ISSN 1725-2555

Official Journal of the European Union

L 188

English edition

Legislation

Volume 52

18 July 2009

Contents

[1] Text with EEA relevance

Price: EUR 22

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

REGULATION (EC) No 595/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 June 2009

on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

Whereas:

(1) The internal market comprises an area without internal frontiers in which the free movement of goods, persons, services and capital must be ensured. To that end a comprehensive Community type-approval system for motor vehicles is in place. The technical requirements for the type-approval of motor vehicles with regard to emissions should therefore be harmonised to avoid requirements that differ from one Member State to another and to ensure a high level of environmental protection.

(2) This Regulation is a new separate regulation in the context of the Community type-approval procedure under Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 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) [3]. Therefore, Annexes IV, VI and XI to that Directive should be amended accordingly.

(3) Following the request of the European Parliament, a new regulatory approach has been introduced in Community vehicle legislation. This Regulation should therefore lay down only fundamental provisions on vehicle emissions, whereas the technical specifications should be laid down by implementing measures adopted under the comitology procedures.

(4) The Sixth Community Environment Action Programme adopted by Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 [4] establishes the need to reduce pollution to levels which minimise harmful effects on human health, paying particular attention to sensitive populations and to the environment as a whole. Community legislation has established appropriate standards for ambient air quality for the protection of human health and sensitive individuals in particular, as well as for national emission ceilings. Following its communication of 4 May 2001, which established the 'Clean Air For Europe (CAFE) programme', the Commission adopted another communication on 21 September 2005 entitled 'Thematic strategy for air pollution'. One of the conclusions of that thematic strategy is that further

[1] OJ C 211, 19.8.2008, p. 12.
[2] Opinion of the European Parliament of 16 December 2008 (not yet published in Official Journal) and Council Decision of 8 June 2009.
[3] OJ L 263, 9.10.2007, p. 1.
[4] OJ L 242, 10.9.2002, p. 1.

reductions in emissions from the transport sector (air, maritime and land transport), from households and from the energy, agricultural and industrial sectors are needed to achieve EU air quality objectives. In this context, the task of reducing vehicle emissions should be approached as part of an overall strategy. The Euro VI standards are one of the measures designed to reduce the actual in-use emissions of air pollutants such as particulate pollutants (PM) as well as ozone precursors such as nitrogen oxides (NO_x) and hydrocarbons.

(5) Achieving EU air quality objectives requires a continuous effort to reduce vehicle emissions. For that reason, industry should be provided with clear information on future emission limit values and should be allowed an appropriate period of time in which to attain them and pursue the requisite technical developments.

(6) In particular, a reduction in NO_x emissions from heavy duty vehicles is necessary to improve air quality and comply with limit values for pollution and national emission ceilings. Setting limit values for NO_x emissions at an early stage should provide long-term, European Union-wide planning certainty for vehicle manufacturers.

(7) In setting emission standards it is important to take into account the implications for competitiveness of markets and manufacturers, the direct and indirect costs imposed on business and the benefits that accrue in terms of stimulating innovation, improving air quality, reducing health costs and increasing life expectancy.

(8) Unrestricted access to vehicle repair information, via a standardised format which can be used to retrieve the technical information, and effective competition on the market for vehicle repair and maintenance information services are necessary to improve the functioning of the internal market, particularly as regards the free movement of goods, freedom of establishment and freedom to provide services. A great proportion of such information is related to on-board diagnostic (OBD) systems and their interaction with other vehicle systems. It is necessary to lay down technical specifications to be followed by the manufacturers concerning the provision of information on their websites, along with targeted measures to ensure reasonable access for small and medium-sized enterprises (SMEs).

(9) Not later than 7 August 2013, the Commission should review the operation of the system of unrestricted access to vehicle repair and maintenance information with a view to determining whether it would be appropriate to consolidate all provisions governing access to vehicle repair and maintenance information within the revised framework legislation on type-approval. If the provisions governing access to such information are consolidated in this way, the corresponding provisions of this Regulation should be repealed, as long as existing rights of access to repair and maintenance information are preserved.

(10) The Commission should encourage the development of an international standard format for unrestricted and standardised access to vehicle repair and maintenance information, for example through the work of the European Committee for Standardisation (CEN).

(11) It is essential to establish a common European standard for the format of vehicle OBD and vehicle repair and maintenance information. Until such time as that standard is adopted, vehicle OBD and vehicle repair and maintenance information for heavy duty vehicles should be presented in a readily accessible manner and in a format guaranteeing non-discriminatory access. The information should be made available on the websites of manufacturers, or, if this is not feasible due to the nature of the information, in another appropriate format.

(12) The Commission should keep under review emissions which are, as yet, unregulated and which arise as a consequence of the wider use of new fuel formulations, engine technologies and emission control systems. The Commission should also, where necessary, submit a proposal to the European Parliament and to the Council with a view to regulating such emissions.

(13) It is appropriate to encourage the introduction of alternative fuel vehicles, which can have low NO_x and particulate emissions. Thus, limit values for hydrocarbons, non-methane hydrocarbons and methane should be introduced.

(14) In order to ensure that emissions of ultrafine particulate pollutants (PM 0,1 μm and below) are controlled, the Commission should be empowered to adopt a number-based approach to emissions of particulate pollutants in addition to the mass-based approach which is currently used. The number-based approach to emissions of particles should draw on the results of the Particulate measurement programme (PMP) of the United Nations Economic Commission for Europe (UN/ECE) and be consistent with the existing ambitious objectives for the environment.

(15) In order to achieve these environmental objectives, it is appropriate to indicate that the particle number limits are likely to reflect the highest levels of performance currently obtained with particle filters by using the best available technology.

(16) The Commission should adopt worldwide harmonised driving cycles in the test procedure that provides the basis for EC type-approval emissions regulations. The application of portable emissions measurement systems for verifying the actual in-use emissions and the introduction of procedures to control off-cycle emissions should also be considered.

(17) Retrofitting heavy duty vehicles with diesel particle filters could result in higher nitrogen dioxide (NO_2) emissions. As part of the thematic strategy on air pollution, the Commission should therefore draft a legislative proposal to harmonise national legislation on retrofitting and ensure that it incorporates environmental conditions.

(18) OBD systems are important to control emissions during the use of a vehicle. Due to the importance of controlling real-world emissions, the Commission should keep under review the requirements for such systems and the tolerance thresholds for monitoring faults.

(19) In order to monitor the contribution of this sector, as a whole, to the global emissions of greenhouse gases, the Commission should introduce the measuring of fuel consumption and carbon dioxide (CO_2) emissions of heavy duty vehicles.

(20) In order to promote the market for clean and energy efficient vehicles, the Commission should study the feasibility and the development of a definition and a methodology of energy consumption and CO_2 emissions for whole vehicles and not only for engines, without prejudice to the use of virtual and actual testing. Such a definition and the methodology should also cover alternative driveline concepts (e.g. hybrid vehicles) and the effects of improvements on vehicles such as aerodynamics, weight, loading capacity and rolling resistance. If a suitable method of presentation and comparison can be identified, the derived fuel consumption and CO_2 emissions should be made publicly available for separate vehicle types.

(21) In order to better control actual in-use emissions including off-cycle emissions and to facilitate the in-service conformity process, a testing methodology and performance requirements based on the use of portable emission measurement systems should be adopted within an appropriate timeframe.

(22) With a view to meeting EU air quality objectives, the Commission should introduce harmonised provisions to ensure that off-cycle emissions from heavy duty engines and vehicles are appropriately controlled over a broad range of engine and ambient operating conditions.

(23) The correct functioning of the after-treatment system, and more specifically in the case of NO_x, is the basic requirement for fulfilling the established standards for pollutant emissions. In this context, measures to guarantee the proper operation of systems relying on the use of a reagent should be introduced.

(24) Member States are able, by means of financial incentives, to accelerate the placing on the market of vehicles which satisfy the requirements adopted at Community level. This Regulation should not affect the right of Member States to include emissions in the method for calculating taxes levied on vehicles.

(25) When Member States draw up measures to ensure retrofitting of existing heavy duty vehicles, such measures should be based on the Euro VI standards.

(26) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

(27) The requirements of engine power of motor vehicles contained in Council Directive 80/1269/EEC of 16 December 1980 on the approximation of the laws of the Member States relating to the engine power of motor vehicles [1] should be introduced in this Regulation and in Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information [2]. Therefore, Regulation (EC) No 715/2007 should be amended accordingly and Directive 80/1269/EEC should be repealed.

(28) In order to simplify Community legislation, it is appropriate to replace the existing heavy duty vehicles emissions legislation, namely Directive 2005/55/EC [3] and Commission Directive 2005/78/EC [4], by a regulation. The use of a regulation should ensure that the detailed technical provisions are directly applicable to manufacturers, approval authorities and technical services and that they can be updated in a fast and efficient way. Therefore Directives 2005/55/EC and 2005/78/EC should be repealed and Regulation (EC) No 715/2007 should be amended accordingly.

---

[1] OJ L 375, 31.12.1980, p. 46.

[2] OJ L 171, 29.6.2007, p. 1.

[3] Directive 2005/55/EC of the European Parliament and of the Council of 28 September 2005 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from compression-ignition engines for use in vehicles, and the emission of gaseous pollutants from positive-ignition engines fuelled with natural gas or liquefied petroleum gas for use in vehicles (OJ L 275, 20.10.2005, p. 1).

[4] Commission Directive 2005/78/EC of 14 November 2005 implementing Directive 2005/55/EC and amending Annexes I, II, III, IV and VI thereto (OJ L 313, 29.11.2005, p. 1).

(29) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1].

(30) In particular, the Commission should be empowered to introduce particle number based limit values in Annex I, to specify, if appropriate, the value of the admissible level of the NO_2 component in the NO_x limit value, to establish specific procedures, tests and requirements for type-approval, as well as a particle number measurement procedure, and to adopt measures concerning off-cycle emissions, the use of portable emissions measurement systems, access to vehicle repair and maintenance information and test cycles used to measure emissions. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(31) Since the objective of this Regulation, namely the realisation of the internal market through the introduction of common technical requirements concerning emissions from motor vehicles and guaranteed access to vehicle repair and maintenance information for independent operators on the same basis as for authorised dealers and repairers, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes common technical requirements for the type-approval of motor vehicles, engines and replacement parts with regard to their emissions.

This Regulation also lays down rules for in-service conformity of vehicles and engines, durability of pollution control devices, OBD systems, measurement of fuel consumption and CO_2 emissions and accessibility of vehicle OBD and vehicle repair and maintenance information.

[1] OJ L 184, 17.7.1999, p. 23.

Article 2

Scope

This Regulation shall apply to motor vehicles of categories M_1, M_2, N_1 and N_2 as defined in Annex II of Directive 2007/46/EC with a reference mass exceeding 2 610 kg and to all motor vehicles of categories M_3 and N_3, as defined in that Annex.

This Regulation shall apply without prejudice to Article 2(2) of Regulation (EC) No 715/2007.

At the request of the manufacturer, the type-approval of a completed vehicle granted under this Regulation and its implementing measures shall be extended to its incomplete vehicle with a reference mass not exceeding 2 610 kg. Type-approvals shall be extended if the manufacturer can demonstrate that all bodywork combinations expected to be built onto the incomplete vehicle increase the reference mass of the vehicle to above 2 610 kg.

At the request of the manufacturer, the type-approval of a vehicle granted under this Regulation and its implementing measures shall be extended to its variants and versions with a reference mass exceeding 2 380 kg provided that it also meets the requirements relating to the measurement of greenhouse gas emissions and fuel consumption established in Regulation (EC) No 715/2007 and its implementing measures.

