balance between the need to streamline and simplify food labelling and the need to help consumers to make well informed choices. The main political issues were: the presentation of nutrition information; the inclusion of origin labelling and whether it should be mandatory for all or certain categories of foods; the application of the general labelling requirements to alcoholic beverages; the responsibilities of food business operators; and the inclusion of specific criteria to improve legibility of information. The developments in the European Parliament and Council during the first reading endorsed the approach of the Commission proposal to strengthen nutrition labelling as a channel for information to consumers to support their ability to choose a balanced diet.

Concerning national legislation in the area of food labelling for specific foods, the increasing number of notifications should be noted.

15.4.12.3. Priorities and planned action

The priority in the general and nutrition labelling sector remains the overhaul of existing legislation in order to optimise this regulatory area. This involves work towards adoption of the proposal for the Regulation on the provision of food information to consumers by the European Parliament and the Council.

Following the adoption of the proposed Regulation it will be necessary to take forward appropriate implementing measures.

In parallel, work will continue on developing guidance for technical issues on nutrition labelling. This comprises guidance on acceptable tolerances between nutrition labelling values and values found by controlling authorities, and guidance on methods of analysis on fibre.

The assessment of draft national measures on additional mandatory labelling requirements for specific foods will continue depending on the notifications of such measures by the Member States.

15.4.12.4. Sector summary

EU food labelling legislation is regulated by Directive 2000/13/EC. This Directive sets the compulsory information that has to be provided to the final consumer, such as the name of the product, the list of ingredients, the use-by date and any special conditions of use. Nutrition labelling rules are laid down in Council Directive 90/496/EEC. This Directive provides harmonised rules on the basic nutrition labelling provided on a voluntary basis or, when necessary, a mandatory basis. In order to modernise and improve EU food labelling rules, the Commission adopted on 30 January 2008 a proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers, which is currently under discussion in the European Parliament and the Council. The priority areas are the adoption of the final Regulation in the coming year, to continue work on technical issues of nutrition labelling and to assess Member State notifications of draft national legislative measures concerning food labelling.

15.4.13. **Nutrition and Health Claims**

15.4.13.1. Current position

General introduction

Regulation (EC) No 1924/2006 of the European Parliament and of the Council, has been applicable since 1 July 2007, and lays down harmonised rules for the use of health or nutrition claims (such as “low fat”, “high fibre” and “helps lower cholesterol”) on foodstuffs. The Regulation aims at ensuring that any claim made on a food label in the EU is clear, accurate and substantiated and will thus enable consumers to make informed and meaningful choices when it comes to food and drinks. This should contribute to a higher level of human health protection, as it ties in with the Commissions campaign for healthier lifestyle choices by allowing citizens to know exactly what they are consuming. The Regulation also strives to ensure fair competition and to promote and protect innovation in the area of food. Only products offering genuine health or nutritional benefits will be allowed to refer to that on their labels.

Among the principles laid down in the Regulation, nutrient profiles were foreseen to be established by January 2009. Nutrient profiles have to determine whether foods are eligible to bear claims on the basis of their nutrient composition and will be based primarily on the levels of nutrients for which excessive intakes in the overall diet are not recommended (e.g. fat, saturated fat, salt and sugars).

The Regulation has two routes for authorising health claims; either via adoption of the EU list of permitted health claims based on national lists (the so-called article 13 list of functional claims) or via authorisation procedures based on applications directly from food business

operators.

Regarding nutrition claims, the Regulation included in its Annex a list of such authorised claims.

Report of work done in 2010

In 2010, further development of the nutrient profiles system and analysis of its impact were performed following EFSA's advice in 2008. The Commission services have put forward draft measures taking into account the opinion of EFSA, Member States, and stakeholders. These draft measures raised considerable public interest, showing that longer discussion was needed, thus delaying the Commission Decision on this matter.

Concerning nutrition claims, an amendment adding 5 new nutrition claims was adopted in the beginning of 2010. The new nutrition claims are related to the content in fatty acids such as omega-3 fatty acids, and conditions for the use of such claim guarantee a minimum content of these fatty acids in foods bearing these claims.

The Commission authorised and rejected the first health claims under the Regulation. In total, since 2009, 13 were authorised and 52 were rejected of those based on applications directly from food business operators. Such health claims refer to the reduction of disease risk, to children's development and health of children, or newly scientific evidence and/or include a request for protection of proprietary data.

Concerning the EU list of permitted health claims based on national lists further work was done to consolidate the unexpected high number (44.000) of health claims from the Member States. Examination of the national lists showed that Member States had applied the relevant criteria differently when preparing the lists and in certain cases not applied them at all. Consequently, consolidating the national lists into a single list including the claims for which the Authority should give scientific advice, required further discussions with the Member States, stretching throughout 2009/2010. The list submitted to EFSA was finalised with the submission of an addendum in March 2010. The consolidated list contains more than 4600 health claims.

Meetings with Member States' experts have been held on a monthly basis to facilitate discussions on the application of the Regulation and to prepare the votes in the Standing Committee on the authorisation of health and nutrition claims. Guidance documents aimed at the food business operators and enforcement authorities are being developed. The guidance strives to ensure that only valid applications are submitted to EFSA and that authorised claims are used in compliance with the Regulation.

15.4.13.2. Evaluation based on the current situation

Though key implementation measures, such as the nutrient profiles, still need to be adopted, the application of the new Regulation is already showing signs of its effects. The decisions on permitted and not permitted claims in 2010, though limited in numbers, resulted in strong messages passed onto the market for the benefit of the European consumer and fair competition on the market.

The new rules on **nutrition claims** on fatty acids such as "Source of Omega-3 fatty acids" ensure that consumers will have significant contributions of these fatty acids when choosing

foods bearing such claims. Few Member States had rules for the use of these claims and therefore the introduction of harmonised rules is an improvement of consumer information that could help consumers to make healthier choices.

15.4.13.3. Priorities and planned actions

Priorities

The priority remains to ensure a smooth implementation of the Regulation, meeting the objectives of that legislation in terms of both protecting consumers and harmonizing the use of nutrition and health claims within the EU. The work in this area will focus on the adoption of measures establishing nutrient profiles and of the EU list of permitted claims.

Planned action

Nutrient profiles have to be set up in accordance with the basic Regulation, as they are necessary to complete the implementing rules and allow an efficient functioning of that legislative framework.

Concerning the list of permitted Article 13 health claims, on 27 September 2010 the Commission announced its intention to adopt it in two steps: one for all claims other than those on botanical ingredients, and a subsequent consideration of claims on botanicals. The Commission and the Member States received from EFSA 3 series of opinions providing advice on 1944 health claims in the consolidated list. 2 more series of opinions are expected by June 2011. The adoption of the EU list of permitted health claims is expected for end of 2011 or the beginning of 2012. EFSA advice on the assessed health claims is being scrutinized and discussed with the Member States and stakeholders with a view to prepare the list.

15.4.13.4. Sector summary

Implementing Regulation (EC) N° 1924/2006 on nutrition and health claims made on food was a major task in 2009 and 2010. Substantial preparatory work has been completed for the establishment of specific nutrient profiles, and further development of the nutrient profiles system and analysis of its impact were performed. Five additional nutrition claims were proposed and received a favourable opinion from the Regulatory Committee, and have been included in the list at the beginning of 2010. Regarding health claims based on applications directly from food business operators, 13 were authorised and 52 were rejected by the Commission on the basis of the scientific opinions published by EFSA.

Concerning the EU List of permitted health claims based on national lists further work was done to consolidate the unexpected high number (44.000) of health claims submitted by the Member States. EFSA evaluated a very substantial number of such claims included in the consolidated list.

15.4.14. **Dietetic foods**

15.4.14.1. Current position

General introduction

Directive 2009/39/EC on foodstuffs intended for particular nutritional uses (recast of Council Directive 89/398/EEC, hereafter referred to as the Framework Directive) establishes requirements on product composition and appropriate consumer information for foods that are suitable to fulfil the particular nutritional requirements of certain groups of the population.

Foods for particular nutritional uses, or dietetic foods, are defined as foodstuffs which owing to their composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability. The labelling of these products must include the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives its particular nutritional characteristics.

For a number of these groups specific legislation has already been adopted. There are Commission Directives on foods for infants and young children, foods for weight reduction, medical foods and gluten-free foods. There are two groups of foods covered by the Framework Directive and mentioned in its Annex for which no specific rules have been elaborated so far: food products for people with diabetes and foods for sports people.

Products that do not belong to the abovementioned categories are required to undergo a notification procedure in the Member States, with a view to facilitating the official monitoring and the placing on the market of innovative products.

Report of work done in 2010

The Framework Directive on dietetic foods is now more than 30 years old and a number of issues have arisen in relation to its scope and implementation. Many relate to the continued evolution of EU food legislation. Of particular importance is the adoption of the Directive on food supplements, the Regulation on the addition of vitamins and minerals and of certain other substances to foods and the Regulation on nutrition and health claims made on foods. Following the developments in the food market over the last decade and due to the broad definition mentioned above, many 'normal' foods now claim particular nutritional benefits due to their composition.

These elements render the revision of this legislation necessary.

An impact assessment to support the revision of the legislation on dietetic foods was therefore undertaken in 2009 and submitted to the Impact Assessment Board which issued a favourable opinion on 20 December 2010.

15.4.14.2. Evaluation based on the current situation

It is clear from surveys, reports and comments from stakeholders and national competent authorities that recently adopted food legislation overlaps to a large extent with some of the underlying principles of the dietetic food framework legislation. Consequently, the application of each piece of legislation to dietetic foods might be unclear for businesses or Member States. Discussions have highlighted difficulties in particular with regard to the interpretation of the definition of dietetic foods.

There is also a need to consider the legislation on dietetic foods in relation to the more "strategic goals" of ensuring a better and simplified legal framework to facilitate innovation. The impact assessment on the revision of the Framework Directive on dietetic foods therefore

also considers the need to simplify the legislative framework for businesses and Competent Authorities and to reduce administrative burdens. Particular attention is given on small businesses to ensure that any change made to the legislation is easily communicated and simple to implement.

15.4.14.3. Priorities and planned actions

Priorities

The main priority is to continue on the ongoing work related to the revision of the legislation on foods for particular nutritional uses, otherwise called dietetic foods.

Three key objectives must be achieved through the revision: 1) ensure appropriate consumer information, 2) ensure the free movement of goods within the internal market and with third countries, and 3) minimise burdens on food business operators and ensure suitable flexibility and clarity for small businesses.

The Commission services will now start the work on the draft proposal on the basis of the preferred option identified in the Impact Assessment.

Planned action

The adoption of a proposal by the Commission is scheduled for 2011.

15.4.14.4. Sector summary

The need to optimise the existing legal framework on dietetic foods to take into account the more recent developments in food legislation (food supplements, fortified foods, claims) and to clarify their interactions with the dietetic food legislation is considered under the revision of the framework Directive on dietetic foods. On the basis of the impact assessment, the Commission has assessed all the potential impacts that various options for the revision could have on the management of dietetic foods. The adoption of a proposal by the Commission is foreseen for 2011.

Food Supplements and addition of vitamins and minerals and of certain other substances to foods

15.4.14.5. Current position

General introduction

Directive 2002/46/EC of the European Parliament and of the Council on food supplements partially harmonises the rules applicable to the placing of food supplements on the market.

The scope of the Directive covers all food supplements. However, only the specific rules applicable to the use of vitamins and minerals in the manufacture of food supplements are laid down in the Directive. In accordance with Article 4(8) of the Directive, the Commission adopted on 5 December 2008 a Report[512] on the use of substances other than vitamins and minerals in food supplements which concludes that the existing EU legal instruments already

512 COM(2008)824.

constitute a sufficient legislative framework for regulating this area and does not consider it opportune to lay down specific rules for substances other than vitamins or minerals for use in foodstuffs. Therefore, the use of substances other than vitamins or minerals in the manufacture of food supplements continues to be subject to the rules in force in national legislation.

Regulation (EC) No 1925/2006 of the European Parliament and of the Council, which is applicable as of 1 July 2007, harmonises the provisions laid down in Member States that relate to the addition to foodstuffs of vitamins and minerals and of certain other substances, such as amino acids, essential fatty acids, fibre, various plants and herbal extracts. The objective of this Regulation is to ensure the effective functioning of the internal market whilst providing a high level of consumer protection.

Report of work done in 2010

In 2010, the Commission requested the EFSA to evaluate the safety of other vitamin and mineral substances for use in foods based on dossiers submitted by food business operators. The Commission followed the assessment work carried out by EFSA.

15.4.14.6. Evaluation based on the current situation

In order to complete the harmonization in that sector, the two acts mentioned above foresee that maximum amounts should be set up for use of the vitamins and minerals listed in their Annexes in foods and in food supplements.

An impact assessment report to analyse the economic, social and environmental impacts of the options for the setting of maximum amounts is being finalized.

15.4.14.7. Priorities and planned actions

Priorities

In the area of food supplements and of fortified foods, the priority remains the completion of the harmonization for the use of vitamins and minerals.

Planned actions

Future activities in the field of food supplements and of fortified foods relate to the adoption of implementing measures which include, *inter alia*, the setting of maximum amounts of vitamins and minerals and the updating of the positive list of substances in the Annexes to the Directive.

The lists of vitamins and minerals and their forms that may be added to foods including food supplements will be updated.

15.4.14.8. Sector summary

Directive 2002/46/EC and Regulation (EC) No 1925/2006 of the European Parliament and of the Council respectively harmonise partially the rules applicable to the placing of food supplements on the market and the addition of vitamins and minerals and of certain other substances to foodstuffs.

The completion of the harmonization should take place in the near future with the setting up of maximum amounts for the use of the substances concerned.

15.4.15. **Novel foods**

15.4.15.1. Current position

General introduction

Novel foods are foods and food ingredients that have not been used for human consumption to a significant degree within the EU before 15 May 1997. Regulation (EC) No 258/97 of the European Parliament and of the Council lays out detailed rules for the authorisation of novel foods and novel food ingredients.

Companies that want to place a novel food on the EU market need to submit their application in accordance with Commission Recommendation 97/618/EC which concerns the scientific information and the safety assessment report required.

The Commission adopted on 14 January 2008 a proposal for a Regulation of the European Parliament and the Council on novel foods, based on Article 114 TFEU, which would revise and replace the existing legislation.

Report of work done in 2010

A total of 6 novel foodstuffs (puree and concentrate from *Morinda citrifolia*; Ferric Sodium EDTA, Ferrous Ammonium Phosphate by a Commission Decision and Sucromalt, Guar gum and Magnolia bark extract pursuant to their initial assessment carried by a Member State which did not receive objections) were authorised for marketing in the EU. The authorisation of bee venom as novel food ingredient was refused following the initial assessment. Around 50 novel food products that were substantially equivalent to existing foods or food ingredients were notified according to the simplified procedure in 2010.

15.4.15.2. Evaluation based on the current situation

The current legislation lays down a decentralized procedure leading to a long (3-5 years) and costly process which may prevent companies, in particular SMEs, from innovating in the food sector. The Commission's proposal addressed these points, in particular through a centralised evaluation and authorisation procedure and to provide for better conditions for innovation in the food sector.

The European Parliament adopted its opinion in second reading on the novel food proposal on 7 July 2010 and reconfirmed most of the amendments adopted at first reading. Following the rejection of these amendments by the Council, the conciliation procedure has been launched.

The inter-institutional debate has remained focused on the issues of animal cloning for food production and to a lesser extent on nanotechnology in food.

On cloning, the Commission adopted on 19 October 2010 a report to the Council and the European Parliament on all aspects of animal cloning for food production.

The report, based on the EFSA opinion[513] and statements[514], clearly establishes that food derived from clones and their offspring does not differ from conventional food as regards food safety. However animal welfare concerns, linked to the use of the technique, have been identified in the case of clones.

To address the animal welfare issues of cloned animals, the report concludes that the Commission intends to propose legislation to suspend for 5 years the use of the cloning technique in the EU for food production purposes and traceability of their reproductive material.

More specifically, the report proposes a) a temporary suspension of the use of the cloning technique for the reproduction of all food producing animals; b) a temporary suspension of the use of these animals for food production; c) a temporary suspension of the marketing of food from these animals; and d) the establishment of the traceability of imports of semen and embryos to allow farmers and industry to set up data banks of offspring in the EU.

On nanotechnologies, the draft definition of "engineered nanomaterials" has been supported by the European Parliament, the Council and the stakeholders. A provision has also been introduced in the Novel Food Regulation allowing for its adaptation to the scientific developments at EU or international levels. It was agreed that all food ingredients containing such nanomaterials would need a pre-market authorisation.

As regards the labelling of food containing nanomaterials, the Commission is in favour of the introduction of a mandatory labelling requirement for all such foodstuffs to ensure a proper consumer information through the food information proposal.

15.4.15.3. Evaluation based on the current situation results

Priorities

Taking into account the objectives of the Commission's proposal of improving the authorisation procedure of novel foods, and of providing for better conditions for innovation in the food sector, the priority is to reach agreement in conciliation on the proposal.

Planned actions

Compromise solutions on the main negotiation issues should be found without delay, during the conciliation phase. The Commission will provide all the necessary support to facilitate a final agreement. The Commission also intends to perform an impact assessment and to prepare a legislative proposal on cloning as foreseen in its report.

15.4.15.4. Sector summary

The current legislation on novel foods does not allow for an efficient authorization procedure and for stimulating innovation in the food sector. The proposal currently under conciliation procedure aims at adapting the legislative framework in these respects. In that context

513 http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902019540.htm
514 http://www.efsa.europa.eu/cs/BlobServer/Statm_of_Efsa/sc_statementej_RN319_en.pdf?ssbinary=true

discussions gave rise to a debate on the issues of the safety implications and ethical concerns of the use of cloning and nanotechnologies in the food sector.

15.4.16. **Food contact materials**

15.4.16.1. Current Situation

Presentation of the legislation

Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food (FCM) sets out the basic requirements for a harmonised European market on food contact materials, while ensuring a high level of protection of human health. This legal act empowers the Commission to set material particular rules in specific legislation.

Specific legislation exists for ceramics, regenerated cellulose film, plastic food contact materials and recycled plastics, and active and intelligent materials.

Report of work done in 2010

In order to facilitate the application of current rules on plastics intended to come into contact with food a draft Commission Regulation on plastic materials and articles intended to come into contact with food was endorsed by the Standing Committee on 10 September 2010. The proposal draws together fourteen Directives covering basic rules for plastic materials and removes obsolete and contradictory rules and outdated analytical methods. It updates the list of authorised substances in accordance with the scientific assessment by the EFSA, and of food simulants and testing regime according to scientific knowledge. The draft Commission Regulation also clarifies the approach for the authorisation of nanomaterials. All explanatory parts will be compiled in a separate guidance document. The new proposal, which is expected to be adopted in 2011, will speed up the authorisation of new substances and simplify rules on migration test, therefore it will definitely ensure a better application of current EU law in the field.

Following the continuous high number of non-compliant plastic kitchenware originating from China notified through the Rapid Alert System on Feed and Food (RASFF) during the last years, a draft Commission Regulation laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from People's Republic of China and Hong Kong Special Administrative Region, China, was endorsed by the Standing Committee on 25 November 2010.

Following the EFSA Scientific Opinion on Bisphenol A (BPA)[515] adopted on 23 September 2010, and the notification of national bans by Denmark and France as set out in Article 18 of Regulation (EC) No 1935/2004, a draft Commission Directive amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles was endorsed by the Standing Committee on 25 November. The measure is based on the precautionary principle referred to in Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the EFSA and laying down procedures

[515] http://www.efsa.europa.eu/en/scdocs/scdoc/1829.htm

in matters of food safety[516], which allows EU to provisionally adopt measures on the basis of available pertinent information, pending an additional assessment of risk and a review of the measure within a reasonable period of time.

15.4.16.2. Evaluation based on current situation

Harmonisation of legislation for plastic food contact materials started in 1980 and led to fourteen Directives. The draft Commission Regulation on plastic materials and articles intended to come into contact with food to be adopted in 2011 will simplify the application of the legal provisions for plastic materials.

While the harmonisation of legislation on plastic food contact materials at EU level is nearly complete, only the basic principles are set out for other materials such as paper and board, printing inks, adhesives. The lack of harmonised measures at EU level creates problems in particular where Member States do not have legislation in place and specific rules for compliance with general safety requirements for food contact materials remains unclear. Member States would welcome the development of EU measures for certain materials. A system tackling not-yet harmonised materials should be developed. This system will have to avoid overregulation of the sector and at the same time should be efficient and be able to ensure that the safety of citizens is guaranteed.

Taking into account the recent EFSA Opinions on lead[517] and cadmium[518], the Council Directive on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs[519] needs to be revised.

15.4.16.3. Priorities and planned actions

Priorities

First priorities are the adoption of the draft Commission Regulation on plastic materials and articles intended to come into contact with food and of the draft Commission Directive amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles in 2011.

Once the draft Commission Regulation on plastic materials and articles intended to come into contact with food is adopted, which will repeal Directive 2002/72/EC, it will be amended accordingly to reflect the restrictions concerning Bisphenol A proposed in the draft Commission Directive amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles.

The draft Commission Regulation laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from People's Republic of China and Hong Kong Special Administrative Region, China, is planned to be adopted in the first half of2011.

Planned actions

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516 OJ L 31, 1.2.2002, p. 1.
517 http://www.efsa.europa.eu/en/scdocs/scdoc/1570.htm
518 http://www.efsa.europa.eu/en/scdocs/scdoc/980.htm
519 OJ L 277, 20.10.1984, p. 12.

A roadmap for setting out the policy regarding not yet harmonised materials (Paper and board, glass, wood, cork, metals and alloys, textiles, adhesives, ion-exchange resins, printing inks, silicones, varnishes and coatings and waxes) will be drafted in 2011.

The Council Directive on the approximation of the laws of the Member State relating to ceramic articles intended to come into contact with foodstuffs (84/500/EEC) will be updated during 2011 to take into account opinions by EFSA on lead and cadmium.

Adoption of regulation(s) updating the list of authorised substances to be used in plastic food contact materials following the adoption of opinions by EFSA.

15.4.16.4. Summary by sector

The legislation on food contact materials will gain in clarification once the draft Commission Regulation on plastic materials and articles intended to come into contact with food developed in 2010 is adopted. The update of the legislation on ceramics following the recent EFSA opinions on lead and cadmium will adjust the legislation to current scientific knowledge. The preparation of the roadmap for the setting out the policy on not-yet harmonised materials will avoid possible problems that Member States may face due to lack of specific requirements for these materials at national level.

The implementation of the draft Commission Regulation laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from People's Republic of China and Hong Kong Special Administrative Region, China, will reinforce the controls of imported plastic products and therefore the enforcement of the EU legislation.

15.4.17. **Plant Health**

15.4.17.1. Current position

General introduction presenting the legislation

The plant health legislation provides the framework for the protection of the EU territory against the introduction of organisms that are harmful to plants and not yet present or, if locally present, not widespread and under official control. Therefore, all plants and some plant products are subject to phytosanitary requirements at import; a restricted number of plant species require phytosanitary guarantees for internal movements within the EU. This preventative approach avoids expensive curative action afterwards or loss of agricultural production or environmental damage.

Report of work done in 2010

The Commission's strategy in the plant health field continued on the lines initiated in 2009, i.e. focussing on a correct implementation of existing legislation, while developing a new plant health law.

The correct implementation of the current *acquis* was ensured by a stricter enforcement of existing legislation, a revision of some emergency measures and an appropriate budget for co-financing eradication actions in Member States. Stricter enforcement and strengthening of existing legislation was put in place for several emergency measures against the introduction

or spread of harmful organisms. This was the case with a strict follow-up of the implementation of existing measures against the spread of pine wood nematode B*ursaphelenchus xylophilus* in conifers in Portugal, as well as for a new isolated outbreak on the Spanish side of the Portugal/Spain frontier. The emergency measures to prevent the introduction of the Chinese longhorn beetle and the measures to contain the further spread of the red palm weevil – *Rhynchophorus ferrugineus* which threatens most palms species in the Mediterranean areas were updated. For Western corn rootworm - *Diabrotica virgifera virgifera* in maize, an impact assessment was elaborated to underpin the development of a new EU control strategy, as this pest is now widespread in certain areas within the EU.

The existing phytosanitary policy for the import of potatoes from Egypt was prolonged for one year. Phytosanitary restrictions for the import of Japanese and Korean bonsai, Argentinean and Chilean strawberry plants and oak logs from the USA were renewed for a ten year period. The recognition of zones in the EU with an extra protection against certain harmful organisms was screened and updated where necessary.

Upon request of Germany, Spain, France, Italy, Cyprus and Portugal, and in order to ensure a better and harmonised protection against the spread of new pests and diseases in the territory of the Union, the EU co-financed the national eradication campaigns against harmful organisms for a total amount of EUR 7,3 million. The campaigns concerned actions against longhorn beetles (*Anoplophora chinensis* and *A. glabripennis*), red palm weevil (*Rhynchophorus ferrugineus*), Western corn rootworm (*Diabrotica virgifera virgifera*), round-headed apple tree borer (*Saperda candida*) and pine wood nematode (B*ursaphelenchus xylophilus*).

In parallel, the initiative to develop a new common plant health strategy has been further elaborated. The existing regime aims to protect the EU territory against introduction and spread of regulated organisms which are harmful to plants. It lays down specific requirements for imports of all plants and some plant products into the EU and for internal movement of a limited number of plants within the EU. During 2010, an overall evaluation of the current plant health regime was finalised with the input of an external contractor. The evaluation results and recommendations were presented to the Member States and stakeholders during two conferences and comments have been collected. Terms of reference were developed for an extra study in preparation of an impact assessment for new policy options, and the study was contracted out.

15.4.17.2. Evaluation based on the current situation

The monitoring of the implementation and updates of the current plant health *acquis* needs to continue to offer a harmonised protection of the EU territory against harmful organisms. However, due to several important changes since the first EU plant health legislation was adopted in 1977, including globalisation of trade, accession of new Member States, and the environmental expectations of society, a global revision of the plant health strategy is needed.

15.4.17.3. Priorities and planned action

Priorities

The completion of the new plant health strategy with a better focus on prevention is the major priority. The revisions of the emergency measures against pine wood nematode and against

Western corn rootworm have to be accomplished in order to reflect better the situation in situ.

Planned action

The results of the 2010 evaluation study and the additional 2011 impact assessment study, will allow the Commission to develop a proposal for a new plant health law. This process includes extensive input from Member States and stakeholders.

As far as the EU control strategy against the spread of Western Corn Rootworm is concerned, an impact assessment has been launched and will allow the review of the existing emergency measures in 2011.

15.4.17.4. Summary by sector

Regular updates of existing phytosanitary emergency measures, prolongation of temporary import conditions for specific plant material, revision of protected zones and verification of correct implementation of EU *acquis* was continued in 2010 to keep the existing plant health legislation operational. In parallel, all preparatory work has been initiated in 2010 to allow the development of a proposal for a new plant health law in 2011.

15.4.18. **Plant reproductive material – Plant Variety Rights – Plant Genetic Resources**

15.4.18.1. Current position

General introduction presenting the legislation

The sector of plant reproductive material consists of the three work areas:

- legislation on marketing of seed and plant propagating material
- legislation on plant variety rights and
- international initiatives on plant genetic resources.

The legislation on the marketing of seed and plant propagating material consists of 12 basic Council Directives. The two pillars of the legislation concern (1) the registration of new plant varieties and (2) the inspection (e.g. certification) of seed and propagating material for marketing of such varieties. Detailed requirements, depending on the type of plant species, are set for the registration of new varieties and quality inspection of lots prior to marketing.

The EU plant variety rights regime was created by Council Regulation (EC) No 2100/94. On the basis of a single application to the Community Plant Variety Office based in Angers (France), a breeder may be granted an EU-wide intellectual property right for his/her new variety.

The objectives of the International Treaty on Plant Genetic Resources for Food and Agriculture are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use. The Commission on Genetic Resources for Food and Agriculture is an intergovernmental forum for negotiations and discussions by Governments on matters related to biodiversity for food and agriculture.

Report of work done in 2010

Seed and plant propagating material

In the sector of seeds and plant propagating material, the current legislation was kept updated and further developed. However, an increasing part of the work concentrated on the review of the legislation. A specific working group 'on seeds and propagating material' for the stakeholders of the sector hold a number of meetings to discuss the legislative work.

The common catalogues on varieties of agricultural and vegetable plant species were updated 12 times and both had a consolidated edition published. Altogether over 1800 new varieties of agricultural plant species and 1000 vegetable varieties were included in the catalogues. The Community list of Forest Reproductive Material was also regularly updated and a new common catalogue for vine propagating material was created. In 2010, the Member States made 20 requests for less stringent requirements on minimum germination under Regulation (EC) 217/2006 and accepted by the Commission. In August 2010, the Commission adopted Directive 2010/60/EU providing for certain derogations for marketing of fodder plant seed mixtures intended for use in the preservation of the natural environment. Concerning the review of the legislation, an external study to collect necessary data for the impact assessment was carried out. The impact assessment was elaborated and Member States and stakeholders were extensively consulted.

Plant Variety Rights

In 2010 the number of applications for plant variety rights increased compared with 2009. Currently, more than 17 500 varieties of plants are protected under the EU system. As the EU plant variety rights regime dates back to more than 15 years, Directorate-General Health and Consumers launched an external evaluation, which started in May 2010.

Genetic Resources

Some preparatory meetings for the upcoming meeting of the contracting parties of the International Treaty in 2011 were organised.

15.4.18.2. Evaluation based on the current situation

The impact assessment on the review of the seeds and plant propagating material legislation is ongoing and a public consultation is foreseen for the beginning of 2011. Several working group meetings with the Member States to prepare new legislation have been held and legal drafting is under way. Notwithstanding the work done on the review of the legislation, different actions have been undertaken to ensure the updating and adaptation to current needs as well as the administrative procedure of the seeds and plant propagating material legislation. This was carried out in a timely manner. The new rules on the preservation seed mixture were adopted as planned. Following the adoption of Council Directive 2008/90/EC on the marketing of fruit plant propagating material and fruit plants intended for fruit production (recast), work is under way to update and develop the implementing rules.

15.4.18.3. Priorities and planned action

Priorities

The priority of the sector is to finalise the necessary impact assessment and the development of a legal proposal for the review of the legislation on marketing of seeds and plant propagating material. Another priority of the sector is to finalise the evaluation of plant variety rights legislation and to prepare a conference to present and discuss the results and the future of the plant variety rights regime. There is a legal obligation to adopt all requested implementing measures for fruit plants before 30 September 2012 when the basic Directive enters into force.

Planned action

Concerning the review of the legislation, the aim is to finalise the necessary impact assessment in 2011 and to prepare a proposal for the new legislative framework in 2011. The revision will be aligned with other ongoing revisions, like the revision of the plant health legislation and Regulation (EC) No 882/2004 on official controls, foreseen for 2012. Therefore it is likely that some additional information gathering for the impact assessments will need to be carried out in 2011. Depending on the outcome of the evaluation results of the PVR regime a recast of the current legislation could be foreseen. The results of the evaluation will be discussed with the stakeholders in course of 2011, including through the organisation of a conference. The fruit implementing measures are foreseen to be adopted in 2011.

15.4.18.4. Summary by sector

Two Commission Directives and 9 Decisions were adopted in 2010. The work on impact assessment work on the review of the seeds and plant propagating material legislation and on the implementing measures for the fruits plants are both ongoing. A new major project on evaluating the legislation on plant variety rights started. In addition, important pre-legislative work for the seeds and plant propagating material review and on issues related to plant variety rights legislation was carried out.

15.4.19. **Animal Health – including non food-borne zoonotic diseases**

15.4.19.1. Current position

General introduction

Animal health is an important factor for a functioning agriculture and internal market and the safe supply of food. It has been part of the EU *acquis* from the very beginning of the EU and legislation in force dates back to the 1960s. Animal health legislation has been adapted over the years, in order to accommodate new diseases such as BSE or changes in the spread of existing diseases such as avian influenza or bluetongue. Outbreaks of e.g. classical swine fever and foot and mouth disease have triggered adoption of specific legislation.

The result is a body of law of over 60 acts (mostly Directives) laying down horizontal and vertical principles for intra-EU trade, imports of animals and their products, health and movement controls (veterinary checks), the notification of diseases and financial support.

Formal complaint cases in this area are few. Most refer to isolated cases of alleged incorrect implementation at local level which usually cannot be solved by the EU institutions but have to be dealt with in national courts.

Nevertheless, requests for interpretation and the difficulties arising from the complexities and

inconsistencies have shown that this framework does not fully comply with more modern requirements for simplicity, transparency and flexibility. Thus in 2007 the Commission presented its plans to improve the situation through a New Animal Health Strategy[520]. This triggered a broad consultation involving stakeholders, trade partners and institutions. As a result, a Communication on an Animal Health Action Plan[521] was published in 2008, listing all the actions considered necessary up to 2013 for a new approach to animal health. The most important action is the preparation of a proposal on a new animal health law.

Against this background the challenge to address acute animal health concerns effectively remains. Animal health is under consistent threat from outbreaks within the EU, in neighbouring countries or on the territory of trade partners. Diseases such as classical or African swine fever and foot and mouth disease, which cause heavy economic losses, are constantly at EU gates. Modified agricultural practices increase the importance of fish diseases and tuberculoses. Changes in the environment, especially in the climate, foster the spread of bluetongue.

Report of work done in 2010

In 2010 the Commission pursued the actions to implement the Animal Health Action Plan mentioned above.

Serious disease outbreaks can have devastating impacts on farmers, society and the economy, and the new strategy is based on the principle that "prevention is better than cure" and thus puts greater focus on precautionary measures, disease surveillance, controls and research. The aim is to reduce the incidence of animal disease and minimise the impact of outbreaks when they do occur.

One part of this approach is the review of the existing animal health legislation while creating an overarching EU Animal Health Law. It will in particular provide the principle rules for some fundamental issues, such as responsibilities of animal keepers, business operators, competent veterinary authorities, as well as concerning disease prevention and protection from biological threats (biosecurity). It will clarify the links between animal health policy and other relevant EU policies and thus ensure coherence. The new law will embrace the principles of Smart Legislation by providing flexibility to adapt to new circumstances and to take account of new developments in science, relevant technology and animal husbandry.

The best possible implementation and enforcement of the new rules will be assisted by careful alignment of those with the applicable general rules on official controls for the animal health area as laid down by Regulation (EC) No 882/2004, by amending that Regulation and creating further detailed control rules as necessary.

Preparatory work continued in 2010 for a proposal and impact assessment of this law. The above key issues have been discussed on several occasions and in various fora (such as the Working Group of the Chief Veterinary Officers and the Animal Health Advisory Committee). A web-based public consultation was open from the beginning of the year to mid-March to collect data on foreseen implementation and administrative costs and burdens.

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520 COM(2007)539final.
521 COM(2008)545final.

The intra-EU movement of pet and companion animals (such as dogs and cats) is of practical importance to citizens. The relevant Regulation[522] was amended in 2010 to, finally, fully harmonise the regime in the whole EU, after a limited (1,5 year) prolongation of the special regime to facilitate transition. During the negotiations the Commission declared its intention to align the whole Regulation (and not only the amended Articles) to the provisions of Articles 290 and 291 of the TFEU (new comitology) and handled the matter with urgency. It was also identified that less than optimal legal clarity, readability and "user-friendliness" of the Regulation compromises its uniform implementation and compliance across the EU.

New rules are applicable as from 1 January 2010 in the area of electronic identification of ovine and caprine animals. The Commission addressed this issue in several fora, informed all concerned about the details, and regularly required reports from Member States on their efforts to correctly implement these rules. Assistance to Member States included a high level conference on traceability, partially dedicated to this subject and even field visits to Member States (e.g. UK) where implementation proved to be challenging.

Preparatory work has been ongoing on the area of bovine identification for a proposal to amend the relevant Regulation[523]. This Regulation has been identified in the past as burdensome by the High Level Group on Administrative Burden. The planned changes intend to facilitate the use of modern electronic identification technology in the sector, lessen administrative burden for holding registers, passports and beef labelling while adhering to the objectives of the Regulation. They also intend to align the Regulation to the Articles 290 and 291 of the TFEU. This will facilitate future implementation and compliance.

The provisions of Council Decision 79/542/EEC regulating certain aspects of the import of specific live animals and fresh red meat into the EU were recast in a Commission Regulation and the Decision was repealed. This was due to fundamental changes in the regulatory framework on this area but also to provide increased clarity and transparency. New model import certificates incorporating public health provisions were laid down. These integrated models assist all concerned stakeholders to comply with the rules and enable authorities to check compliance more easily. An ample transitional period was provided for smooth changeover from the old to the new regime.

Directive 2008/73/EC has a deadline of 1 January 2010 for transposition and implementation. Member States were reminded, and possible problems were discussed in the Standing Committee on the Food Chain and Animal Health. Most Member States have transposed and implemented its provisions, but 2 infringements for non-communication of national measures are ongoing against Austria and Portugal.

In 2010 the first ever series of trainings for official veterinarians on rules in the area of bee health and bee keeping as well as for exotic zoo animals started and will continue into 2011.

The control of the spread of bluetongue continued to be successful. However the evaluation of the current legal environment based on direct experience with an ongoing vaccination campaign indicated that although it is effective, it is less than optimal. The rules are complex, often difficult to apply for local farmers, traders, local and national veterinary services and other stakeholders and more restrictive than they could be.

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522 Regulation (EC) No 998/2003.

523 Regulation (EC) No 1760/2000.

Because of this, a specific reflection on bluetongue continued in 2010 and led to a new Commission proposal to change the Directive. The key elements of this proposal (and a subsequent amendment to the implementing rules) relate to the facilitation of preventive use of modern, inactivated vaccines with less restriction for increased simplification, proportionality and sustainability.

In 2010 simplification and streamlining of the animal health implementing rules for the movements (including imports) of semen, ova, and embryos of the equine, ovine and caprine species and ova and embryos of the porcine species took place. It comprised an amendment to the relevant Annex to Directive 92/65/EEC and was followed up by a complete recast of the eight relevant Commission Decisions into three new Commission Decisions. The whole exercise created better alignment of the substantial rules to international standards, new model certificates as well as the management of lists of establishments from which such products can originate.

Successful disease control relies not only on an adequate legal framework but also on its implementation. In 2010, Member States again have responded to outbreaks in a swift and successful manner. None of the outbreaks had an impact on public health or led to major economic losses. The framework to adopt rapid safeguard measures was kept updated, as well as constant re-evaluation of the situation, the legal requirements and best possible implementation, mostly with the experts from the Member States in the Standing Committee on the Food Chain and Animal Health.

15.4.19.2. Evaluation based on the current situation

Considering the above, the animal health framework for handling various disease generally is adequate and effective. It can however be improved by smarter and more efficient solutions. Hence the area is currently in a phase of reform with the purpose to identify opportunities of further enhancing efficiency and to reduce unnecessary burdens.

15.4.19.3. Evaluation based on the current situation results

Priorities

The combat of disease outbreaks is the first priority dictated by the circumstances. The second priority remains the further development of the Animal Health Strategy as a long term goal.

Planned action

In 2011 work will continue on the creation of the Animal Health Law with the view that the final proposal could be adopted in early 2012. The proposal to amend Regulation (EC) No 1760/2000 is expected to be finalised in the first part of 2011. Preparatory work will continue throughout 2011 on the important area of how the EU finances certain animal health measures (whether emergency measures or planned and systematic eradication of diseases). This should result in late 2012 in an impact assessment and proposal for the review of Decision 2009/470/EC, the financial instrument for EU veterinary expenditure. On the area of pet animals, developments in 2010 both in the European Parliament and Council necessitate a recast of the whole Regulation.

15.4.19.4. Summary of Sector

This sector faces major overhaul. The goal is to consolidate a long term and largely successful and profound collaboration into a more modern system by integrating tried and tested methods within an improved framework. The challenge to swiftly and effectively react to epidemics will remain.

15.4.20. **Zootechnics**

15.4.20.1. Current position

Zootechnical legislation is closely linked with the Animal Health *acquis* as it establishes minimum genetic criteria to ensure free trade in breeding animals and their genetic material (semen, embryos). The current system of EU zootechnical legislation was established in the 1980s by the Council in order to remove barriers to trade. The result is a body of law of over 30 pieces of legislation (6 basic Directives and their implementing acts) laying down principles on the registration of breeding animals in herd books and the work of breeding organisations.

Report of work done in 2010

A series of consultations has taken place with stakeholders and Member States. Advice was given to the Member States on the implementation of the legislation.

15.4.20.2. Evaluation based on the current situation

The present system generally works well. But the provisions of the basic zootechnical legislation granting implementing or delegating powers to the Commission are not consistent with the requirements of Articles 290 and 291 of the TFEU. In addition the relevant Council texts are scattered across 11 similar but in certain details different acts. A similar pattern can be seen at Commission level. This compromises the coherence, full implementation, accessibility and legal clarity of this *acquis*. This can also cause unjustified obstacles to EU trade and threaten the uniform application of EU law. A significant volume of complaints suggest that both Member States and economic operators are finding it difficult to apply this legislation in practice.

Hence it has been recognised that there is scope to clarify and simplify the legislation as well adapt it to the TFEU. In addition complaint cases have identified several problems in the current framework which need to be handled, such as:

- It does not specifically address cross-border activities of approved breeding organisations, while these organisations increasingly serve breeders in several Member States and breeding programmes are carried out at international level.

- Due to lack of clarity of the legislation there are disparities in the application and the implementation of zootechnical legislation. This can cause unjustified obstacles to EU trade and threaten the uniform application of EU law.

15.4.20.3. Evaluation based on the current situation results

Priorities

The first priority is to recast the legislation as soon as possible into one single piece of

legislation. The second priority is to support Member States in the implementation of the current legislation.

Planned action for 2011 and beyond

Recast of the legislation and its adaptation to the TFEU is planned for the first half of 2011.

15.4.21. **Animal by-products**

15.4.21.1. Current Situation

General introduction

Animal by-products not intended for human consumption include slaughterhouse waste, fallen stock and dairy products going to animal feed, as well as a variety of other products for different applications. The health rules for those animal by-products are currently laid down in Regulation (EC) No 1774/2002 and a number of implementing measures. The Regulation relies on a risk-based categorisation of animal by-products, which determines the options for their use and obligations for their disposal. Experience with the application of the Regulation since 2003 revealed that the interaction with other EU legislation, its risk-benefit ratio, and the proportionality of the prescribed measures in particular as regards their use for technical applications, posed problems and needed to be reviewed. Therefore, based on a Commission proposal, the European Parliament and the Council adopted Regulation (EC) No 1069/2009, which replaces Regulation (EC) No 1774/2002 as from 4 March 2011.

Report of work done in 2010

Regulation (EC) No 1069/2009 only establishes the general principles for animal by-products and leaves its implementation to Commission measures. Therefore the Commission carried out wide consultations with stakeholders in 2010. Based on those consultations, a draft implementing Regulation was submitted to the Standing Committee on the Food Chain and Animal Health and received a favourable opinion. It is foreseen to be adopted and published in good time for the application of Regulation (EC) No 1069/2009.

The training of officials and some stakeholders on the new principles has already started under the "Better Training for Safer Food" initiative, with 4 trainings done in 2010.

15.4.21.2. Evaluation based on the current situation

The new implementing rules for Regulation (EC) No 1069/2009 replace the technical standards set out in the 11 Annexes to Regulation (EC) No 1774/2002, as well as in more than 10 separate Commission measures by a single, more coherent legal act. They specify the obligations of commercial operators handling animal by-products and of the control authorities of Member States and they lay down specific requirements for the hygienic handling, processing, tracing and placing on the market of such by-products. The new rules determine under which conditions certain animal by-products (which were until now excluded from any use), may be used, under appropriate health conditions. Thus, the new implementing rules contribute to further simplification of the EU law and a further reduction in administrative burden for business operators.

15.4.21.3. Evaluation based on the current situation results

Planned Action

The Commission will ensure that the new implementing rules continue to be updated in the light of progress in science and technology, particularly as regards new processes for the treatment of animal by-products, which are subject to a risk assessment by the European Food Safety Authority. In addition, in the course of 2011, further "Better Training for Safer Food" training courses will be organised in order to contribute to a smooth transition to the new legal framework.

Summary of Sector

Significant achievements were made in 2010. The challenge now is to further assist the players in the sector (both the authorities of the Member States and the economic operators) to learn, understand, correctly implement and enforce the new rules and obtain the maximum benefit.

15.4.22. **Feed**

15.4.22.1. Current position

General introduction presenting the legislation

The relevant Treaty provisions for legislation in the Feed sector are Article 43 and Article 168(4)(b) of the TFEU.

As regards the *feed marketing and feed labelling* sector, new Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 applies since the 1 September 2010. It lays down rules on the placing on the market and use of feed for both food-producing and non-food producing animals within the EU, including requirements for labelling, packaging and presentation. Feed materials and compound feed are both covered by this Regulation.

Council Directive 90/167/EEC still applies to *medicated feed,* but new legislation is in preparation (see below).

As regards the *feed additives* sector, Regulation (EC) No 1831/2003 of the European Parliament and of the Council provides for the rules on the authorisation for placing on the market and use, including labelling, of these products. Detailed rules for the preparation and presentation of applications for authorisation are laid down in Commission Regulation (EC) No 429/2008, while the Community Reference Laboratory (CRL)'s duties and tasks are set out in Commission Regulation (EC) No 378/2005.

Undesirable substances in feed are governed by Council and European Parliament Directive 2002/32/EC.

Report of work done in 2010

Feed marketing and labelling

Regulation (EC) No 767/2009 on the placing on the market and use of feed entered into application on 1 September 2010. It constitutes an essential piece of legislation to ensure a

high level of feed safety and thus of public health, but also to provide adequate information for users and consumers and to strengthen the effective functioning of the Internal Market.

In 2010 the management tools for the harmonised implementation of the new regime were established, including the following actions:

- After the adoption of the Catalogue of feed materials, collaboration with the feed business sectors enabled the development of an updated and modernised version of this key tool. The coverage of the feed materials listed in the draft new Catalogue, which has already been endorsed by the Standing Committee, is significantly increased and the information about their properties is improved.

- Guidelines clarifying the borderlines between different types of feed were defined.

- The list of prohibited materials in feed was updated.

- Transitional measures for the application of the new labelling rules were adopted to facilitate compliance of feed operators to the new legislation.

- The permitted tolerances for the compositional labelling of feed were adapted to scientific and technological developments.

- The list of dietetic feed was updated further to operators' requests.

Medicated feed

Council Directive 90/167/EEC on medicated feed is outdated and not consistent with current legislation on both feed and veterinary medicinal products. Preparatory work for recasting and modernising the legislation for this specific type of products was carried out in 2010, including:

- the finalisation of an external study on the evaluation of the EU legislative framework in the field of medicated feed;

- exchanges within the Standing Committee on the situation within the Member States;

- the launch of the impact assessment in advance of the drafting of the legislative proposal.

Feed additives

In 2010, nearly 30 Regulations concerning additives authorisations were adopted by the Commission after completion of a procedure involving EFSA, the CRL and the Member States, and applicants' requests of confidentiality of the data submitted have been processed by the Commission.

The preparatory work for the re-evaluation of current additives authorisations, as provided for in Regulation (EC) No 1831/2003, continued in view of the large amount of applications received by the deadline of 8 November 2010. This important challenge was successfully taken up with the reception and management by the Commission of several hundred

applications covering all essential existing feed additives. This allows the continuity of relevant authorisations and therefore supports good animal health and welfare within the EU.

A Regulation clarifying the "non-additive" status of a series of products was adopted by the Commission, in order to bring clarity to operators regarding "borderline" products.

As regards the labelling of feed additives and premixtures, clarification and simplification of the rules laid down in Regulation (EC) No 1831/2003 were achieved with the entry into force on 1 September 2010 of amending provisions contained in Regulation (EC) No 767/2009.

Undesirable substances in feed

In 2010, maximum levels of certain contaminants in feed were reviewed in the context of Directive 2002/32/EC, taking account of EFSA risk assessments. In addition, work and discussion with the Member States and stakeholders continued as regards the acceptability of detoxification processes and as regards the consolidation of the annexes to Directive 2002/32/EC.

Regular discussion took place with the Member States and stakeholders concerning feed contamination cases reported through the RASFF.

Committee and expert groups

The management of the above mentioned feed sectors is subject to close co-operation with the Member States through regular (generally monthly) meetings of the Standing Committee on the Food Chain and Animal Health, section on Animal Nutrition, and punctual expert groups meetings where appropriate.

International issues

In 2010, the Commission continued its participation to the work of task forces in OIE, CODEX and FAO in the feed sector.

15.4.22.2. Evaluation based on the current situation

The adoption in 2010 of key implementing measures of Regulation (EC) No 767/2009 concerning the *marketing and labelling of feed* ensured the effective and uniform application of the new regime from 1 September 2010. In particular, clarification of the status of certain "borderline" products and modernisation of the Catalogue of feed materials bring more legal certainty to feed operators in the EU.

EU legislation on *medicated feed* is obsolete and not in line with current legislation on feed, in particular the Feed Hygiene Regulation, but also with legislation on veterinary medicines. This makes the preparation of new legislation in this sector a priority action, as provided for in the Commission Work Programme

In the field of *undesirable substances* in animal feed, the setting of maximum levels of contaminants is decided through successive amendments to the Annex to Directive 2002/32/EC. This complicates the legibility of such measures. It is necessary to integrate and re-structure all amendments into a new tool. In addition, the analysis and management of RASFF notifications may result in amendments to the existing legislation where needed.

Planned action

As regards the *feed marketing and labelling* sector, it is intended to adopt further implementing measures in order to ensure the optimal application of Regulation (EC) No 767/2009.

For the *medicated feed* sector, a full impact assessment will be carried out in 2011, taking into account the preparatory work already carried out, in order to present by 2012, as provided for in the Commission Work Programme, a Commission proposal recasting and modernising the legislation in this field. This initiative will be in a package with the revision of the Directive on veterinary medicinal products.

The main challenge in the *feed additives* area will be the optimal implementation of the review exercise of all current authorisations, in collaboration with EFSA and the EU Reference Laboratory. This will result in a thorough "cleaning" of the Register of feed additives with the withdrawal of additives which were not subject to any re-evaluation applications. In addition, requests for the authorisation of feed additives submitted to the Commission will continue to be processed within the time-limits prescribed by Regulation (EC) No 1831/2003. It is also envisaged to study the possibility of a revision of the labelling rules, including concerning claims, laid down in Regulation (EC) No 1831/2003.

As far as *undesirable substances* in feed are concerned, in addition to the continuous review of maximum levels in the framework of Directive 2002/32/EC, it is envisaged to take measures concerning the presence of pharmaceuticals in feed for non-target animals and to adopt measures on acceptability criteria for detoxification/decontamination processes in feed. Work concerning the consolidation of the annexes of Directive 2002/32/EC will continue in 2011.

More generally, adaptation of the feed legislation will be needed in order to comply with the provisions of the Lisbon Treaty concerning delegated and implementing acts.

15.4.22.3. Summary by sector

In summary, the following actions are to be considered as main priorities for 2011 and beyond in the feed sector:

- management of a full impact assessment and preparation of new legislation in the field of medicated feed;
- adoption of further implementing measures of Regulation (EC) No 767/2009 on the placing on the market and use of feed;
- implementation of the re-evaluation exercise of current feed additives authorisations.

15.4.23. **Import controls on live animals and food from animal origin**

15.4.23.1. Current position

General introduction presenting the legislation

Live animals and products of animal origin (such as meat, eggs and fish) and animal products not intended for human consumption (such as semen and embryos) are considered to represent a high risk because they can be vectors for the transmission of diseases not only to humans, but also to livestock. Apart from the threats to human health, the threats to animal health are particularly worrying due to the detrimental effects of the spread of disease on European livestock production.

Live animals and animal products can only enter the EU through approved border inspection posts (BIPs) under strictly harmonised import conditions. These require that such imports are sourced from approved third countries, from approved or registered establishments and that the veterinary certificates accompanying the consignments are signed by the competent authority of the exporting country providing detailed information as to the public and animal health status of the products and their conformity with the EU's import requirements. In the event of a serious animal disease outbreak in a third country, import restrictions may be established to prevent the introduction of the disease in the EU.

Upon arrival, BIP staff carries out mandatory controls including documentary, identity and physical checks to verify that the goods conform to their description and meet EU import conditions. Physical checks are always required in the case of live animals, however such checks may be reduced for animal products when they meet harmonised import conditions and when veterinary agreements - proving that the third country can offer the same or equivalent levels of safety to those of the EU - are in place. Targeted analytical checks may form part of the physical check.

Once a consignment has satisfactorily undergone these checks a Common Veterinary Entry Document (CVED) is issued allowing the goods to be released for free circulation. There is close co-operation between veterinary and customs authorities, who do not permit the release of animals or animal products unless and until a CVED has been issued.

Report of work done in 2010

A roadmap of the review of the legislative framework of the import controls on live animals and products of animal origin was developed in the context of the review of the Official Food and Feed Controls Regulation (EC No 882/2004) on official controls on food and feed safety, animal health and animal welfare. This Regulation will serve as the basic act for the new legislation on live animals and products of animal origin that will be developed.

In 2010, two Commission decisions were adopted to amend the list of border inspection posts approved in accordance with Directives 91/496/EEC and 97/78/EC:

- Commission Decision 2010/277/EU of 12 May 2010 amending Decision 2009/821/EC as regards the lists of border inspection posts and veterinary units in Traces;

- Commission Decision 2010/617/EU of 14 October 2010 amending Decision 2009/821/EC as regards the lists of border inspection posts and veterinary units in Traces.

In the last quarter of 2010, a report was prepared to the Council and the Parliament on the effectiveness and consistency of sanitary and phytosanitary controls on imports of food, feed,

animals and plants.

Directorate-General Health and Consumers also contributed to a Commission Project Group aimed at developing technical specifications for establishing national Single Windows linking national electronic customs clearance systems with the CVED in TRACES. The establishment of the Single Windows will reduce administrative burden and deepen the cooperation between customs and veterinary services involved in import controls.

The programme *Better Training for Safer Food (BTSF)* has a specific training module for the staff of BIPs to facilitate a harmonised approach to imports by BIPs. Several training courses for this module took place in 2010.

15.4.23.2. Evaluation based on the current situation

The General Food Law and the Official Food and Feed Controls Regulation (EC No 882/2004) will continue to provide the general framework for the control of foodstuffs and of other products of relevance for the food chain, while a number of new and innovative steps will be taken to consider how the current system can evolve towards a more efficient mechanism for the handling of coordinated import controls at EU borders.

The review of its provisions will consolidate this integrated approach by looking at the rules currently applicable to veterinary controls on import of live animals and products of animal origin currently laid down in Council Directives 91/496/EEC and 97/78/EC respectively.

Changes to the Official Food and Feed Controls Regulation are planned as part of the wider initiative to recast and simplify EU legislation - in the areas of food and feed safety, animal health, animal welfare and plant health – initiated in 2004. The aim is to ensure an integrated approach to official controls in all areas related to the food chain.

15.4.23.3. Priorities and planned action

15.4.23.4. Priorities

The priorities are to:

- Introduce mechanisms to better link the level of controls to the level of the associated risks to better target resources and increase the efficiency of controls;
- Optimise the legislation to ensure that policy goals are met;
- Simplify and clarify the legislation;
- Take into consideration the burdens to business and enforcers;
- Introduce new technologies into the legislation;
- Clarify and streamline the interaction with other EU legislation regarding import controls, in particular customs legislation.

Planned action

In operational terms, this will require the improvement of current tools, such as the TRACES database, and the possible development of new ones, to allow risk management decisions on imported goods to fully take into account the risk profile of a given consignment considering its associated hazard and origin. This will be supported by data mining and handling functions to provide for more harmonisation of import controls across EU borders, and a consistent and transparent process to determine border controls. The use of electronic databases including electronic certification should be promoted to reduce administrative burden and to enhance co-operation between different authorities involved in import controls.

15.4.23.5. Summary

The review and update of the legislative rules governing import controls on live animals and products of animal origin will bring about a more holistic approach, which will serve to reinforce the efficiency of the EU's import control regime, ensure an optimal allocation of resources and make it easier to promote and defend the EU's regulatory model. In addition, the legislation will also address the many challenges posed by emerging technologies, new diseases and globalisation.

Relations with International Organisations

In 2010 Directorate-General Health and Consumers continued its participation to plenary sessions and preparatory meetings of the Codex Alimentarius Commission (CAC) and of the World Trade Organisation/Sanitary and Phytosanitary Committee. The accession of the EU and its representation by the Commission are clearly defined in Council Decision 2003/822/EC.

15.4.24. **Animal welfare**

15.4.24.1. Current Situation

General introduction

Animals are keys to food supply and human nutrition. Animal welfare concerns have grown in the society and there is a growing insistence on high animal welfare standards. As the world's largest trader (exports plus imports), Europe leads in promoting high levels of animal welfare. TFEU recognises that animal are sentient beings and animal welfare requirements must be taken into account when drafting and implementing EU policies.

Animal welfare in holdings/on the farm

Council Directive 98/58/EC on the protection of animals kept for farming purposes sets general rules for the protection of animals of all species kept for the production of food, textiles or for other farming purposes. It defines general principles and minimum standards on appropriate feeding, comfort and prevention of unnecessary suffering. More specific rules apply to species raised in intensive systems such as laying hens, broilers, calves and pigs.

Animal welfare during transport

Council Regulation (EC) No 1/2005 on the protection of animals during transport and related operations intends to reduce the stress and harm that animals can experience when moved. It sets general principles and introduces standards for vehicles and equipment, and requirements

for those dealing with animals when being transported.

Animal welfare at the time of killing

Every year nearly 360 million pigs, sheep, goats and cattle, several billion poultry and 25 million fur animals are slaughtered in the EU for production purposes. The control of contagious diseases may require the killing of thousands to millions of animals.

Directive 93/119/EC on the protection of animals at the time of slaughter or killing laid down minimum requirements applicable to the killing of animals for production purposes within and outside slaughterhouses. From 1 January 2013, it will be replaced by Council Regulation (EC) No 1099/2009.

Ban on cat and dog fur

Regulation (EC) No 1523/2007 of 11 December 2007 bans the placing on the market and the import to, or export from, the EU of cat and dog fur, and products containing such fur. The ban applies since 31 December 2008.

Complaints:

3. The number of complaints on animal welfare remains relatively high, partly because in recent years the general public, together with Civil Society, have become more aware of issues related to animal welfare standards. The Commission is often placed in a position of resolving difficult judgement calls involving:

- The fact that a number of welfare requirements are in conflict with some economic interests;

- The fact that animal welfare science is a relatively new area and consequently stakeholders are not aware of the benefits of respecting some provisions of the EU legislation.

Different levels of priority are given to animal welfare in Member States due to the following factors:

- The need for compromise on minimum standards which lead to complaints against Member States applying stricter rules;

- Animal welfare does not receive the same level of prioritisation in the political agenda of each Member State.

In 2010, most of the complaints were either related to the conditions of transport of animals or to the conditions under which pigs are kept.

Report of work done in 2010

Strategic initiatives

During 2010, the Commission mandated an external consultant to carry out an evaluation of the EU policy on animal welfare. The outcomes of the study were made available in December 2010.

Several communication actions were organised aiming at improving the level of knowledge of inspectors in Member States within the framework of "Better Training for Safer Food", or facilitating the exchange of best practices between stakeholders in order to improve enforcement. In addition, the Commission carried out specific actions to raise the awareness of the general public on animal welfare. The first international conference on animal welfare education was organised in Brussels on 1 and 2 October 2010.

Animal welfare in holdings/on the farm

Following the results of the EU funded research project Welfare Quality, the Commission is working on the possibility to integrate animal based welfare indicators into future legislation on farm animals. To this effect, the Commission mandated the EFSA to assess the welfare indicators currently available in dairy cows and see how these could be used to address EFSA recommendations on the welfare of dairy cows. The Commission intends to extend this approach to other farm species (pigs, beef cattle, calves, broilers, laying hens) in the next two years.

The proper implementation of Directive 1999/74/EC on the protection of laying hens in order to avoid possible internal market distortions is a priority for the Commission which is closely following the actions taken so far by Member States to phase out battery cages by 1 January 2012. During 2010, the Commission monitored closely the situation through FVO visits and Member States reports. Regular discussions within the framework of the Standing Committee on the Food Chain and Animal Health and meetings of Chief Veterinary Officers took place in order to collect and review the data on the state of play of the implementation. In particular, the Commission requested Member States to provide updated data and national plans for the proper implementation of Council Directive 1999/74/EC.

The Commission continues to work to obtain a better implementation of Directive 2009/120/EC on the protection of pigs. To this effect, the Commission organised a second workshop on the welfare of pigs in Parma on 11 November 2010. The aim is to exchange on best farming practices pig welfare between Member States and main stakeholders. In particular, it represents a constructive approach to address some of the difficulties met by Member States to fully implement EU requirements on the welfare of pigs such as avoidance of routine tail docking and providing adequate enrichment material. Furthermore, the future implementation of group housing of sows and gilts in all pig holdings by 1 January 2013 was discussed.

Directive 2007/43/EC on the protection of broilers applies since 30 June 2010. In July 2010, EFSA published scientific opinions on the impact of genetic selection of broilers and on the welfare of grand-parents and parents of broilers. The Commission will use EFSA scientific opinions to prepare the report to the European Parliament and the Council on the welfare of broilers required by the Directive.