Article 3

Definitions

For the purposes of this Regulation, the following definitions shall apply:

1. 'engine' means the motive propulsion source of a vehicle for which type-approval as a separate technical unit, as defined in point 25 of Article 3 of Directive 2007/46/EC, may be granted;

2. 'gaseous pollutants' means the exhaust gas emissions of carbon monoxide, NO_x, expressed in NO_2 equivalent, and hydrocarbons;

3. 'particulate pollutants' means components of the exhaust gas which are removed from the diluted exhaust gas at a maximum temperature of 325 K (52 °C) by means of the filters described in the test procedure for verifying average tailpipe emissions;

4. 'tailpipe emissions' means the emission of gaseous and particulate pollutants;

5. 'crankcase' means the spaces in, or external to, an engine which are connected to the oil sump by internal or external ducts through which gases and vapours can be emitted;

6. 'pollution control device' means those components of a vehicle that control and/or limit tailpipe emissions;

7. 'on-board diagnostic (OBD) system' means a system on board a vehicle or connected to an engine which has the capability of detecting malfunctions, and, if applicable, of indicating their occurrence by means of an alert system, of identifying the likely area of malfunction by means of information stored in computer memory, and of communicating that information off-board;

8. 'defeat strategy' means an emission control strategy that reduces the effectiveness of the emission controls under ambient or engine operating conditions encountered either during normal vehicle operation or outside the type-approval test procedures;

9. 'original pollution control device' means a pollution control device or an assembly of such devices covered by the type-approval granted for the vehicle concerned;

10. 'replacement pollution control device' means a pollution control device or an assembly of such devices intended to replace an original pollution control device and which can be approved as a separate technical unit, as defined in point 25 of Article 3 of Directive 2007/46/EC;

11. 'vehicle repair and maintenance information' means all information required for diagnosis, servicing, inspection, periodic monitoring, repair, re-programming or re-initialising or the remote diagnostic support of the vehicle and which the manufacturers provide for their authorised dealers and repairers, including all subsequent amendments and supplements to such information. This information includes all information required for fitting parts or equipment onto vehicles;

12. 'manufacturer' means the person or body who is responsible to the approval authority for all aspects of the type-approval or authorisation process and for ensuring conformity of production. It is not essential that the person or body be directly involved in all stages of the construction of the vehicle, system, component or separate technical unit which is the subject of the approval process;

13. 'independent operator' means undertakings other than authorised dealers and repairers which are directly or indirectly involved in the repair and maintenance of motor vehicles, in particular repairers, manufacturers or distributors of repair equipment, tools or spare parts, publishers of technical information, automobile clubs, roadside assistance operators, operators offering inspection and testing services, operators offering training for installers, manufacturers and repairers of equipment for alternative fuel vehicles;

14. 'alternative fuel vehicle' means a vehicle designed to be capable of running on at least one type of fuel that is either gaseous at atmospheric temperature and pressure, or substantially non-mineral oil derived;

15. 'reference mass' means the mass of the vehicle in running order less the uniform mass of the driver of 75 kg and increased by a uniform mass of 100 kg;

16. 'tampering' means inactivation, adjustment or modification of the vehicle emissions control or propulsion system, including any software or other logical control elements of those systems, that has the effect, whether intended or not, of worsening the emissions performance of the vehicle.

The Commission may adapt the definition in point 7 of the first subparagraph to reflect technical progress in OBD systems. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(2).

Article 4

Obligations of the manufacturers

1. Manufacturers shall demonstrate that all new vehicles sold, registered or put into service within the Community, all new engines sold or put into service within the Community and all new replacement pollution control devices requiring type-approval pursuant to Articles 8 and 9, which are sold or put into service within the Community, are type-approved in accordance with this Regulation and its implementing measures.

2. Manufacturers shall ensure that type-approval procedures for verifying conformity of production, durability of pollution control devices and in-service conformity are followed.

The technical measures taken by the manufacturer shall be such as to ensure that the tailpipe emissions are effectively limited, pursuant to this Regulation and its implementing measures, throughout the normal life of the vehicles under normal conditions of use.

For that purpose, the mileage and period of time by reference to which the tests for durability of pollution control devices undertaken for type-approval and testing of conformity of in-service vehicles or engines are to be carried out shall be the following:

(a) 160 000 km or five years, whichever is the sooner, in the case of engines fitted to vehicles of category M_1, N_1 and M_2;

(b) 300 000 km or six years, whichever is the sooner, in the case of engines fitted to vehicles of category N_2, N_3 with a maximum technically permissible mass not exceeding 16 tonnes and M_3 Class I, Class II and Class A, and Class B with a maximum technically permissible mass not exceeding 7,5 tonnes;

(c) 700 000 km or seven years, whichever is the sooner, in the case of engines fitted to vehicles of category N_3 with a maximum technically permissible mass exceeding 16 tonnes and M_3, Class III and Class B with a maximum technically permissible mass exceeding 7,5 tonnes.

3. The Commission shall establish specific procedures and requirements for the implementation of paragraphs 1 and 2 of this Article. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(2).

Article 5

Requirements and tests

1. Manufacturers shall ensure compliance with the emission limits set out in Annex I.

2. Manufacturers shall equip vehicles and engines so that the components likely to affect emissions are designed, constructed and assembled so as to enable the vehicle or engine, in normal use, to comply with this Regulation and its implementing measures.

3. The use of defeat strategies that reduce the effectiveness of emission control equipment shall be prohibited.

4. The Commission shall adopt measures for the implementation of this Article including measures in relation to the following:

(a) tailpipe emissions, including test cycles, the use of portable emissions measurement systems for verifying the actual in-use emissions, verifying and limiting off-cycle emissions, the setting of limits for particle numbers while retaining the existing ambitious environmental requirements, and emissions at idling speed;

(b) crankcase emissions;

(c) OBD systems and in-service performance of pollution control devices;

(d) durability of pollution control devices, replacement pollution control devices, conformity of in-service engines and vehicles, conformity of production and roadworthiness;

(e) CO_2 emissions and fuel consumption;

(f) granting extension of type-approvals;

(g) test equipment;

(h) reference fuels such as petrol, diesel, gaseous fuels and biofuels, such as bioethanol, biodiesel and biogas;

(i) measurement of engine power;

(j) correct functioning and regeneration of pollution control devices;

(k) specific provisions to ensure the correct operation of NO_x control measures; such provisions shall ensure that vehicles cannot be operated if the NO_x control measures are inoperative due, for example, to lack of any required reagent, incorrect exhaust gas recirculation (EGR) flow or deactivation of EGR.

Those measures, designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(2).

Article 6

Access to information

1. Manufacturers shall provide unrestricted and standardised access to vehicle OBD information, diagnostic and other equipment, tools including any relevant software and vehicle repair and maintenance information to independent operators.

Manufacturers shall provide a standardised, secure and remote facility to enable independent repairers to complete operations which involve access to the vehicle security system.

In the case of multi-stage type-approval, the manufacturer responsible for the respective type-approval shall also be responsible for communicating repair information relating to the particular stage to both the final manufacturer and independent operators. The final manufacturer shall be responsible for communicating information about the whole vehicle to independent operators.

Articles 6 and 7 of Regulation (EC) No 715/2007 shall apply *mutatis mutandis*.

Until the adoption of the relevant standard, for example through the work of CEN, the vehicle OBD and vehicle repair and maintenance information shall be presented in an easily accessible, non-discriminatory manner.

That information shall be made available on the websites of manufacturers, or, if this is not feasible due to the nature of the information, in another appropriate format.

2. The Commission shall establish and update, for the implementation of paragraph 1, the appropriate technical specifications relating to the way in which vehicle OBD and vehicle repair and maintenance information shall be provided. The Commission shall take into account current information technology, foreseeable vehicle technology developments, existing ISO standards and the possibility of a worldwide ISO standard.

The Commission may adopt other measures necessary for the implementation of paragraph 1.

Those measures, designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(2).

Article 7

Obligations concerning systems using a consumable reagent

1. Manufacturers, repairers and operators of the vehicles shall not tamper with systems which use a consumable reagent.

2. Operators of the vehicles shall ensure that vehicles are not being driven without a consumable reagent.

Article 8

Timetable for application of type-approval of vehicles and engines

1. With effect from 31 December 2012, national authorities shall refuse, on grounds relating to emissions, to grant EC type-approval or national type-approval in respect of new types of vehicles or engines which do not comply with this Regulation and its implementing measures.

Type-approval technical certificates corresponding to the emission stages prior to Euro VI may be granted to vehicles and engines intended for export to third countries, provided such certificates clearly state that the vehicles and engines in question cannot be placed on the Community market.

2. With effect from 31 December 2013, national authorities shall, in the case of new vehicles which do not comply with this Regulation and its implementing measures, consider certificates of conformity to be no longer valid for the purposes of Article 26 of Directive 2007/46/EC and shall, on grounds relating to emissions, prohibit the registration, sale and entry into service of such vehicles.

With effect from the same date and except in the case of replacement engines for in-service vehicles, national authorities shall prohibit the sale or use of new engines which do not comply with this Regulation and its implementing measures.

3. Without prejudice to paragraphs 1 and 2 of this Article, and subject to entry into force of the implementing measures referred to in Article 4(3), Article 5(4) and in the first subparagraph of Article 6(2), if a manufacturer so requests, national authorities may not, on grounds relating to emissions of vehicles, refuse to grant EC type-approval or national type-approval for a new type of vehicle or engine, or prohibit the registration, sale or entry into service of a new vehicle and the sale or use of new engines, where the vehicle or engines concerned comply with this Regulation and its implementing measures.

Article 9

Obligations of Member States concerning type-approval of replacement parts

The sale or installation on a vehicle of new replacement pollution control devices intended to be fitted on vehicles approved under this Regulation and its implementing measures shall be prohibited if they are not of a type in respect of which a type-approval has been granted in compliance with this Regulation and its implementing measures.

Article 10

Financial incentives

1. Subject to the entry into force of the implementing measures to this Regulation, Member States may provide for financial incentives that apply to motor vehicles in series production, which comply with this Regulation and its implementing measures.

Those incentives shall apply to all new vehicles put on the market of the Member State concerned, which comply with this Regulation and its implementing measures. However, they shall cease to apply on 31 December 2013 at the latest.

2. Subject to the entry into force of the implementing measures to this Regulation, Member States may grant financial incentives for retrofitting in order to meet the emission limit values set out in Annex I of in-use vehicles and for scrapping vehicles which do not comply with this Regulation and its implementing measures.

3. For each type of motor vehicle, the financial incentives referred to in paragraphs 1 and 2 shall not exceed the additional cost of the technical devices used to ensure compliance with the emission limits specified in Annex I, including the cost of installation on the vehicle.

4. The Commission shall be informed of plans to institute or change the financial incentives referred to in paragraphs 1 and 2.

Article 11

Penalties

1. Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and its implementing measures and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 7 February 2011 and shall notify it without delay of any subsequent amendment affecting them.

2. The types of infringements by manufacturers which are subject to a penalty shall include:

(a) making false declarations during the approval procedures or procedures leading to a recall;

(b) falsifying test results for type-approval or in-service conformity;

(c) withholding data or technical specifications which could lead to recall or withdrawal of type-approval;

(d) use of defeat strategies;

(e) refusal to provide access to information.

The types of infringements by manufacturers, repairers and operators of the vehicles which are subject to a penalty shall include tampering with systems which control NO_x emissions. This shall include, for example, tampering with systems which use a consumable reagent.

The types of infringements committed by operators of the vehicles which are subject to a penalty shall include driving a vehicle without a consumable reagent.

Article 12

Redefinition of specifications

1. After the completion of the relevant parts of the PMP of the UN/ECE, conducted under the auspices of the World Forum for Harmonisation of Vehicle Regulations, the Commission shall, without lowering the level of environmental protection within the Community:

(a) introduce as an additional control upon emissions of particulate matter particle number based limit values set at a level appropriate to the technologies actually being used at that time to meet the particulate mass limit;

(b) adopt a measurement procedure for particle number.

The Commission shall also, without lowering the level of environmental protection within the Community, specify a limit value for emissions of NO_2 in addition to that for total emissions of NO_x, if appropriate. The limit for emissions of NO_2 shall be set at a level reflecting the performance of then existing technologies.

Those measures, designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(2).

2. The Commission shall establish correlation factors between the European transient cycle (ETC) and the European steady state cycle (ESC) as described in Directive 2005/55/EC, and the worldwide harmonised transient driving cycle (WHTC) and the worldwide harmonised steady state driving cycle (WHSC) and shall adapt the limit values to that effect. Those measures, designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(2).

3. The Commission shall keep under review the procedures, tests and requirements referred to in Article 5(4) as well as the test cycles used to measure emissions.

If the review finds that those procedures, tests, requirements and test cycles are no longer adequate or no longer reflect actual world emissions, they shall be adapted so as to adequately reflect the emissions generated by real driving on the road. Those measures, designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(2).

4. The Commission shall keep under review the pollutants listed in point 2 of Article 3. If the Commission concludes that it is appropriate to regulate the emissions of additional pollutants, it shall submit to the European Parliament and to the Council a proposal for amending this Regulation.

Article 13

Committee procedure

1. The Commission shall be assisted by the Technical Committee — Motor Vehicles (TCMV) established by Article 40(1) of Directive 2007/46/EC.

2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 14

Implementation

The Commission shall adopt the implementing measures referred to in Article 4(3), Article 5(4), Article 6(2) and Article 12(1)(a) and (b) by 1 April 2010.

Article 15

Amendments to Regulation (EC) No 715/2007

Regulation (EC) No 715/2007 is hereby amended as follows:

1. Article 5(3) shall be amended as follows:

(i) after point (h), the word 'and' shall be deleted;

(ii) the following point shall be added:

'(j) measurement of engine power.';

2. Article 14(6) shall be deleted.

Article 16

Amendments to Directive 2007/46/EC

Annexes IV, VI and XI to Directive 2007/46/EC are amended in accordance with Annex II to this Regulation.

Article 17

Repeal

1. Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC are repealed with effect from 31 December 2013.