Animal welfare during transport

The number of complaints and numerous requests for specific amendments reveal that Council Regulation (EC) No 1/2005 on the transport of animals is not properly enforced. As foreseen this Regulation, the Commission is preparing a report on the welfare of animals being transported in the EU.

The report will take into account scientific evidence on the welfare needs of animals as presented in the recent scientific opinion produced by the EFSA. The Commission plans to adopt the report in September 2011. In the light of the conclusions of the report and the outcome of the following discussions with the Council and the European Parliament, the Commission will decide on which actions are necessary to ensure proper implementation of the current legislation, and it will analyse if changes to the legislation are needed.

Meanwhile, the Commission is taking concrete actions to ensure a better and more harmonised enforcement of Regulation (EC) No 1/2005. The Commission organised in December 2010 a meeting with the contact points in charge of transport of the Member States in order to exchange practical experience on controls on the transport of live animals.

The Commission launched a call for proposals for a preparatory action of EUR 4 million on high quality control posts, which was successfully awarded in 2010. The action will be performed in 2011-2012 and will include the renovation of 12 control posts as well as the development of a certification scheme. It will include training and communication to stakeholders.

Animal welfare at the time of killing

Following complaints, the Commission launched a survey on the way Member States competent authorities granted the derogation from stunning in the case of ritual slaughter. The results of the survey have been analysed and will be communicated to the Member States in 2011 for improving the situation.

FVO Inspections Findings

Laying hens

The FVO carried audits in 25 Member States between 2008 and 2010 in order to assess the situation in the laying hen sector regarding in particular the state of preparedness of Member States to implement the ban on battery cages from 1 January 2012. As mentioned earlier, the situation is quite variable between Member States: some are already implementing the ban, others took actions and will ready by 1 January 2012 and others are late in putting the necessary measures in place to implement the ban on battery cages by the legal deadline.

In the pig sector there is a general lack of enforcement of long standing requirements such as provision of enrichment materials and avoidance of routine tail-docking. The state of preparedness for Member States to implement group housing of sows and gilts in all pig holdings by 1 January 2013 is quite variable and will need to be closely monitored over the next two years.

Concerning the transport of animals, the requirements of vehicles for long journeys and the control of journey times are in general not sufficiently applied. The conditions of transport of horses for slaughter are still a problematic issue.

Although on farm emergency slaughter has been implemented in a number of Member States, the issue of the transport of injured cows to slaughterhouses continues to be a significant problem in others.

15.4.24.2. Evaluation based on the current situation

Animal welfare remains an issue attracting public attention given that ordinary citizens are keenly interested in how livestock is raised and whether the required animal welfare standards are being respected. Member States are key in ensuring implementation of animal welfare legislation. The Member States' role is not only crucial in ensuring transposition of Directives in this area but also in effectively deploying the resources and mechanisms needed to ensure compliance with the EU's animal welfare requirements.

Some resources are devoted to dealing with situations for which the Commission lacks powers to regulate. Stray dogs and cats, for instance, do not fall under the scope of the Treaty but yet the Commission devotes considerable resources in replying to citizens complaining about cruelty towards pet animals.

The different relevance and political weight that animal welfare has amongst Member States makes it difficult to set rules that satisfy agriculture, animal welfare organisations and consumers at the same time.

The evaluation performed in 2010 identified several areas for improvement, and in particular enforcement, research, communication, education and international issues. The Commission will work in 2011 to present a second EU strategy for the protection and welfare of animals 2011-2015, which will set up the main policy objectives for the forthcoming years on animal welfare.

Priorities

Enforcement difficulties have been identified as one of the key problems to be addressed in the future strategy for animal welfare. Different possibilities will be explored in the framework of the future strategy to tackle the issue.

It will remain important to react swiftly and adequately to the concerns of interested stakeholders. The FVO will continue to put an emphasis on establishing data on the compliance of Member States with EU rules on animal welfare in order to detect shortcomings but also in order to understand more precisely why certain Member States have difficulties to comply with welfare rules.

The Commission will continue to raise awareness on animal welfare by developing further already existing tools such as "Farmland" and developing new education tools targeted towards children, and by pursuing its active participation in the "Better Training for Safer Food" programme.

Planned Actions

In 2011, the Commission will prepare the second EU strategy for animal welfare 2011-2015. This document will laid down the specific objectives and actions needed for the forthcoming years on animal welfare at EU level. Several reflections are ongoing and in particular the Commission will consider the suggestion of the European Parliament to propose a general EU framework law. Such a law could be the occasion to introduce new principles in particular animal based indicators as developed by the Welfare Quality Project, an EU research based project on animal welfare.

A number of actions which have been initiated in the previous years will be maintained and expanded.

Concerning farm animals, the Commission will continue to work for a better implementation of the current EU legislation. Priorities will be given to help Member States to be ready to implement the ban on battery cages by 1 January 2012, and to the proper enforcement of certain requirements of the Directive on the protection of pigs. The Commission will work to facilitate the future implementation of group housing of sows by 1 January 2013.

Concerning broilers, the Commission will launch an evaluation study in order to prepare a report to the European Parliament and to the Council concerning the influence of genetic parameters on identified deficiencies resulting in poor welfare of chickens and the state of play of the Directive.

Concerning the transport of animals, the Commission will work on a report to the European Parliament and to the Council on the impact of Regulation (EC) No 1/2005 on the protection of animals during transport, using the EFSA scientific opinion which updates the scientific information available on the welfare of animals during transport as well as the results of the study on transport which was launched in 2010. The Commission report is planned for adoption in September 2011.

The implementation of the ban on cat and dog fur within the EU will be assessed on the basis of questionnaires sent to the Member States, in a report which the Commission intends to submit to the European Parliament and to the Council by December 2011.

15.4.24.3. Summary of Sector

The challenge in this sector is to reply to the growing concerns of European citizens' on animal welfare both in the EU and internationally, and to balance the expectations of animal welfare organisations with the requirements of a competitive agriculture, while seeking to simplify legislation and reduce administrative burden.

15.5. Overall evaluation

15.5.1. **Better application of the health and consumer acquis is everyone's concern**

The Commission seeks to use the full extent of its Treaty powers in these policy areas that have such a direct impact on citizens, consumers and economic operators. To do so Directorate-General Health and Consumers endeavours to engage society at large so that everyone reaps the benefits of the *acquis* in this area. But the Commission cannot alone deliver better application of this *acquis* without the cooperation of the Council, the European Parliament and Member States. Member States are primarily responsible for implementation and the Commission works to build partnerships and bridges of cooperation to ensure that legislation becomes reality on the ground.

Cooperation between Commission services and national enforcers and experts is essential, starting from the design phase of any new legislation. Evaluations carried out by the Commission assess systematically the actual application of the relevant EU legislation and will contribute to the preparation of subsequent impact assessments, which measure the real impact of intended changes on the daily lives of citizens and on other stakeholders.

The Commission is mindful that this area of legislation is often technical, complicated and not easy to understand by enforcers, economic operators and ordinary citizens. Every effort is being made to promote a regulatory environment that is modern, simple and proportionate but that does not weaken the necessary health protection afforded by the policies in this area.

This area is very close to many concerns that citizens have about Europe. The Commission will seek to increase transparency on actions being taken by Member States' enforcement actors to ensure compliance. At the same time the Commission will seek to empower citizens, consumers and patients through information to enable them to support implementation practices and outcomes in Member States.

15.5.2. *Prevention*

The Commission continued in 2010 to issue or to update implementation guidelines on the correct application of its policy areas. In the public health policy area, the Commission, by adopting Decision 2010/453/EC, established guidelines concerning the conditions of inspections and control measures, training and qualification of officials in the field of human tissues and cells provided for in Directive 2004/23/EC. In the consumer policy area the Commission, by adopting Decision 2010/15/EU, revised the RAPEX guidelines. This revision was necessary because of the significant increase in the number of notifications through the RAPEX network that has be followed up in the Member States and of the need to increase the traceability of dangerous products notified via the system.

In addition the Commission organised workshops to assist the Member States with the implementation of Directives which they are in the process of transposing (for example the implementation of the Organs Directive 2010/53/EU) or with national authorities and stakeholders to promote an exchange of information and best practices between industry and veterinary experts from Member States (for example on how to minimise animal suffering during pig tail docking).

For the implementation and consistent application of Directive 91/414/EEC concerning the placing of plant protection products on the market, the Commission continued to develop further guidelines. Currently 47 guidelines documents are available to the public.

In 2006 the Commission launched a training programme entitled "Better Training for Safer Food". This is an EU training strategy for food and feed law, animal health and welfare rules and plant health rules. Training is designed for Member State's and third country's competent authority's staff involved in official control activities. It aims to keep them up-to-date with EU law in the areas specified above and to ensure more uniform and efficient controls across the EU and on imports to the EU. Better Training for Safer Food comprises training programmes on subjects where needs for improved application of EU law have been identified. The number of programmes and the number of people trained have increased each year since the initiative's launch. Further new training actions are to be launched in 2011. These include training on new subjects such as Audit systems/Internal auditing, TRACES[524] and quality schemes.

[524] TACES: TRAde Control and Expert System (a trans-European network for veterinary health which notifies, certifies and monitors imports, exports and trade in animals and animal products).

Another type of prevention is provided for in Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations. This Directive obliges Member States to notify to the Commission, before they are adopted, draft acts containing technical standards and regulations. During 2010 the Commission services responsible for health and consumers examined around 220 notifications of draft legislation.

The rapid alert system for food and feed (RASFF) is an effective tool to exchange information about national measures taken responding to serious risks detected in relation to food or feed[525]. This is a concrete and visible result of a successful European integrated approach to ensure food safety. It helps Member States to act more rapidly and in a coordinated manner in response to a health threat caused by food or feed. Its effectiveness is ensured by keeping its structure simple: it consists essentially of clearly identified contact points in the Commission and at national level, and exchanging information in a clear and structured way by means of templates. The Commission together with Member States continues to work hard in further shaping this essential tool that contributes to high food safety standards in the EU, preventing dangerous food or feed from reaching the consumer and allowing swift action to be taken to remove such products from the market. In 2010 a total of 3358 original notifications were transmitted through the RASFF; of which 592 were classified as alert, 1188 as information and 1578 as border rejections.

The EU rapid information system RAPEX (for dangerous non-food consumer products found and consequently withdrawn from the market) is a similar tool. In 2010, 2244 notifications were exchanged through the system. Following the entry into force of Regulation (EC) No 765/2008 the scope of the system was extended.

Discussions with Member States in expert groups or with stakeholders in, for example, workshops, often identify areas of difficulty in fully appreciating the nature of specific legislative instruments. The Commission services often provide detailed interpretations of specific provisions in order to achieve broad but uniform understanding of specific provisions.

15.5.3. *Regular review of legislation*

The health and consumer legislation is regularly reviewed after careful evaluation of impacts as well as continuous and fruitful dialogue with citizens, consumers and other stakeholders in order to:

- optimise the legislation for ensuring that policy goals are met;
- enhance the effectiveness of the legal framework;
- simplify and clarify the legislation;
- take into consideration the burdens to business and enforcers;
- to introduce new technologies into the legislation;

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525 The legal basis of RASFF is Article 50 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1.

- clarify the interaction with other EU legislation.

In 2010, as a result of that work, the adoption of Regulation (EU) No 1235/2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products as well as Directive and the adoption of Directive 2010/84/EU amending as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use, finalised the revision of several key pieces of legislation.

Evaluations of existing legislation have been carried out and will be the basis of impact assessments in 2011 for future major legislative revisions (e.g. in the plant health legislation and the plant seed legislation). Further evaluations have been launched (inter alia on the plant variety rights legislation).

15.5.4. *Audits, Inspections and market surveillance*

Another aspect of prevention is the ability of the Commission services to see for themselves the realities of enforcement on the ground.

Enforcement of the food safety legislation would be weak if the FVO was not able to examine whether Member States and third countries from which food is imported, properly apply food and feed safety controls.

Each year the FVO develops an audit and inspection programme identifying priority areas and countries. It carries out around 250 audits and inspections, including both general and specific audits, annually. Following each, a report is issued which sets the actions needed to improve compliance. The large majority of weaknesses in control systems identified by the FVO are addressed through specific action plans drawn up by national authorities in response to its recommendations.

In recent years, the FVO has developed overall country profiles for each Member State and for the EU's main trading partners. These profiles bring together and summarise the results of general and specific audits and inspections over time and across all relevant sectors. They can thus help to identify systemic weaknesses in the overall design and application of national control systems. As these results are progressively refined and validated, remedial action can be proposed that address the underlying causes that are common to a number of specific sectors, for example, the absence of a system of documentary records of controls or the absence of an effective system of sanctions for non-compliance.

The FVO regularly carries out general follow-up missions in order to monitor the action taken by Member States to address the concerns identified by FVO in its recommendations. Directorate-General Health and Consumers has reorganised its structure in order to enhance the enforcement in the food safety area (including animal health and welfare and plant health). An enforcement Unit ensures a coordinated and sustained approach to all enforcement issues through improved decision making. Its task is supported by a recently developed internal database which enables to coordinate progress towards the resolution of particular enforcement issues that, on the basis of risk analyses, need to be followed up.

In the consumer policy area the Commission for the fourth time carried out a market

surveillance exercise in the form of a sweep on sites selling tickets for cultural and sporting events. Such sweeps allow the Commission to identify the existing incompliant conditions on websites and through contacts with the involved companies to obtain corrections on the websites.

Conclusion

The above shows the Commission's determination to fully implement its *acquis* in the policy areas of consumers, food safety and public health and to up-date its regulatory framework, if necessary. Consumers can be confident that the safety of their food is protected by strict enforcement of controls. Trade can take place under conditions of uniform and high safety levels, which allow markets to focus on price, quality and consumer preferences. The Commission remains ready to manage any emergencies or other unforeseen circumstances in this area having always in mind the welfare, well-being and protection of European citizens.

16. HOME AFFAIRS

16.1. Immigration and integration

16.1.1. Current position: General introduction

EU legislation in the field of immigration and integration currently consists of nine directives.

Regarding legal migration, four sets of measures have been adopted:

- a first set of measures adopted in 2003: the Family Reunification Directive 2003/86[526] and the Long-term Residents Directive 2003/109[527];
- Directive 2004/81 on the residence permit issued to third-country nationals who are victims of trafficking in human beings or who have been the subject of an action to facilitate illegal immigration, who cooperate with the competent authorities[528];
- the Students Directive 2004/114[529] and the Researchers Directive 2005/71[530]; and
- the Highly qualified Workers Directive 2009/50[531] ('EU Blue Card').

Three directives concern irregular immigration:

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526 Council Directive 2003/86 of 22 September 2003 on the right to family reunification, OJ L 251, 3.10.2003, p. 12.

527 Council Directive 2003/109/EC of 25 November 2003 concerning the status of third-country nationals who are long-term residents, OJ L 16, 23.1.2004, p. 44.

528 OJ L 261, 6.8.2004, p. 19.

529 Council Directive 2004/114/EC of 13 December 2004 on the conditions of admission of third-country nationals for the purposes of studies, pupil exchange, unremunerated training or voluntary service, OJ L 375, 23.12.2004, p. 12.

530 Council Directive 2005/71/EC of 12 October 2005 on a specific procedure for admitting third-country nationals for the purposes of scientific research, OJ L 289, 3.11.2005, p. 15.

531 Council Directive 2009/50/EC of 25 May 2009 on the conditions of entry and residence of third-country nationals for the purposes of highly qualified employment, OJ L 155, 18.6.2009, p. 17.

- the Carriers Liability Directive 2001/51[532] and Directive 2002/90[533] defining facilitation of unauthorised entry, transit and residence; and

- the Employer Sanctions Directive 2009/52[534], which aims to reduce illegal immigration by prohibiting the employment of illegal staying migrant workers and providing for sanctions against employers who infringe the prohibition.

The EU's comprehensive migration policy continues to be developed, so efforts in this area are as much about developing new legislation as ensuring the correct application of existing legislation. Regarding labour migration, in its 2005 Policy Plan on Legal Migration[535], the Commission announced its intention to present proposals for a general framework directive and directives for specific categories of paid workers.

The first such directive — the EU Blue Card — was adopted in 2009, and discussions continued in the European Parliament and Council on the proposed 'Single Permit' Directive[536]. The Commission presented proposals for Directives on seasonal workers and intra-corporate transferees in July 2010, and discussions in the European Parliament and Council are ongoing.

16.1.2. Current position: Report on work done in 2010

In line with the Stockholm Programme's call on the Commission to evaluate and, where necessary, to review the Family Reunification Directive, taking into account the importance of integration measures[537], the Commission intends to carry out a wider consultation — in the form of a Green Paper — on the future of the family reunification regime.

In 2010, the Commission presented a Report on the Victims of Trafficking Directive (2004/81)[538]. It found that the number of residence permits issued on the basis of this Directive was significantly lower than the number of victims identified. This proved that the potential of this Directive is being underused.

As regards presumed infringements disclosed by complaints, the case in the Netherlands concerning the high level of fees charged to those applying for long-term residents' permits is still pending before the Court of Justice. In another infringement case, concerning the same point, but against Cyprus, the results of the ECJ judgment will be applied accordingly.

The Commission continued the infringement procedure against Austria regarding rules under which third-country national students are permitted to work in that Member State. The

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532 Council Directive 2001/51 of 28 June 2001 supplementing the provisions of Article 26 of the Convention implementing the Schengen Agreement of 14 June 1985, OJ L 187, 10.7.2001, p. 45.

533 Council Directive 2002/90 of 28 November 2002 defining the facilitation of unauthorised entry, transit and residence, OJ L 328, 5.12.2002, p. 17.

534 Directive 2009/52/EC of the European Parliament and of the Council of 18 June 2009 providing for minimum standards on sanctions and measures against employers of illegally staying third-country nationals, OJ L 168, 30.6.2009, p. 24.

535 COM(2005) 669 final.

536 Proposal for a Council Directive on a single application procedure for a single permit for third-country nationals to reside and work in the territory of a Member State and on a common set of rights for third-country workers legally residing in a Member State, COM (2007) 638 final of 23.10.2007.

537 Presidency Conclusions, document EUCO 6/09. The Programme itself is in document 17024/09.

538 COM(2010) 493 final.

Commission considers that the Students Directive 2004/114 requires that third-country national students be allowed to work under less restrictive conditions.

Regarding the management of the existing *acquis*, a meeting of the contact committee on legal migration directives in December 2010 provided the opportunity for a useful exchange of views between the Commission and national experts involved in their application. A meeting of national contact points appointed under the Long-term Residents Directive 2003/109 was also held. Alongside discussions in the contact committee, the European Migration Network[539] (EMN) continued to be a means for Member States (and the Commission) to address *ad hoc* queries to obtain a quick overview on how other Member States transpose specific provisions of the directives. The Committee on Immigration and Asylum (CIA) provided a forum for the Commission to give up-dated information to Member States on the legal *acquis*, as well as allowing Member States to comment on factual aspects of their transposition in the context of the Commission's reports.

Work continued on the external transposition studies for the Students Directive and the updated study on the Long-term Residents Directive, commissioned with a view to preparing implementation reports on the directives. In cooperation with Commission department in the area of Research, the contract for an external study on the Researchers Directive was launched. The final study is due in August 2011. These three studies will form the basis of the Commission's reports on the application of the directives in question.

Regarding the transposition of new legislation, Member States have to transpose the EU Blue Card into national law by June 2011, and the Employer Sanctions Directives by July 2011. Meetings of the contact committees were held in late 2009 and in 2010 (two meetings for the EU Blue Card, three meetings for Employers' Sanctions), enabling a useful exchange of views between the Commission and national experts involved in the national transposition of the directives.

Legislative discussions in the Council and European Parliament continued on the 'Single Permit' Directive for labour migration. This will provide for a single permit (residence and work) and basic socio-economic rights for migrant workers. Negotiations also started on proposals adopted in July 2010 on seasonal workers and intra-corporate transferees.

16.1.3. Evaluation based on the current situation

Bearing in mind that it took until 2009 to fully transpose directives dating from 2005 and earlier EU-wide, there is a pressing need for Member States to reinforce their efforts to complete transposition of the most recent directives in this field, the EU Blue Card and Employer Sanctions, by the mid-2011 deadline. By end of 2010, only one Member State had communicated its full transposition measures for these to the Commission.

The Commission has continued to pursue the most important presumed infringements disclosed by complaints, and it will go on doing so.

Legislative activity (preparing new proposals as well as legislative discussions themselves) continued to be important in this sector. The Lisbon Treaty has introduced co-decision in the

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[539] Council Decision 2008/381/EC of 14 May 2008 establishing a European Migration Network, OJ L 131, 21.5.2008, p. 7.

area of legal immigration, thus giving an enhanced role to the European Parliament. This has given impetus to legislative discussions on the general framework directive for a single permit and rights.

16.1.4. Evaluation results: Priorities

The main priorities are:

1. Ensuring the correct application of existing legal migration directives;

2. Ensuring the correct and timely transposition of the Blue Card and Employers' Sanctions Directives;

3. Preparing Commission reports on the application of existing directives;

4. Ensuring appropriate follow-up to the Report on the Victims of Trafficking Directive.

16.1.5. Evaluation results: Planned action (2011 and beyond)

As regards priorities 1 and 2, the Commission will examine Member States' transposition measures for the Blue Card and Employer Sanctions Directives, and will take action as appropriate for non-transposition and incorrect transposition of the Directives. In addition it will actively follow up complaints about the application of the other legal migration directives in Member States.

As regards priority 3, the Commission will in 2011 present reports on the Long-term Residents, Students and Researchers Directives. On the basis of these, the Commission will decide what further action is needed.

As regards priority 4, the Commission will examine all cases of problems in applying this directive. This may involve contacting Member States and/or launching procedural steps for non-compliance, where appropriate, in accordance with Article 258 TFEU. In its report on the Victims of Trafficking Directive, the Commission also announced that it may consider the need for amendments.

Other activity will include:

– Contributions to the Commission's intervention before the Court of Justice with regard to requests by national courts for preliminary rulings on the interpretation of EU legislation in the area of legal migration;

– Continued discussions in the "contact committees", allowing Member States an open forum in which to discuss questions or problems they have identified in their transposition of the Directives.

16.1.6. Summary

The Commission will prepare reports on the Students, Researchers and Long-term Residents Directives. Given the ongoing development of the EU's comprehensive migration policy, it will also give attention to the legislative process to ensure coherence with directives already

adopted. Ensuring the correct transposition of the two Directives adopted in 2009 will be a priority.

16.2. Asylum

16.2.1. Current position: General introduction

Following the entry into force of the Treaty of Lisbon, asylum policy is now regulated by Article 78 TFEU. The asylum *acquis* is essentially composed of four directives (Reception Conditions[540], Qualification[541], Asylum Procedures[542] and Temporary Protection[543]) and three regulations (Dublin[544], Eurodac[545] and European Asylum Support Office[546]). The directive on the status of third-country nationals who are long-term residents[547] is also relevant for asylum policy. Amendments to all these legal instruments (except the European Asylum Support Office Regulation) are currently being negotiated by the co-legislators.

Regarding asylum policy, the main development in 2010 was the continuation of negotiations on legal instruments for the second phase of the Common European Asylum System (CEAS). Negotiations gathered pace, especially during the second semester, as the Belgian Presidency had made asylum one of its priorities. Significant progress was made on some legal instruments, *e.g.* with the formal adoption of the instruments aiming at the creation of the European Asylum Support Office (EASO) and a compromise reached between the European Parliament and the Council on the extension of the legal system for third-country nationals with long-term resident status to include persons with international protection (modification of Directive 20003/109/EC). Concerning the Qualification Directive, in the course of 2010, the Presidencies proposed several compromise amendments and an important number of reservations was lifted. Progress was also made on the 'Joint EU Resettlement Programme'. Discussions were however difficult on some instruments, in particular with limited progress on the Asylum Procedures Directive, the Reception Conditions Directive and the Dublin Regulation. As far as the EURODAC Regulation is concerned, the Commission aims with a new proposal at allowing for a rapid agreement by the co-legislators, and thereby facilitate

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540 06.02.2003 Council Directive 2003/9/EC of 27 January 2003 laying down minimum standards for the reception of asylum seekers; OJ L 031, 06.02.2003 p. 18 – 25.

541 30.09.2004 Council Directive 2004/83/EC of 29 April 2004 on minimum standards for the qualification and status of third country nationals or stateless persons as refugees or as persons who otherwise need international protection and the content of the protection granted; OJ L 304, 30.09.2004 p. 12 – 23.

542 13.12.2005 Council Directive 2005/85/EC of 1 December 2005 on minimum standards on procedures in Member States for granting and withdrawing refugee status OJ L 326, 13.12.2005, p. 13.

543 20.07.2001 Council Directive 2001/55/EC of 20 July 2001 on minimum standards for giving temporary protection in the event of a mass influx of displaced persons and on measures promoting a balance of efforts between Member States in receiving such persons and bearing the consequences thereof; OJ L 212, 07.08.2001, p. 12 – 23.

544 25.02.2003 Council Regulation (EC) No 343/2003 of 18 February 2003 establishing the criteria and mechanisms for determining the Member State responsible for examining an asylum application lodged in one of the Member States by a third-country national; OJ L 50, 06.02.2003, p. 1 – 10.

545 15.12.2000 Council Regulation (EC) No 2725/2000 of 11 December 2000 concerning the establishment of 'Eurodac' for the comparison of fingerprints for the effective application of the Dublin Convention; OJ L 316, 15.12.2000, p. 1 – 10.

546 29.05.2010 Regulation (EU) no 439/2010 of the European Parliament and of the Council of 19 May 2010 establishing a European Asylum Support Office; OJ L 132, 29.05.2010, p. 11- 28**.**

547 23.1.204 Council Directive 2003/109/EC of 25 November 2003 concerning the status of third-country nationals who are long-term residents Official Journal L 16, 23.1.2004, p. 44–53.

progress on the whole asylum package as well as the timely set up of the IT Agency (that should also be responsible for the management of EURODAC).

As far as the EASO is concerned the co-legislators formally approved the creation of the EASO and Member States decided that its seat would be in Valletta, Malta. Since then, the Commission has been actively working with a view to preparing the start of EASO's operations, and it should be fully operational by 19 June 2011.

16.2.2. **Current position: Report on work done in 2010**

The Commission decided in June 2010 to refer Belgium to the Court of Justice for failure to communicate measures fully transposing the Asylum Procedures Directive further to infringement proceeding initiated in 2008. In September 2010, the Commission received notification of full transposition, so the infringement proceeding was closed.

In June 2010, the Commission decided to refer Ireland to the Court of Justice for failure to communicate measures fully transposing the Asylum Procedures Directive. Ireland delivered its Defence to the Court of Justice on 25 November 2010. It indicated that it intended to adopt measures transposing the provisions of the Asylum Procedures Directive in the near future.

In March 2010, the Commission proposed closing three cases of non-communication against Sweden, Spain and Cyprus, further to notifications of full transposition of the Asylum Procedures Directive; and to close two cases of non-communication against Sweden and Spain concerning the Qualification Directive.

The Commission has taken steps to review reported deficiencies in the asylum system in Greece. The reports raised concerns as to whether the Greek asylum system is in compliance with the minimum standards prescribed by EU law, particularly those set out in the Asylum Procedures Directive, the Qualification Directive and the Reception Conditions Directive. In November 2009, the Commission sent Greece a letter of formal notice followed by a supplementary letter of formal notice in June 2010.

An Action Plan has been drawn up and submitted to the Commission in August 2010. The Commission, Member States, the European Asylum Support Office, UNHCR and other European Partners have signalled their commitment to assist Greece in this process (by financial and other means). In December 2010, Member States experts visited Greece under Commission financing, to provide advice in the areas of backlog management, training and screening/registration of asylum applications. The expert reports drafted in collaboration with UNHCR have become the basis for planning future supporting measures. The provision of EU assistance to Greece will continue in 2011, with the support of the Commission and EASO and in close cooperation with UNHCR.

16.2.3. Evaluation based on the current situation

In line with ambitions the Council articulated in the Hague Programme adopted in 2004, and the Stockholm Programme agreed in December 2009, as well as in the Commission's own 2008 Policy Plan on Asylum, the scope of the asylum *acquis* needs to be extended and enhanced to ensure successful completion of the Common European Asylum System (CEAS).

More specifically, EU asylum legislation should guarantee:

– higher levels of protection generally;

– a more level playing field for persons seeking asylum in different Member States;

– more efficient treatment of asylum applications;

– better coordination of external aspects of asylum policy;

– more solidarity between Member States in sharing the burdens associated with receiving asylum seekers.

Moreover, the Commission is particularly concerned by the fact that rates of recognition of asylum seekers as qualifying for protection still vary very considerably among Member States, despite common minimum standards and a significant degree of harmonisation via the current *acquis*,. This can be attributed to a number of causes, including insufficiently far-reaching legislative harmonisation, variation in the manner in which current legislation is applied in practice, and variation in the nature of information on the situation in countries-of-origin on which asylum decisions are taken.

In view of these shortcomings, the Commission intends to continue to pursue a 'twin-track' approach. This will consist of working to extend and improve the EU *acquis*, as well as consolidating it by:

(a) taking infringement actions against Member States for non-transposition and/or incorrect application of the *acquis*, and

(b) enhancing practical cooperation activities, particularly by ensuring that the European Asylum Support Office is placed on a sound footing.

16.2.4. Evaluation results: Priorities and planned action (2011 and beyond)

To date, the Commission has given priority to creating and further developing EU legislation in the asylum field, and to facilitating practical cooperation among Member State authorities.

The Commission intends to pursue the following priorities regarding development, application and monitoring of EU law in the coming years:

– Further development of EU legislation, notably as regards the amendment of existing legislative instruments and the possible adoption of new ones;

– Pursuit of practical cooperation efforts to improve the practical implementation/application of the *acquis* in Member States, particularly as regards ensuring an effective transition to setting up the EASO;

– Monitoring and evaluating the implementation of EU legislation;

– Contribution to the Commission's intervention before the Court of Justice with regard to requests by national courts for preliminary rulings on the interpretation of EU legislation, and follow-up of individual complaints about compliance with EU legislation in Member States.

16.2.5. Summary

EU law in the asylum field is still being developed. Some shortcomings have been identified in the scope and impact of the existing *acquis* and in the manner in which it is applied. The priority in the short to medium term should be to extend and improve the legislation. At the same time, practical cooperation among Member States needs to be intensified with a view to ensuring more consistency in their application of the *acquis*, particularly by ensuring the successful establishment of a European Asylum Support Office. The Commission will continue to monitor and evaluate implementation of the law, to intervene before the Court of Justice with regard to requests by national courts for preliminary rulings on interpretation of the law, and to follow up complaints against Member States for incorrect application of the *acquis*.