2. References made to the repealed Directives shall be construed as references to this Regulation.

Article 18

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 7 August 2009. However, Articles 8(3) and 10 shall apply from 7 August 2009 and points 1(a)(i), 1(b)(i), 2(a), 3(a)(i), 3(b)(i), 3(c)(i), 3(d)(i) and 3(e)(i) of Annex II shall apply from 31 December 2013.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 June 2009.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
Š. FÜLE

ANNEX I

Euro VI emission limits

	Limit values							
	CO (mg/kWh)	THC (mg/kWh)	NMHC (mg/kWh)	CH_4 (mg/kWh)	NO_X (1) (mg/kWh)	NH_3 (ppm)	PM mass (mg/kWh)	PM (2) number (#/kWh)
ESC (CI)	1 500	130			400	10	10	
ETC (CI)	4 000	160			400	10	10	
ETC (PI)	4 000		160	500	400	10	10	
WHSC (3)								
WHTC (3)								

Note:
PI = positive ignition.
CI = compression ignition.
(1) The admissible level of NO_2 component in the NO_x limit value may be defined at a later stage.
(2) A number standard is to be defined at a later stage and no later than 1 April 2010.
(3) The limit values relating to WHSC and WHTC, replacing the limit values relating to ESC and ETC, will be introduced, at a later stage, once correlation factors with respect to the current cycles (ESC and ETC) have been established, no later than 1 April 2010.

ANNEX II

Amendments to Directive 2007/46/EC

Directive 2007/46/EC is hereby amended as follows:

1. Part I of Annex IV shall be amended as follows:

(a) the table shall be amended as follows:

(i) points 40 and 41 shall be deleted;

(ii) the following point shall be inserted:

Subject	Regulatory act reference	Official Journal reference	Applicability									
			M_1	M_2	M_3	N_1	N_2	N_3	O_1	O_2	O_3	O_4
'41a Emissions (Euro VI) heavy duty vehicles/ access to information	Regulation (EC) No 595/2009	OJ L 188, 18.7.2009, p. 1	X[12]	X[12]	X	X[12]	X[12]	X'				

(iii) the following note shall be added:

'([12]) For vehicles with a reference mass exceeding 2 610 kg which are not type-approved (at the manufacturer's request and provided their reference mass does not exceed 2 840 kg) under Regulation (EC) No 715/2007.';

(b) in the Appendix, the table shall be amended as follows:

(i) points 40 and 41 shall be deleted;

(ii) the following point shall be inserted:

	Subject	Regulatory act reference	Official Journal reference	M_1
'41a	Emissions (Euro VI) heavy duty vehicles, with the exception of the whole set of requirements relating to on-board diagnostics (OBDs) and access to information/access to information	Regulation (EC) No 595/2009	OJ L 188, 18.7.2009, p. 1	A'

2. in the Appendix to Annex VI, the table shall be amended as follows:

(a) points 40 and 41 shall be deleted;

(b) the following point shall be inserted:

Subject	Regulatory act reference	As amended by	Applicable to versions
'41a Emissions (Euro VI) heavy duty vehicles/access to information	Regulation (EC) No 595/2009'		

3. Annex XI shall be amended as follows:

(a) in Appendix 1, the table shall be amended as follows:

(i) points 40 and 41 shall be deleted;

(ii) the following point shall be inserted:

Item	Subject	Regulatory act reference	$M_1 \leq 2\,500$ [1] kg	$M_1 > 2\,500$ [1] kg	M_2	M_3
'41a	Emissions (Euro VI) heavy duty vehicles/access to information	Regulation (EC) No 595/2009	G + H	G + H	G + H	G + H'

(b) in Appendix 2, the table shall be amended as follows:

(i) points 40 and 41 shall be deleted;

(ii) the following point shall be inserted:

Item	Subject	Regulatory act reference	M_1	M_2	M_3	N_1	N_2	N_3	O_1	O_2	O_3	O_4
'41a	Emissions (Euro VI) heavy duty vehicles/access to information	Regulation (EC) No 595/2009	X	X	X	X	X	X'				

(c) in Appendix 3, the table shall be amended as follows:

(i) points 40 and 41 shall be deleted;

(ii) the following point shall be inserted:

Item	Subject	Regulatory act reference	M_1
'41a	Emissions (Euro VI) heavy duty vehicles/access to information	Regulation (EC) No 595/2009	X'

(d) in Appendix 4, the table shall be amended as follows:

(i) points 40 and 41 shall be deleted;

(ii) the following point shall be inserted:

Item	Subject	Regulatory act reference	M_2	M_3	N_1	N_2	N_3	O_1	O_2	O_3	O_4
'41a	Emissions (Euro VI) heavy duty vehicles/access to information	Regulation (EC) No 595/2009	H	H	H	H	H'				

(e) in Appendix 5, the table shall be amended as follows:

(i) points 40 and 41 shall be deleted;

(ii) the following point shall be inserted:

Item	Subject	Regulatory act reference	Mobile crane of category N_3
'41a	Emissions (Euro VI) heavy duty vehicles/access to information	Regulation (EC) No 595/2009	V'

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 47(2), 55, 71(1), 80(2), 95, 152(4)(a) and (b), 175(1), and 285(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Having regard to the opinion of the European Central Bank [2],

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [4] has been amended by Decision 2006/512/EC [5], which introduced the regulatory procedure with scrutiny for the adoption of measures of general scope designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure laid down in Article 251 of the Treaty, *inter alia*, by deleting some of those elements or by supplementing the instrument with new non-essential elements.

(2) In accordance with the statement of the European Parliament, the Council and the Commission [6] concerning Decision 2006/512/EC, for the regulatory procedure with scrutiny to be applicable to instruments adopted in accordance with the procedure laid down in Article 251 of the Treaty which are already in force, those instruments must be adjusted in accordance with the applicable procedures.

(3) Since the amendments made to instruments for this purpose are technical in nature and concern committee procedure only, they do not, in the case of Directives, need to be transposed by the Member States,

HAVE ADOPTED THIS REGULATION:

Article 1

The instruments listed in the Annex are hereby adapted, in accordance with that Annex, to Decision 1999/468/EC, as amended by Decision 2006/512/EC.

Article 2

References to provisions of the instruments listed in the Annex shall be understood to be references to those provisions as adapted by this Regulation.

Article 3

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 June 2009.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
Š. FÜLE

[1] OJ C 224, 30.8.2008, p. 35.
[2] OJ C 117, 14.5.2008, p. 1.
[3] Opinion of the European Parliament of 16 December 2008 (not yet published in the Official Journal) and Council Decision of 28 May 2009.
[4] OJ L 184, 17.7.1999, p. 23.
[5] OJ L 200, 22.7.2006, p. 11.
[6] OJ C 255, 21.10.2006, p. 1.

ANNEX

1. ENTERPRISE

1.1. **Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 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** [1]

As regards Directive 97/68/EC, the Commission should be empowered in particular to establish the conditions under which amendments which are necessary in the light of adaptation to technical progress should be adopted. Since those measures are of general scope and are designed to amend non-essential elements of Directive 97/68/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 97/68/EC is hereby amended as follows:

1. in Article 4(2), the last sentence shall be replaced by the following:

'The Commission shall amend Annex VIII. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2).';

2. Article 7a(4) shall be replaced by the following:

'4. The Commission shall adapt Annex VII to integrate the additional and specific information which may be required as regards the type-approval certificate for engines to be installed in inland waterway vessels. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2).';

3. Article 14 shall be replaced by the following:

'*Article 14*

The Commission shall adopt any amendments which are necessary in order to adapt the Annexes, with the exception of the requirements specified in section 1, sections 2.1 to 2.8 and section 4 of Annex I, to technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2).';

4. Article 14a shall be replaced by the following:

'*Article 14a*

The Commission shall study possible technical difficulties in complying with the stage II requirements for certain uses of the engines, in particular mobile machinery in which engines of classes SH:2 and SH:3 are installed. If the Commission studies conclude that for technical reasons certain mobile machinery, in particular, multi-positional, hand-held engines intended for professional use, cannot meet those requirements by the deadlines laid down, it shall submit, by 31 December 2003, a report accompanied by appropriate proposals for extensions of the period referred to in Article 9a(7) and/or further derogations, not exceeding five years in duration, save in exceptional circumstances, for such machinery. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2).';

[1] OJ L 59, 27.2.1998, p. 1.

5. Article 15 shall be amended as follows:

(a) paragraph 2 shall be replaced by the following:

'2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

(b) paragraph 3 shall be deleted;

6. in Annex I, point 4.1.2.7, the last sentence shall be replaced by the following:

'The Commission shall define the control area to which the percentage not to be exceeded is to apply and the excluded engine operating conditions. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2).';

7. in Annex III, the last paragraph of point 1.3.2 shall be replaced by the following:

'Prior to the introduction of the cold/hot composite test sequence, the Commission shall modify the symbols (Annex I, section 2.18), the test sequence (Annex III) and the calculation equations (Annex III, Appendix 3). Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(2).'.

1.2. **Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices** [1]

As regards Directive 98/79/EC, the Commission should be empowered in particular to adopt particular health monitoring measures and to amend Annex II. Since those measures are of general scope and are designed to amend non-essential elements of Directive 98/79/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of prohibitions, restrictions or particular requirements for certain products.

Accordingly, Directive 98/79/EC is hereby amended as follows:

1. Article 7 shall be replaced by the following:

'*Article 7*

1. The Commission shall be assisted by the Committee set up by Article 6(2) of Directive 90/385/EEC.

2. Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

[1] OJ L 331, 7.12.1998, p. 1.

4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 184, 17.7.1999, p. 23.';

2. Article 10(5) shall be replaced by the following:

'5. Member States shall take all necessary measures to ensure that the notifications referred to in paragraphs 1 and 3 are registered immediately in the databank described in Article 12.

The procedures for implementing this Article and in particular those referring to the notification and the concept of significant change shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).';

3. Article 11(5) shall be replaced by the following:

'5. Member States shall on request inform the other Member States of the details referred to in paragraphs 1 to 4. The procedures implementing this Article shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).';

4. Article 12(3) shall be replaced by the following:

'3. The procedures implementing this Article shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).';

5. Article 13 shall be replaced by the following:

'*Article 13*

Where a Member State considers, in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed pursuant to Article 36 of the Treaty, the availability of such products should be prohibited, restricted or made subject to particular requirements, it may take any necessary and justified transitional measures. It shall then inform the Commission and all the other Member States, giving the reasons for its decision. The Commission shall consult the interested parties and the Member States and, where the national measures are justified, adopt necessary Community measures.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 7(4).';

6. Article 14(1) shall be replaced by the following:

'1. Where a Member State considers that:

(a) the list of devices in Annex II should be amended or extended; or

(b) the conformity of a device or category of devices should be established, by way of derogation from the provisions of Article 9, by applying one or more given procedures taken from amongst those referred to in Article 9,

it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures.

Where those measures concern matters referred to in point (a), designed to amend non-essential elements of this Directive, they shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).

Where those measures concern matters referred to in point (b), they shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).'.

1.3. **Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity** [1]

As regards Directive 1999/5/EC, the Commission should be empowered in particular to adopt a decision specifying, for apparatus within certain equipment classes or apparatus of particular types, which of the additional requirements apply, to determine the date of application, including, where appropriate, a transitional period, of certain additional essential requirements to specific equipment classes or apparatus of particular types, and to decide on the form of the equipment class identifier to be affixed on specific types of radio equipment. Since those measures are of general scope and are designed to amend non-essential elements of Directive 1999/5/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 1999/5/EC is hereby amended as follows:

1. Article 3(3) shall be replaced by the following:

'3. The Commission may decide that apparatus within certain equipment classes or apparatus of particular types shall be so constructed that:

(a) it interworks via networks with other apparatus and that it can be connected to interfaces of the appropriate type throughout the Community; and/or that

(b) it does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service; and/or that

(c) it incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected; and/or that

(d) it supports certain features ensuring avoidance of fraud; and/or that

(e) it supports certain features ensuring access to emergency services; and/or that

(f) it supports certain features in order to facilitate its use by users with a disability.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15a.';

2. Article 5(3) shall be replaced by the following:

'3. In the case of shortcomings of harmonised standards with respect to the essential requirements, the Commission may, after consulting the committee and in accordance with the procedure laid down in Article 14, publish in the *Official Journal of the European Union* recommendations on the interpretation of harmonised standards or on the conditions under which compliance with those standards raises a presumption of conformity. After consultation of the committee and in accordance with the procedure laid down in Article 14, the Commission may withdraw harmonised standards by publication of a notice in the *Official Journal of the European Union*.';

[1] OJ L 91, 7.4.1999, p. 10.

3. Article 6(2) shall be replaced by the following:

'2. In taking a decision regarding the application of essential requirements under Article 3(3), the Commission shall determine the date of application of the requirements.

If it is determined that an equipment class needs to comply with particular essential requirements under Article 3(3), any apparatus of the equipment class in question which is first placed on the market before the date of application of the Commission's determination can continue to be placed on the market for a reasonable period to be determined by the Commission.

The measures referred to in the first and second subparagraphs, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15a.';

4. the following Article shall be inserted:

'Article 15a

Regulatory procedure with scrutiny

Where reference is made to this Article, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

5. point 5 of Annex VII shall be replaced by the following:

'5. The equipment class identifier must take a form to be decided by the Commission.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15a.'.

1.4. **Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products** [1]

As regards Regulation (EC) No 141/2000, the Commission should be empowered in particular to adopt definitions of 'similar medicinal product' and 'clinical superiority'. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 141/2000, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 141/2000 is hereby amended as follows:

1. Article 3(2) shall be replaced by the following:

'2. The Commission shall, in accordance with the regulatory procedure referred to in Article 10a(2), adopt the necessary provisions for implementing paragraph 1 of this Article in the form of an implementing Regulation.';

2. Article 5(8) shall be replaced by the following:

'8. The Agency shall forthwith forward the final opinion of the Committee to the Commission, which shall adopt a decision within 30 days of receipt of the opinion. Where, in exceptional circumstances, the draft decision is not in accordance with the opinion of the Committee, the decision shall be adopted in accordance with the regulatory procedure referred to in Article 10a(2). The decision shall be notified to the sponsor and communicated to the Agency and to the competent authorities of the Member States.';

[1] OJ L 18, 22.1.2000, p. 1.

3. Article 8(4) shall be replaced by the following:

'4. The Commission shall adopt definitions of "similar medicinal product" and "clinical superiority" in the form of an implementing Regulation.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10a(3).';

4. the following Article shall be inserted:

'*Article 10a*

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use, referred to in Article 121(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use (*).

2. Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 311, 28.11.2001, p. 67.
(**) OJ L 184, 17.7.1999, p. 23.'.

1.5. **Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use** ([1])

As regards Directive 2001/20/EC, the Commission should be empowered in particular to adopt principles relating to good clinical practice and detailed rules in line with those principles, to lay down specific requirements and to adapt certain provisions. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2001/20/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2001/20/EC is hereby amended as follows:

1. Article 1(3) shall be replaced by the following:

'3. The Commission shall adopt the principles relating to good clinical practice and detailed rules in line with those principles and shall, if necessary, revise those principles and detailed rules to take account of technical and scientific progress. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3).

The principles and detailed rules shall be published by the Commission.';

([1]) OJ L 121, 1.5.2001, p. 34.

2. Article 13(1) shall be replaced by the following:

'1. Member States shall take all appropriate measures to ensure that the manufacture or importation of investigational medicinal products is subject to the holding of authorisation.

The Commission shall lay down the minimum requirements which the applicant and, subsequently, the holder of the authorisation must meet in order to obtain the authorisation.

Those measures, designed to amend non-essential elements of this Directive, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3).';

3. Article 20 shall be replaced by the following:

'*Article 20*

The Commission shall adapt this Directive to take account of scientific and technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3).';

4. Article 21 shall be replaced by the following:

'*Article 21*

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use, referred to in Article 121(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use (*).

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 311, 28.11.2001, p. 67.'

1.6. **Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products** [1]

As regards Directive 2001/82/EC, the Commission should be empowered in particular to adapt certain provisions and annexes, and to lay down specific conditions of application. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2001/82/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2001/82/EC is hereby amended as follows:

1. Article 10(3) shall be replaced by the following:

'3. By way of derogation from Article 11, the Commission shall establish a list of substances essential for the treatment of *equidae* and for which the withdrawal period shall be not less than six months according to the control mechanisms laid down in Decisions 93/623/EEC and 2000/68/EC.

[1] OJ L 311, 28.11.2001, p. 1.

That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).';

2. in Article 11(2), the third subparagraph shall be replaced by the following:

'However, the Commission may modify those specific withdrawal periods. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).';

3. in Article 13(1), the fourth subparagraph shall be replaced by the following:

'However, the 10-year period provided for in the second subparagraph shall be extended to 13 years in the case of veterinary medicinal products for fish or bees or other species designated by the Commission.

That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).';

4. in Article 17(1), the second subparagraph shall be replaced by the following:

'If it appears justified in the light of new scientific evidence, the Commission may adapt points (b) and (c) of the first subparagraph. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).';

5. in Article 39(1), the third subparagraph shall be replaced by the following:

'The Commission shall adopt those arrangements in the form of an implementing regulation. That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).';

6. Article 50a(2) shall be replaced by the following:

'2. The Commission shall adopt any amendments which may be necessary in order to adapt the provisions of paragraph 1 to take account of scientific and technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).';

7. in Article 51, the first paragraph shall be replaced by the following:

'The principles and guidelines of good manufacturing practice for veterinary medicinal products referred to in Article 50(f) shall be adopted by the Commission in the form of a Directive addressed to the Member States. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).';

8. in Article 67, point (aa) shall be replaced by the following:

'(aa) veterinary medicinal products for food-producing animals.

However, Member States may grant exemptions from this requirement according to criteria established by the Commission. The establishment of those criteria, being a measure designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).

Member States may continue to apply national provisions until either:

(i) the date of application of the decision adopted in accordance with the first subparagraph; or

(ii) 1 January 2007, if no such decision has been adopted by 31 December 2006;';

9. Article 68(3) shall be replaced by the following:

'3. The Commission shall adopt any amendments to the list of substances referred to in paragraph 1.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).';

10. Article 75(6) shall be replaced by the following:

'6. The Commission may amend paragraph 5 in the light of the experience gained from its operation.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).';

11. Article 79 shall be replaced by the following:

'*Article 79*

The Commission shall adopt any amendments which may be necessary to update Articles 72 to 78 to take account of scientific and technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).';

12. Article 88 shall be replaced by the following:

'*Article 88*

The Commission shall adopt any changes which are necessary in order to adapt Annex I to take account of technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).';

13. Article 89 shall be amended as follows:

(a) the following paragraph shall be inserted:

'2a. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

(b) paragraph 4 shall be replaced by the following:

'4. The rules of procedure of the Standing Committee shall be made public.'.

1.7. **Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery** [1]

As regards Directive 2006/42/EC, the Commission should be empowered in particular to establish the conditions for updating the indicative list of safety components and for the measures regarding the restriction of the placing on the market of potentially hazardous machinery. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2006/42/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2006/42/EC is hereby amended as follows:

1. Article 8 shall be replaced by the following:

'*Article 8*

Specific measures

1. The Commission may take any appropriate measure relating to the following:

(a) updating the indicative list of safety components in Annex V referred to in Article 2(c);

(b) restricting the placing on the market of machinery referred to in Article 9.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).

2. The Commission, acting in accordance with the advisory procedure referred to in Article 22(2), may take any appropriate measure connected with the practical application of this Directive, including measures necessary to ensure cooperation of Member States with each other and with the Commission, as provided for in Article 19(1).';

2. Article 9(3) shall be replaced by the following:

'3. In the cases referred to in paragraph 1, the Commission shall consult the Member States and other interested parties, indicating the measures it intends to take in order to ensure, at Community level, a high level of protection of the health and safety of persons.

Taking due account of the results of this consultation, it shall adopt the necessary measures.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).';

3. Article 22 shall be amended as follows:

(a) paragraph 3 shall be replaced by the following:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

(b) paragraph 4 shall be deleted.

[1] OJ L 157, 9.6.2006, p. 24.

2. ENVIRONMENT

2.1. **Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT)** [1]

As regards Directive 96/59/EC, the Commission should be empowered in particular to fix the reference methods of measurement to determine the PCB content of contaminated materials and the technical standards for the other methods of disposing of PCBs, and, if necessary, to determine, solely for the purpose of Article 9(1)(b) and (c), other less hazardous substitutes for PCBs. Since those measures are of general scope and are designed to amend non-essential elements of Directive 96/59/EC by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 96/59/EC is hereby amended as follows:

1. Article 10 shall be replaced by the following:

'Article 10

1. The Commission shall make available, in accordance with the regulatory procedure referred to in Article 10a(2), a list of the production names of capacitors, resistors and inductance coils containing PCBs.

2. The Commission shall:

(a) fix the reference methods of measurement to determine the PCB content of contaminated materials. Measurements effected before the determination of the reference methods shall remain valid;

(b) if necessary determine, solely for the purpose of Article 9(1)(b) and (c), other less hazardous substitutes for PCBs.

The Commission may fix technical standards for the other methods of disposing of PCBs referred to in the second sentence of Article 8(2).

The measures referred to in the first and second subparagraphs, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10a(3).';

2. the following Article shall be inserted:

'Article 10a

1. The Commission shall be assisted by the Committee set up by Article 18 of Directive 2006/12/EC of the European Parliament and of the Council (*).

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 114, 27.4.2006, p. 9.'.

[1] OJ L 243, 24.9.1996, p. 31.

2.2. **Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption** ([1])

As regards Directive 98/83/EC, the Commission should be empowered in particular to adapt Annexes II and III to scientific and technical progress and to set out certain details on monitoring in Annex II. Since those measures are of general scope and are designed to amend non-essential elements of Directive 98/83/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 98/83/EC is hereby amended as follows:

1. Article 7(4) shall be replaced by the following:

'4. Community guidelines for the monitoring prescribed in this Article may be drawn up in accordance with the management procedure referred to in Article 12(2).';

2. Article 11(2) shall be replaced by the following:

'2. At least every five years, the Commission shall amend Annexes II and III to make the necessary adaptations to scientific and technical progress.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).';

3. Article 12(3) shall be replaced by the following:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

4. Article 13 shall be amended as follows:

(a) paragraph 4 shall be replaced by the following:

'4. The formats and the minimum information for the reports provided for in paragraph 2 shall be determined having special regard to the measures referred to in Article 3(2), Article 5(2) and (3), Article 7(2), Article 8, Article 9(6) and (7) and Article 15(1), and shall if necessary be amended in accordance with the management procedure referred to in Article 12(2).';

(b) paragraph 6 shall be replaced by the following:

'6. Together with the first report on this Directive as mentioned in paragraph 2, Member States shall also produce a report to be forwarded to the Commission on the measures they have taken or plan to take to fulfil their obligations pursuant to Article 6(3) and Annex I, Part B, note 10. As appropriate, a proposal on the format of this report shall be submitted in accordance with the management procedure referred to in Article 12(2).';

5. Article 15(3) shall be replaced by the following:

'3. That request shall be examined in accordance with the management procedure referred to in Article 12(2).';

([1]) OJ L 330, 5.12.1998, p. 32.

6. in Annex I, Part C, point 1 of note 10 shall be replaced by the following:

'1. The Commission shall adopt the measures required under Note 8 on monitoring frequencies, and Note 9 on monitoring frequencies, monitoring methods and the most relevant locations for monitoring points in Annex II. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).

When elaborating those measures the Commission shall take into account, inter alia, the relevant provisions under existing legislation or appropriate monitoring programmes including monitoring results as derived from them.';

7. in Annex II, table A, point 2 shall be replaced by the following:

'2. *Audit monitoring*

The purpose of audit monitoring is to provide the information necessary to determine whether or not all of the Directive's parametric values are being complied with. All parameters set in accordance with Article 5(2) and (3) must be subject to audit monitoring unless it can be established by the competent authorities, for a period of time to be determined by them, that a parameter is not likely to be present in a given supply in concentrations which could lead to the risk of a breach of the relevant parametric value. This point does not apply to the parameters for radioactivity, which, subject to Notes 8, 9 and 10 in Annex I, Part C, will be monitored in accordance with monitoring requirements adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).';

8. in Annex III, point 1, the first subparagraph shall be replaced by the following:

'The following principles for methods of microbiological parameters are given either for reference, whenever a CEN/ISO method is given, or for guidance, pending the possible future adoption by the Commission of further CEN/ISO international methods for those parameters. Member States may use alternative methods, providing the provisions of Article 7(5) are met.

Those measures on further CEN/ISO international methods, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).'.

2.3. **Regulation (EC) No 2037/2000 of the European Parliament and of the Council of 29 June 2000 on substances that deplete the ozone layer** [1]

As regards Regulation (EC) No 2037/2000, the Commission should be empowered in particular to amend Annex VI; to establish and reduce the calculated level of methyl bromide that can be placed on the market or used by importers or producers for their own account for quarantine and preshipment purposes; to determine a mechanism for the allocation of quotas of the calculated levels of methyl bromide to each producer and importer; to adopt, if necessary, modifications and, where appropriate, time frames for phase-out of the critical uses of halons listed in Annex VII; to take a decision on whether to adapt the end-date of prohibition of the use of hydrochlorofluorocarbons; to modify the list and dates with regard to control of the use of hydrochlorofluorocarbons; to modify the list of items related to the request for an import licence and Annex IV; to amend the list of products containing controlled substances and of Combined Nomenclature codes in Annex V; and to advance the date of export prohibition of recovered, recycled and reclaimed halon for critical uses, and to modify the reporting requirements. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2037/2000, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

[1] OJ L 244, 29.9.2000, p. 1.

Accordingly, Regulation (EC) No 2037/2000 is hereby amended as follows:

1. in Article 2, the 16th indent shall be replaced by the following:

'— "processing agent" means controlled substances used as chemical processing agents in those applications listed in Annex VI, in installations existing on 1 September 1997, and where emissions are insignificant. The Commission shall, in the light of those criteria, and in accordance with the management procedure referred to in Article 18(2), establish a list of undertakings in which the use of controlled substances as processing agents shall be permitted, laying down maximum emission levels for each of the undertakings concerned.