16.3. European visa policy

16.3.1. **Current situation: Report on work done in 2010**

In July 2009, the European Parliament and Council adopted a Regulation establishing a Community Code on Visas[548], applicable since 5 April 2010. The Visa Code recasts the legal framework for the common visa policy and enhances transparency, equal treatment of applicants and legal certainty, and it harmonises procedures for issuing short-stay visas. It includes *inter alia* provisions on mandatory motivation of visa refusal and right to appeal (applicable as from 5 April 2011), harmonised deadlines for the visa handling process, enforcement of local Schengen cooperation and development of consular representation at local level.

In line with Article 51 of the Visa Code, the Commission elaborated two Commission decisions providing operational instructions on the practical application of the Visa Code, i.e. the Commission Decision of 19 March 2010 establishing the Handbook for the processing of visa applications and the modification of issued visas[549] and the Commission Decision of 11 June 2010 establishing the Handbook for the organisation of visa sections and local Schengen cooperation[550].

16.3.2. Evaluation based on the current situation

As the Visa Code has only recently become applicable, efforts were focused mainly on ascertaining together with Member States that the new provisions were correctly interpreted, through discussions in the Visa Working Party and the Visa Committee. It was not considered opportune to open infringement proceedings, since no flagrant systematic practice infringing the Visa Code had been observed.

Under the Visa Code, Member States are required to try to harmonise their practices in the framework of local Schengen cooperation in each third country.

In 2010, the Commission continued to receive complaints from individuals that EU law had been incorrectly implemented in the field of visas. After examination, it appeared that, when

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548 Regulation (EC) No 810/2009 of the European Parliament and of the Council of 13 July 2009 establishing a Community Code on Visas.

549 C(2010) 1620 final.

550 C(2010) 3667 final.

well founded, these complaints reflected some weaknesses in the current Visa *acquis*. These will be resolved thanks to implementation of the Visa Code and sustained efforts in the framework of local Schengen cooperation.

16.3.3. Evaluation results: Priorities and planned action (2011 and beyond)

In light of important changes that intervened on 5 April 2010 and those due on 5 April 2011, the Commission considers that ensuring timely, correct and efficient implementation of the new legislative framework by all Member States is a priority. The Commission will undertake systematic screening of Member States' implementation of the Visa Code's provisions, particularly those with a significant impact on visa applicants.

Due to the importance of visa policy in EU external relations, as well as the impact of an efficient visa policy on combating irregular migration, the Commission closely monitors implementation of the Visa Code. Existing fora such as the Visa Working Group in Council or the Visa Committee will continue to play an important role in identifying issues of common interest and solving them in an appropriate way.

At local level, the involvement of EU delegations in local Schengen cooperation should increase, and they should play a stronger role in ensuring that the common visa policy is implemented correctly and in a harmonised way by all Member States' consulates.

16.4. Document Security (European passport and residence permits)

16.4.1. **Current situation: Report on work done in 2010**

Regarding infringement procedures on residence permits, the case against Italy was withdrawn from the Court in September 2010 as Italy had started to issue residence permits in conformity with Regulation (EC) No 1030/2002.

Regarding non-conformity with Regulation (EC) No 2252/2004 on passports, reasoned opinions were sent to Bulgaria and Cyprus in March 2010. Following confirmation that biometric passports were being issued, the case against Bulgaria was closed in September 2010 and the case against Cyprus is expected to be closed in early 2011. Belgium was sent a letter of formal notice for non-conformity with Regulation (EC) No 2252/2004 on passports as regards the implementation of the second biometric identifier (fingerprints).

16.4.2. Evaluation results: Priorities and planned action (2011 and beyond)

The main priorities are:

(1) Ensuring correct implementation of Regulation 2252/2004. The vast majority of Member States have now correctly implemented the Regulation. However, further measures are needed in terms of infringement policy and to carry out the conformity testing of specimens notified by Member States.

(2) Ensuring correct implementation of Regulation 1030/2002 on residence permits (incorporating facial image); deadline: May 2011.

(3) Facilitating Member States' implementation of the complex Public Key Infrastructure (required to protect personal data stored on documents) for both residence permits and

passports.

In 2011, conformity testing of 2nd generation biometric passports (with a chip storing facial image and fingerprints) will be carried out by the Joint Research Centre, and the Commission will decide on any subsequent infringement procedures as appropriate.

16.5. Border management and return policy

16.5.1. Current position: General introduction

In the field of border management and return policy, the Commission mainly carried out monitoring of the application of EU law. This resulted in the follow-up of one infringement proceeding launched in 2008, and several consultations between the Commission and some Member States via EU Pilot. Moreover, the Commission handled multiple consultations with Member States on the compatibility of draft bilateral agreements with third countries in the framework of the Local Border Traffic Regulation. Strategic priority was given to preparing the ground for timely, correct transposition of the European Parliament and Council Directive 2008/115/EC on common standards and procedures in Member States for returning illegally staying third-country nationals (the 'Return Directive').

16.5.2. Current position: Report on work done in 2010

The Commission has received and followed up several complaints from individuals and written questions from Members of European Parliament related to the incorrect application of EU law in the field of border management, particularly of the Schengen Borders Code. Most of these concern non-compliance with provisions related to the abolition of internal border controls at land and air borders and to the removal of obstacles to traffic at road crossing points at internal borders between Member States.

Furthermore, the Commission drafted a proposal to amend the Schengen Borders Code as a result of experience since its entry into force. Adoption is expected in early 2011.

Within the framework of the Local Border Traffic (LBT) Regulation, multiple consultations took place between the Commission and a number of Member States on the compatibility between bilateral draft agreements with third countries and the LBT Regulation. There were exchanges of information and informal advice, and experts' meetings, as well as formal exchanges of correspondence.

Regarding implementation of Council Directive 2004/82/EC on the obligation of carriers to communicate passenger data, the evaluation of transposition measures communicated by Member States has been completed by closing the non-communication case against Poland.

Regarding return policy, action focused on cases of non-communication of transposition of Directive 2001/40/EC on mutual recognition of decisions on the expulsion of third country nationals closing one remaining case against Malta and Directive 2003/110/EC on assistance in cases of transit for the purposes of removal by air closing the case against Spain.

To facilitate the correct, consistent transposition of the Return Directive, Commission Services convened three meetings of a Contact Group in 2010. This group provides an informal forum for exchanging views between Member States and the Commission on how to meet requirements set out in the directive. The Commission also organised two workshops,

bringing together Member States and key stakeholders in the return process, namely international and non-governmental organisations which have concrete practical experience on selected issues. They focused on how best to apply specific provisions in the directive. The topics discussed were the requirement to provide alternatives to detention, and the return of unaccompanied minors.

The deadline for transposing all provisions of the directive into national law (except for those relating to free legal aid) expired on 24 December 2010. The deadline for provisions relating to free legal aid will expire on 24 December 2011. All Member States, with the exception of the United Kingdom and Ireland, are bound by the Return Directive. By the end of 2010, only six Member States had notified measures that they consider constitute full transposition of the directive: the Czech Republic, Estonia, Greece, Spain, Portugal and Slovakia. A further four Member States had notified measures which they consider as constituting partial transposition by the same date: Belgium, Latvia, Lithuania and Sweden. The Commission will examine these notifications in the course of 2011.

According to the doctrine of direct effect developed by the European Court of Justice, provisions of a directive which confer rights on individuals and which are sufficiently clear and unconditional become directly effective from the end of the time limit for implementing the directive. Many of the provisions of the Return Directive fulfil these requirements and therefore have to be directly applied by national administrative and judicial authorities in Member States, even if they have not yet transposed the directive.

16.5.3. Evaluation based on the current situation

The correct application of EU legislation in the field of border management, particularly in the absence of internal border controls, has a substantial impact on the area without internal borders in which the free movement of persons has to be ensured. Alleged internal border checks at land borders and at airports were again reported during 2010. The Commission is closely monitoring the situation regarding internal border zones. It is also following developments regarding the dismantling of remaining traffic obstacles at road crossing-points at internal borders.

In October 2010, the Commission adopted a report to the European Parliament and the Council on the application of Title III (Internal borders) of the Schengen Borders Code[551]. In the report, the Commission paid particular attention to the practical application of Article 21 of the Schengen Borders Code (police checks within the territory, particularly in internal border zones), to difficulties related to the removal of obstacles to traffic at road crossing-points at internal borders, and to difficulties arising from the reintroduction of border controls at internal borders.

In November 2010, the Commission adopted a proposal for a Regulation of the European Parliament and of the Council on setting up an evaluation mechanism to verify application of the Schengen *acquis*[552]. The proposal is currently under discussion in the Council and European Parliament. It organises in more detail the Commission's power to carry out unannounced on-site visits to verify the absence of controls at internal borders. The

[551] COM(2010) 554 final.
[552] COM(2010) 624 final.

Commission is of the opinion that such visits would make a significant contribution to the correct application of EU law as regards the abolition of internal border controls.

In the field of return, the Commission continued its successful experience of organising a Contact Group (or Contact Committee) in 2010. This facilitates the correct and consistent transposition of the Return Directive. Since the directive was adopted at the end of 2008, Commission services have convened six such meetings, including three in 2010. The Contact Group, and related Workshops on specific return-related topics, are highly appreciated by Member States. They have contributed to better transposition of the directive and to better general understanding of its provisions. The Group will therefore continue meeting during 2011, though the transposition deadline expired in December 2010. It is expected that these meetings will go on facilitating correct application of the directive at national level in the coming years and will facilitate transposition where this has not yet taken place.

16.5.4. Evaluation results: Priorities

In 2010, priority was given to following up complaints received from citizens and questions from Members of European Parliament regarding checks carried out on persons in internal border zones and at airports, and to remaining obstacles to traffic at road crossing points at internal borders. The Commission regularly addressed Member State national authorities to obtain explanations, particularly on alleged checks on persons within internal border zones, and it sought information on remaining traffic obstacles, concerning their progressive removal.

In the field of return, strategic priority was given to preparing the ground for timely, correct transposition of the Return Directive 2008/115/EC. Several complaints related to return issues were received, but no concrete follow-up could be given, as the transposition period for the directive had not yet expired.

16.5.5. Evaluation results: Planned action (2011 and beyond)

As one of its fundamental objectives, the Commission will continue to closely monitor the correct application of EU legislation on dismantling internal border controls and remaining traffic obstacles. The Commission's proposal on the Schengen evaluation mechanism could undoubtedly contribute to accomplishing this. Priority will thus be given to following up complaints received from individuals and questions from Members of European Parliament. The Commission will continue to seek explanations from relevant Member States regarding alleged border checks and remaining traffic obstacles at internal borders. The Commission will take all measures necessary, including the launching of infringement procedures, to ensure the correct application of EU law.

Moreover, the Commission will continue to have consultations with Member States and to analyse the compatibility of draft local border traffic agreements with EU law. The Commission submitted a second report on the implementation and functioning of the local border traffic regime to the European Parliament and Council and this was adopted on 9 February 2011.

During 2011, strategic priority will be given to examining national measures notified to the Commission for transposition of the Return Directive 2008/115/EC. The Commission will be assisted in this task by an external contractor with relevant expertise in the national laws of Member States. Infringement proceedings will be launched against Member States which

have not communicated transposition measures. The Commission will, moreover, continue to convene the Contact Group during 2011, to facilitate the correct application of the directive at national level, and to facilitate the transposition of the Return Directive 2008/115/EC where this has not yet been done. Once the transposition deadline has expired, the Commission will become more active regarding complaints and petitions from stakeholders (NGOs, etc) calling for action to be taken against Member States which have allegedly incorrectly transposed the directive, or which are allegedly not applying or incorrectly applying aspects of it. This could result in infringement proceedings against some Member States. Depending on the number of complaints received, there will be a need to set priorities.

16.6. Security

16.6.1. Data Retention Directive

Current position: General introduction

On 15 September 2007, Member States should have brought into force legal instruments to comply with the Data Retention Directive 2006/24/EC. In all, 18 Member States[553] invoked the clause of Article 15(3) that allowed them to postpone application of the directive to the retention of communications data relating to internet access, internet telephony and internet e-mail until 15 March 2009.

Current position: Report on work done in 2010

In 2010, the Commission continued non-communication cases against four Member States: against Greece and Ireland, condemned by the European Court of Justice on 26 November 2009 (cases C-211/09 and C-202/09 respectively), against Sweden, condemned in February 2010 in case C-185/09, and against Austria, condemned in July 2010 in Case C-189/09.

In May 2010, the Commission sent Greece a letter of formal notice pursuant to Article 260 TFEU. A similar letter was sent to Sweden in June 2010.

The Commission closed an infringement case against Luxembourg after receiving its national transposition measures.

Evaluation based on the current situation

The evaluation report that the Commission intended to submit to the Council and Parliament further to Article 14 of the directive, due on 15 September 2010, was postponed until early 2011 to take on board further data and analysis. The state of notifications will also be included in that evaluation.

Evaluation results: Priorities and planned action (2011 and beyond)

The Commission will proceed with pending infringement cases and open new ones against Member States where the applicable law was annulled because of rulings of Constitutional Courts, unless the Member States concerned enact new legislation.

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553 The Netherlands, Austria, Estonia, United Kingdom, Cyprus, Greece, Luxemburg, Slovenia, Sweden, Lithuania, Latvia, Czech Republic, Belgium, Poland, Finland, Germany and upon accession Bulgaria and Romania.

16.6.2. European Programme for Critical Infrastructure Protection

Current position: General introduction

The Directive 2008/114/EC on the Identification and Designation of European Critical Infrastructures and the Assessment of the Need to Improve their Protection was adopted in December 2008 and entered into force in January 2009.

Its objectives are:

– To establish a procedure to identify European Critical Infrastructures (ECIs);

– To establish a procedure to designate infrastructures as European Critical Infrastructures;

– To devise a common approach to assess whether it is necessary to improve the protection of such infrastructures.

Current position — Report on work done in 2010

The deadline for implementing Directive 2008/114/EC is January 2011, and most Member States are working on identifying potential ECIs in the energy and transport sectors. Generally, work on identification is being carried out at national level by working groups bringing together the relevant national ministries or agencies, as well as associations of operators.

By the end of 2010, 14 Member States had notified measures that they consider constitute full transposition of the directive. A further two Member States had notified measures which they consider as constituting partial transposition by the same date. The Commission will examine these notifications in the course of 2011 and take the necessary actions also in respect of Member States which will not notify measures by the deadline.

The Commission continued to offer its support to the process of identification of potential ECIs. Two workshops have taken place at the Joint Research Centre in Ispra, with a view to exchanging practices and information on the implementation procedure in Member States. Both workshops also provided an opportunity to discuss the general framework for reviewing the directive, and both Member States and Commission made preliminary contributions on the structure and content of the process leading to the review.

Evaluation based on the current situation

The situation and volume of work in 2010 was stable and focused on exchanging information and good practices on the identification and designation of ECI experience in Member States.

Evaluation results: Priorities and planned action (2011 and beyond)

The review of Council Directive 2008/114/EC will begin in January 2012, i.e. three years after its entry into force. For a smooth review process, mutual trust and a sound basis for discussion between Member States, the Commission and the European Parliament must be established as early as possible. This is particularly important, as the legal basis of the directive changed with the entry into force of the Lisbon Treaty.

The voluntary ‘implementation’ workshops and the CIP contact point meetings will remain

the backbone of the review process throughout 2011 and beyond. If needed, extra meetings could be added, or side-events dedicated to preparing the review. In addition, the Commission will procure a separate study to inform the review process.

The Commission will deliver summary reports providing results from these workshops. Shortly before the start of the review process (January 2012), the Commission, supported by Member States, will put forward a general report summarising preparatory activities. This report will be the starting point for political discussions at Council level.

Moreover, a general discussion on the European Programme for Critical Infrastructure Protection will start in 2011.

16.6.3. Directive on preventing and combating trafficking in human beings, and protecting victims, replacing Framework Decision 2002/629/JHA

Current position: General introduction

In March 2010, the European Commission tabled a proposal for a new directive on trafficking in human beings, aimed at further approximating legislation and penalties, ensuring successful prosecution, better protection of victims and assistance to them, and prevention of trafficking. In December 2010, political agreement was reached on a final text.

The objectives of the directive are:

– To approximate substantive criminal law;

– To bring robust provisions on victims' rights in criminal procedures and on assistance;

– To facilitate prosecution of offenders, including extraterritorial jurisdiction;

– To step up preventive measures to discourage the demand that fosters trafficking.

16.6.4. Third pillar instruments

Current position: Report on work done in 2010

Monitoring in the context of ex-third pillar instruments was mainly done on the basis of implementation reports. These had to be produced following specific provisions in articles in the legal instrument itself.

In the case of the Council Framework Decision 2008/919/JHA of 28 November 2008, amending Framework Decision 2002/475/JHA on combating terrorism, Article 3 requested Member States to take the measures necessary to comply with the Framework Decision by 9 December 2010. During 2010, the Commission assisted Member States by organising two expert meetings on the transposition of the Framework Decision, on 19 April and 28 June.

The Commission is currently preparing an update of the first implementation report on the application of Framework Decision 2003/568/JHA of 22 July 2003 on combating corruption in the private sector. The report will be issued in mid-2011.

Also being prepared is an implementation report on Decision 2007/845/JHA, concerning cooperation between Asset Recovery Offices of the Member States in the field of tracing

and identification of proceeds of crime, or other property related to crime.

The Council Framework Decision 2008/841/JHA of 24 October 2008 on the fight against organised crime required Member States to take measures necessary to comply with its provisions before 11 May 2010 and to communicate the text of transposing legislation to the General Secretariat of the Council and to the Commission.

The Swedish Framework Decision (Council Framework Decision 2006/960/JHA) concerning simplification of the exchange of information and criminal intelligence across the European Union required the Commission to submit an evaluation report to the Council before 18 December 2010. Just four months after the implementation deadline had expired, the Commission organised a conference that sought to review implementation of this instrument. The outcome of that conference, including detailed replies to the Commission's questionnaire, fed into a second conference on implementation, also organised in 2010.

Evaluation based on the current situation

Regarding the Council Framework Decision 2008/919/JHA of 28 November 2008 amending Framework Decision 2002/475/JHA on combating terrorism, only three Member States fully complied with their obligations and informed the Commission in time about provisions to transpose the Framework Decision. The Commission has sent a reminder to the other Member States concerned. The deadline set for submitting notifications is 4 March 2011.

Evaluation results: Priorities and planned action (2011 and beyond)

In accordance with Article 3(2) of the Framework Decision 2008/919/JHA and on the basis of information received from Member States, the Commission will prepare a report to assess whether Member States have taken the measures necessary to comply with the Framework Decision.

The second report on implementation of Framework Decision 2003/568 on combating corruption in the private sector and the report on implementation of Decision 2007/845/JHA concerning cooperation between Asset Recovery Offices of the Member States in the field of tracing and identification of proceeds of crime, or other property related to, crime, are scheduled for 2011.

Regarding Council Framework Decision 2008/841/JHA on the fight against organised crime, on the basis of a Council report based on information provided by Member States and a written report transmitted by the Commission, the Council will, before 11 November 2012, assess the extent to which Member States have complied with the Framework Decision.

17. JUSTICE

17.1. Free movement of persons

17.1.1. Current Position

17.1.1.1. Introduction

Free movement is a core right of EU citizens and their family members. It is one of the most

cherished rights by EU citizens. Citizenship of the Union confers on every EU citizen a primary and individual right to move and reside freely in the EU. It should therefore be strictly enforced.

Article 21(1) TFEU stipulates that every citizen of the Union shall have the right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give them effect. These limitations and conditions are to be found in Directive 2004/38/EC[554] which codified the existing legislation and case-law in the area of free movement, streamlined the procedures, cut the red tape and simplified the legal text in the interest of reader-friendliness and clarity.

17.1.1.2. Report of work done in 2010

Building on the 2008 report[555] on the application of Directive 2004/38/EC which concluded that the transposition of the Directive in Member States was not satisfactory and identified a large number of shortcomings and following the 2009 guidelines[556] for better transposition and application of Directive 2004/38/EC which provided guidance to Member States on how to apply Directive 2004/38/EC correctly, in 2010 the Commission focused on enforcing the EU rules on free movement.

In accordance with the priorities established by the previous Annual Report on the Control of Application of Community law, the Commission held bilateral meetings with almost all Member States to discuss the issues of implementation of Directive 2004/38/EC identified as problematic. By the end of 2010, the Commission met the authorities of 22 Member States[557], thus largely complying with its commitments.

A group of Member States' experts on the practical application of Directive 2004/38/EC established in 2009 met three times in 2010 to discuss issues related to the correct application of EU law in the area of free movement, particularly on fighting abuses and frauds. The exchange of views, know-how and best practices are contributing towards improved implementation of EU law and the case-law of the Court of Justice of the European Union. The group continues to meet on a regular basis.

In 2010, the Commission continued to deal with a large number of enquiries and complaints in the area of free movement of persons; 781 enquiries and complaints were received.There were also 44 written EP questions and 31 petitions in this area.

The Commission made an extensive use of informal dispute-settlement mechanisms, such as SOLVIT. According to the 2010 report on development and performance of the SOLVIT

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554 Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States (OJ L 158 of 30 April 2004, p. 77).

555 COM(2008)840 final.

556 COM(2009)313 final.

557 Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Ireland, Spain, France, Italy, Latvia, Hungary, Malta, Austria, Poland, Portugal, Romania, Slovak Republic, Slovenia, The Netherlands, Finland, Sweden, United Kingdom.

network[558], in 2010 SOLVIT centres closed 306 cases concerning residence rights, which amounted to 23% of the total of all SOLVIT cases, managing to solve 91% of them. There was a decrease in cases in comparison to 2009 (549 cases handled and closed) because one Member State has reduced the delays in handling applications for residence cards for EU citizens' family members, in response to the high number of problems flagged, among others by SOLVIT. Progress has also been made with regard to other cases under Article 258 TFEU, where priority was given to older cases.

Concerning cases raising issues of principle or having particularly far reaching negative impact for citizens, the United Kingdom informed the Commission in October 2010 that it has abolished delays in handling applications for residence cards for EU citizens' family members. A simplified guide on EU law for EU citizens on freedom of movement was updated, published and widely distributed in 2010 in all EU languages.

17.1.2. **Evaluation based on the current situation**

The analysis and the work done by the Commission in 2010 showed that the situation in the area of free movement of persons requires further improvement.

In October 2010, the Commission adopted the EU citizenship report 2010 "Dismantling the obstacle to EU citizens' rights"[559], which gives a comprehensive overview of the obstacles citizens still face and makes proposals on how they can best be removed. The report underlines the fact that the right to free movement is hindered by divergent and incorrect application of EU law and by cumbersome administrative procedures. To facilitate free movement of EU citizens and their third-country family members, the Commission will enforce EU rules strictly, including on non-discrimination, by promoting good practices and increased awareness of EU rules on the ground and by stepping up the dissemination of information to EU citizens about their free movement rights.

Alike, the 2008 report on the application of Directive 2004/38/EC concluded that the overall transposition of the Directive was rather disappointing. The situation improved gradually in 2010. The 2009 guidelines and the exchange of views and information with the Member States during the bilateral meetings held in 2010 provided them further guidance on what legislative amendments are needed in their national legislation and on how to apply the Directive 2004/38/EC correctly, with the objective of dismantling the obstacles to free movement of EU citizens and of making the EU an area of security, freedom and justice. To address the unsatisfactory implementation, the Commission continued working in 2010 at technical level with the Member States within the group of experts. The work of the group in 2010 focused on the sensitive areas of fighting frauds and abuses, but also on how to improve information about residence rights.

Many EU citizens have complained about Member States not implementing correctly their national law transposing EU law in the area of free movement of EU citizens. The complaints concern various problematic areas in the field of free movement and residence rights. An important issue addressed by the Commission in 2010 related to the delays in handling residence applications of EU citizens and their family members in the United Kingdom. Some

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558 Report under finalisation.

559 COM(2010) 603 final

350 individual complaints were received by the Commission on this issue since October 2008 alleging that the authorities of that Member State were failing to meet the deadlines imposed by national and EU law. Following contacts with the Member State, a comprehensive solution was implemented and in October 2010 the Commission was informed that the backlog has been cleared and that measures were taken to avoid such backlogs in future. The Commission will continue to closely monitor the situation.

This particular issue underlines the crucial role Member States play in the practical implementation of EU law and that correct transposition must be accompanied by robust measures enabling national authorities to effectively apply the law. This is even more important in the areas of direct concern to large groups of EU citizens, such as residence applications.

In 2010 first positive results could be visible, since a significant number of Member States, following the bilateral meetings and exchanges with the Commission, modified their law or announced amendments including a precise calendar to ensure full transposition of Directive 2004/38/EC thoroughly discussed. Improvement of transposition will remain a priority for the Commission in 2011.

17.1.3. **Evaluation results**

17.1.3.1. Priorities

In 2011 the Commission will pursue the infringement cases related to the incorrect transposition of Directive 2004/38/EC. It will also address the infringement proceeding raising issues of principle or having particularly far reaching negative impact for citizens.

17.1.3.2. Planned action (2011 and beyond)

As from 2011 the Commission will step up its efforts to ensure that the Directive is correctly transposed and implemented across the EU, using fully its powers under the Treaty and launching infringement proceedings, when necessary.

The Commission will continue working at technical level with the Member States in the group of experts.

The Commission will continue to inform EU citizens about their rights under the Directive. An updated simplified guide on EU law for EU citizens on freedom of movement, which was launched in 2010, will continue to be widely distributed. The Commission will encourage Member States to launch awareness-raising campaigns to inform EU citizens of their rights under Article 34 of the Directive.

17.1.4. **Summary**

The Commission attaches great importance to the concrete fulfilment of the fundamental and personal right of EU citizens and their family members to move and reside freely. The transposition and implementation of the Directive in Member States need to be further completed. The Commission has been stepping up its efforts to ensure full enforcement and

will continue to work closely together with Member States to solve more problematic issues of free movement and share best practices. Together with intensified information to citizens this should bring real improvements in the daily life of EU citizens and their family members.

17.2. Citizenship

17.2.1. Current position

17.2.1.1. Introduction

Article 22 of the Treaty on the Functioning of the European Union grants the right to EU citizens to vote and to stand as candidates in municipal and European elections in the Member State where they reside, without holding the nationality of that State. These rights were put into effect by Directive 1993/109/EC[560] as regards European Parliament elections and Directive 1994/80/EC[561] as regards municipal elections. Directive 1994/80 was modified by Directive 1996/30/EC and Directive 2006/106/EC in view of consecutive enlargements of the Union.

17.2.1.2. Report of work done in 2010

In October 2010, the Commission adopted the Report on the implementation of EU law in the 2009 European elections[562]. The report concludes that on the whole, the legal conditions allowing EU citizens to exercise their right to vote and to stand as candidates in their Member State of residence are fulfilled. As for the few issues of transposition of Directive 93/109/EC and of the Act of 1976 that were identified in the report, a number of EU Pilot (pre-infringement) cases have been opened during 2010.

In particular, six cases were opened concerning the transposition of Directive 93/109/EC, one case concerning the implementation of the Act of 1976 on the election of Members of the European Parliament and five cases concerning the right of EU citizens to become members or to found a political party in the Member State where they reside.

The Commission has also dealt with 97 enquiries and complaints on citizenship and electoral rights of the EU citizens: 55 on citizenship and 42 on electoral rights. In 2010, there were 14 written EP questions and 5 petitions in this area. This shows the increasing awareness and interest of EU citizens concerning their electoral rights.

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560 Council Directive 93/109/EC of 6 December 1993 laying down detailed arrangements for the exercise of the right to vote and stand as a candidate in elections to the European Parliament for citizens of the Union residing in a Member State of which they are not nationals.

561 Council Directive 94/80/EC of 19 December 1994 laying down detailed arrangements for the exercise of the right to vote and to stand as a candidate in municipal elections by citizens of the Union residing in a Member State of which they are not nationals.

562 Report on the election of Members of the European Parliament (1976 Act as amended by Decision2002/772/EC, Euratom) and on the participation of European Union citizens in elections for theEuropean Parliament in the Member State of residence (Directive 93/109/EC); COM(2010)605

17.2.2. **Evaluation based on the current situation**

Essentially, all Member States transposed the Union legislation in electoral matters. No infringement proceedings were open as of 31 December 2010. The situation in the field of the electoral rights of EU citizens can be considered broadly satisfactory.

However, as a result of a compatibility study concluded in February 2009, EU Pilot (pre-infringement) cases were opened in 2010. The replies of the Member States are currently under examination.

As far as the right of EU citizens to vote and stand as candidates in the municipal elections in the Member State of residence is concerned, a Commission Report assessing the implementation of Directive 93/109/EC is planned for 2011.

17.2.3. **Evaluation results**

17.2.3.1. Priorities:

In 2011, the Commission will continue the work to ensure conformity of national legislations of Member States with Directive 93/109/EC (participation of EU citizens in European elections) and Directive 94/80/EC (participation of EU citizens in municipal elections) and to ensure conformity across the EU member States with the 1976 Act on the elections of the representatives of the European Parliament.

17.2.3.2. Planned action (2011 and beyond)

As from 2011, the Commission will step up its efforts to ensure that the instruments in electoral matters are correctly transposed and implemented. The Commission will continue working at technical level with the Member States in the group of experts and launch infringement proceedings when necessary.

A report on the implementation of Directive 94/80/EC (participation of EU citizens in municipal elections) is planned for 2011.

On the basis of a study on possible developments of the EU law on electoral rights, concluded in 2010, and in the light of the 2010 report on European elections, the Commission is considering options to better achieve the objectives of Directive 93/109/EC. The objective is to improve the efficiency of the administrative proceedings to facilitate participation of candidates in the elections, as well as to improve the information exchange mechanism for preventing double voting.

A proposal to amend the Directive, presented by the Commission in 2006[563], is currently with the Council and negotiations are suspended. Any new step for improvements has to take into account the outcome of the electoral reform ongoing in the European Parliament which may have a direct effect on the Directive.

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563 COM(2006)791Proposal for a Council Directive amending Directive 93/109.

17.2.4. **Summary**

Electoral rights of the EU citizens accompany their right to free movement and are part of the rights attached to the Citizenship of the Union: EU law in the electoral field grants the right to the EU citizens to participate in municipal and European elections in the Member State where they reside without holding the nationality of that State. Detailed arrangements for the exercise of these rights are to be found in Directive 94/80/EC with regard to municipal elections and in Directive 93/109/EC with regard to European elections. The Act of 1976 on the election of representatives of the European Parliament as amended by Council Decision 2002/772/EC, lays down common principles for the Member States in the organisation of the European elections.

Transposition of Union law in electoral matters can generally be considered satisfactory. However, EU Pilot (pre-infringement) cases were opened in 2010 addressing a number of issues. These issues concern inter alia details of the arrangements in the organisation of elections, such as the procedure for registering voters or candidates on the electoral rolls. They also concern the possibility of founding or participate in a political party for those EU citizens residing in another EU Member State who want to stand as candidates in municipal and European elections.

The Commission should continue to focus on checking and ensuring correct transposition and implementation of Directives 93/109/EC and 94/80/EC and of the Act of 1976, as amended by Council Decision 2002/772. This will need close work at technical level with the Member States and use of infringement proceedings, where necessary.

The Commission shall report on the implementation of Directive 94/80/EC on municipal elections in its Report planned for 2011. The Commission will also pursue preparatory work to consider how to go forward with the modification of Directive 93/109.

17.3. Fundamental rights

17.3.1. **Current Position**

17.3.1.1. Introduction

With the entry into force of the Lisbon Treaty the Charter is now legally binding on the EU's institutions and on Member States when they are implementing EU law. The foreseen accession of the EU to the European Convention of Human Rights will complement the strong protection of fundamental rights that already exists in the Union's legal order through the EU's own Charter of Fundamental Rights and the case law on fundamental rights developed over time by the Court of Justice.

The important number of letters received by the Commission reveals a strong interest and expectation from citizens on fundamental rights. It also reveals that more information is needed to explain that the Commission has no general powers to intervene in cases of violations of fundamental rights and that it can do so only if an issue of Union law is involved.

The Commission shall ensure that when implementing EU legislation, Member States strictly respect fundamental rights and that cases involving fundamental rights should be treated as a matter of priority. This obligation will become even more essential when the EU will gain full membership to the European Convention of Human Rights.

17.3.1.2. Report of work done in 2010

The Commission has published on 19 October 2010 a Communication setting the "Strategy for the effective implementation of the Charter of Fundamental Rights by the European Union"[564]. The objective of the Charter Strategy is to make the fundamental rights as effective as possible. The respect of the rights enshrined in the Charter must be upheld throughout the entire legislative process. The Commission reinforced the evaluation of the impact on fundamental rights of its legislative proposals by establishing a "Fundamental Rights Check-List" to check systematically the compliance of the proposals with the Charter.

The 2010 Report on the Application of the EU Charter of Fundamental Rights, to be adopted in 2011, will show that all Commission departments in 2010 received more than 4000 letters from the general public on fundamental rights issues. Approximately one third concerned situations where the Charter could apply, while the rest did not involve Union law and fell outside the powers of the Commission to control the application of Union law. Approximately half of petitions and questions from the European Parliament concerned cases where the Charter could apply and the rest were related to issues outside of EU competence.

The EU Treaty (Article 6 paragraph 2 TEU) requires the EU to become a member of the European Convention on Human Rights. The Commission has thus recommended on 17 March 2010 to the Council to open accession negotiations with the Council of Europe. On the basis of a mandate agreed by the Council, the Commission launched accession negotiations on 7 July 2010. The EU's accession to the European Convention of Human Rights will complement the strong protection of fundamental rights that already exists in the Union's legal order through the EU's own Charter of Fundamental Rights and the fundamental rights developed over time by the Court of Justice.

17.3.2. **Evaluation based on the current situation**

The 2010 Charter Strategy pointed out that for the rights enshrined in the Charter to be effective the public needs to be well informed about these rights and how to enforce them in practice when they are violated. Citizens should know where they can turn for assistance in cases of violations of fundamental rights. The Commission will promote awareness raising and will explain in particular what it can and cannot do.

17.3.3. **Evaluation results**

The Charter Strategy announced the presentation of an Annual Report on the Application of the EU Charter of the Fundamental Rights, as an essential tool in implementing the rights and

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564 Communication from the Commission of 19 October 2010 on the Strategy for the effective implementation of the Charter of Fundamental Rights by the EU, COM/2010/0573 final, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0573:FIN:EN:PDF

freedoms of the Charter. These annual reports will track the progress being made and also the new concerns that are arising. The Annual Report will be the track record on the implementation of all the provisions of the Charter.

17.3.4. **Summary**

The Charter needs to be put into practice whenever EU law applies, so that people can effectively enjoy their fundamental rights. That is why the Commission, in 2010, adopted a Strategy on the effective implementation of the Charter. The Charter Strategy pointed out the need to inform the public about fundamental rights and how to enforce them in practice when they are violated.

17.4. Protection of personal data

17.4.1. **Current position**

17.4.1.1. Introduction

Personal data is collected and used in many aspects of everyday life. The protection of personal data is a fundamental right, which requires that individuals must be protected with regard to the processing of personal data. Personal data should be able to flow freely from one Member State to another. In order to remove the obstacles to the free movement of such data without diminishing the protection of personal data at the level of the EU, Directive 95/46/EC (the data protection Directive) was developed to harmonise national provisions in this field.

In 2010, the Commission continued the monitoring of the correct application of the Directive 95/46/EC on data protection, the main piece of legislation in this area.

As concerns the protection of personal data processed in the framework of police and judicial cooperation in criminal matters, the Commission started monitoring the implementation of Framework Decision 2008/977/JHA at the end of 2010. Member States were obliged to have taken the necessary measures and to have informed the Commission by 27 November 2010.

17.4.1.2. Report of the work done in 2010

The year 2010 has been marked by the ongoing works in the context of the reform of the data protection framework. Two stakeholder conferences were organised in June/July 2010 which were based on a list of questions prepared by the Commission. The contributions provided valuable insight on issues covered by Directive 95/46/EC which need to be revised. In November 2010, the Commission presented a comprehensive approach on personal data protection in the EU.

In parallel, works started on an impact assessment on a new legal framework, replacing and amending the legal instruments currently in force in the area of data protection.

The Commission has received 87 letters (information/documents requests and complaints) from citizens, 55 parliamentary questions and 3 petitions in 2010.

In 2010, the Commission was also dealing with 13 infringement cases in the data protection field. The number of cases referring to the incorrect application of the data protection

directive was higher than the non-conformity cases.

The conclusions of the European Court of Justice in an infringement case against Germany on the lack of independence of the data protection authority of 9.3.2010 (C-518/07) were essential and allowed the Commission to advance a similar case against Austria, bringing the matter before the Court of Justice at the end of 2010. As the data protection authorities have the crucial task of protecting the fundamental right to data protection, the Commission will continue to investigate the correct application of the provision contained in Article 28 of Directive 95/46/EC referring to the independence of data protection authorities.

The Commission advanced a case against the UK for concerns in relation to the transposition of Directive 95/46/EC and its application by UK courts. The Commission has worked with the UK authorities to resolve a number of issues, but several remained, notably limitations of the Information Commissioner's Office's powers or the possibility of courts in the UK to refuse the right to have personal data rectified or erased. Therefore the Commission adopted a reasoned opinion against the UK.

17.4.2. **Evaluation based on the current situation**

The situation and volume of work in 2010 was stable regarding the infringement cases. The number of letters and enquiries has decreased while the number of parliamentary questions increased.

In terms of implementation of the Directive, the increased level of harmonisation that might have provided a solution has not been obtained. The improvement, which was hoped for and which could have resolved the difficulties identified during the first and the second review of the implementation of the Directive was neither achieved by the guidance of case law and of the opinions of the Article 29 Working Party nor through the Commission's infringement policy. Additionally developments such as the impact of new technologies and globalisation, divergent approaches in national law, application and enforcement, created uncertainties and contributed to administrative burden.

No new infringement cases have been opened in 2010.

17.4.3. **Evaluation results**

17.4.3.1. Priorities

The priority during 2010 was to advance with the elaboration of a new legal framework for data protection. The Commission has succeeded to identify/analyse a number of issues to be covered by the new instrument.

The Commission has also made significant progress in the handling of infringement cases which have been pending for a number of years.

17.4.3.2. Planned action (2011 and beyond)

The primary objective for 2011 will be the adoption of the new legislative framework for data

protection.

The Commission will also present a report on the implementation of Framework Decision 2008/977/JHA which will be based on the information received from the Member States. A stakeholder conference was held scheduled on 2 February 2011. Member States were given the possibility to discuss problems they encountered in the implementation process and to highlight issues they consider important in view of the currently ongoing review of the data protection framework.

The implementation of the ruling of the European Court on the lack of independence of the data protection authority in Germany was closely monitored. A letter of formal notice under Article 260(2) TFEU was notified to Germany on 7 April 2011 as Germany had not complied with the Court's ruling.

17.4.4. **Summary**

Work towards the reform of the current legislative data protection framework was the major objective in 2010. The adoption of the reform package is due in 2011.

Until the adoption of the new legislation, the Commission will continue to monitor the application of Directive 95/46/EC.

17.5. Judicial cooperation in civil matters

17.5.1. **Current position**

17.5.1.1. Introduction

Judicial cooperation in civil matters aims to contribute to the creation of a genuine European area of justice based on mutual recognition and trust. In particular, it aims to promote the elimination of obstacles to the good functioning of cross-border civil proceedings in the Member States and thus improve the daily life of citizens and businesses mainly by fostering access to justice. In this context, a considerable number of instruments have been adopted in the area of civil, commercial and family law establishing European rules on jurisdiction, applicable law, recognition and enforcement of judgements for cross-border civil justice cases.

17.5.1.2. Report of the work done in 2010

- <u>New legislation</u>

On 24 March 2010, the Commission adopted a package of proposals to respond to a request by a group of Member States to establish enhanced cooperation in the area of the law applicable to divorce and legal separation[565]. The enhanced cooperation package consists of two parts: first, a Council Decision that authorises enhanced cooperation for 14 Member

[565] Proposal for a Council Decision No …/2010/EU authorising enhanced cooperation in the area of the law applicable to divorce and legal separation, COM(2010) 104 final/2 and Proposal for a Council Regulation (EU) implementing enhanced cooperation in the area of the law applicable to divorce and legal separation, COM(2010)105 final/2.

States and, second, a Council Regulation containing the actual measures applying in participating Member States.

On 12 July 2010, the Council of the European Union, with the consent of the European Parliament, authorised 14 Member States to go ahead with the first enhanced cooperation in the history of the European Union and implement rules enabling international couples to agree on which law would apply to their divorce or legal separation[566]. The proposal will increase flexibility and autonomy by giving spouses a possibility to choose the law which will apply to their divorce. The new Regulation[567] entered into force on 30 December 2010 and will apply as from 21 June 2012.

Proposed legislation

Following the 2009 Report evaluating the application of Regulation 44/2001 (Brussels I) and the Green Paper identifying ways to improve its functioning, a Proposal for the amendment to Regulation (EC) n°44/2001 (Brussels I) was adopted on 14 December 2010[568].

Preparatory legislative work

The Impact assessment on Proposals for a Regulation on matrimonial property rights and property rights of registered partnerships was finalised with the view to propose two Regulations to cover questions on jurisdiction, applicable law recognition and enforcement of judgements of international couples' property rights.

A Green Paper on the free circulation of documents within the European Union was adopted on 14 December 2010. In this paper, the Commission asks questions on how to improve the free circulation of public documents, such as diplomas, proof of nationality, property deeds. The Green Paper is open for consultation until April 2011.

As to the evaluation exercises, evaluation studies on the Legal Aid Directive and the EEO Regulation as well as the assignment of claims under the Rome I Regulation were launched in 2010.

External Competence

During 2010 negotiations concerning the proposal for a Council Decision on the signature and conclusion of the Convention on the International Recovery of Child Support and Other Forms of Family Maintenance continued at the Council; the negotiations are now progressing towards a definitive agreement which could be reached in the course of 2011.

The first two Commission's decisions based on Regulations No 662/2009 and 664/2009 were adopted and three Commission Decisions with Denmark were signed[569].

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566 Council Decision 2010/405/EU of 12 July 2010 authorising enhanced cooperation in the area of the law applicable to divorce and legal separation, OJ L 189, 22.7.2010, p. 12.

567 Council Regulation N 1259/2010/EU of 20 December 2010 implementing enhanced cooperation in the area of the law applicable to divorce and legal separation, OJ L 343, 3.12.2010, p. 10.

568 COM (2010) 748 final.

569 Commission Decision authorising Denmark to ratify the 1995 Unidroit Convention on Stolen or Illegally Exported Cultural Objects – Commission Decision of 22.4.2010 authorising Denmark to ratify

Cooperation with other international organisations (as HCCH, Council of Europe, UNIDROIT, UNCITRAL, CIEC) has been further carried out with participation in the relevant meetings and follow-up of the Conventions in the area of civil judicial cooperation.

Monitoring of enlargement issues and contacts with European Neighbour Policy countries continued on a regular basis.

The international negotiations related to the Space Protocol to the Cape Town Convention progressed.

European Judicial Network in civil and commercial matters (EJN)

In 2010, the European Judicial Network in civil and commercial matters prepared the entry into force of its amending decision (Decision 568/2009/EC), especially with respect to the association of the legal professions to the network, new tasks for the contact points and various projects aimed at increasing the level of awareness of the Network with the judicial authorities, citizens and companies.

In 2010, five contact points meetings have been organised which were dealing, amongst others, with the following topics: parental responsibility, the European order for payment procedure, the European Small Claims Procedure, the service of documents, legal aid and the migration of the EJN website to the European e-Justice portal.

A citizens' guide to cross-border civil litigation in the European Union has been published in 2010 on the portal of the EJN.

17.5.2. **Evaluation based on the current situation**

In 2010, the Commission continued to monitor the correct application of the civil justice *acquis*. The Commission answered 91 complaints. The number of infringement cases pending decreased from 14 to 4. The remaining ones will be dealt with in the forthcoming period.

The Commission is also contributing to the correct interpretation of *acquis* through observations to the preliminary questions to the Court of Justice. With the entering into force of the Lisbon Treaty, which allows also first instance courts to ask the Court of Justice for preliminary rulings, their number has increased considerably in the area of civil justice.

In the area of family law, the new urgent preliminary ruling procedure (PPU) is available since 1 March 2008 and has also increased the number of cases. The new procedure enables the Court of Justice to deal much more quickly with issues relating to the area of freedom, security and justice. Such an issue may arise, for example, in proceedings concerning parental responsibility if the jurisdiction under EU law of the national court hearing the case depends on the answer to the question referred for a preliminary ruling.

In 2010, Commission observations were made in 20 cases in civil justice, 4 of them being "PPU" procedures doubling in number compared to 2009.

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the Protocol to amend the Convention on Third Party Liability in the Field of Nuclear Energy of 29 July 1960, as amended by the Additional Protocol of 28 January 1964 and by the Protocol of 16 November 1982 – Commission Decision of 22.4.2010 authorising Denmark to ratify the International Convention on Civil Liability for Bunker Oil Pollution Damage, 2001 (the Bunkers Convention).

The Commission gave opinions on 14 preliminary questions which concerned the application of the Regulation (EC) 44/2001 (Brussels I), the most important one being the *Pammer – Alpenhof* ruling.

In the Cases C-585/08 and C-144/09 *Pammer – Alpenhof*, the Court of Justice explained the rules of jurisdiction in European Union law that are applicable to consumer contracts, in relation to services offered on the internet. Mere use of a website by the trader does not in itself trigger application of the rules of jurisdiction for the protection of consumers in other Member States.

In the family law area, 4 of the Preliminary ruling cases were 'PPU' procedures relating to the interpretation of Regulation (EC) No 2201/2003 (the 'Brussels II a Regulation').

In the Case C-211/10 *PPU* the Court of Justice ruled that the enforcement of a certified judgment which required the return of the child could not be refused either on account of a judgment delivered subsequently by a court of the Member State of enforcement or on account of a change of circumstances after its delivery. In Case C-400/10 *PPU*, the Court of Justice stated that the removal of a child by a parent to another Member State was wrongful only if it was in breach of custody rights granted by national law. Furthermore, the Court ruled that national legislation under which the acquisition of rights of custody by a father who was not married to the mother of the child was dependent on his obtaining a court judgment was not in breach of the right to respect for private and family life protected by the Charter of Fundamental Rights of the EU. The Court of Justice's judgment in Case C-491/10 *PPU* clarifies that the court with jurisdiction in the Member State of enforcement cannot oppose the enforcement of a certified judgment, ordering the return of a child who has been wrongfully removed, on the ground that the court of the Member State of origin which handed down that judgment may have infringed Article 42 of Regulation (EC) No 2201/2003 interpreted in accordance with Article 24 of the Charter of Fundamental Rights of the European Union. In Case C-497/10 *PPU* the Court of Justice was given the opportunity to interpret the concept of 'habitual residence' for the purposes of the provisions of Regulation (EC) No 2201/2003 that make reference to a child's habitual residence in a Member State.

Awareness raising activities

The Commission published a citizens' guide to cross-border civil litigation in the European Union in all languages. The European Union has a system of laws in place designed to help individuals and businesses with cross-border litigations. The Guide aims to explain these laws and the principles behind these European procedures and how citizens can choose whether they want to use them. The "Compendium of Community Legislation on Judicial Cooperation in civil and commercial matters" was published in all languages and distributed in the 27 Member States.

In October 2010, at the same time as the European Day of Civil Justice, the Commission published a Eurobarometer survey in civil justice.

17.5.3. **Evaluation results**

17.5.3.1. Planned action (2011 and beyond)

A wide range of activities has been launched in order to improve the conditions for cross-border trade and consumer rights, such as the revision of the Brussels I regulation and the

legislative proposal on attachment of bank accounts which will contribute to reducing costs for businesses in line with the objectives of the flagship initiative Industrial policy for the globalisation era. Together with the foreseen legislation on European contract law, these activities strongly aim at improving consumer confidence in cross-border trade and increase business activities in cross-border trade.

The proposals on matrimonial property rights and property rights of registered partnerships are planned to be adopted in 2011. Both Regulations will include provisions on jurisdiction rules, applicable law rules, and recognition and enforcement rules. As regards applicable law, the proposed Regulations will in particular provide for objective criteria, allowing determining the law applicable to the assets of the couples and should also explore the spouses' possibilities of choosing, to a certain extent, the law applicable to their assets. The proposals will also deal with the question of jurisdiction. Its provisions will have to be consistent with existing or future rules, relating to divorce proceedings and successions.

17.5.4. **Summary**

With the aim of facilitating the life of individuals and businesses involved in cross-border litigation, a wide range of activities has taken place in the area of judicial cooperation in civil matters during 2010. The European Union adopted new legislation on the question of the law applicable to divorce and legal separation using for the first time in its history the enhanced cooperation procedure. Intense preparatory legislative work has been carried out by means of impact assessment studies, evaluation reports and Green Paper consultations. A proposal for revising existing legislation has been put forward to improve and facilitate the circulation of judgments across the European Union. Particular attention has been given to the correct implementation and application of the civil justice *acquis*. The role of the European Judicial Network in civil and commercial matters has been reinforced. Numerous preliminary questions to the Court of Justice of the European Union gave the Commission the opportunity to contribute to the interpretation of civil justice instruments. With regard to the Union's external competence, cooperation with international organisations and negotiations on questions of private international law were carried out. Last but not least, various activities took place aiming at measuring and raising public awareness across the EU of civil justice instruments and procedures.

17.6. Consumer and marketing law

17.6.1. **Current position**

17.6.1.1. Introduction

There are more than 500 million consumers in Europe and their expenditure represents over half of the EU’s gross domestic product (GDP). Consumers are essential to economic growth and job creation in a large market of products and services.

Directorate-General Justice's responsibility for consumer and marketing law is embedded in the Commission's Consumer Policy Strategy as well as in the implementation of the Stockholm Programme, the aim of which is to create an area of freedom, security and justice for Europe's citizens. The objective in consumer and contract law is to maintain and develop an effective legislative framework which promotes the economic interests of European consumers and ensures an open, fair and transparent internal market. This will allow consumers to exercise real choice, give them the required protection, while providing a

level playing field and predictable rules for businesses and excluding rogue traders, thereby helping consumers and businesses take full advantage of the market's potential.

Directorate-General for Justice is in charge of eight directives in the area of consumer and marketing law. In 2010 it was active in both monitoring the transposition and application of these directives as well as the modernisation of the *acquis*.

17.6.1.2. Report of the work done in 2010

- Review of the Package Travel Directive

In the framework of the potential revision of the Package Travel Directive (90/314/ EEC), a public consultation was open until 7 February 2010. It mainly focused on possible ways of solving problems with the current rules. It also aimed to quantify the impacts of various possible legislative options. At the same time a public consultation on air passenger rights was initiated. It touched on a related topic, namely the possible introduction of passenger protection in the event of airline bankruptcy (There is currently no insolvency protection for standalone air tickets, i.e. for flights which are not included in a travel package). In April 2010, the Commission held a stakeholders' workshop to discuss different policy options. In the second half of 2010, the Commission worked on the impact assessment for the revision of the Directive taking account the parallel impact assessment on passenger protection in the event of airline insolvency.

- Negotiations on the proposal for a new directive on consumer rights

The co-decision legislative process in relation to the proposal for a new Directive on consumer rights has now come to a successful conclusion. The proposal, which was adopted by the Commission in 2008, intended to bring together and update the Distance Selling Directive 97/7/EC, the Doorstep Selling Directive 85/577/EEC, the Consumer Sale of Goods Directive 99/44/EC and the Unfair Contract Terms Directive 93/13/EEC, thereby reducing the legal fragmentation in the internal market. Intense negotiations on the proposal under the Belgian presidency led to the adoption of a general approach by the Council on 24 January 2011. The general approach focuses on distance and off-premises contracts and foresaw, with the exception of three opening clauses, to fully harmonise the information requirements, the right of withdrawal and the provisions on delivery and passing of risk. Directives 99/44/EC and 93/13/EEC would remain unchanged. The European Parliament adopted the agreed text in plenary on 23 June 2011. Formal adoption of the new Directive by the Council is expected in October 2011.

- Transposition, application and interpretation of the existing directives

Directive 2005/29/EC on Unfair Commercial Practices

The national laws transposing Directive 2005/29/EC have been in force in all Member States since the beginning of 2010. However, the transposition of the Directive continues to pose a number of challenges considering the important legal impact of full harmonisation in a broad area which was characterised by considerable differences in national rules and policies.

In order to ensure an adequate implementation of the Directive in the Member States, the Commission continued its transposition checks and discussions with Member States and stakeholders with a view to solving transposition problems. In this connection,

the Commission intervened in various cases referred to the Court of Justice for preliminary rulings, such as C-540/08 *Mediaprint* and C-122/10 *Ving Sverige* (judgement issued on 12 May 2011). In the Mediaprint case, the Court had to examine the compatibility of an Austrian provision banning the sale of newspapers combined with the possibility to take part in a competition (i.e. sales of newspapers with so-called "bonuses"), and stated that "[…] *the Directive must be interpreted as precluding a national provision, such as that at issue in the main proceedings, which lays down a general prohibition on sales with bonuses and is not only designed to protect consumers but also pursues other objectives*".

In 2010 the Commission started the preparation of the report on the application of the Directive (as provided for by Article 18 of the Directive) and launched a call for tender for a study to assess the application of the Directive in the fields of financial services and immovable property. In the report the Commission will address various issues including the effects of full harmonisation in areas such as sales promotions.

To promote a common understanding and to develop a uniform application of the Directive, the Commission worked on the development of a legal (online) database for the Directive. The database will make available to the public information on the transposition and implementation measures in the Member States, relevant decisions of the European Court of Justice, the leading national jurisprudence and administrative practice, relevant legal literature, guidelines from national authorities, codes of conduct etc. This database was launched at a conference in July and will be publicly available as from July 2011.

Other consumer protection directives

In 2010 the Commission continued infringement proceedings resulting from systematic checks on the quality of transposition of certain consumer protection directives. In addition, its services dealt with a number of complaints identifying potential implementation problems. The Commission also replied to numerous parliamentary questions and correspondence from citizens.

In particular, the Commission closed all infringement proceedings based on the inadequate transposition of Directive 93/13/EEC on unfair terms in consumer contracts which were opened in 2008. In 2010 the two remaining cases were closed since the CZ and SK changed their legislation following a reasoned opinion[570].

Three out of the nine infringement cases opened in 2009[571] in relation to deficiencies in the transposition of Directive 99/44/EC on the sale of consumer goods and associated guarantees were closed after a letter of formal notice. In six cases the Commission issued reasoned opinions in 2010. Two of these cases were closed following legislative changes in the Member States concerned[572]. In the four remaining cases[573] the Member States concerned have announced legislative changes.

In relation to Directive 90/314/EEC on package travel, PL, following the Commission's letter of formal notice, amended its national rules transposing Article 7 of the Directive. This

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570 Commission's press release IP/09/1451.
571 Commission's press release IP/09/1032.
572 Luxembourg and Greece.
573 Czech Republic, Estonia, Poland and Slovenia.

provision obliges Member States to ensure that consumers are guaranteed a refund of the money paid over and repatriation in case of the organiser's insolvency.

Finally, there were a number of new requests for preliminary rulings under Article 267 TFEU in relation to different consumer protection directives as well as rulings on questions that had previously been submitted to the Court of Justice. Some of these cases are mentioned below.

In Case C-215/08 *E. Friz* the Court ruled that Directive 85/577/EEC does apply to contracts concerning a consumer's entry in a closed-end real property fund established in the form of a partnership even though the principal purpose of joining is not to become a member of that partnership, but is a means of capital investment. If the consumer exercises his right of withdrawal from such partnership, Article 5 (2) of Directive 85/577/EEC does not preclude a national law according to which the consumer's claim against that partnership is calculated on the basis of the value of his interest at the date of his withdrawal from this membership; the consumer may thus get back less than the value of his capital contribution or have to participate in the losses of that fund.

In Case C-511/08 *Heinrich Heine* on a preliminary request from a German court concerning Directive 97/7/EC on distance contracts, the Court found that the provisions of Directive 97/7/EC on the legal consequences of the withdrawal clearly have as their purpose not to discourage consumers from exercising this right. Therefore, the directive precludes national legislation which, in the context of a distance contract, allows the supplier to charge the costs of delivering the goods to the consumer after the latter has exercised his right of withdrawal.

In Case C-484/08, *Caja de Ahorros y Monte de Piedad de Madrid*, the Court of Justice confirmed that, given its minimum harmonisation character, Directive 93/13/EEC on unfair terms in consumer contracts does not preclude national legislation which authorises a judicial review as to the unfairness of contractual terms which relate to the definition of the main subject-matter of the contract or to the adequacy of the price and remuneration, even in the case where those terms are drafted in plain, intelligible language[574].

In Case C-137/08 *VB Pénzügyi Lízing* the Court of Justice further developed its case law on Article 6(1)[575] of Directive 93/13/EEC on unfair terms in consumer contracts. Following on from previous judgments in relation to this provision[576] the Court concluded that national courts must investigate of their own motion whether a term conferring exclusive territorial jurisdiction in a contract concluded between a seller or supplier and a consumer, which is the subject of a dispute before it, falls within the scope of Directive 93/13 and, if it does, assess of its own motion whether such a term is unfair[577].

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574 See point 1 of the operative part of the Court's judgment of 3 June 2010.

575 Article 6 (1) reads: "Member States shall lay down that unfair terms used in a contract concluded with a consumer by a seller or supplier shall, as provided for under their national law, not be binding on the consumer and that the contract shall continue to bind the parties upon those terms if it is capable of continuing in existence without the unfair terms."

576 E.g. Cases C-243/08 *Pannon GSM,* and C-40/08 *Asturcom Telecomunicaciones.*

577 See point 3 of the operative part of the Court's judgment of 9 November 2010.

In Case C-76/10[578] *Pohotovosť s.r.a.* the Court of Justice established, in line with existing case law[579], that also in connection with the assessment of execution requests for arbitration awards which were granted in the absence of the consumer and have become final, national courts are obliged to examine, of their own motion, whether a sanction (e.g. a penalty) which was applied in the arbitration award is disproportionate, where they have available to them the necessary legal and factual elements and in so far as, under national rules of procedure, such an assessment can be carried out in similar actions of a domestic nature. The Court also concluded that the lack of indication of the annual percentage rate of charge required under the consumer credit legislation may be a decisive factor when determining whether the cost of the credit is expressed in plain intelligible language in the sense of Article 4 of Directive 93/13[580].

In the joined cases C-585/08 and C-144/09 Pammer & Alpenhof, concerning Directive 90/314/EEC on package travel, the Court confirmed that a voyage by freighter (which included accommodation) could be considered to be a "package travel" under the Directive.

17.6.2. **Evaluation based on the current situation**

The *acquis* in consumer and contract law has been transposed by all Member States. The quality of the transposition of several directives has improved or is about to improve in specific Member States due, in particular, to infringement proceedings. Several questions on the interpretation of particular provisions have been clarified through rulings by the Court of Justice. Specific implementation problems, may, however, still be discovered through new complaints and requests for preliminary rulings.

Continued efforts will be necessary in particular in relation to the assessment of the quality of transposition of Directive 2005/29/EC on Unfair Commercial Practices.

Since the time-limit for the transposition of Directive 2008/122/EC on timeshare will run out in February 2011, the monitoring of the transposition of this Directive will be made in the next period.

17.6.3. **Evaluation results**

17.6.3.1.Priorities

The revision of the Package Travel Directive (90/314/EEC) will be a priority in 2011.

In addition, the assessment of the implementation of Directive 2005/29/EC on unfair commercial practices and the preparation of the Report on the application of the Directive will receive particular attention. The same applies to the announced communication on the review of Directive 2006/114/EC on misleading and comparative advertising.

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578 Order of the Court of Justice of 16 November 2010, in particular point 54 and point 1 of the operative part. This case is also relevant from the point of view of the consumer credit legislation, which is in the remit of DG SANCO.

579 See in particular C-40/08 *Asturcom Telecomunicaciones*.

580 See, in particular, paragraphs 71 and 72, as well as point 3 of the operative part.

The monitoring of the timely transposition of Directive 2008/122/EC on timeshare, and, at a later stage, of the quality of the national transposition measures will also constitute an important objective for the Commission's services.

17.6.3.2. Planned action (2011 and beyond)

Several initiatives in the field of consumer and marketing law are included in the Commission's action plan for the implementation of the Stockholm Programme for the creation of an area of freedom security and justice for European Citizens in the period 2010-2014. Moreover, the Commission plans to issue a Consumer Agenda in the first quarter of 2012. The Consumer Agenda will build on the results achieved by the Commission's Consumer Policy Strategy for 2007-2013 and will bring together a number of initiatives in different areas which aim at improving the situation for Europe's consumers. It will contribute to fighting a number of obstacles to EU economic growth and improve the protection of consumers. Compared to the current Strategy, it will focus on the empowerment of consumers throughout the consumption life-cycle in a constantly changing environment. For example, it will address the challenges consumers face because of the increased importance of digital products and the online environment, increased complexity of decision making (information overload, more responsibility shifted to consumers), the need to move towards more sustainable patterns of consumption, population ageing and social inclusion/vulnerable consumers.

The actions planned in the coming years aim to improve the legislative framework, achieve transparency of the applicable rules and to ensure effective implementation in the Member States.