In the light of new information or technical developments, including the review provided for in Decision X/14 of the Meeting of the Parties to the Protocol, the Commission may:

(a) amend the list of undertakings referred to above in accordance with the management procedure referred to in Article 18(2);

(b) amend Annex VI. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

2. Article 4 shall be amended as follows:

(a) the third subparagraph of point (iii) of paragraph 2 shall be replaced by the following:

'The Commission shall take measures to reduce the calculated level of methyl bromide which producers and importers may place on the market or use for their own account for quarantine and preshipment in the light of technical and economic availability of alternative substances or technologies, and of the relevant international developments under the Protocol. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(b) paragraph 3(ii) shall be replaced by the following:

'(ii) The Commission may amend the mechanism for the allocation of quotas to each producer and importer of the calculated levels set out in points (d) to (f), applicable for the period 1 January 2003 to 31 December 2003 and for each 12-month period thereafter.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(c) paragraph 4(iv) shall be replaced by the following:

'(iv) Paragraph 1(c) shall not apply to the placing on the market and use of halons that have been recovered, recycled or reclaimed in existing fire protection systems until 31 December 2002 or to the placing on the market and use of halons for critical uses as set out in Annex VII. Each year the competent authorities of the Member States shall notify to the Commission the quantities of halons used for critical uses, the measures taken to reduce their emissions and an estimate of such emissions, and the current activities to identify and use adequate alternatives.

Each year the Commission shall review the critical uses listed in Annex VII and, if necessary, adopt modifications and, where appropriate, time frames for phase-out, taking into account the availability of both technically and economically feasible alternatives or technologies that are acceptable from the standpoint of the environment and health.

Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

3. Article 5 shall be amended as follows:

(a) the fifth subparagraph of point (c)(v) of paragraph 1 shall be replaced by the following:

'The Commission shall submit the result of the review to the European Parliament and to the Council. It shall, as appropriate, take a decision on whether to adapt the date of 1 January 2015. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(b) paragraph 6 shall be replaced by the following:

'6. The Commission may, in the light of experience with the operation of this Regulation or to reflect technical progress, amend the list and the dates set out in paragraph 1 but may in no case extend the periods set out therein, without prejudice to the exemptions provided for in paragraph 7.

Those measures, designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

4. Article 6(5) shall be replaced by the following:

'5. The Commission may amend the list of items mentioned in paragraph 3 and Annex IV.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

5. Article 9(2) shall be replaced by the following:

'2. A list of products containing controlled substances and of Combined Nomenclature codes is given in Annex V for guidance of the Member States' customs authorities. The Commission may add to, delete items from or amend that list in the light of the lists established by the Parties.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

6. Article 11(1)(d) shall be replaced by the following:

'(d) recovered, recycled and reclaimed halon stored for critical uses in facilities authorised or operated by the competent authority to satisfy critical uses listed in Annex VII until 31 December 2009, and products and equipment containing halon to satisfy critical uses listed in Annex VII. Following a review undertaken by 1 January 2005 by the Commission of exports of such recovered, recycled and reclaimed halon for critical uses the Commission may prohibit such exports earlier than 31 December 2009. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

7. Article 18(3) shall be replaced by the following:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

8. Article 19(6) shall be replaced by the following:

'6. The Commission may amend the reporting requirements laid down in paragraphs 1 to 4 to meet commitments under the Protocol or to improve the practical application of those reporting requirements.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).'.

2.4. **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** [1]

As regards Regulation (EC) No 166/2006, the Commission should be empowered in particular to adopt measures referred to in Article 8(3); to adapt Annexes II or III to scientific or technical progress; and to adapt Annexes II and III as a result of the adoption by the Meeting of the Parties to the UNECE Protocol on Pollutant Release and Transfer Registers of any amendment to the Annexes to that Protocol. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 166/2006, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 166/2006 is hereby amended as follows:

1. Article 8(3) shall be replaced by the following:

'3. Where the Commission determines that no data on the releases from diffuse sources exist, measures to initiate reporting on releases of relevant pollutants from one or more diffuse sources shall be taken using, where appropriate, internationally approved methodologies.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).';

2. Article 18 shall be replaced by the following:

'*Article 18*

Amendments to the Annexes

The Commission shall make any necessary amendments to the annexes for the following purposes:

(a) the adaptation of Annexes II or III to scientific or technical progress;

(b) the adaptation of Annexes II and III as a result of the adoption by the Meeting of the Parties to the Protocol of any amendment to the Annexes to the Protocol.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).';

3. the following paragraph shall be added to Article 19:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

[1] OJ L 33, 4.2.2006, p. 1.

2.5. **Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality** ([1])

As regards Directive 2006/7/EC, the Commission should be empowered in particular to adapt, in the light of scientific and technical progress, the methods of analysis for the parameters and sampling rules set out in Annex I and Annex V respectively, and to specify the EN/ISO standard on the equivalence of microbiological methods. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2006/7/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2006/7/EC is hereby amended as follows:

1. Article 15 shall be replaced by the following:

'*Article 15*

Technical adaptations and implementing measures

1. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), lay down the following:

(a) detailed rules for the implementation of Article 8(1), Article 12(1)(a) and Article 12(4);

(b) guidelines for a common method for the assessment of single samples.

2. The Commission shall adopt the following measures:

(a) the specification of EN/ISO standard on the equivalence of microbiological methods for the purposes of Article 3(9);

(b) any amendments necessary in order to adapt the methods of analysis for the parameters set out in Annex I in the light of scientific and technical progress;

(c) any amendments necessary in order to adapt Annex V in the light of scientific and technical progress.

Those measures, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 16(3).

3. The Commission shall present a draft of the measures to be taken in accordance with paragraph 1(a) with respect to Article 12(1)(a) by 24 March 2010. Before doing so, it shall consult representatives of Member States, regional and local authorities, relevant tourist and consumer organisations and other interested parties. After the adoption of relevant rules, it shall publicise them via the Internet.';

2. Article 16(3) shall be replaced by the following:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

([1]) OJ L 64, 4.3.2006, p. 37.

2.6. **Directive 2006/21/EC of the European Parliament and of the Council of 15 March 2006 on the management of waste from extractive industries** ([1])

As regards Directive 2006/21/EC, the Commission should be empowered in particular to adopt provisions necessary for the implementation of Article 13(6); to complete the technical requirements for waste characterisation contained in Annex II; to interpret the definition in point 3 of Article 3; to define the criteria for the classification of waste facilities in accordance with Annex III; to determine harmonised standards for sampling and analysis methods; and to adapt the Annexes to scientific and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2006/21/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2006/21/EC is hereby amended as follows:

1. Article 22 shall be replaced by the following:

'*Article 22*

1. The Commission shall, in accordance with the regulatory procedure referred to in Article 23(2), adopt the following:

(a) provisions necessary for the harmonisation and regular transmission of the information referred to in Article 7(5) and Article 12(6);

(b) technical guidelines for the establishment of the financial guarantee in accordance with the requirements of Article 14(2);

(c) technical guidelines for inspections in accordance with Article 17.

2. The Commission shall lay down provisions necessary for the following, prioritising points (b), (c) and (d):

(a) the implementation of Article 13(6), including technical requirements relating to the definition of weak acid dissociable cyanide and its measurement method;

(b) the completion of the technical requirements for waste characterisation contained in Annex II;

(c) the interpretation of the definition contained in point 3 of Article 3;

(d) the definition of the criteria for the classification of waste facilities in accordance with Annex III;

(e) the determination of any harmonised standards for sampling and analysis methods needed for the technical implementation of this Directive.

Those measures, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(3).

3. The Commission shall make the necessary amendments to the Annexes for the purpose of adapting them to scientific and technical progress. Those amendments shall be made with a view to achieving a high level of environmental protection.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(3).';

([1]) OJ L 102, 11.4.2006, p. 15.

2. Article 23(3) shall be replaced by the following:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

3. EUROSTAT

3.1. **Council Regulation (EC) No 2494/95 of 23 October 1995 concerning harmonised indices of consumer prices** [1]

As regards Regulation (EC) No 2494/95, the Commission should be empowered in particular to adopt rules to be followed to ensure the comparability of HICPs and to maintain and improve their reliability and relevance. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2494/95, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 2494/95 is hereby amended as follows:

1. in Article 3, the words 'in Article 14' shall be replaced by the words 'in Article 14(2)';

2. the third paragraph of Article 4 shall be replaced by the following:

'The Commission (Eurostat) shall adopt rules to be followed to ensure the comparability of HICPs. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

3. Article 5(3) shall be replaced by the following:

'3. The Commission shall adopt implementing measures for this Regulation which are necessary in order to ensure the comparability of HICPs and to maintain and improve their reliability and relevance. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3). The Commission shall request the ECB to provide an opinion on the measures which it proposes to submit to the Committee.';

4. in Article 8(3), the words 'in Article 14' shall be replaced by the words 'in Article 14(2)';

5. Article 9 shall be replaced by the following:

'*Article 9*

Production of results

Member States shall process the data collected in order to produce the HICP, which shall be a Laspeyres-type index, covering the categories of the Coicop international classification (classification of individual consumption by purpose) (*), which shall be adapted by the Commission for the purposes of establishing comparable HICPs. The Commission shall determine the methods, procedures and formulae to ensure that the comparability requirements are met. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

(*) Published by the United Nations, series F No 2, revision 3, table 6.1, amended by the OECD (DES/NI/86,9), Paris 1986.';

[1] OJ L 257, 27.10.1995, p. 1.

6. in Article 11, the words 'in Article 14' shall be replaced by the words 'in Article 14(2)';

7. Article 14 shall be replaced by the following:

'*Article 14*

Committee procedure

1. The Commission shall be assisted by the Statistical Programme Committee established by Council Decision 89/382/EEC, Euratom (*), hereinafter referred to as "the Committee".

2. Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 181, 28.6.1989, p. 47.
(**) OJ L 184, 17.7.1999, p. 23.';

8. the second paragraph of Article 15 shall be replaced by the following:

'In those reports, the Commission shall state its views on the operation of the procedures described in Article 14 and shall propose any amendments it considers appropriate.'.

3.2. **Council Regulation (EC) No 577/98 of 9 March 1998 on the organisation of a labour force sample survey in the Community** ([1])

As regards Regulation (EC) No 577/98, the Commission should be empowered in particular to adopt additional variables, to adapt the definitions, the edits to be used and the codification of the variables, and to draw up the list of structural variables, the minimum sample size and the survey frequency. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 577/98, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 577/98 is hereby amended as follows:

1. in the third indent of the fifth paragraph of Article 1, the words 'in Article 8' shall be replaced by the words 'in Article 8(2)';

2. paragraphs 2, 3 and 4 of Article 4 shall be replaced by the following:

'2. A further set of variables, hereinafter referred to as an "ad hoc module", may be added to supplement the information described in paragraph 1.

Each year a programme of ad hoc modules covering several years shall be adopted by the Commission.

That programme shall specify, for each ad hoc module, the subject, the reference period, the sample size (equal to or less than the sample size determined according to Article 3) and the deadline for the transmission of the results (which may be different from the deadline according to Article 6).

([1]) OJ L 77, 14.3.1998, p. 3.

The Member States and regions covered and the detailed list of information to be collected in an ad hoc module shall be drawn up at least 12 months before the beginning of the reference period for that module.

The volume of an ad hoc module shall not exceed 11 variables.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 8(3).

3. The definitions, the edits to be used, the codification of the variables, the adjustment of the list of survey variables made necessary by the evolution of techniques and concepts, and a list of principles for the formulation of the questions concerning the labour status shall be drawn up by the Commission. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 8(3).

4. On a proposal from the Commission, a list of variables, hereinafter referred to as "structural variables", may be identified from among the survey characteristics specified in paragraph 1 which need to be surveyed only as annual averages with reference to 52 weeks rather than as quarterly averages. That list of structural variables, the minimum sample size and the survey frequency shall be drawn up by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 8(3). Spain, Finland and the United Kingdom may survey the structural variables with reference to a single quarter during a transition period until the end of 2007.';

3. Article 8 shall be replaced by the following:

'*Article 8*

Committee procedure

1. The Commission shall be assisted by the Statistical Programme Committee established by Council Decision 89/382/EEC, Euratom (*).

2. Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 181, 28.6.1989, p. 47.
(**) OJ L 184, 17.7.1999, p. 23.'.

3.3. **Council Regulation (EC) No 1165/98 of 19 May 1998 concerning short-term statistics** [1]

As regards Regulation (EC) No 1165/98, the Commission should be empowered in particular to approve and implement the European sample schemes, to adapt the Annexes and to determine the measures for implementing this Regulation, including the measures to accommodate economic and technical developments concerning the collection and statistical processing of data and the transmission of the variables. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1165/98, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

[1] OJ L 162, 5.6.1998, p. 1.

Accordingly, Regulation (EC) No 1165/98 is hereby amended as follows:

1. Article 4(2)(d) shall be replaced by the following:

'(d) participation in European sample schemes coordinated by Eurostat in order to produce European estimates.

The details of the schemes referred to in the first subparagraph shall be as specified in the Annexes. Measures for their approval and implementation shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).