They include the revision of the Package Travel Directive (90/314/EEC), a Communication followed by a possible legislative proposal to bring existing EU consumer *acquis* in line with developments in the digital environment, as well as different activities in relation to the Directive on Unfair Commercial Practices (2005/29/EC). The latter actions involve increased transparency through the launch of the legal online database, the examination of the transposition in the Member States as well as the possible review of the Directive in connection with the report on the application of the Directive. This report as well as the planned communication on the Misleading and Comparative Advertising Directive (2006/114/EC) may lead to new legislative proposals.

The Commission will also have to decide whether and how the existing public database on the national rules transposing eight consumer protection directives and their application is to be continued beyond 2011.

Effective implementation by the Member States will remain a very important aspect. Therefore the Commission will supervise the transposition of recent directives (e.g. Directive 2008/122/EC on timeshare and the new Consumer Rights Directive once it has been implemented) and respond to complaints and, where appropriate, initiate infringement proceedings.

17.6.4. **Summary**

The combined action of Commission and Member States in 2010 has led to a high degree of conformity with the *acquis* in the area of consumer and marketing law. There are however important challenges ahead. In the near future one of the challenges is to create a more

coherent framework for cross-border shopping through clearer, simplified and harmonised rules that are uniformly enforced by national authorities, to increase EU-wide consumer confidence and enable consumers and businesses to fully benefit from the potential offered by the internal market. The implementation of the new Consumer Rights Directive will constitute one step towards this goal, but further action will be needed. This will require continued efforts by all players and, in particular, the Member States, whose role is to transpose and enforce Union law. Consumers and their organisations may help also by signalling problems in the implementation of particular rules.

17.7. Judicial cooperation in criminal matters

17.7.1. Current position

17.7.1.1. Introduction

With the entry into force of the Lisbon Treaty and the abolition of the pillars structure, the implementation of Framework Decisions in the field of judicial cooperation in criminal matters is expected to become less problematic in future. There is widespread recognition that implementation of third pillar instruments has been very poor. In the former third pillar, the Commission did not have enforcement powers and therefore could not start infringement procedures against Member States who did not implement Framework Decisions (or who implemented them belatedly or incorrectly).

17.7.1.2. Report of the work done in 2010

There are currently 12 mutual recognition instruments in criminal law, out of which five ought to have been implemented before or by 2010.

Out of the 12 instruments, only the European Arrest Warrant instrument has been implemented satisfactorily and on time. Framework Decision 2002/584/JHA on the European Arrest Warrant has been transposed by all Member States. Since the Framework Decision came into operation, in general the time taken to execute a warrant is provisionally estimated to have fallen from more than nine months to five weeks. This does not include frequent cases where the person consents to surrender, for which the average time taken is two weeks.

Implementation of the other instruments has not been satisfactory. In particular 4 instruments have been merely partially implemented so far:

- Council Framework Decision 2001/220/JHA of 15 March 2001 on the standing of victims in criminal proceedings has been poorly implemented. Although the scope of this Member States' initiative covering most of the rights of victims of all types of crimes is still relevant, European societies have evolved and there is growing awareness and a changing judicial culture to better address the rights and needs of victims of crime. This legislation has not been effective in meeting the desired outcome of addressing the needs of victims and achieving minimum standards across the EU. No Member State can claim to have fully implemented the instrument. The ineffectiveness of this legislation is also due to ambiguous drafting, lack of concrete obligations and lack of infringement possibilities under the former 3d pillar. In 2010, the Commission's services have carried out three expert meetings, a public consultation and an external impact assessment study, which confirmed these findings and helped to elaborate options for EU legislation.

- Council Framework Decision 2005/214/JHA of 24 February 2005 on the application of the principle of mutual recognition to financial penalties[581] has been implemented in 22 Member States, while implementation (or notification) from 5 Member States is still missing. Besides delays in its transposition, the quality of implementation leaves much to be desired. While some of the most important issues such as the abolition of dual criminality and the recognition of decisions without further formality are properly reflected in the implementing provisions, the grounds for refusal have been implemented mostly as obligatory grounds and additional grounds have been added in contravention of the Framework Decision. Little information is still available on its practical application.

- Council Framework Decision 2003/577/JHA of 22 July 2003 on the execution in the European Union of orders freezing property or evidence[582] has been implemented by 23 Member States. Little information is still available on the practical application of the legislation. Feedback from practitioners seems to indicate that the certificate to request the execution of freezing orders is rather difficult to complete and does not contain all the necessary fields. Therefore, judicial authorities tend to prefer recourse to the mutual legal assistance forms.

- Council Framework Decision 2006/783/JHA of October 2006 applies the principle of mutual recognition to confiscation orders issued by a court competent in criminal matters for the purpose of facilitating enforcement of such confiscation orders in a Member State other than the one in which the confiscation order was issued. The implementation report adopted by COM in August 2010 (delay resulted from the low number of notifications received by the deadline set by the FD: only two notifications were received on time) showed that the degree of implementation of FD is clearly not satisfactory. Thirteen Member States implemented the FD and notified it the Commission (at least informally) by the end of February 2010, fifteen months after the deadline set by the Framework Decision. The national implementing provisions received from the thirteen Member States are generally satisfactory and can be considered to be in line with the Framework Decision, especially regarding the most important issues such as the abolition of dual criminality checks and the recognition of decisions without further formality. Unfortunately, the analysis of grounds for refusal of recognition shows that almost all Member States included in their national legislation several additional grounds, in contravention of the Framework Decision. At present, notifications on the implementation of the Framework Decision have been received from 17 Member States.

Since the rules currently in force do not allow the Commission to initiate infringements proceedings in respect of legislation adopted before 1 December 2009 (for a transitional period of five years from the entry into force of the Lisbon Treaty), DG Justice had decided to launch an array of initiatives designed to improve the implementation record in this area, in particular by providing Member States with guidance and help during the implementation stage. These initiatives have included: a series of workshops with national legislators and practitioners on the three Framework Decisions mentioned above, preparation of handbooks for practitioners; streamlined contact with national authorities responsible for implementation; participation of Commission officials in national training for judges and prosecutors.

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581 Council Framework Decision 2005/214/JHA of 24 February 2005 on the application of the principle of mutual recognition to financial penalties, OJ L 76/16 of 22.3.2005.

582 Council Framework Decision 2003/577/JHA of 22 July 2003 on the execution in the European Union of orders freezing property or evidence, *OJ* L 196 of 2.8.2003, p. 45.

17.7.2. **Evaluation based on the current situation**

Workshops carried out in 2010 contributed to creating a new forum for discussion and exchange of information on the practical application of the Framework Decision and prompted implementation by a number of Member States. Workshops have been instrumental in increasing compliance with the Framework Decision and in streamlining contact between national authorities and the Commission, which in turn lead to better quality of implementing legislation. They have also allowed demonstrating an increasing cross-border use between certain Member States.

However, the degree of implementation of the three instruments above is still not satisfying.

17.7.3. **Evaluation results**

17.7.3.1. Priorities

The number of legislative proposals to be adopted in 2011 or already on the table imposes a prioritisation of the work. On that basis, the main priorities for 2011:

- Recast the Framework Decisions on the standing of victims in criminal proceedings in the framework of a broader package of legislative and non legislative measures to improve the situation of victims of crime;
- Recast the Framework Decisions on mutual recognition of confiscation orders and freezing orders;
- Monitoring the correct implementation of the Framework Decisions on probation orders and custodial sentences (see below);
- Monitoring of the conformity of national measures transposing Directive 2004/80 (compensation for victims of intentional crime).

17.7.3.2. Planned action (2011 and beyond)

Conclusions from the workshops and other meetings on the instruments led to the decision on recasting the Framework Decisions mentioned above in the framework of the 2011 Working Programme in view of achieving better quality legislation as well as improving effective measures in the fight of the cross-border criminality. Legislative proposals on all instruments will be adopted in 2011.

At the same time the Commission's implementation strategy will be continued concerning other instruments. In an attempt to prevent problems stemming from implementation at an earlier stage, Implementation Workshops with national legislators and practitioners this year will concern Framework Decisions 2008/947/JHA on probation measures and 2008/909/JHA on custodial sentences (transfer of prisoners), for which the implementation periods are still running until December 2011. Streamlined contacts with Member States may include implementation "package meetings", where all the different services involved in the implementation work could benefit from the expertise of the Commission services.

The legislative and non legislative package on victims' rights to be adopted in 2011 will include concrete measures to improve the implementation of the new legislation such as elaborating handbooks, exchange of best practices and training of officials which will be in contact with victims.

Regarding Directive 2004/80/EC on compensation for victims of violent intentional crime, and although infringement procedures were already launched against two Member States for lack of communication of national transposing measures (Greece) and for non transposition (Italy), there is increasing evidence, largely based on NGOs and citizens' letters, parliamentary requests and petitions, that these two Member States might still not be compliant with the current Directive. The implementation of the Directive is currently under exam by the Commission which will shortly take action under the EU pilot scheme.

The Commission will also present a report on the application of Framework Decision 2002/584/JHA on the European Arrest Warrant.

17.7.4. **Summary**

The EU has only been legislating in this area for around 10 years. The expertise of Member States' national legislators is therefore still limited. In order to reduce this gap, the Commission has undertaken a number of initiatives to improve the situation, including: implementation workshops on a regional basis, on top of the regular expert meetings which take place in Brussels; streamlined contacts between national administrations and Commission services, possibly coupled by meetings in the capitals; dissemination of implementation handbooks.

Since the entry into force of the Lisbon Treaty, the Commission can exercise enforcement powers, straight away as concerns newly adopted legislation and subject to a period of five years as concerns Framework Decisions adopted before 1 December 2009. Until then, the Commission will continue to monitor the correct application of criminal justice instruments by other means.

17.8. Antidiscrimination and gender equality

17.8.1. **Current position**

17.8.1.1. Introduction

The legislative *acquis* in the field of gender equality and anti-discrimination is composed of 11 Directives, based mainly on the specific Treaty provisions: Article 157 TFEU (former Article 141 TEC) for gender equality and Article 19 TFEU (former Article 13 TEC) for antidiscrimination.

The number of infringement proceedings concerning this field used to be high due to a combination of non-conformity and non-communication cases. The majority of these cases were non-conformity cases opened in the period 2005-2007 following conformity check of recently transposed directives. During the period 2008-2010 the number of infringements has steadily decreased following amendments to national laws in the Member States which brought the national legislation in line with the EU *acquis*: more than 100 cases at the end of

2008, 74 at the end of 2009 and 45 at the end of 2010. By the end of 2010, the last remaining non-communication cases were expected to be closed in early 2011 following adoption of national transposing laws.

17.8.1.2. Report of work done in 2010

New legislation adopted

- Directive 2010/18/EU of 8 March 2010 implementing the revised Framework Agreement on parental leave concluded by BUSINESSEUROPE, UEAPME, CEEP and ETUC and repealing Directive 96/34/EC,

- Directive 2010/41/EU of 7 July 2010 on the application of the principle of equal treatment between men and women engaged in an activity in a self-employed capacity and repealing Directive 86/613/EEC.

Directive 2010/18/EU implements the revised framework agreement on parental leave concluded by the social partners at European level. The Directive extends workers' rights to parental leave from three to four months for each parent. *The Directive will allow working parents to better balance family and work.* To encourage a more equal take-up of leave by both parents, at least one of the four months shall be provided on a non-transferable basis. The transposition deadline for the Directive is 8 March 2012.

Directive 2010/41/EU strengthens social protection of self-employed workers with a view to removing disincentives to female entrepreneurship and improves the social protection of "assisting" spouses who often work in the self-employed sector without enjoying the corresponding rights. The Directive grants for the first time at EU level a maternity allowance to self-employed workers. Self-employed workers are also granted a leave period of at least 14 weeks should they choose to take it. The Directive marks an important step forward in terms of increasing social protection and providing equal economic and social rights for self-employed men and women, and their partners. The transposition deadline for the Directive is 5 August 2012.

There are Member States which have already notified transposing measures for both directives, therefore well in advance of the transposition deadlines in 2012.

New legislation in preparation

In the area of gender equality and anti-discrimination, two 2008 legislative proposals remained under discussion in 2010:

- a proposal for a Directive implementing the principle of equal treatment between persons irrespective of religion or belief, disability, age or sexual orientation outside employment,

- a proposal for a Directive amending Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding.

Concerning the proposal for a Directive implementing the principle of equal treatment between persons irrespective of religion or belief, disability, age or sexual orientation outside employment the Council negotiations continued at technical level in 2010. However, no

significant progress has been registered in the Council.

Council discussions on the proposal for a Directive amending Directive 92/85/EEC also continued in 2010. The European Parliament commissioned a cost – benefit study of the amendments and in its first reading position in October 2010 proposed considerable amendments to the proposal. These amendments raised concerns in a number of Member States as regards the cost of the Directive and remained under analysis until the end of 2010.

Monitoring of infringements

All Member States have transposed Directives 2000/43/EC, 2000/78/EC and 2002/73/EC. One procedure for non-communication of national measures to transpose Directive 2004/113/EC and two procedures for Directive 2006/54/EC remained still open at the end of 2010. However, in one of the proceedings concerning Directive 2006/54/EC Member State had already notified national transposition and in the two other proceedings the national law had been adopted and the cases were pending the entry into force of the national laws on 1.1.2011.

To monitor the application of the EU legislation in the area of gender equality and anti-discrimination the Commission took the following action in 2010:

- With regard to ensuring the conformity with Article 157 TFUE, the Commission was analysing the new legislative package adopted by one Member State (FR) whilst the Article 260 TFEU proceedings against IT and EL could be closed in November 2010 since the gender differences in pensionable age were corrected in both Member States.

- Concerning Directive 2000/43/EC, the Commission closed five cases (SE, LV, SI, CZ and DE) ; seven other cases for incorrect transposition remained open at the end of 2010,.

- Concerning Directive 2000/78/EC, the Commission closed six cases (CZ, HU, LV, LT, SE and DE); eight other cases for incorrect transposition remained open at the end of 2010.

- Concerning transposition of Directive 2006/54/EC five non-communication proceedings (BE, EE, IT, LU and UK) were closed whilst proceedings against two Member States (AT, PL) remained technically open until the end of the year; in the meantime AT had already notified the national transposing law.

- Concerning transposition of Directive 2004/113/EC the non-communication proceedings against UK were closed, whilst proceedings against PL remained open until the end of the year.

- Concerning Directive 2002/73/EC, six cases (DE, LT, LV, SI, IT and IE) for incorrect transposition were closed, the Commission being satisfied with the amendments introduced or the explanations given. Thirteen proceedings remained open, but a number of these were heading for a solution following legislative amendments at national level.

Contribution to preliminary rulings:

The Commission's services also contributed to a number of preliminary rulings received by the Court of Justice under Article 267 TFEU (ex Article 234 TEC) in connection to the application of the gender equality and anti-discrimination *acquis*. The cases below worth

particular attention:

In Case C-149/10, *Chatzi,* the Court was asked whether a mother who gives birth to twins is entitled to two periods of parental leave, one period for each child, or whether she is entitle to only one period of parental leave corresponding to the birth. Indeed, children have the right to protection and care as is necessary for their well-being. In its ruling, the Court considered that the right to protection and care of the child does not mean however that children have to be acknowledged as having an individual right to see their parents obtain parental leave.

Case C-555/07, *Kücükdeveci*: In Germany, the notice periods which an employer must comply with in the case of dismissal increase progressively according to the length of the employment relationship. Periods of employment completed by an employee before reaching the age of 25 were not taken into account for calculating the notice period. The Court found that the German rules on dismissal were discriminatory as they contain a difference of treatment based on age which cannot be justified.

In Case *C-45/09, Rosenbladt*, the Court was asked whether a collective agreement providing that the working relationship automatically terminates when the employee has reached the age of 65 is in accordance with Article 2 (1) prohibiting the discrimination on ground of age and 6(1)[583] of Directive 2000/78. The Court replied that Article 6 of the Directive does not preclude such national provisions, to the extent that such provisions are objectively justified by a legitimate aim related to employment policy (social policy objective).

In addition, the Commission's services handled an important number of complaints coming from citizens. The Commission also replied to numerous parliamentary questions and requests for information from citizens.

17.8.2. **Evaluation based on the current situation**

The monitoring of the transposition of the two antidiscrimination directives adopted in 2000 and of the gender equality directive adopted in 2002 gave initially rise to a high number of infringement cases, but many of these could be closed in 2010. This led to a considerable decrease in the number of infringement proceedings, but the work still needs to be continued in 2011. In 2010 work was underway to check the conformity of legislation in BG and RO with the existing *acquis*.

The number of infringement cases can be expected to decrease further although the work on conformity checks of Directive 2004/113/EC and Directive 2006/54/EC is likely to lead to opening of new proceedings in 2011.

The work done in 2010 led to significant progresses towards conformity with the EU legislation in the in the area of anti-discrimination and gender equality. It can be assessed that the full transposition of the legal *acquis* was almost achieved by the end of 2010. Whilst three proceedings for non communication of national measures to transpose the two most recently adopted Directives (2004/113/EC and 2006/54/EC) remained open at the end of 2010, the

583 Article 6(1) reads: "Notwithstanding Article 2(2), Member States may provide that differences of treatment on grounds of age shall not constitute discrimination, if, within the context of national law, they are objectively and reasonably justified by a legitimate aim, including legitimate employment policy, labour market and vocational training objectives, and if the means of achieving that aim are appropriate and necessary".

national laws had been adopted and the proceedings were expected to be ready for closure in early 2011.

The only two proceedings under Article 260 TFEU (IT and EL) were successfully closed in November 2010 following compliance by the Member States with the Court rulings. Dealing with these cases had been one of the priorities set for 2010.

17.8.3. **Evaluation results**

17.8.3.1. Priorities

The main priorities for 2011 will be:

- Monitoring of the conformity of national measures transposing Directives 2004/113/EC and 2006/54/EC, since full transposition of these two directives was foreseen by the beginning of 2011.
- Continuing the negotiations on the two legislative proposals on the table.
- Dealing with the pending infringement cases as quickly as possible.

17.8.3.2. Planned action (2011 and beyond)

> In the area of gender equality and anti-discrimination, the negotiation of the two legislative proposals from 2008 currently on the table remains a priority. The Commission will have to continue its efforts to facilitate the adoption of these proposals.

On infringements the efforts will concentrate on advancing with the existing infringement cases as quickly as possible. After analysing the replies from Member States, the Commission will either refer them to the Court or close them.

Since full transposition of Directives 2004/113/EC and 2006/54/EC will be achieved by the beginning of 2011, the new priority will be to monitor the conformity of national transposition measures with the two Directives. This may lead to opening of new infringement proceedings in the future.

In 2012 the transposition deadline of Directives 2010/18/EU and 2010/41/EU will expire, which will gradually set as a new priority towards 2012 and beyond monitoring the transposition of these two directives.

17.8.4. **Summary**

The Commission will continue to use all the available means to monitor the application of EU law in the field and to deal with the workload resulting from this monitoring work. This will include the use of a number of different tools such as CHAP and EU Pilot, but also external expertise and information from Equality Bodies and Networks of Independent Legal Experts.

National Equality Bodies will continue to contribute to a reduction in the number of complaints concerning this area of EU law, in the areas in which they are competent (so far gender and race).

18. TRADE

Trade policy is governed by Article 207 of the Treaty on the Functioning of the European Union. The bulk of the Union legislation in this field takes the form of regulations, for example, the basic anti-dumping and countervailing duty regulations, the Generalised System of Preferences Regulation, the Trade Barriers Regulation and the Import and Export Regulations.[584] There are only two directives. These directives are Council Directive 98/29/EC of 7 May 1998 on harmonisation of the main provisions concerning export credit insurance for transactions with medium and long-term cover and Council Directive 84/568/EEC of 27 November 1984 concerning the reciprocal obligations of export credit insurance organizations of the Member States acting on behalf of the State or with its support, or of public departments acting in place of such organizations, in the case of joint guarantees for a contract involving one or more subcontracts in one or more Member States of the European Communities. There were no infringements cases open during 2010 concerning these directives.

It is not expected that there will be any significant work required on the transposition of these directives in 2011.

19. ENLARGEMENT

19.1. Current position – Most important legal instruments and related work and reporting on 2010

(1) General introduction

Enlargement policy is based on Article 49 of the EU Treaty. Association agreements with candidate or potential candidate countries may contain certain rights and obligations which are directly applicable under EU law. Violation of such provisions by a Member State could therefore be subject to infringement proceedings.
This is in particular the case for the 1963 EEC-Turkey Association Agreement, its 1970 Additional Protocol and related Association Council Decisions, particularly Decision 1/80. The Stabilisation and Association Agreements with the former Yugoslav Republic of Macedonia (2004), Croatia (2005), Albania (2009) and Montenegro (2010) and the Interim Agreements on Trade and Trade-related issues with Bosnia and Herzegovina (2008) Serbia (2010) fall into the same category of EU law, partly liable for trial in the European Court of Justice as far as implementation or application by Member States is concerned.

(2) Report of work done in 2010

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584 Council Regulation (EC) No 384/96 of 22 December 1995 on protection against dumped imports from countries not members of the European Community as amended; Council Regulation (EC) No 2026/97 of 6 October 1997 on protection against subsidized imports from countries not members of the European Community as amended; Council Regulation (EC) No 732/2008 of 22 July 2008 applying a scheme of generalised tariff preferences for the period from 1 January 2009 to 31 December 2011 as amended; Council Regulation (EC) No 3286/94 of 22 December 1994 laying down Community procedures in the field of the common commercial policy in order to ensure the exercise of the Community's rights under international trade rules, in particular those established under the auspices of the World Trade Organization as amended; Council Regulation (EC) No 260/2009 of 26 February 2009 on the common rules for imports and Council Regulation (EEC) No 2603/69 of the Council of 20 December 1969 establishing common rules for exports.

The Commission has received correspondence and complaints from citizens related to legal acts and agreements in the field of enlargement. However, they mainly concerned alleged violations of obligations by the third country or other matters not directly related to the application of EU law by Member States.

The Court has issued four judgements in 2010 on the interpretation of standstill clauses under the EEC-Turkey Association Agreement referred by national jurisdictions for preliminary ruling. Moreover, the Court has ruled in April 2010 that the Dutch legislation and practice to charge Turkish workers higher fees for issuing or prolonging their residence permits than those required for EU nationals in a comparable situation was contrary to EU law.

In 2010, the Commission received more complaints and inquiries related to the application and interpretation of certain provisions, including standstill clauses, of the EEC/Turkey Association Agreement, which are being examined in cooperation with the governments concerned. Following comprehensive explanations by the government, the Commission continued to thoroughly assess possible infringements in several other cases, which concern alleged breaches of the standstill clauses set out in the 1970 Additional Protocol and the Association Council Decision No1/80.

19.2. Evaluation based on the current situation

All complaints received on the application of EU law by a Member State concern the application of the EEC/Turkey Association Agreement. Taking into account the references to preliminary rulings pending at the Court, this confirms that the application and interpretation of this Association Agreement is still subject to a variety of legal interpretations with regard to residence and work of Turkish citizens in Member States. In addition, the number of judicial decisions interpreting the scope of application of the EEC-Turkey Association Law has triggered an increasing number of complaints in this field.

Other Stabilisation and Association Agreements with Western Balkan countries which have entered into force are, so far, not subject to any infringement case.

The number of complaints has slightly increased but does not yet require additional prioritisation.

19.3. Evaluation results

There is only one priority in the area of enlargement and that is the application of the EEC/Turkey Association Agreement. This priority remains unchanged given the limited number of cases.

19.4. Summary

Infringement procedures in the area of enlargement are rare in comparison to other policy areas. All pending cases at the Court and the Commission concern the alleged violation of directly applicable provisions, particularly standstill clauses, under the EEC/Turkey Association Agreement.

20. EUROSTAT

20.1. General introduction

Ensuring the quality of statistical information is both an operational and a legal requirement

insofar as European statistics production must respect the principles set out in Article 338 of the TFEU and in Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics[585], and in the various sectoral legislative instruments[586].

Moreover, in accordance with Decision 1578/2007/EC on the Community statistical programme 2008 to 2012[587], compliance monitoring of European legislation in the field of statistics is a specific objective of strategic importance for the medium to long-term development of European statistics:

"The quality of Community statistics comprises the fundamental requirement of compliance with the principles of the Treaty and the secondary legislation. Therefore, a vigorous and systematic monitoring of the application of the legislation is a priority. A global and coherent compliance strategy structured around the principles of a realistic legislative policy, the obligation of Member States to apply systematically the statistical legislation and a coherent and systematic monitoring of compliance, will be followed. Close contacts with the competent national authorities throughout all of the phases is part of the compliance process".

20.2. Report of work done in 2010

Since 2006, about the Commission monitors the state of play of legislation in the field of statistics and recommend possible follow-up actions. In addition, the ESS Committee (European Statistical System Committee) has been regularly informed of the actions carried out by the Commission in the field of compliance monitoring.

As for the previous years, the non-compliance with the transmission deadlines remained the principal problem in 2010. However, and even if a large part of the statistical legislation is affected by this transmission problem, constant work and frequent operational contacts allow a regular improvement of the respect of legislation.

Furthermore, it appears also that the evaluation of quality remains a difficult exercise, even at operational level. However, Regulation (EC) No 223/2009 establishes a new framework for quality (article 12) with a list of specific criteria which should be used for the assessment of quality. Those criteria should be systematically included in all new statistical legislation through a standard article.

The improvement of the overall situation can generally be confirmed. Member States in default are making serious efforts to fully comply when they are challenged at suitable level. In most cases, Member States react positively to reminders. In several cases, a solution to the difficulties could be found thanks to reciprocal collaboration with the National Institutes. This collaborative approach has been applied also in the only ongoing infringement procedure concerning statistics (against Greece), where close contacts with Greek authorities have ensured progress in relation to the grievances contained in the letter of formal notice.

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585 OJ L 87, 31.3.2009, p. 164.

586 As an indication, the *legal* corpus in the field of statistics comprises around 300 acts of secondary legislation, of which about one third are basic acts, i.e. acts of the Council and/or of the EP.

587 Decision 1578/2007/EC of the European Parliament and the Council of 11 December 2007 on the Community statistical programme 2008 to 2012 - Point 3.2 of Annex I – (OJ L 344, 28.12.2007, p. 15).

It is important to notice that in order to ensure a complete follow up of compliance with European statistical legislation, there are also parallel systems in place which serve the purpose of ensuring fulfilment of the complex methodological rules discussed with Member States at different sectoral statistical Committees and expert Working Groups.

21. HUMAN RESOURCES AND SECURITY

21.1. Current position – Most important legal instruments and related work and reporting on 2010

21.1.1. General introduction

In the field of human resources, the Commission seeks to guarantee that European Union law is correctly applied to EU staff by ensuring that Member States adopt legislation and implementing provisions in compliance with 1) the Protocol on Privileges and Immunities of the European Union as well as with 2) the Regulations and Rules applicable to officials and other servants of the EU.

In particular, the following legal texts are applicable:

- Council Regulation (EEC, Euratom, ECSC) No 259/68 of 29 February 1968 and amendments thereto,

- The Protocol on the Privileges and Immunities of EU (PPI), annexed to the Treaty on the European Union of 2010,

- Other agreements between the European Commission and Member States regarding the functioning of the Institutions' services.

21.1.2. Report of work done in 2010

In 2010, the Commission pursued infringements by proceeding directly against national rules providing for the imposition of taxes on EU Institutions based in Brussels, in violation of the provisions providing for a tax exemption under Article 3 of the PPI.

The Commission has continued to make additional arrangements for the transfer of pension rights for officials and other servants of the European Union who had either originally worked and acquired pension rights in Member States (transfer in) or who leave the Institutions (transfer out). This ongoing process has been quite successful and some of the competent national authorities have already fulfilled their obligations in this regard. In other cases, the Commission services continue to insist with the national authorities to arrange for this right provided in the Staff Regulation ('SR') to be correctly implemented.

The Commission monitored the coverage of staff by the sickness' insurance scheme in all Members States in line with the rules provided by the SR. In this framework, actions were taken to ensure that there was no discrimination linked with the status of non-resident in a Member State.

In 2010, the Court of Justice declared not to have jurisdiction to rule on the action of the European Commission seeking a judgment to confirm that Belgium should comply with its

undertaking, to subsidise the cost of equipment for European Schools (Case C-132/09).

21.2. Evaluation based on the current situation

As regards the transfer of pension rights and taking into account the direct applicability of the SR, some Member States have failed to adopt the necessary internal rules allowing these transfers even several years after having joined the EU. As regards new Member States, some are still working on basic legislation, while others on implementing regulations. However, it should be stressed that even if the implementing regulations are in place, their practical application is not always guaranteed.

In this area, the Commission continues to seek pro-active solutions outside or in parallel with the infringement procedure provided under Article 258 of the Treaty on the functioning of the European Union. Contacts are regularly organised between the institution's administration and the competent authorities of the Member States in order to anticipate and resolve matters, as far as possible, which could otherwise lead to such proceedings.

The tax laws applied by Member States both to the European Institutions and staff are carefully examined and checked for possible infringements of Articles 3 and 12 of the PPI. Complaints relating to national taxation in violation of the PPI are sometimes lodged by current or former staff of European Institutions. Taking into account the obligation of EU to assist its staff members and their families in proceeding against any attack to them by reason of their position or duties, the Commission grants legal assistance for ensuring that the benefits provided by the PPI are respected in all Member States. Only in few cases, when national procedures do not allow for the conflict to be settled in a satisfactory manner, the Commission would consider it necessary to launch infringement procedures against Member States.

21.3. Evaluation results

21.3.1. Priorities

The priorities in the human resources field remain the same as those which were identified in previous years. Implementation of national rules for permitting a correct application of the SR and the other rules applicable to officials and other servants of the Union is one of the major issues in this sector.

On the basis of statutory rules, the Commission's services continue to assess whether assistance, in the form of legal support, against presumed infringements of Article 12 of PPI in the field of taxation has to be granted to current or former staff.

21.3.2. Planned action

In this context, the collaboration with Member States has proven to be of great assistance for solving conflicts and ensuring the correct application of the Union legislation.

Nevertheless, despite the efforts of the Human Resources Services in helping national authorities to fulfil their obligations within a reasonable timeframe, the Commission will not refrain from proceeding with infringement procedures under Article 258 of the Treaty where required.

22. BUDGET

22.1. Current situation

22.1.1. General introduction

The main three own resources financing the EU budget are: traditional own resources, the VAT-based own resource and the balancing resource based on Member States' gross national income (GNI). The own resources system is at present under review.
In particular, the following legal texts are applicable:

- Articles 311 and 322(2) of the Treaty on the Functioning of the European Union,
- Council Decision 2007/436/EC, Euratom on the system of the Communities' own resources,
- Council Regulation (EC, Euratom) No 1150/2000 implementing the above decision,
- Council Regulation (EEC, Euratom) No 1553/89 on the definitive uniform arrangements for the collection of own resources accruing from value added tax.

Additional budgetary revenue is secured under Articles 3 and 4 of the Protocol on the Privileges and Immunities of the EU (PPI), annexed to the above Treaty as Protocol n° 7.

The main rules for budget execution are contained in Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities as last amended by Regulation (EC, Euratom) No 1081/2010 of 24 November 2010.

22.1.2. Report of work done in 2010

In 2010, the Commission detected 278 anomalies in the area of traditional own resources (of which 120 in the course of on-the-spot inspections) and set 52 reservations in the area of VAT/GNI (= 52 VAT+ 0 GNI). Correspondingly, 649 accounting actions for traditional own resources and 183 for VAT/GNI were generated for potential corrective payments (principal amounts and belated interest) by Member States. Most of the newly detected anomalies could be solved at an initial stage in bilateral discussions with Member States, including senior level management meetings, or in the Advisory Committee on Own Resources.

Regarding infringements, in 2010 the follow-up to the Court judgments of 15 December 2009 and 4 March 2010 concerning duty-free imports of military and dual use goods made by seven Member States continued. Three other 2010 Court judgments (C-423/08 of 17 June 2010, C-442/08 of 1 July 2010 and C-334/08 of 8 July 2010) in favour of the Commission in the field of Own Resources as well as two pending Court cases were followed up, amongst which the priority case against Germany relating to the refusal of the German authorities to cooperate with the European Court of Auditors with regard to the administrative VAT cooperation of Member States under Council Regulation (EC) No 1798/2003. Six infringement cases were closed in 2010, of which five related to earlier Court decisions in favour of the Commission.

22.2. Evaluation

The Commission's work on infringements and the important clarifications provided by Court decisions in recent years in the area of own resources have allowed to keep the number of conflicts and differences of interpretation between the Commission and the Member States at

a low level. Problems were encountered with the availability of supporting documentation. This issue should be addressed in the revision of the regulation for the next financing framework period.

22.3. Evaluation results

(1) Priorities

The priorities set up in the 2009 Annual Report were maintained in 2010. In setting priorities in the field of infringements, the Commission has to take account of the system of own resources which provides for solidarity and joint financing of the EU budget. Accordingly, where a Member State does not establish own resources or omits the recovery of established amounts, the financial charge of the other Member States increases. In view of assuring equal treatment of Member States a strict monitoring by the Commission services and, if necessary, infringement proceedings, are essential. The Commission takes legal action whenever a satisfactory solution cannot be found in bilateral contacts and discussions with Member States in the Advisory Committee for Own Resources. Priorities are assigned based on the seriousness of infringements and their impact on the budget.

(2) Planned action

The Lisbon Treaty introduced new financial provisions (Article 310 *et seq.* TFEU) in the system of own resources and the Budget Review addresses the '*Reform of EU financing*'. There is therefore an opportunity to reinforce the sincere cooperation between the Union and the Member States as prescribed by Article 4 (3) of the Treaty on the EU. In budgetary infringement cases where the Court of Justice examines to which extent Member States are obliged to make available Own Resources, Member States should keep all necessary documentation enabling a swift follow-up of the Court's decisions. Article 3 of Council Regulation n° 1150/2000 already contains a general obligation for Member States to keep supporting documents concerning the establishment and making available of own resources. Recent experience with the follow-up of Court decisions suggests that this obligation may need to be reinforced in case of infringements.

22.4. Summary

In general, Member States contribute timely and correctly to the EU budget and comply with the budgetary legislation, which ensures a stable and smooth financing of the EU budget. In this light, keeping the existing priorities as mentioned above is appropriate.

23. ANNEX I - LIST OF MEASURES IN FORCE AND OTHER RELEVANT INSTRUMENTS REFERRED TO IN THE TEXT OF THE DOCUMENT

I. ENTERPRISE AND INDUSTRY

I.1. REACH

- REACH and its implementing legislation are available through the following link:

http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/index_en.htm

- REACH and its links to previous legislation on restriction is available here:

http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/market-restrictions/index_en.htm

I.2 Classification, labelling and packaging:

http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/index_en.htm

I.3 Pyrotechnic Articles and Explosives

http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/index_en.htm

I.4 Drug precursors

http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/index_en.htm

I.5 Detergents

http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/index_en.htm

I.6 Fertilisers

http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/index_en.htm

I.7 Textiles/clothing, footwear and wood

http://ec.europa.eu/enterprise/sectors/textiles/single-market/textiles-names-legislation/index_en.htm

I.8 Non-harmonised area

Treaty provisions:

http://ec.europa.eu/enterprise/policies/single-market-goods/files/treaties/tfeu_en.pdf#page=15

Regulation Mutual recognition regulation:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0021:0029:en:PDF

Guide to the application of Treaty provisions governing the free movement of goods:

http://ec.europa.eu/enterprise/policies/single-market-goods/files/goods/docs/art34-36/new_guide_en.pdf

II. EMPLOYMENT, SOCIAL AFFAIRS AND INCLUSION

List of measures in force

II.1. Free movement of workers and coordination of social security schemes

II.1.1. Free movement of workers

Art. 45 TFEU

Regulation (EEC) No 1612/68 of the Council of 15 October 1968 on freedom of movement for workers within the Community. A codification of this regulation is under way.

Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States.

II.1.2 Social Security

- Article 48 TFUE
- Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons, self-employed persons and to the members of their families moving within the Community.
- Regulation (EC) No 859/2003 of the Council of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality.
- Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security schemes.
- Regulation (EC) No 987/2009 of the European Parliament and of the Council of

16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems.

- Regulation (EC) No 988/2009 of the European Parliament and of the Council of 16 September 2009 amending Regulation (EC) No 883/2004 on the coordination of social security systems, and determining the content of its Annexes.

Recently adopted measures due to enter into force in the sector of the coordination of social security systems

- Regulation (EC) No 1231/2010 of the Council extending the provisions of Regulation (EC) No 883/2004 and of Regulation (EC) No 987/2009 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality.

II.2. Labour Law

II.2.1. Working conditions

- Directive 96/71/EC[588] of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services
- Council Directive 97/81/EC[589] of 15 December 1997 concerning the Framework Agreement on part-time work concluded by UNICE, CEEP and the ETUC - Annex : Framework agreement on part-time work;
- Council Directive 98/23/EC[590] of 7 April 1998 on the extension of Directive 97/81/EC on the framework agreement on part-time work concluded by UNICE, CEEP and the ETUC to the United Kingdom of Great Britain and Northern Ireland;
- Council Directive 1999/70/EC[591] of 28 June 1999 concerning the framework agreement on fixed-term work concluded by ETUC, UNICE and CEEP;
- Council Directive 1999/63/EC[592] of 21 June 1999 concerning the Agreement on the organisation of working time of seafarers concluded by the European Community Shipowners Association (ECSA) and the Federation of Transport Workers' Unions in the European Union (FST);
- Council Directive 2000/79/EC[593] of 27 November 2000 concerning the European Agreement on the Organisation of Working Time of Mobile Workers in Civil Aviation concluded by the Association of European Airlines (AEA), the European Transport Workers' Federation (ETF), the European Cockpit Association (ECA), the European Regions Airline Association (ERA) and the International Air Carrier Association (IACA);
- Directive 2003/88/EC[594] of the European Parliament and of the Council of 4 November 2003 concerning certain aspects of the organisation of working time;
- Council Directive 2005/47/EC[595] of 18 July 2005 on the Agreement between the Community of European Railways (CER) and the European Transport Workers' Federation (ETF) on certain aspects of the working conditions of mobile workers engaged in interoperable cross-border services in the railway sector;
- Directive 2008/104/EC[596] of European Parliament and of the Council of 19 November 2008 on temporary agency work.
- Council Directive 2009/13/EC implementing the Agreement concluded by the European Community Shipowners' Associations (ECSA) and the European Transport Workers' Federation (ETF) on the Maritime Labour Convention, 2006 and amending Directive 1999/63/EC

II.2.2. Information and consultation of workers

- Council Directive 94/45/EC[597] of 22 September 1994 on the establishment of a European Works Council or a procedure in Community-scale undertakings and

588 OJ L 18, 21.1.1997, p. 1–6
589 OJ L 14, 20.1.1998, p. 9–14
590 OJ L 131, 5.5.1998, p. 10–10
591 OJ L 244, 16.9.1999, p. 64–64
592 OJ L 167, 2.7.1999, p. 33–37
593 OJ L 302, 1.12.2000, p. 57–60
594 OJ L 299, 18.11.2003, p. 9–19
595 OJ L 195, 27.7.2005, p. 15–17
596 OJ L 327, 5.12.2008, p. 9-14
597 OJ L 254, 30.9.1994, p. 64–72

Community-scale groups of undertakings for the purposes of informing and consulting employees;

- Council Directive 97/74/EC[598] of 15 December 1997 extending, to the United Kingdom of Great Britain and Northern Ireland, Directive 94/45/EC on the establishment of a European Works Council or a procedure in Community-scale undertakings and Community-scale groups of undertakings for the purposes of informing and consulting employees
- Council Directive 2006/109/EC[599] of 20 November 2006 adapting Directive 94/45/EC on the establishment of a European Works Council or a procedure in Community-scale undertakings and Community-scale groups of undertakings for the purposes of informing and consulting employees, by reason of the accession of Bulgaria and Romania;
- Council Directive 2001/86/EC[600] of 8 October 2001 supplementing the Statute for a European company with regard to the involvement of employees;
- Council Directive 2003/72/EC[601] of 22 July 2003 supplementing the Statute for a European Cooperative Society with regard to the involvement of employees;
- Directive 2002/14/EC[602] of the European Parliament and of the Council of 11 March 2002 establishing a general framework for informing and consulting employees in the European Community - Joint declaration of the European Parliament, the Council and the Commission on employee representation;
- Directive 2009/38/EC on the establishment of a European Works Council or a procedure in Community-scale undertakings and Community-scale groups of undertakings for the purposes of informing and consulting employees (Recast).

II.2.3. Protection of workers

- Council Directive 91/383/EEC[603] of 25 June 1991 supplementing the measures to encourage improvements in the safety and health at work of workers with a fixed-duration employment relationship or a temporary employment relationship;
- Council Directive 91/533/EEC[604] of 14 October 1991 on an employer's obligation to inform employees of the conditions applicable to the contract or employment relationship;
- Council Directive 94/33/EC[605] of 22 June 1994 on the protection of young people at work;
- Council Directive 98/59/EC[606] of 20 July 1998 on the approximation of the laws of the Member States relating to collective redundancies;
- Directive 2008/94/EC[607] of the European Parliament and of the Council of 22 October 2008 on the protection of employees in the event of the insolvency of their employer (codified version);

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598 OJ L 365, 31.12.1994, p. 46–51
599 OJ L 363, 20.12.2006, p. 416–417
600 OJ L 294, 10.11.2001, p. 22–32
601 OJ L 207, 18.8.2003, p. 25–36
602 OJ L 80, 23.3.2002, p. 29–34
603 OJ L 206, 29.7.1991, p. 19–21
604 OJ L 288, 18.10.1991, p. 32–35
605 OJ L 216, 20.8.1994, p. 12–20
606 OJ L 225, 12.8.1998, p. 16–21
607 OJ L 283, 28.10.2008, p. 36-42

- Council Directive 2001/23/EC[608] of 12 March 2001 on the approximation of the laws of the Member States relating to the safeguarding of employees' rights in the event of transfers of undertakings, businesses or parts of undertakings or businesses;

II.3. Health and safety at work

- Directive 89/391/EEC[609] of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work;
- Council Directive 89/654/EEC[610] of 30 November 1989 concerning the minimum safety and health requirements for the workplace (first individual directive within the meaning of Article 16(1) of Directive 89/391/EEC);
- Directive 2009/104/EC[611] of the European Parliament and of the Council of 16 September 2009 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC – Codification of Directive 89/655/EEC, as amended by Directives 95/63/EC and 2001/45/EC);
- Council Directive 89/656/EEC[612] of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16(1) of Directive 89/391/EEC);
- Council Directive 90/269/EEC[613] of 29 May 1990 on the minimum health and safety requirements for the manual handling of loads where there is a risk particularly of back injury to workers (fourth individual directive within the meaning of Article 16(1) of Directive 89/391/EEC);
- Council Directive 90/270/EEC[614] of 29 May 1990 on the minimum safety and health requirements for work with display screen equipment (fifth individual directive within the meaning of Article 16(1) of Directive 89/391/EEC);
- Directive 2004/37/EC[615] of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (sixth individual directive within the meaning of Article 16(1) of Directive 89/391/EEC - Codification of Directive 90/394/EEC);
- Directive 2000/54/EC[616] of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) - Codification of Directive 90/679/EEC);
- Council Directive 92/57/EEC[617] of 24 June 1992 on the implementation of minimum safety and health requirements at temporary or mobile construction sites (eight individual directive within the meaning of Article 16(1) of Directive 89/391/EEC);

608 OJ L 82, 22.3.2001, p. 16–20
609 OJ L 183, 29.6.1989, p. 1
610 OJ L 393, 30.12.1989, p. 1
611 OJ L 260, 3.10.2009, p. 5
612 OJ L 393, 30.12.1989, p. 18
613 OJ L 156, 21.6.1990, p. 9
614 OJ L 156,21.6.1990, p. 14
615 OJ L 229, 29.6.2004, p. 23
616 OJ L 262, 17.10.2000, p. 21
617 OJ L 245, 26.8.1992, p. 6

- Council Directive 92/58/EEC[618] of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (ninth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC);
- Council Directive 92/91/EEC[619] of 3 November 1992 concerning the minimum requirements for improving the safety and health protection of workers in the mineral-extracting industries through drilling (eleventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC);
- Council Directive 92/104/EEC[620] of 3 December 1992 on the minimum requirements for improving the safety and health protection of workers in surface and underground mineral-extracting industries (twelfth individual directive within the meaning of Article 16(1) of Directive 89/391/EEC);
- Council Directive 93/103/EC[621] of 23 November 1993 concerning the minimum safety and health requirements for work on board fishing vessels (thirteenth individual directive within the meaning of Article 16(1) of Directive 89/391/EEC);
- Council Directive 98/24/EC[622] of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual directive within the meaning of Article 16(1) of Directive 89/391/EEC);
- *Commission Directives establishing indicative exposure limit values:*
- Commission Directive 91/322/EEC[623] of 29 May 1991 on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work
- Commission Directive 2000/39/EC[624] of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/E on the protection of the health and safety of workers from the risks related to chemical agents at work
- Commission Directive 2006/15/EC[625] of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC
- Commission Directive 2009/161/EU[626] of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC
- Directive 1999/92/EC[627] of the European Parliament and of the Council of 16 December 1999 on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres (fifteenth individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)
- Directive 2002/44/EC[628] of the European Parliament and of the Council of 25 June 2002 on the minimum health and safety requirements regarding the exposure of workers to

618 OJ L 245, 26.8.1992, p. 23
619 OJ L 348, 28.11.1992, p. 9
620 OJ L 404, 31.12.1992, p. 10
621 OJ L 307, 13.12.1993, p. 1
622 OJ L131, 5.5. 1998, p. 11
623 OJ L177, 5.7. 1991, p. 22
624 OJ L 142, 16.6.2000, p. 47
625 OJ L 38, 9.2.2006, p. 36
626 OJ L 338 of 19.12.2009, p. 87
627 OJ L 23, 28.1.2000, p. 57
628 OJ L 177, 6.7.2002, p. 13

the risk arising from physical agents (vibration) (sixteenth individual directive within the meaning of Article 16(1) of Directive 89/391/EEC);

- Directive 2003/10/EC[629] of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risk arising from physical agents (noise) (seventeenth individual directive within the meaning of Article 16(1) of Directive 89/391/EEC);
- Directive 2004/40/EC[630] of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC); as amended by Directive 2008/46/EC[631]
- Directive 2006/25/EC[632] of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation) (19th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC);
- Council Directive 2010/32/EU[633] of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU;
- Council Directive 92/29/EEC[634] of 31 March 1992 on the minimum safety and health requirements for improved medical treatment on board vessels;
- Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work[635]
- Directive 2007/30/EC[636] of the European Parliament and of the Council of 20 June 2007 amending Council Directive 89/391/EEC, its individual Directives and Council Directives 83/477/EEC, 91/383/EEC, 92/29/EEC and 94/33/EC with a view to simplifying and rationalising the reports on practical implementation.

III ENERGY

III.1. Legislation in force

Primary law

- **Article 194 TFEU**: the insertion of a specific legal basis for energy in the Treaty on the Functioning of the European Union has strengthened EU energy policy. This Article consolidates and clarifies the competences of the EU in the field of energy. The use of Art. 194 TFEU is without prejudice to the application of other provisions of the Treaty.
- Article 192 TFEU: environmental measures which affect the energy mix.
- Article 122 TFEU: short term measures necessary to react to an actual crisis.
- Articles 170 and 171 TFEU: trans-European networks
- Article 113 TFEU: energy taxation

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629 OJ L 42, 15.2.2003, p. 38
630 OJ L 184, 24.5.2004, p. 1
631 OJ L 114, 26.4.2008, p. 88
632 OJ L 114, 27.4.2006, p. 38
633 OJ L 134, 1.6.2010, p. 66
634 OJ L 113, 30.4.1992, p. 19
635 OJ L 330, 16.12.2009, p. 28
636 OJ L 165, 27.6.2007, p. 21

- Articles 258 and 260 TFEU: so-called "infringement procedures".

Secondary Law

- The texts of current Community legislation on energy are available in section 12 of the EUR-Lex database

  http://eur-lex.europa.eu/en/legis/20100301/chap12.htm

Euratom

Primary Law: Euratom Treaty

A number of provisions of the Treaties vest the Commission with specific powers:

– **Article 33 Euratom Treaty**: Verification of conformity of draft legislation in the field of radiation protection and education and training (the Commission may issue recommendations).

– **Article 37 Euratom Treaty**: Assessment of national plans for the release of radioactive waste into the environment, before approval by the national authorities (the Commission shall deliver an opinion).

– **Article 38 Euratom Treaty**: In cases of urgency, the Commission shall issue a directive requiring the Member State concerned to take, within a period laid down by the Commission, all necessary measures to prevent infringement of the basic standards and to ensure compliance with regulations. Article 38 of the Euratom Treaty institutes also a special derogative procedure from the general infringement procedure, allowing the Commission or any Member State concerned to bring the matter before the Court of Justice if the State in question fails to comply with the Commission directive within the period laid down therein.

– **Articles 41/43 Euratom Treaty**: This notification procedure on nuclear investments requires that any new investment related to nuclear activities has to be communicated to the Commission which shall, in return, send its views to the Member State concerned.

– **Article 77 Euratom Treaty**: The Commission shall satisfy itself that, in the territories of member states, (a) ores, source materials and special fissile materials are not diverted from their intended uses as declared by the users; (b) the provisions relating to supply and any particular safeguarding obligations assumed by the Community under an agreement concluded with a third state or an international organisation are complied with.

– **Article 78 Euratom Treaty**: Operators shall declare to the Commission the basic technical characteristics of the installations, to the extent that knowledge of these characteristics is necessary for the attainment of the objectives set out in Article 77.

– **Article 81 Euratom Treaty**: The Commission's nuclear inspectors (Commission's staff!) shall at all times have access to all places and data and to all persons who, by reason of their occupation, deal with materials, equipment or installations subject to the safeguards. If the carrying out of an inspection is opposed, it can be carried out compulsorily (after decision of

the president of the Court of Justice; or, even, after Commission's written order, if there is danger in delay).

– **Article 82 Euratom Treaty**: In case of infringement to the safeguards provisions established by its safeguards inspectors, the Commission may issue a directive calling upon the Member State concerned to take, by a time limit set by the Commission, all measures necessary to bring such infringement to an end. Possible direct referral of the matter to the Court of Justice, if the Member State in question does not comply with the Commission directive in the timeframe set up therein, in derogation from the general infringement procedure.

– **Article 83 Euratom Treaty**: In the event of an infringement on the part of persons or undertakings of the obligations on nuclear safeguards, the Commission may impose the following sanctions, in order of severity : (a) a warning ; (b) the withdrawal of special benefits such as financial or technical assistance ; (c) the placing of the undertaking for a period not exceeding four months under the administration of a person or board appointed by common accord of the Commission and the state having jurisdiction over the undertaking; (d) total or partial withdrawal of source materials or special fissile materials.

– **Article 103 Euratom Treaty**: assessment of draft international agreements in the fields of the Euratom Treaty (the Commission may issue comments on the drafts)

– **Articles 141 and 143 Euratom Treaty** have been repealed as of 30/11/2009; Articles 258 and 260 TFEU now apply.

– **Article 145 Euratom Treaty**: if the Commission considers that a person or undertaking has committed an infringement of this Treaty (other than to the safeguards provisions), it shall call upon the member state having jurisdiction over that person or undertaking to cause sanctions to be imposed in respect of the infringement in accordance with its national law. If the state concerned does not comply with such a request within the period laid down by the Commission, the latter may bring an action before the Court of Justice to have the infringement of which the person or undertaking is accused established.

Secondary law

- The Community *acquis* related to Title II, Chapter 3, can be consulted in section 15 of the EUR-Lex database, the Community *acquis* (heading 15.10.20.10 "Nuclear Safety and Radioactive Waste").

  http://eur-lex.europa.eu/en/legis/20100301/chap15102010.htm

- A comprehensive list of *acquis* and case-law related to the Euratom Treaty can be consulted in the annexes to the Commission staff working paper (SEC (2007) 347) accompanying the Communication on the 50 years of the Euratom Treaty (COM(2007) 124 final) at

  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52007SC0347:EN:NOT

III.2. Legislation adopted in 2010

General

- Council Regulation n° 617/2010 of 24 June 2010 concerning the notification to the Commission of investment projects in energy infrastructure within the EU & repealing Regulation (EC) n° 736/96 (OJ L 180, 15.7.2010, p. 7).

- Commission Regulation n°833/2010 of 21 September 2010 implementing Council Regulation n°617/2010 concerning the notification to the Commission of investment projects in energy infrastructure within the European Union (OJ L 248, 22.9.2010, p. 36).

Internal electricity and gas market

- Commission Decision of 10 November 2010 amending Chapter 3 of Annex 1 to Regulation (EC) No 715/2009 of the European Parliament and of the Council on conditions for access to the natural gas transmission networks (OJ L 293, 11.11.2010, p. 67).

- Commission Regulation (EU) No 774/2010 of 2 September 2010 on laying down guidelines relating to inter-transmission system operator compensation and a common regulatory approach to transmission charging (OJ L 233, 3.9.2010, p. 1)

- Commission Regulation (EU) No 838/2010 of 23 September 2010 on laying down guidelines relating to inter-transmission system operator compensation and a common regulatory approach to transmission charging (OJ L 250, 24.9.2010, p. 5)

Security of supply - gas

- Regulation (EU) No 994/2010 of the European Parliament and of the Council of 20 October 2010 concerning measures to safeguard security of gas supply and repealing Directive 2004/67/EC (OJ L 295, 12.11.2010, p. 1)

Energy Performance of Buildings

- Directive 2010/31/EU of the European Parliament and of the Council of 19 May 2010 on the energy performance of building (recast) (OJ L 153, 18.6.2010, p. 13)

Energy efficiency of products

- Directive 2010/30/EU of the European Parliament and of the Council of 19 May 2010 on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products (OJ L 153, 18.6.2010, p; 1)

- Commission Delegated Regulation (EU) No 1059/2010 of 28 September 2010 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of household dishwashers (OJ L 314, 30.11.2010, p. 1)

- Commission Delegated Regulation (EU) No 1061/2010 of 28 September 2010 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of household washing machines (OJ L 314, 30.11.2010, p. 47)

- Commission Delegated Regulation (EU) No 1062/2010 of 28 September 2010

supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of televisions (OJ L 314, 30.11.2010, p. 64)

- Commission Delegated Regulation (EU) No 1060/2010 of 28 September 2010 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of household refrigerating appliance (OJ L 314, 30.11.2010, p. 17)

- Commission Regulation (EU) 1016/2010 of 10 November 2010 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for household dishwashers (OJ L 293, 11.11.2010, p. 31)

- Commission Regulation (EU) 1015/2010 of 10 November 2010 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for household washing machines (OJ L 293, 11.11.2010, p. 21)

- Commission Regulation (EU) No 347/2010 of 21 April 2010 amending Commission Regulation (EC) No 245/2009 as regards the ecodesign requirements for fluorescent lamps without integrated ballast, for high intensity discharge lamps, and for ballasts and luminaires able to operate such lamps (OJ L 104, 24.4.2010, p. 20)

Euratom

- Revised Commission recommendation on the application of Art. 37 of the Euratom Treaty was adopted in October 2010 (210/635/Euratom, OJ L 279, 23.10.2010, p. 36-67)

- Regulation (Euratom) No 647/2010 of the Council of 13 July 2010 on financial assistance of the Union with respect to the decommissioning of Units 1 to 4 of the Kozloduy Nuclear Power Plant in Bulgaria (Kozloduy Programme) (OJ L 189, 22.7.2010, p. 9).

- *Commission Decision C(2010)6885 on the procedures related to the programming and monitoring of the measures and financial assistance under the Bohunice, Ignalina and Kozloduy programmes for the period 2007 to 2013* was adopted on 8 October 2010 and repealed Commission Decision C(2007)5538.

- *Commission Decision C(2010)6971 on the financing of additional Community contributions to the Nuclear Decommissioning Assistance Programmes for Bohunice, Ignalina and Kozloduy in 2010* was adopted on 12 October 2010.

III.3. New measures proposed or in preparation in 2010

Internal electricity and gas market

- Proposal for a Regulation of the European Parliament and of the Council on energy market integrity and transparency (COM(2010(726) final).

Euratom

- Proposal for a Council Directive on the **management of spent fuel and radioactive waste** (COM(2010)618, 3.11.2010).

- **Proposal of Revision and recast of the Basic Safety Standards:** The revision of the Basic Safety Standards is also the opportunity for the consolidation of existing radiation protection legislation involving four other Directives and incorporating one Commission Recommendation. The draft text of the Directive is complete and the drafting of the Impact Assessment Report is in an advanced stage. The Article 31 Group of Experts gave its opinion in February 2010.

- **Negotiating mandate for a Euratom-Australia cooperation agreement**: The proposal of a Council Decision on the new mandate to renegotiate the Euratom-Australia agreement, due to expire in 2012. The Council adopted the negotiating mandate for a revised agreement on 12 July 2010. The text of the agreement will be submitted to Council for approval during the 1st quarter of 2011.

- **Negotiating mandate for a Euratom-South Africa cooperation agreement** was adopted by the Council on 25 October 2010.

IV MOBILITY and TRANSPORT

Current Legislation:

Single Sky and Modernisation of air traffic control

Air safety (Legal basis: Article 100(2) (ex-Article 80 par.2)

Newest legislation

- Regulation (EU) No 996/2010 of the European Parliament and of the Council of 20 October 2010 on the investigation and prevention of accidents and incidents in civil aviation repealing Directive 94/56/EC (OJ 12.11.2010)

Infrastructures and airports

Newest legislation:

- Regulation (EU) No 255/2010 of 25 March 2010 laying down common rules on air traffic flow management.

- Regulation (EC) No 545/2009 of the European Parliament and of the Council of 18 June 2009 amending Regulation (EEC) No 95/93 on common rules for the allocation of slots at Community airports.

- Directive 2009/12/EC of the European Parliament and of the Council of 11 March 2009 on airport charges.

Aviation security

- Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC)

No 2320/2002, as amended;

- Commission Regulation (EC) No 272/2009 of 2 April 2009 supplementing the common basic standards on civil aviation security laid down in the Annex to Regulation (EC) No 300/2008 of the European Parliament and the Council, as amended;

- Commission Regulation (EU) No 1254/2009 of 18 December 2009 setting criteria to allow Member States to derogate from the common basic standards on civil aviation security and to adopt alternative security measures;

- Commission Regulation (EU) No 18/2010 of 8 January 2010 amending Regulation (EC) No 300/2008 of the European Parliament and of the Council as far as specifications for national quality control programmes in the field of civil aviation security is concerned;

- Commission Regulation (EU) No 72/2010 of 26 January 2010 laying down procedures for conducting Commission inspections in the field of civil aviation security;

- Commission Regulation (EU) No 185/2010 of 4 March 2010 laying down detailed measures for the implementation of the common basic standards on aviation security, as amended;

- Commission Decision C(2010)/774 of 13 April 2010 laying down detailed measures for the implementation of the common basic standards on aviation, as amended.

V. TAXATION and CUSTOMS UNION

V.1 Situation in the sector of CUSTOMS

The following webpage contains a list of legal measures in the **customs area** adopted since 2003:

http://ec.europa.eu/taxation_customs/common/legislation/legislation/customs/index_en.htm

- Relevant **Treaty** provisions:

Art 18;

Art 23-27 TCE;

Art 95 (approximation of laws);

Art 133;

Art 135.

- Relevant **secondary EU law** acts:
  - **Council Regulation (EEC) No 2913/92** (Council Regulation (EEC) No 2913/92 establishing the EU Customs Code)
  - **Commission Regulation (EEC) No 2454/93 (**provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the EU Customs Code);

- **The Common Customs Tariff** (Combined Nomenclature and tariff measures): Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and the duty relief legislation (Council Regulation (EEC) No 918/83 of 28 March 1983 setting up a EU system of relief from customs duty);
- **Regulation (EC) No 1889/2005 of the European Parliament and of the Council**;
- **International agreements** in customs matters or the customs provisions of international agreements;
- Specific legislation on customs control (counterfeit, drug precursors, cultural goods, cash control) in particular :
- **Council Regulation (EC) No 1383/2003**;
- **Council Regulation (EC) No 111/2005**;
- **Council Regulation (EEC) No 3911/92**.