European sample schemes shall be established when national sample schemes do not meet the European requirements. Furthermore, Member States may opt to take part in European sample schemes when such schemes create possibilities for substantial reductions in the cost of the statistical system or the burden on business which meeting the European requirements entails. Participation in a European sample scheme shall satisfy the conditions of a Member State for the supply of the variable concerned in accordance with the objective of such a scheme. European sample schemes may target the conditions, the level of detail and the deadlines for data transmission.';

2. in Article 16(1), the words 'in Article 18' shall be replaced by the words 'in Article 18(2)';

3. Articles 17 and 18 shall be replaced by the following:

'*Article 17*

Implementing measures

The Commission shall determine the measures for implementing this Regulation, including the measures to accommodate economic and technical developments concerning the collection and statistical processing of data and the transmission of the variables. In doing so, consideration shall be given to the principle that the benefits of the measure must outweigh its cost, and to the principle that major additional resources are not involved either for Member States or for enterprises as compared with the original provisions of this Regulation. In particular, the measures for implementing this Regulation shall include:

(a) the use of particular units (Article 2);

(b) the updating of the list of variables (Article 3);

(c) the definitions and the appropriate forms of the transmitted variables (Article 3);

(d) the establishment of European sample schemes (Article 4);

(e) the frequency of compilation of the statistics (Article 5);

(f) the levels of breakdown and aggregation to be applied to the variables (Article 6);

(g) the transmission deadlines (Article 8);

(h) the criteria for the measurement of quality (Article 10);

(i) the transition periods (Article 13(1));

(j) derogations granted during the transition periods (Article 13(2));

(k) the institution of pilot studies (Article 16);

(l) the first base year to be applied for time series in NACE Rev. 2;

(m) for time series prior to 2009, to be transmitted according to NACE Rev. 2, the level of detail, the form, the first reference period, and the reference period.

The measures referred to in points (j) and (k) shall be adopted in accordance with the regulatory procedure referred to in Article 18(2).

The measures referred to in points (a) to (i) and (l) and (m), designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).

Article 18

Committee procedure

1. The Commission shall be assisted by the Statistical Programme Committee established by Council Decision 89/382/EEC, Euratom (*).

2. Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 181, 28.6.1989, p. 47.
(**) OJ L 184, 17.7.1999, p. 23.';

4. Annex A (Industry) shall be amended as follows:

(a) point (a) (Scope) shall be replaced by the following:

'(a) Scope

This Annex applies to all activities listed in Sections B to E of NACE Rev. 2, or, as the case may be, to all products listed in Sections B to E of the CPA. The information is not required for 37, 38.1, 38.2 and 39 of NACE Rev. 2. The list of activities may be revised by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(b) paragraph 3 of point (b) (Observation unit) shall be replaced by the following:

'3. The use of other observation units may be decided by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(c) point (c) (List of variables) shall be amended as follows:

(i) the last sentence of paragraph 2 shall be replaced by the following:

'The Commission shall determine the conditions for assuring the necessary data quality. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(ii) paragraphs 3 and 4 shall be replaced by the following:

'3. Starting from the beginning of the first reference period the information on new orders (Nos 130, 131, 132) may be approximated by an alternative leading indicator, which may be calculated from business opinion survey data. This approximation is permitted for a period of five years from the date of entry into force of the Regulation. This period shall be extended by up to five years more unless decided differently by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).

4. Starting from the beginning of the first reference period the information on persons employed (No 210) may be approximated by the number of employees (No 211). This approximation is permitted for a period of five years from the date of entry into force of the Regulation. This period shall be extended by up to five years more unless decided differently by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(iii) the last sentence of paragraph 8 shall be replaced by the following:

'The list of activities may be revised by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(iv) the last sentence of paragraph 10 shall be replaced by the following:

'The list of activities may be revised by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(d) paragraph 2 of point (d) (Form) shall be replaced by the following:

'2. In addition, the production variable (No 110) and the hours-worked variable (No 220) are to be transmitted in working-day adjusted form.

Wherever other variables show working-day effects, Member States may also transmit those variables in working-day adjusted form. The list of variables to be transmitted in working-day adjusted form may be amended by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(e) paragraphs 8 and 9 of point (f) (Level of detail) shall be replaced by the following:

'8. For the import price variable (No 340), the Commission may determine the terms for applying a European sample scheme as defined in point (d) of the first subparagraph of Article 4(2). Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).

9. The variables on the non-domestic markets (Nos 122, 132 and 312) are to be transmitted according to the distinction into euro-zone and non-euro-zone. The distinction is to be applied to the total industry defined as NACE Rev. 2 Sections B to E, the MIGs, the Section (1 letter) and Division 2-digit level of NACE Rev. 2. The information on NACE Rev. 2 D and E is not required for variable 122. In addition, the import price variable (No 340) is to be transmitted according to the distinction into euro-zone and non-euro-zone. The distinction is to be applied to the total industry defined as CPA Sections B to E, the MIGs, the Section (1 letter) and Division 2-digit level of CPA. For the distinction into the euro-zone and non-euro-zone, the Commission may determine the terms for applying European sample schemes as defined in point (d) of the first subparagraph of Article 4(2). Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3). The European sample scheme may limit the scope of the import price variable to the import of products from non-euro-zone countries. The distinction into the euro-zone and non-euro-zone for the variables 122, 132, 312 and 340 does not need to be transmitted by those Member States that have not adopted the euro as their currency.';

(f) in point (j) (Transition period), all references to Article 18 shall be replaced by references to Article 18(2);

5. Annex B (Construction) shall be amended as follows:

(a) paragraph 4 of point (b) (Observation unit) shall be replaced by the following:

'4. The use of other observation units may be decided by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(b) point (c) (List of variables) shall be amended as follows:

(i) paragraph 3 shall be replaced by the following:

'3. Starting from the beginning of the first reference period the information on persons employed (No 210) may be approximated by the number of employees (No 211). This approximation is permitted for a period of five years from the date of entry into force of the Regulation. This period shall be extended for up to five years more unless decided differently by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(ii) the last subparagraph of paragraph 6 shall be replaced by the following:

'The Commission shall decide no later than 11 August 2008 whether to invoke Article 17(b) so as to replace the construction costs variable with the output price variable with effect from base year 2010. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(c) paragraph 2 of point (d) (Form) shall be replaced by the following:

'2. In addition, the variables on production (Nos 110, 115, 116) and the hours-worked variable (No 220) are to be transmitted in working-day adjusted form. Wherever other variables show working-day effects, Member States may also transmit those variables in working-day adjusted form. The list of variables to be transmitted in working-day adjusted form may be amended by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(d) in point (j) (Transition period), all references to Article 18 shall be replaced by references to Article 18(2);

6. Annex C (Retail trade and repair) shall be amended as follows:

(a) paragraph 2 of point (b) (Observation unit) shall be replaced by the following:

'2. The use of other observation units may be decided by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(b) point (c) (List of variables) shall be amended as follows:

(i) paragraph 3 shall be replaced by the following:

'3. Starting from the beginning of the first reference period the information on persons employed (No 210) may be approximated by the number of employees (No 211). This approximation is permitted for a period of five years from the date of entry into force of the Regulation. This period shall be extended for up to five years more unless decided differently by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(ii) the last subparagraph of paragraph 4 shall be replaced by the following:

'The Commission shall decide no later than 11 August 2008 whether to invoke Article 17(b) so as to include the variable hours worked (No 220) and the variable gross wages and salaries (No 230) with effect from the base year 2010. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(c) paragraph 2 of point (d) (Form) shall be replaced by the following:

'2. The turnover variable (No 120) and the volume of sales variable (No 123) are also to be transmitted in a working-day adjusted form. Wherever other variables show working-day effects, Member States may also transmit those variables in working-day adjusted form. The list of variables to be transmitted in working-day adjusted form may be amended by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(d) paragraph 2 of point (g) (Deadlines for data transmission) shall be replaced by the following:

'2. The variables shall be transmitted for turnover (No 120) and the deflator of sales/volume of sales (No 330/123) within one month for the level of detail specified in paragraph 3 under heading (f) of this Annex. Member States may choose to participate for the turnover and deflator of sales/volume of sales variables No 120 and 330/123 with contributions according to the allocation of a European sample scheme as defined in point (d) of the first subparagraph of Article 4(2). The terms of the allocation are to be determined by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(e) in point (j) (Transition period), all references to Article 18 shall be replaced by references to Article 18(2);

7. Annex D (Other services) shall be amended as follows:

(a) paragraph 2 of point (b) (Observation unit) shall be replaced by the following:

'2. The use of other observation units may be decided by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(b) point (c) (List of variables), is amended as follows:

(i) paragraph 2 shall be replaced by the following:

'2. Starting from the beginning of the first reference period the information on persons employed (No 210) may be approximated by the number of employees (No 211). This approximation is permitted for a period of five years from the date of entry into force of the Regulation. The period shall be extended by up to five years more unless decided differently by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(ii) the last subparagraph of paragraph 4 shall be replaced by the following:

'The Commission shall decide no later than 11 August 2008 whether to invoke Article 17(b) so as to include the variable hours worked (No 220) and the variable gross wages and salaries (No 230) with effect from base year 2010. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(c) paragraph 2 of point (d) (Form) shall be replaced by the following:

'2. The turnover variable (No 120) is also to be transmitted in working-day adjusted form. Wherever other variables show working-day effects, Member States may also transmit those variables in working-day adjusted form. The list of variables to be transmitted in working-day adjusted form may be amended by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(d) the last paragraph of point (e) (Reference period) shall be replaced by the following:

'The Commission shall decide no later than 11 August 2008 whether to invoke Article 17(e) in connection with a revision of the frequency of compilation of the turnover variable. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(e) paragraph 6 of point (f) (Level of detail) shall be replaced by the following:

'6. The Commission may amend the list of activities and groupings no later than 11 August 2008. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

(f) in points (i) (First reference period) and (j) (Transition period), all references to Article 18 shall be replaced by references to Article 18(2).

3.4. **Council Regulation (EC) No 530/1999 of 9 March 1999 concerning structural statistics on earnings and on labour costs** ([1])

As regards Regulation (EC) No 530/1999, the Commission should be empowered in particular to adapt the definition and breakdown of the information to be provided, and to lay down the quality evaluation criteria. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 530/1999, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

([1]) OJ L 63, 12.3.1999, p. 6.

Accordingly, Regulation (EC) No 530/1999 is hereby amended as follows:

1. Articles 11 and 12 shall be replaced by the following:

'*Article 11*

Implementation measures

The following measures necessary for the implementation of this Regulation, including measures to take account of economic and technical changes, shall be adopted by the Commission for each reference period at least nine months before the beginning of the reference period:

(i) the definition and breakdown of the information to be provided (Article 6),

(ii) the appropriate technical format for the transmission of the results (Article 9),

(iii) quality evaluation criteria (Article 10),

(iv) derogations, in duly justified cases, for the years 2004 and 2006 respectively (Article 13(2)).

The measures referred to in points (ii) and (iv) shall be adopted in accordance with the regulatory procedure referred to in Article 12(2).

The measures referred to in points (i) and (iii), designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).

Article 12

Committee procedure

1. The Commission shall be assisted by the Statistical Programme Committee established by Council Decision 89/382/EEC, Euratom (*).

2. Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 181, 28.6.1989, p. 47.
(**) OJ L 184, 17.7.1999, p. 23.';

2. Article 13(2) shall be replaced by the following:

'2. For the years 2004 and 2006 respectively, derogations from Articles 3 and 6 may be decided in so far as the national statistical system requires major adaptations, in accordance with the regulatory procedure set out in Article 12(2).'.

3.5. **Regulation (EC) No 450/2003 of the European Parliament and of the Council of 27 February 2003 concerning the labour cost index** [1]

As regards Regulation (EC) No 450/2003, the Commission should be empowered in particular to adapt the definitions and amend the technical specifications, include new sections in the survey, adapt the breakdown of indices by economic activities, define the quality criteria, establish feasibility studies and take decisions pursuant to their results, and determine the methodology to be used for chaining the index. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 450/2003, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 450/2003 is hereby amended as follows:

1. Article 2(4) shall be replaced by the following:

'4. The Commission may take measures to redefine the technical specification of the index and revise the weighting structure. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).';

2. Article 3(2) shall be replaced by the following:

'2. The inclusion of economic activities defined by NACE Rev.2 sections O to S in the scope of this Regulation shall be determined by the Commission, taking into account the feasibility studies defined in Article 10. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).';

3. Article 4 shall be replaced by the following:

'*Article 4*

Breakdown of variables

1. The data shall be broken down by economic activities defined by NACE Rev. 2 sections and by further disaggregations, defined by the Commission, not beyond the level of NACE Rev. 2 divisions (2-digit level) or groupings of divisions, taking account of contributions to total employment and to labour costs at Community and national levels. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).

Labour cost indices shall be provided separately for the three labour cost categories identified below:

(a) total labour costs;

(b) wages and salaries, defined by reference to item D.11 in Annex II to Regulation (EC) No 1726/1999;

(c) employers' social contributions plus taxes paid by the employer less subsidies received by the employer, as defined by the sum of items D.12 and D.4 less D.5 in Annex II to Regulation (EC) No 1726/1999.

2. An index estimating total labour costs, excluding bonuses, where bonuses are defined by D.11112 in Annex II to Regulation (EC) No 1726/1999, shall be provided, broken down by economic activities defined by the Commission, and shall be based on the NACE Rev. 2 classification, taking into account the feasibility studies defined in Article 10. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).';

[1] OJ L 69, 13.3.2003, p. 1.

4. Article 8 shall be replaced by the following:

'*Article 8*

Quality

1. The current data and back data transmitted shall satisfy separate quality criteria to be defined by the Commission. That measure, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).

2. The Member States shall provide annual quality reports to the Commission, beginning in 2003. The content of the reports shall be defined by the Commission. That measure, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).';

5. Articles 11 and 12 shall be replaced by the following:

'*Article 11*

Implementing measures

The following measures for implementing this Regulation, including measures to take account of economic and technical changes, shall be laid down by the Commission:

(a) the definition, in accordance with Article 4(1), of the disaggregations to be included in the fixed structure;

(b) the technical specification of the index (Article 2);

(c) the inclusion of NACE Rev. 2 sections O to S (Article 3);

(d) the breakdown of indices by economic activities (Article 4);

(e) the format for transmission of results and the adjustment procedures to be applied (Article 6);

(f) the separate quality criteria for current and back data transmitted and contents of quality reports (Article 8);

(g) the transition period (Article 9);

(h) the establishment of feasibility studies and decisions pursuant to their results (Article 10); and

(i) the methodology to be used for chaining the index (Annex).

The measures referred to in points (e), (g) and (h) shall be adopted in accordance with the regulatory procedure referred to in Article 12(2).

The measures referred to in points (a), (b), (c), (d), (f) and (i), designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).

Article 12

Committee procedure

1. The Commission shall be assisted by the Statistical Programme Committee established by Council Decision 89/382/EEC, Euratom (*).

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 181, 28.6.1989, p. 47.';

6. point 3 of the Annex shall be replaced by the following:

'3. The methodology for chaining the index will be defined by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 12(3).'.

3.6. **Regulation (EC) No 1552/2005 of the European Parliament and of the Council of 7 September 2005 on statistics relating to vocational training in enterprises** ([1])

As regards Regulation (EC) No 1552/2005, the Commission should be empowered in particular to adapt the definitions and sampling methods, to define the specific data to be collected and to determine the quality requirements for the data and the transmission arrangements. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1552/2005, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 1552/2005 is hereby amended as follows:

1. Article 5(2) shall be replaced by the following:

'2. Having regard to the specific national size distribution of enterprises and the evolution of policy needs, Member States may extend the definition of the statistical unit in their country. The Commission may also decide to extend that definition, if such extension would substantially enhance the representativeness and the quality of the result of the survey in the Member States concerned. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

2. Article 7(3) shall be replaced by the following:

'3. Sampling and precision requirements, the sample sizes needed to meet those requirements, and the detailed specifications of the NACE Rev. 2 and size categories into which the results can be broken down shall be determined by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

3. Article 8(2) shall be replaced by the following:

'2. The specific data to be collected with respect to training and non-training enterprises and to the different forms of vocational training shall be determined by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

([1]) OJ L 255, 30.9.2005, p. 1.

4. Article 9(4) shall be replaced by the following:

'4. The quality requirements for the data to be collected and transmitted for Community statistics on vocational training in enterprises, the structure of the quality reports referred to in paragraph 2 and any measures necessary for assessing or improving the quality of the data shall be determined by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

5. Article 10(2) shall be replaced by the following:

'2. The Commission shall determine the first reference year for which the data are to be collected. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

6. Articles 13 and 14 shall be replaced by the following:

'*Article 13*

Implementing measures

The measures necessary to take account of economic and technical developments concerning the collection, transmission and processing of the data shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Other measures for the implementation of this Regulation, including the appropriate technical format and interchange standard of the electronically transmitted data, shall be adopted by the Commission in accordance with the regulatory procedure referred to in Article 14(2).

Article 14

Committee procedure

1. The Commission shall be assisted by the Statistical Programme Committee established by Council Decision 89/382/EEC, Euratom (*).

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 181, 28.6.1989, p. 47.'.

4. INTERNAL MARKET

4.1. **Regulation (EC) No 2195/2002 of the European Parliament and of the Council of 5 November 2002 on the Common Procurement Vocabulary (CPV)** [1]

As regards Regulation (EC) No 2195/2002, the Commission should be empowered in particular to update the structure and codes of the CPV and to make technical adjustments to any of the Annexes to that Regulation in order to provide users with a tool adapted to their needs and to developments in the market. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2195/2002, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

[1] OJ L 340, 16.12.2002, p. 1.

When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments of a purely technical nature.

Accordingly, Articles 2 and 3 of Regulation (EC) No 2195/2002 shall be replaced by the following:

'*Article 2*

The Commission shall adopt the measures necessary for the revision of the CPV. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 3(2). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 3(3).

Article 3

1. The Commission shall be assisted by the Committee established by Council Decision 71/306/EEC (*).

2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 185, 16.8.1971, p. 15.'.

4.2. **Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors** [1]

As regards Directive 2004/17/EC, the Commission should be empowered in particular to make technical adjustments to certain provisions of the Directive and its Annexes, in line with technical progress or developments in Member States, and to revise the thresholds for application of the arrangements. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/17/EC, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

On grounds of efficiency and because of the time-limits imposed by the procedures laid down for calculation and publication, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the revision of certain thresholds.

When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments of a purely technical nature.

Accordingly, Directive 2004/17/EC is hereby amended as follows:

1. Article 68 shall be replaced by the following:

'*Article 68*

Committee procedure

1. The Commission shall be assisted by the Committee established by Council Decision 71/306/EEC (*).

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

[1] OJ L 134, 30.4.2004, p. 1.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time-limits laid down in Article 5a(3)(c), (4)(b) and (4)(e) of Decision 1999/468/EC shall be set at four, two and six weeks respectively.

5. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

_____

(*) OJ L 185, 16.8.1971, p. 15.';

2. Article 69 shall be amended as follows:

(a) the first subparagraph of paragraph 1 shall be replaced by the following:

'The Commission shall verify the thresholds established in Article 16 every two years from 30 April 2004, and shall, if necessary, with regard to the second subparagraph, revise them. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 68(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 68(5).';

(b) the first subparagraph of paragraph 2 shall be replaced by the following:

'At the same time as performing the revision under paragraph 1, the Commission shall align the thresholds laid down in Article 61 (design contests) with the revised threshold applicable to service contracts. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 68(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 68(5).';

3. Article 70 shall be replaced by the following:

'*Article 70*

Amendments

1. The Commission may amend, in accordance with the advisory procedure referred to in Article 68(2):

(a) the procedure for sending and publishing data referred to in Annex XX, on grounds of technical progress or for administrative reasons;

(b) the procedures for the drawing-up, transmission, receipt, translation, collection and distribution of the notices referred to in Articles 41, 42, 43 and 63;

(c) in the interests of administrative simplification as provided for in Article 67(3), the procedures for the use, drawing-up, transmission, receipt, translation, collection and distribution of the statistical reports referred to in Article 67(1) and (2).

2. The Commission may amend the following:

(a) the list of contracting entities in Annexes I to X so that they fulfil the criteria set out in Articles 2 to 7;

(b) the procedures for specific references to particular positions in the CPV nomenclature in the notices;

(c) the reference numbers in the nomenclature set out in Annex XVII, in so far as this does not change the material scope of the Directive, and the procedures for reference in the notices to particular positions in that nomenclature within the categories of services listed in the Annex;

(d) the reference numbers in the nomenclature set out in Annex XII, insofar as this does not change the material scope of the Directive, and the procedures for reference to particular positions of that nomenclature in the notices;

(e) Annex XI;

(f) the technical details and characteristics of the devices for electronic receipt referred to in points (a), (f) and (g) of Annex XXIV;

(g) the technical procedures for the calculation methods set out in the second subparagraph of Article 69(1) and the second subparagraph of Article 69(2).

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 68(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 68(5).'.

4.3. **Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts** ([1])

As regards Directive 2004/18/EC, the Commission should be empowered in particular to make technical adjustments to certain provisions of the Directive and its Annexes, in line with technical progress or developments in Member States, and to revise the thresholds for application of the arrangements. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/18/EC, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

On grounds of efficiency and because of the time-limits imposed by the procedures laid down for calculation and publication, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the revision of certain thresholds.

When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments of a purely technical nature.

Accordingly, Directive 2004/18/EC is hereby amended as follows:

1. Article 77 shall be replaced by the following:

'Article 77

Committee procedure

1. The Commission shall be assisted by the Committee established by Council Decision 71/306/EEC (*).

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The time-limits laid down in Article 5a(3)(c), (4)(b) and (4)(e) of Decision 1999/468/EC shall be set at four, two and six weeks respectively.

([1]) OJ L 134, 30.4.2004, p. 114.

5. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 185, 16.8.1971, p. 15.';

2. Article 78 shall be amended as follows:

(a) the first subparagraph of paragraph 1 shall be replaced by the following:

'The Commission shall verify the thresholds established in Article 7 every two years from 30 April 2004 and shall, if necessary, revise them. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 77(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 77(5).';

(b) paragraph 2 shall be replaced by the following:

'2. At the same time as the revision under paragraph 1, the Commission shall align:

(a) the thresholds established in point (a) of the first paragraph of Article 8, in Article 56 and in the first subparagraph of Article 63(1) on the revised threshold applying to public works contracts;

(b) the threshold established in Article 67(1)(a) on the revised threshold applying to public service contracts awarded by the contracting authorities referred to in Annex IV;

(c) the thresholds established in point (b) of the first paragraph of Article 8 and in Article 67(1)(b) and (c) on the revised threshold applying to public service contracts awarded by contracting authorities other than those referred to in Annex IV.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 77(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 77(5).';

3. Article 79 shall be replaced by the following:

'*Article 79*

Amendments

1. The Commission may amend, in accordance with the advisory procedure referred to in Article 77(2):

(a) the procedures for the drawing-up, transmission, receipt, translation, collection and distribution of the notices referred to in Articles 35, 58, 64 and 69 and the statistical reports provided for in the fourth subparagraph of Article 35(4) and in Articles 75 and 76;

(b) the procedure for sending and publishing data referred to in Annex VIII, on grounds of technical progress or for administrative reasons.

2. The Commission may amend the following:

(a) the technical procedures for the calculation methods set out in the second subparagraph of Article 78(1) and in Article 78(3);

(b) the procedures for specific reference to specific positions in the CPV nomenclature in the notices;

(c) the lists of bodies and categories of bodies governed by public law in Annex III, when, on the basis of the notifications from the Member States, such amendment proves necessary;

(d) the lists of central government authorities in Annex IV, following the adaptations necessary to give effect to the Agreement;

(e) the reference numbers in the nomenclature set out in Annex I, in so far as this does not change the material scope of this Directive, and the procedures for reference to particular positions of that nomenclature in the notices;

(f) the reference numbers in the nomenclature set out in Annex II, in so far as this does not change the material scope of this Directive, and the procedures for reference in the notices to particular positions in that nomenclature within the categories of services listed in the Annex;

(g) the technical details and characteristics of the devices for electronic receipt referred to in points (a), (f) and (g) of Annex X.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 77(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 77(5).'.

5. HEALTH AND CONSUMER PROTECTION

5.1. **Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food** [1]

As regards Regulation (EEC) No 315/93, the Commission should be empowered in particular to establish maximum tolerances for specific contaminants. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EEC) No 315/93 by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Any delay in the establishment of maximum tolerances for specific contaminants could represent a threat to human or animal health. When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of those tolerances.

Accordingly Regulation (EEC) No 315/93 is hereby amended as follows:

1. the first subparagraph of Article 2(3) shall be replaced by the following:

'In order to protect public health and pursuant to paragraph 1, the Commission may where necessary establish the maximum tolerances for specific contaminants. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 8(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 8(4).';

2. Article 4(2) shall be replaced by the following:

'2. The Commission shall examine the reasons given by the Member State referred to in paragraph 1 as soon as possible in the Standing Committee for Foodstuffs, set up by Council Decision 69/414/EEC (*), and shall deliver its opinion immediately and take any necessary measures aimed at confirming, amending or repealing the national measure, in accordance with the regulatory procedure laid down in Article 8(2).

(*) OJ L 291, 19.11.1969, p. 9.';

3. in the fourth subparagraph of Article 5(3), the words 'Article 8' shall be replaced by the words 'Article 8(2)';

[1] OJ L 37, 13.2.1993, p. 1.