V.2 INDIRECT TAXATION

The following webpage contains a list of legal measures in the **tax area** adopted since 2003:

http://ec.europa.eu/taxation_customs/common/legislation/legislation/taxation/index_en.htm

Existing measures in force (situation on 31/12/2010)

Relevant **Treaty** (**TFEU)** provisions:

Mainly:

Art 110;

Additional:

Art 45

Art 49

Art 56

Art 63

Art 113

Relevant secondary EU law acts

Directive 2010/88/EU

Directive 2010/66/EU

Directive 2010/45/EU

Directive 2010/23/EU

Directive 2010/12/EU

Directive 2009/162/EU

Directive 2009/132/EC

Directive 2009/69/EC

Directive 2009/55/EC

Directive 2009/47/EC

Directive 2008/118/EC

Directive 2008/117/EC

Directive 2008/55/EC

Directive 2008/9/EC

Directive 2008/8/EC

Directive 2007/75/EC

Directive 2007/74/EC

Directive 2006/138/EC

Directive 2006/112/EC

Directive 2006/98/EC

Directive 2006/79/EC

Directive 2003/96/EEC

Directive 2002/10/EC

Directive 95/60/EC

Directive 95/59/EC

Directive 92/84/EEC

Directive 92/83/EEC

Directive 92/80/EEC

Directive 92/79/EEC

Directive 91/680/EEC

Directive 86/560/EEC

Directive 86/247/EEC

Directive 83/648/EEC

Directive 83/182/EEC

Directive 78/1032/EEC

Directive 72/230/EEC

Directive 69/463/EEC

Directive 68/297/EEC

Council Regulation (EU) N° 904/2010

Commission Regulation (EC) 1174/2009

Council Regulation (EU) N° 37/2009

Council Regulation (EU) N° 143/2008

Commission Regulation (EC) No 1179/2008

Council Regulation (EC) 1777/2005

Commission Regulation (EU) N° 1925/2004

Council Regulation (EU) N° 1798/2003

V.3 DIRECT TAXATION

The following webpage contains a list of legal measures in the **tax area** adopted since 2003:

http://ec.europa.eu/taxation_customs/common/legislation/legislation/taxation/index_en.htm

Existing measures in force (situation on 31/12/2010)

- Relevant **Treaty (TFEU)** provisions:

  Art 21;

  Art 45 (to 48);

  Art 49 (to 54);

  Art 56 (to 62);

  Art 63 (to 66);

Art 115;

- Relevant **secondary EU law** acts:

  Directive 77/799/EEC (+2 amending directives);

  Directive 90/434/EEC (+1 amending directive);

  Directive 90/435/EEC (+1 amending directive);

  Directive 2003/48/EC;

  Directive 2003/49/EC (+1 amending directive);

  Directive 2008/7/EC;

  Directive 2008/55/EC;

  Directive 2009/133/EC.

VI EDUCATION AND CULTURE

A full list of relevant provisions, which also includes non-binding provisions, can be found at:

- http://eur-lex.europa.eu/en/legis/20100101/chap1630.htm for education and training
- http://eur-lex.europa.eu/en/legis/20100101/chap1640.htm for culture
- http://ec.europa.eu/sport/white-paper/doc/wp_on_sport_en.pdf for sport

A guide to the rights of mobile students in the European Union – a European Commission staff working document, mentioned above:

- http://ec.europa.eu/education/yom/wpguidance_en.pdf
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VII HEALTH AND CONSUMERS

Main Measures in Force 31/12/2010

VII.1 Public Health

*Relevant EU **Treaty** provisions:*

Art 114 TFEU

Art 168(4) TFEU

Relevant secondary European Union law acts:

- Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States

concerning the manufacture, presentation and sale of tobacco products

- Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

- Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products

- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

- Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components

- Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events

- Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments

- Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells

- Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells

- Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community

- Commission Decision 2003/534/EC of 17 July 2003 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions and amending Decision 2002/253/EC as regards the case definitions for communicable diseases

- Commission Decision 2007/875/EC of 18 December 2007 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions

- Commission Decision 2000/96/EC of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of

the European Parliament and of the Council

- Commission Decision 2003/542/EC of 17 July 2003 amending Decision 2000/96/EC as regards the operation of dedicated surveillance networks

- Commission Decision 2009/312/EC of 2 April 2009 amending Decision 2000/96/EC as regards dedicated surveillance networks for communicable diseases,

- Commission Decision 2009/539/EC of 10 July 2009 amending Decision 2000/96/EC on communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council

- Commission Decision 2000/57/EC of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council.

- Commission Decision 2008/351/EC of 28 April 2008 amending Decision 2000/57/EC as regards events to be reported within the early warning and response system for the prevention and control of communicable diseases

- Commission Decision 2009/547/EC of 10 July 2009 amending Decision 2000/57/EC on early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council

- Commission Decision 2002/253/EC of 19 March 2002 laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council

- Commission Decision 2008/426/EC of 28 April 2008 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council

- Commission Decision 2009/363/EC of 30 April 2009 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council

- Commission Decision 2009/540/EC of 10 July 2009 amending Decision 2002/253/EC as regards case definitions for reporting Influenza A(H1N1) to the Community network

- Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty

- Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control

- Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure

with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four

- Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation

- Commission Decision 2010/453/EU of 3 August 2010 establishing guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials, in the field of human tissues and cells provided for in Directive 2004/23/EC of the European Parliament and of the Council

Pharmaceutical Legislation Medicinal Products for Human Use:

http://ec.europa.eu/health/documents/eudralex/vol-1/index_en.htm

Pharmaceutical legislation Medicinal Products for Veterinary Use:

http://ec.europa.eu/health/documents/eudralex/vol-5/index_en.htm

Medical Devices Legislation

http://ec.europa.eu/consumers/sectors/medical-devices/documents/index_en.htm

VII.2 Consumers

*Relevant EU **Treaty** provisions:*

Art 169 TFEU

Relevant secondary European Union law acts:

- Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers

- Council Directive 90/88/EEC of 22 February 1990 amending Directive 87/102/EEC for the approximation of the laws, regulations and administrative provisions of the Member States concerning consumer credit

- Directive 98/7/EC of the European Parliament and of the Council of 16 February 1998 amending Directive 87/102/EEC for the approximation of the laws, regulations and administrative provisions of the Member States concerning consumer credit

- Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety

- Directive 2002/65/EC of the European Parliament and of the Council of 23 September 2002

concerning the distance marketing of consumer financial services and amending Council Directive 90/619/EEC and Directives 97/7/EC and 98/27/EC

- Regulation (EC) No 2006/2004 of the European Parliament and of the Council of 27 October 2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws (the Regulation on consumer protection cooperation)

- Directive 2008/48/EC of the European Parliament and of the Council of 23 April 2008 on credit agreements for consumers and repealing Council Directive 87/102/EEC

- Commission Decision 2006/502/EC of 11 May 2006 requiring Member States to take measures to ensure that only lighters which are child-resistant are placed on the market and to prohibit the placing on the market of novelty lighters

- Commission Decision 2008/322/EC of 18 April 2008 prolonging the validity of Decision 2006/502/EC requiring Member States to take measures to ensure that only lighters which are child-resistant are placed on the market and to prohibit the placing on the market of novelty lighters

- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

- Directive 2009/22/EC of the European Parliament and of the Council of 23 April 2009 on injunctions for the protection of consumers' interests (Codified version)

- Commission Decision 2009/251/EC of 17 March 2009 requiring Member States to ensure that products containing the biocide dimethylfumarate are not placed or made available on the market

- Commission Decision 2009/298/EC of 26 March 2009 prolonging the validity of Decision 2006/502/EC requiring Member States to take measures to ensure that only lighters which are child-resistant are placed on the market and to prohibit the placing on the market of novelty lighters

- Commission Decision 2009/490/EC of 23 June 2009 on the safety requirements to be met by European standards for personal music players pursuant to Directive 2001/95/EC of the European Parliament and of the Council

- Commission Decision 2009/705/EC of 14 September 2009 setting up a European Consumer Consultative Group

- Commission Decision 2010/9/EU of 6 January 2010 on the safety requirements to be met by European standards for bath rings, bathing aids and bath tubs and stands for infants and young children pursuant to Directive 2001/95/EC of the European Parliament and of the Council

- Commission Decision 2010/11/EU of 7 January 2010 on the safety requirements to be met by European standards for consumer-mounted childproof locking devices for windows and balcony doors pursuant to Directive 2001/95/EC of the European Parliament and of the

Council

- Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System RAPEX established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive)

- Commission Decision 2010/153/EU of 11 March 2010 prolonging the validity of Decision 2009/251/EC requiring Member States to ensure that products containing the biocide dimethylfumarate are not placed or made available on the market

- Commission Decision 2010/157/EU of 12 March 2010 prolonging the validity of Decision 2006/502/EC requiring Member States to take measures to ensure that only lighters which are child-resistant are placed on the market and to prohibit the placing on the market of novelty lighters

- Commission Decision 2010/376/EU of 2 July 2010 on the safety requirements to be met by European standards for certain products in the sleep environment of children pursuant to Directive 2001/95/EC of the European Parliament and of the Council

Cosmetics Legislation:

http://ec.europa.eu/consumers/sectors/cosmetics/regulatory-framework/index_en.htm#h2-legislation

VII.3 Food Safety

GMO

*Relevant EU **Treaty** provisions:*

- 34 and 36 of TFEU (Quantitative restrictions-Free movement of goods and grounds for exceptions)

- 114 TFEU (Approximation of Laws)

- 168 TFEU (Protection of Health)

*Relevant **secondary European Union law** acts:*

- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

- Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council

- Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast)

- Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms

- *(Cartagena Protocol)*

- Commission Decision repealing Decision 2006/601/EC on emergency measures regarding the non-authorised genetically modified organism LL RICE 601 in rice products New measures already proposed and due to be adopted

The authorisation Decisions:

- Commission Decision 2010/141/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON863xNK603 (MON-ØØ863-5xMON-ØØ6Ø3-6);

- Commission Decision 2010/140/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON863xMON810 (MON-ØØ863-5xMON-ØØ81Ø-6);

- Commission Decision 2010/139/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON863xMON810xNK603 (MON-ØØ863-5xMON-ØØ81Ø-6xMON- ØØ6Ø3-6);

- Commission Decision 2010/136/EU authorising the placing on the market of feed produced from the genetically modified potato EH92- 527-1 (BPS-25271-9) and the adventitious or technically unavoidable presence of the potato in food and other feed products;

- Commission Decision 2010/432/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507x59122 (DAS-Ø15Ø7-1xDAS-59122-7);

- Commission Decision 2010/428/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122x1507xNK603 (DAS-59122-7xDAS-Ø15Ø7xMON-ØØ6Ø3-6);

- Commission Decision 2010/429/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 x MON 810 (MON-88Ø17-3 x MON-ØØ81Ø-6);

- Commission Decision 2010/420/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034xNK603 (MON-89Ø34-3xMON-ØØ6Ø3-6);

- Commission Decision 2010/426/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xGA21 (SYN-BTØ11-1xMON-ØØØ21-9).

- Commission Decision 2010/135/EU authorising the placing on the market of a

potato product (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch.

FOOD HYGIENE

*Relevant EU **Treaty** provisions:*

Art 43 TFEU

Art 114 TFEU

Art 168 TFEU

*Relevant **secondary European Union law** acts:*

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

- Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

- Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC

- Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

- Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products

- Commission Decision 98/179/EC of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products

- Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results

- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

- Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April

2004 laying down specific hygiene rules for food of animal origin

- Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

- Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

- Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004

- Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for Trichinella in meat

- Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004

- Commission Regulation (EC) No 1162/2009 of 30 November 2009 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council

- Commission Decision 2009/861/EC of 30 November 2009 on transitional measures under Regulation (EC) No 853/2004 of the European Parliament and of the Council as regard the processing of non-compliant raw milk in certain milk processing establishments in Bulgaria

- Commission Decision 2010/89/EU of 9 February 2010 on transitional measures concerning the application of certain structural requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 of the European Parliament and of the Council to certain establishments for meat, fishery products and egg products and cold stores in Romania

- Commission Decision 2010/653/EU of 21 October 2010 amending Annex II to Decision 2009/861/EC on transitional measures under Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the processing of non-compliant raw milk in certain milk processing establishments in Bulgaria

- Commission Regulation (EU) No 15/2011 of 10 January 2011 amending Regulation (EC) No 2074/2005 as regards recognised testing methods for detecting marine biotoxins in live bivalve molluscs

Food Hygiene Overview:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/index_en.htm.

Food Hygiene Guidance documents:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guide_en.htm.

FOOD

- Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
- Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs
- Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods
- Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses
- Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.
- Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.
- Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97.
- Commission Directive 2009/163/EU of 22 December 2009 amending Directive 94/35/EC of the European Parliament and of the Council on sweeteners for use in foodstuffs with regard to neotame.
- Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.
- Commission Directive 2010/37/EU of 17 June 2010 amending Directive 2008/60/EC laying down specific purity criteria on sweeteners.
- Commission Directive 2010/69/EU of 22 October 2010 amending the Annexes to European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners.

- Commission Directive 2010/67/EU of 20 October 2010 amending Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners.

- Commission Directive 2008/128/EC of 22 December 2008 laying down specific purity criteria concerning colours for use in foodstuffs.

- Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production.

- Council Decision 88/389/EEC of 22 June 1988 on the establishment, by the Commission, of an inventory of the source materials and substances used in the preparation of flavourings.

- Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs.

- Regulation (EC) N° 2065/2003 of the European Parliament and of the Council of 10 November on smoke flavourings used or intended for use in or on foods.

- Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC.

- Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food.

- Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation.

- Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation.

- Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.

- Commission Regulation (EU) No 105/2010 of 5 February 2010 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards ochratoxin A.

- Commission Regulation (EU) No 165/2010 of 26 February 2010 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards aflatoxins.

- Commission Regulation (EC) No 1882/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain

foodstuffs.

- Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs.

- Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.

- Commission Regulation (EU) No 178/2010 of 2 March 2010 amending Regulation (EC) No 401/2006 as regards groundnuts (peanuts), other oilseeds, tree nuts, apricot kernels, liquorice and vegetable oil.

- Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs.

- Commission Regulation (EC) No 1151/2009 of 27 November 2009 imposing special conditions governing the import of sunflower oil originating in or consigned from Ukraine due to contamination risks by mineral oil and repealing Decision 2008/433/EC.

- Commission Regulation (EC) No 1152/2009 of 27 November 2009 imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC.

- Commission Regulation (EC) No 1135/2009 of 25 November 2009 imposing special conditions governing the import of certain products originating in or consigned from China, and repealing Commission Decision 2008/798/EC.

- Commission Regulation (EU) 258/2010 of 25 March 2010 imposing special conditions on the imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins, and repealing Decision 2008/352/EC.

- Commission proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers (COM 2008(40) final).

- Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC.

- Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council.

- Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market

- Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

- Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides

- Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

- Commission Regulation (EC) No 1097/2009 of 16 November 2009 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimethoate, ethephon, fenamiphos, fenarimol, methamidophos, methomyl, omethoate, oxydemeton-methyl, procymidone, thiodicarb and vinclozolin in or on certain products

- Commission Regulation (EU) No 915/2010 of 12 October 2010 concerning a coordinated multiannual control programme of the Union for 2011, 2012 and 2013 to ensure compliance with maximum levels of and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin

- Commission Directive 2010/59/EU of 26 August 2010 amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients

- Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

- Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods

- Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs

- Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs

- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

- Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters

- Commission Directive 2003/40/EC of 16 May 2003 establishing the list, concentration limits and labeling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and

spring waters

- Commission Regulation (EU) No 115/2010 of 9 February 2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters

Directorate General for Health and Consumers' Website:

http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/index_en.htm

Nutrition profiles and health claims

The basic act as well as all related legislation and measures adopted may be found at the following address.

http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm

The legislation on **dietetic foods** is based on Article 114 of the TFEU and can be found on the following web link:

http://ec.europa.eu/food/food/labellingnutrition/nutritional/index_en.htm.

The legislation on **food supplements and on the addition of vitamins and minerals and of certain other substances to foodstuffs** is based on Article 114 of the TFEU and can be found on the following web links:

http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm

http://ec.europa.eu/food/food/labellingnutrition/vitamins/index_en.htm

The information related to novel foods can be found at the following address:

http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm

Labelling of foodstuffs:

- General **food labelling**, legislation and decisions on draft national measures notified by Member States:

http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/index_en.htm

Nutrition Labelling:

http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index_en.htm

- Information on the Commission proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers:

http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/proposed_legislation_en.htm

PLANT HEALTH

- Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community

- Commission Regulation (EC) No 1756/2004 of 11 October 2004 specifying the detailed conditions for the evidence required and the criteria for the type and level of the reduction of the plant health checks of certain plants, plant products or other objects listed in Part B of Annex V to Council Directive 2000/29/EC

- Commission Directive 2004/103/EC of 7 October 2004 on identity and plant health checks of plants, plant products or other objects, listed in Part B of Annex V to Council Directive 2000/29/EC, which may be carried out at a place other than the point of entry into the Community or at a place close by and specifying the conditions related to these checks

- Council Directive 69/464/EEC of 8 December 1969 on control of Potato Wart Disease

- Council Directive 74/647/EEC of 9 December 1974 on control of carnation leaf-rollers

- Council Directive 93/85/EC of 4 October 1993 on control of Potato Ring Rot

- Council Directive 98/57/EC of 20 July 1998 on the control of *Ralstonia solanacearum* (Smith) Yabuuchi et al.

- Council Directive 2006/91/EC of 7 November 2006 on control of San José Scale

- Council Directive 2007/33/EC of 11 June 2007 on the control of potato cyst nematodes and repealing Directive 69/465/EEC (from 01/06/2010)

- Commission Directive 92/70/EEC of 30 July 1992 laying down detailed rules for surveys to be carried out for purposes of the recognition of protected zones in the Community

- Commission Directive 93/51/EEC of 24 June 1993 establishing rules for movements of certain plants, plant products or other objects through a protected zone, and for movements of such plants, plant products or other objects originating in and moving within such a protected zone

- Commission Regulation (EC) No 690/2008 of 4 July 2008 recognising protected zones

exposed to particular plant health risks in the Community

- Commission Directive 92/90/EEC of 3 November 1992 establishing obligations to which producers and importers of plants, plant products or other objects are subject and establishing details for their registration

- Commission Directive 92/105/EEC of 3 December 1992 establishing a degree of standardization for plant passports to be used for the movement of certain plants, plant products or other objects within the Community, and establishing the detailed procedures related to the issuing of such plant passports and the conditions and detailed procedures for their replacement

- Commission Directive 93/50/EEC of 24 June 1993 specifying certain plants not listed in Annex V, part A to Council Directive 77/93/EEC, the producers of which, or the warehouses, dispatching centres in the production zones of such plants, shall be listed in an official register

- Commission Directive 94/3/EC of 21 January 1994 establishing a procedure for the notification of interception of a consignment or a harmful organism from third countries and presenting an imminent phytosanitary danger

- Commission Directive 98/22/EC of 15 April 1998 laying down the minimum conditions for carrying out plant health checks in the Community, at inspection posts other than those at the place of destination, of plants, plant products or other objects coming from third countries

- Commission Directive 2008/61/EC of 17 June 2008 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 2000/29/EC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections

SEEDS – PLANT VARIETY

- Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed

- Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed

- Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine

- Council Directive 2008/72/EC of 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed

- Council Directive 92/34/EEC of 28 April 1992 on the marketing of fruit plant propagating material and fruit plants intended for fruit production

- Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production

- Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants

- Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material

- Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species

- Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed

- Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed

- Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes

- Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants

- Commission Decision 80/512/EEC of 2 May 1980 authorizing the Kingdom of Denmark, the Federal Republic of Germany, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands and the United Kingdom not to apply the conditions laid down in Council Directive 66/401/EEC on the marketing of fodder plant seed, as regards the weight of the sample for determination of seed of Cuscuta

- Commission Decision 85/370/EEC of 8 July 1985 authorizing the Netherlands to assess the satisfaction of the varietal purity standards laid down in Annex II to Council Directive 66/401/EEC for seed of apomictic uniclonal varieties of *Poa pratensis*, also on the basis of the results of seed and seedling testing

- Commission Decision 2004/371/EC of 20 April 2004 on conditions for the placing on the market of seed mixtures intended for use as fodder plants

- Commission Directive 2008/124/EC of 18 December 2008 limiting the marketing of seed of certain species of fodder plants and oil and fibre plants to seed which has been officially certified as ‘basic seed’ or ‘certified seed’

- Commission Decision 80/755/EEC of 17 July 1980 authorizing the indelible printing of prescribed information on packages of cereal seed

- Commission Directive 2004/29/EC of 4 March 2004 on determining the characteristics and minimum conditions for inspecting vine varieties

- Commission Directive 93/61/EEC of 2 July 1993 setting out the schedules indicating the conditions to be met by vegetable propagating and planting material, other than seed pursuant to Council Directive 92/33/EEC

- Commission Directive 93/62/EEC of 5 July 1993 setting out the implementing measures concerning the supervision and monitoring of suppliers and establishments pursuant to Council Directive 92/33/EEC on the marketing of vegetable propagating and planting material, other than seed

- Commission Directive 93/48/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by fruit plant propagating material and fruit plants intended for fruit production, pursuant to Council Directive 92/34/EEC

- Commission Directive 93/64/EEC of 5 July 1993 setting out the implementing measures concerning the supervision and monitoring of suppliers and establishments pursuant to Council Directive 92/34/EEC on the marketing of fruit plant propagating material and fruit plants intended for fruit production

- Commission Directive 93/79/EEC of 21 September 1993 setting out additional implementing provisions for lists of varieties of fruit plant propagating material and fruit plants, as kept by suppliers under Council Directive 92/34/EEC

- Commission Directive 93/49/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by ornamental plant propagating material and ornamental plants pursuant to Council Directive 91/682/EEC

- Commission Directive 1999/66/EC of 28 June 1999 setting out requirements as to the label or other document made out by the supplier pursuant to Council Directive 98/56/EC

- Commission Directive 1999/68/EC of 28 June 1999 setting out additional provisions for lists of varieties of ornamental plants as kept by suppliers under Council Directive 98/56/EC

- Commission Regulation (EC) No 1597/2002 of 6 September 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the format of national lists of the basic material of forest reproductive material

- Commission Regulation (EC) No 1598/2002 of 6 September 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the provision of mutual administrative assistance by official bodies

- Commission Regulation (EC) No 1602/2002 of 9 September 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the authorisation of a Member State to prohibit the marketing of specified forest reproductive material to the end-user

- Commission Regulation (EC) No 2301/2002 of 20 December 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the definition of small quantities of seed

- Commission Regulation (EC) No 69/2004 of 15 January 2004 authorising derogations from certain provisions of Council Directive 1999/105/EC in respect of the marketing of forest reproductive material derived from certain basic material

- Commission Decision 2004/678/EC of 29 September 2004 authorising Member States to permit temporarily the marketing of seed of the species *Cedrus libani*, *Pinus brutia* and planting stock produced from this seed not satisfying the requirements of Council Directive 1999/105/EC

- Commission Decision 2005/853/EC of 30 November 2005 authorising France to prohibit the

marketing to the end user, with a view to seeding or planting in certain regions of France, of reproductive material of *Pinus pinaster* Ait. of Iberian Peninsula origin, which is unsuitable for use in such territories under Council Directive 1999/105/EC

- Commission Decision 2005/871/EC of 6 December 2005 releasing Denmark and Slovenia from certain obligations for marketing of forest reproductive material under Council Directive 1999/105/EC

- Commission Decision 2006/665/EC of 3 October 2006 temporarily authorising Spain to approve for marketing seed of the species *Pinus radiata* and planting stock produced from this seed imported from New Zealand which does not satisfy the requirements of Council Directive 1999/105/EC in respect of identification and labelling

- Commission Decision 2007/527/EC of 25 July 2007 authorising Bulgaria and Romania to derogate from Council Directive 1999/105/EC on the marketing of forest reproductive material with regard to the stocks accumulated from 1 January 2003 to 31 December 2006

- Council Decision 2008/971/EC of 16 December 2008 on the equivalence of forest reproductive material produced in third countries

- Commission Decision 2008/989/EC of 23 December 2008 authorising Member States, in accordance with Council Directive 1999/105/EC, to take decisions on the equivalence of the guarantees afforded by forest reproductive material to be imported from certain third countries

- Commission Directive 89/14/EEC of 15 December 1988 determining the groups of varieties of spinach beet and beetroot referred to crop isolation conditions of Annex I to Council Directive 70/458/EEC on the marketing of vegetable seed

- Commission Directive 2003/91/EC of 6 October 2003 setting out implementing measures for the purposes of Article 7 of Council Directive 2002/55/EC as regards the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of vegetable species

- Commission Directive 93/17/EEC of 30 March 1993 determining Community grades of basic seed potatoes, together with the conditions and designations applicable to such grades

- Commission Decision 2004/3/EC of 19 December 2003 authorising, in respect of the marketing of seed potatoes in all or part of the territory of certain Member States, more stringent measures against certain diseases than are provided for in Annexes I and II to Council Directive 2002/56/EC

- Commission Decision 97/125/EC of 24 January 1997 authorizing the indelible printing of prescribed information on packages of seed of oil and fibre plants and amending Decision 87/309/EEC authorizing the indelible printing of prescribed information on packages of certain fodder plant species

- Commission Directive 2003/90/EC of 6 October 2003 setting out implementing measures for the purposes of Article 7 of Council Directive 2002/53/EC as regards the characteristics

to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of agricultural plant species

- Commission Decision 2004/266/EC of 17 March 2004 authorising the indelible printing of prescribed information on packages of seed of fodder plants

- Commission Directive 2008/124/EC of 18 December 2008 limiting the marketing of seed of certain species of fodder plants and oil and fibre plants to seed which has been officially certified as 'basic seed' or 'certified seed'

- Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties

- Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights

- Commission Directive 2009/145/EC of 26 November 2009 providing for certain derogations, for acceptance of vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion and of vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions and for marketing of seed of those landraces and varieties

- Commission Directive 2010/60/EU of 30 August 2010 providing for certain derogations for marketing of fodder plant seed mixtures intended for use in the preservation of the natural environment

ANIMAL HEALTH

- Council Decision 79/542/EEC of 21 December 1976 drawing up a list of third countries from which the Member States authorize imports of bovine animals, swine and fresh meat

- Council Directive 2008/73/EC of 15 July 2008 simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC and 2005/94/EC

- Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field

- Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market

- Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market

- Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal

products

- Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption

- Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters

- Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC

- Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries

- Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97

- Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine

- Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs

- Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC

- Council Directive 90/427/EEC of 26 June 1990 on the zootechnical and genealogical conditions governing intra-Community trade in equidae

- Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC

- Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever

- Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever

- Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness

- Council Directive 2005/94/EC of 20 December 2005 on Community measures for the

control of avian influenza and repealing Directive 92/40/EEC

- Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease

- Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals

- Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue

- Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

- Regulation (EC) No 220/2009 of the European Parliament and of the Council of 11 March 2009 amending Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, as regards the implementing powers conferred on the Commission

- Commission Regulation (EC) No 103/2009 of 3 February 2009 amending Annexes VII and IX to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

- Commission Regulation (EC) No 162/2009 of 26 February 2009 amending Annexes III and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

- Commission Regulation (EC) No 163/2009 of 26 February 2009 amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

- Commission Decision 2009/719/EC of 28 September 2009 authorising certain Member States to revise their annual BSE monitoring programmes

- Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC

- Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents

- Zoonoses and Antimicrobial Resistance (AMR):

  Zoonoses: http://ec.europa.eu/food/food/biosafety/salmonella/index_en.htm

AMR: http://ec.europa.eu/food/food/biosafety/public_consultation_AMR_en.htm

- Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease

- Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community

- Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals

- Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species

- Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species

- Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra- Community trade in and imports of semen of domestic animals of the porcine species

- Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC

- Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals and amending Council Directive 92/65/EEC

- Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC

- Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC

- Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC

- Council Directive 2009/157/EC of 30 November 2009 on pure-bred breeding animals of the bovine species

- Council Directive 88/661/EEC of 19 December 1988 on the zootechnical standards applicable to breeding animals of the porcine species

- Council Directive 89/361/EEC of 30 May 1989 concerning pure-bred breeding sheep and goats

- Council Directive 90/428/EEC of 26 June 1990 on trade in equidae intended for competitions and laying down the conditions for participation therein

- Council Directive 91/174/EEC of 25 March 1991 laying down zootechnical and pedigree requirements for the marketing of pure-bred animals and amending Directives 77/504/EEC and 90/425/EEC

- Council Directive 94/28/EC of 23 June 1994 laying down the principles relating to the zootechnical and genealogical conditions applicable to imports from third countries of animals, their semen, ova and embryos, and amending Directive 77/504/EEC on pure-bred breeding animals of the bovine species

- Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC

- Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption

- Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

- Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae

FEED

*Relevant EU **Treaty** provisions:*

Articles 43 and 168(4)(b) TFEU

*Relevant **secondary European Union law** acts:*

- Commission Directive 81/680/EEC of 30 July 1981 amending Directives 71/250/EEC, 71/393/EEC, 72/199/EEC, 73/46/EEC, 74/203/EEC, 75/84/EEC, 76/372/EEC and 78/633/EEC establishing Community methods of analysis for the official control of feedingstuffs

- Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the

implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives

- Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene

- Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives

- Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC

- Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition

- Directive 2002/32/EC of the European Parliament and the Council of 7 May 2002 on undesirable substances in animal feed

- Commission Directive 2005/7/EC of 27 January 2005 amending Directive 2002/70/EC establishing requirements for the determination of levels of dioxins and dioxin-like PCBs in feedingstuffs

- Commission Directive 2009/8/CE of 10 February 2009 amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels of unavoidable carry-over of coccidiostats or histomonostats in non-target feed

- Commission Regulation (EC) No 124/2009 of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed

- Commission Directive 2008/38/EC of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes

- Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community

- Commission Decision 2010/277/EU of 12 May 2010 amending Decision 2009/821/EC as regards the lists of border inspection posts and veterinary units in Traces

- Commission Decision 2010/617/EU of 14 October 2010 amending Decision 2009/821/EC as regards the lists of border inspection posts and veterinary units in Traces

- Commission Regulation (EU) No 242/2010 of 19 March 2010 creating the Catalogue of feed materials

ANIMAL WELFARE

*Relevant EU **Treaty** provisions:*

Article 13 TFEU

*Relevant **secondary European Union law** acts:*

- Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes
- Council Directive 91/629/EEC of 19 November 1991 laying down the minimum standards for the protection of calves codified in Council Directive 2008/119/EC
- Council Directive 91/630/EEC of 19 November 1991 laying down minimum standards for the protection of pigs codified in Council Directive 2008/120/EC
- Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production
- Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens
- Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97, Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97
- Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing
- Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing
- Regulation (EC) No 1523/2007 of the European Parliament and of the Council of 11 December 2007 banning the placing on the market and the import to, or export from, the Community of cat and dog fur, and products containing such fur

VIII BUDGET

*Relevant EU **Treaty** and **secondary EU law** acts:*

- Articles 311 and 322(2) TFEU
- Council Decision 2007/436/EC, Euratom on the system of the Communities' own resources.
- Council Regulation (EEC, Euratom) No 1553/89 of 29 May 1989 on the definitive uniform arrangements for the collection of own resources accruing from value added tax

- Council Regulation (EC, Euratom) No 1150/2000 of 22 May 2000 implementing Decision 94/728/EC, Euratom on the system of the Communities' own resources
- Protocol (No 7) on the privileges and immunities of the European Union, in particular Articles 3 and 4.

New measures already proposed and due to be adopted in the sector:

- Proposal for a Regulation of the European Parliament and of the Council on the Financial Regulation applicable to the general budget of the European Union (Recast) {SEC(2010) 639} /* COM/2010/0260 final - COD 2010/0154 */.