4. Article 8 shall be amended as follows:

(a) paragraph 3 shall be replaced by the following:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Council Decision 1999/468/EC (*) shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 184, 17.7.1999, p. 23.';

(b) the following paragraph shall be added:

'4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

5.2. **Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes** ([1])

As regards Directive 93/74/EEC, the Commission should be empowered in particular to adopt general provisions regarding the application of the indications contained in the list of intended uses and to adopt amendments, in line with developments in scientific and technical knowledge, to the list of intended uses and the general provisions regarding the application of the indications contained in the list of intended uses. Since those measures are of general scope and are designed to amend non-essential elements of Directive 93/74/EEC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Feedingstuffs intended for particular nutritional purposes are playing an increasing role in the diet of pet animals and are also used in the rearing of productive livestock. The composition and preparation of such feedingstuffs must be specially designed to meet the particular nutritional needs of categories of pets or productive livestock whose process of assimilation, absorption or metabolism could briefly be impaired or is temporarily or irreversibly impaired. Users of such feedingstuffs therefore need to be provided immediately with accurate and meaningful information so that they can make appropriate choices. When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of general provisions regarding the application of the indications contained in the list of intended uses and for the adoption of amendments, in line with developments in scientific and technical knowledge, to the list of intended uses and the general provisions regarding the application of the indications contained in the list of intended uses.

Accordingly, Directive 93/74/EEC is hereby amended as follows:

1. Article 6 shall be replaced by the following:

'*Article 6*

The Commission shall adopt:

(a) a list of intended uses as set out in the Annex no later than 30 June 1994 in accordance with the regulatory procedure referred to in Article 9(2). That list shall contain:

— the indications referred to in points (b), (c), (d) and (e) of Article 5(1), and,

— where appropriate, the indications referred to in Article 5(2) and Article 5(4), second subparagraph,

([1]) OJ L 237, 22.9.1993, p. 23.

(b) general provisions regarding the application of the indications referred to in point (a), including applicable tolerances;

(c) amendments to the measures adopted in accordance with points (a) and (b) in line with developments in scientific and technical knowledge.

The measures provided for in points (b) and (c), designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 9(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 9(4).';

2. Article 8(2) shall be replaced by the following:

'2. The Commission shall initiate as soon as possible the regulatory procedure laid down in Article 9(2) with a view to adopting any appropriate measures aimed at confirming, amending or repealing the national measure.';

3. Article 9(3) shall be replaced by the following:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

5.3. **Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and products** [1]

As regards Directive 96/23/EC, the Commission should be empowered in particular to adopt amendments to the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of Directive 96/23/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 96/23/EC is hereby amended as follows:

1. Article 6 shall be replaced by the following:

'Article 6

1. The plan must conform to the sampling levels and frequencies laid down in Annex IV. However, at the request of a Member State the Commission may, in accordance with the regulatory procedure referred to in Article 33(2), adjust for the Member States concerned the minimum control requirements laid down in Annex IV provided that it is clearly established that such adjustments increase the overall effectiveness of the plan in respect of the Member State concerned and in no way reduce its ability to identify residues of, or cases of illegal treatment with, substances listed in Annex I.

2. Re-examination of the groups of residues to be checked for in accordance with Annex II and determination of the sampling levels and frequencies covering the animals and products referred to in Article 3 and not already laid down in Annex IV shall be carried out by the Commission and on the first occasion within a maximum of 18 months of the adoption of this Directive. In doing so, the Commission shall take account of experience gained under existing national measures and of information forwarded to the Commission under existing Community requirements making such specific product groups subject to monitoring for residues. Those measures, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(4).';

[1] OJ L 125, 23.5.1996, p. 10.

2. Article 8 shall be amended as follows:

(a) the second and third subparagraphs of paragraph 1 shall be replaced by the following:

'Once the Commission has established their conformity, it shall submit the plans for approval in accordance with the regulatory procedure referred to in Article 33(3).

In order to take account of changes in the situation in a given Member State or in a region thereof, of the results of national surveys or of investigations carried out in the framework of Articles 16 and 17, the Commission may, at the request of the Member State concerned or on its own initiative, decide, in accordance with the regulatory procedure referred to in Article 33(2), to approve an amendment or addition to a plan previously approved pursuant to paragraph 2.';

(b) the fifth subparagraph of paragraph 2 shall be replaced by the following:

'Where there are comments from Member States or where the Commission deems the update not to be in conformity or to be insufficient, the Commission shall submit the updated plans to the Standing Veterinary Committee, which must act under the regulatory procedure referred to in Article 33(3).';

3. the third subparagraph of Article 14(1) shall be replaced by the following:

'A list of such designated laboratories shall be drawn up in accordance with the regulatory procedure referred to in Article 33(3).';

4. the second subparagraph of Article 15(1) shall be replaced by the following:

'The detailed rules for the taking of official samples and the routine and reference methods to be employed for the analysis of such official samples shall be specified by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(4).';

5. the sixth subparagraph of Article 20(2) shall be replaced by the following:

'In the light of the experts' opinion, appropriate measures may be taken in accordance with the regulatory procedure referred to in Article 33(2).';

6. the second subparagraph of paragraph 1 and paragraph 2 of Article 21 shall be replaced by the following:

'The Member State concerned shall take the measures necessary to take account of the results of those verifications and shall notify the Commission of the measures taken. Where the Commission considers that the measures taken are insufficient, it shall, after consultation with the Member State in question and having regard to the measures necessary to safeguard public health, take appropriate measures in accordance with the regulatory procedure referred to in Article 33(2).

2. The general rules for implementing this Article, especially as regards the frequency and method of carrying out the verifications referred to in the first subparagraph of paragraph 1 (including cooperation with the competent authorities), shall be determined in accordance with the regulatory procedure referred to in Article 33(3).';

7. Article 29 shall be amended as follows:

(a) the fourth subparagraph of paragraph 1 shall be replaced by the following:

'The Commission shall approve the plan in accordance with the regulatory procedure referred to in Article 33(3). Under the same procedure, guarantees other than those resulting from the implementation of this Directive may be accepted.';

(b) paragraph 2 shall be replaced by the following:

'2. Where the requirements of paragraph 1 are not complied with, inclusion of a third country on the lists of third countries laid down by Community legislation or as a result of the benefit of pre-listing may be suspended in accordance with the regulatory procedure referred to in Article 33(3), at the request of a Member State or by the Commission on its own initiative.';

8. the first subparagraph of Article 30(3) shall be replaced by the following:

'3. If, in cases involving third countries which have concluded equivalence agreements with the Community, the Commission, after making enquiries of the competent authorities of the third countries concerned, concludes that they have failed to fulfil their obligations and the guarantees given by the plans referred to in Article 29(1), it shall cease to allow the country concerned, under the regulatory procedure referred to in Article 33(2), to benefit from the said agreements for the animals and products in question until that third country has made good its shortcomings. The suspension shall be revoked under the same procedure.';

9. Article 32 shall be deleted;

10. Articles 33, 34 and 35 shall be replaced by the following:

'*Article 33*

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up pursuant to Article 58 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 European Food Safety Authority and laying down procedures in matter of food safety (*).

2. Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at fifteen days.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 34

Without prejudice to Article 6(2), Annexes I, III, IV and V may be amended or supplemented by the Commission. In particular, those Annexes may be amended with a view to risk assessment of the following factors:

— potential toxicity of residues in foodstuffs of animal origin,

— likelihood of residues occurring in foodstuffs of animal origin,

Those measures, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(4).

Article 35

The Commission may adopt transitional measures required for the implementation of the arrangements laid down by this Directive.

Transitional measures of general scope, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it with new non-essential elements, and in particular further specifications of the requirements laid down in this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(4).

Other transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 33(2).

(*) OJ L 31, 1.2.2002, p. 1.
(**) OJ L 184, 17.7.1999, p. 23.'.

5.4. **Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients** [1]

As regards Regulation (EC) No 258/97, the Commission should be empowered in particular to adopt data protection arrangements. Since those measures are of general scope and are designed to supplement Regulation (EC) No 258/97 with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 258/97 is hereby amended as follows:

1. in Article 1(3), the words 'Article 13' shall be replaced by the words 'Article 13(2)';

2. in the second subparagraph of Article 3(4), the words 'Article 13' shall be replaced by the words 'Article 13(2)';

3. in Article 4(5), the words 'Article 13' shall be replaced by the words 'Article 13(2)';

4. in Article 7(1), the words 'Article 13' shall be replaced by the words 'Article 13(2)';

5. in Article 8(3), the words 'Article 13' shall be replaced by the words 'Article 13(2)';

6. Article 10 shall be replaced by the following:

'*Article 10*

Detailed rules for the protection of the information provided by the applicant shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(3).';

7. Article 12(2) shall be replaced by the following**:**

'2. The Commission shall examine the grounds referred to in paragraph 1 as soon as possible within the Standing Committee for Foodstuffs. It shall take the appropriate measures aimed at confirming, amending or repealing the national measure in accordance with the regulatory procedure laid down in Article 13(2). The Member State which took the decision referred to in paragraph 1 may maintain it until the measures have entered into force.';

8. Article 13(3) shall be replaced by the following:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

[1] OJ L 43, 14.2.1997, p. 1.

5.5. **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** [1]

As regards Decision No 2119/98/EC, the Commission should be empowered in particular to establish the communicable diseases and the criteria for selection of those diseases to be covered by the Community network, as well as the epidemiological and microbiological surveillance methods. Since those measures are of general scope and are designed to amend non-essential elements of Decision No 2119/98/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

When an emergency situation occurs with regard to the appearance or to new developments of a serious communicable disease, the epidemiological surveillance system should be triggered as soon as possible, in order to ensure protection of the population and public health. When on imperative grounds of urgency the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of decisions determining the communicable diseases, the criteria for the selection of those diseases and the epidemiological and microbiological surveillance methods, as well as for the amendments to the Annex to Decision No 2119/98/EC containing the list of categories of communicable diseases.

Accordingly, Decision No 2119/98/EC is hereby amended as follows:

1. Article 3 shall be amended as follows:

(a) the introductory words shall be replaced by the following:

'With a view to the effective operation of the Community network with regard to epidemiological surveillance and to achieving uniform information within this framework, the following shall be adopted by the Commission:';

(b) the following paragraphs shall be added:

'The measures referred to in points (a), (b) and (e), designed to amend non-essential elements of this Decision, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 7(4).

The measures referred to in points (c), (d), (f), (g) and (h) shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).';

2. Article 6(5) shall be replaced by the following:

'5. Procedures concerning the information and consultation referred to in paragraphs 1, 2 and 3 and procedures concerning the coordination referred to in paragraphs 1 and 4 shall be established in accordance with the regulatory procedure referred to in Article 7(2).';

3. Article 7 shall be amended as follows:

(a) paragraph 3 shall be replaced by the following:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

[1] OJ L 268, 3.10.1998, p. 1.

(b) the following paragraph shall be added:

'4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

4. Article 8 shall be replaced by the following:

'*Article 8*

The Annex may be amended or supplemented by the Commission. Those measures, designed to amend non-essential elements of this Decision, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 7(4).'.

5.6. **Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs** [1]

As regards Directive 2000/13/EC, the Commission should be empowered in particular to adopt certain measures necessary for its implementation. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2000/13/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the amendment of the lists of certain categories of ingredients.

Accordingly, Directive 2000/13/EC is hereby amended as follows:

1. Article 4(3) shall be replaced by the following:

'3. The Community provisions referred to in paragraphs 1 and 2 shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).';

2. Article 6 shall be amended as follows:

(a) point (d) of the second subparagraph of paragraph 3a shall be replaced by the following:

'(d) as regards other products, being measures designed to amend non-essential elements of this Directive, in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).';

(b) the second subparagraph of paragraph 6 shall be amended as follows:

(i) the first indent shall be replaced by the following:

'— ingredients which belong to one of the categories listed in Annex I and are constituents of another foodstuff need only be designated by the name of that category.

Alterations to the list of categories in Annex I may be effected by the Commission. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).

[1] OJ L 109, 6.5.2000, p. 29.

However, the designation 'starch' listed in Annex I must always be complemented by the indication of its specific vegetable origin, when that ingredient may contain gluten,';

(ii) the second indent shall be replaced by the following:

'— ingredients belonging to one of the categories listed in Annex II must be designated by the name of that category, followed by their specific name or EC number; if an ingredient belongs to more than one of the categories, the category appropriate to the principal function in the case of the foodstuff in question shall be indicated.

Amendments to Annex II based on advances in scientific and technical knowledge, being measures designed to amend non-essential elements of this Directive, shall be adopted by the Commission in accordance with the regulatory procedure with scrutiny referred to in Article 20(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 20(4).

However, the designation 'modified starch' listed in Annex II must always be complemented by the indication of its specific vegetable origin, when that ingredient may contain gluten,';

(c) the third subparagraph of paragraph 7 shall be replaced by the following:

'The Community provisions referred to in this paragraph shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).';

(d) the third subparagraph of paragraph 11 shall be replaced by the following:

'Without prejudice to the second subparagraph, Annex IIIa may be amended by the Commission, after an opinion has been obtained from the European Food Safety Authority issued on the basis of Article 29 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 European Food Safety Authority and laying down procedures in matters of food safety (*). Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 20(4).

(*) OJ L 31, 1.2.2002, p. 1.';

3. Article 7 shall be amended as follows:

(a) paragraph 2(d) shall be replaced by the following:

'(d) in the cases determined by the Commission; determination of such cases, being a measure designed to amend non-essential elements of this Directive by supplementing it, shall be carried out in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).';

(b) paragraph 3(d) shall be replaced by the following:

'(d) in the cases determined by the Commission; determination of such cases, being a measure designed to amend non-essential elements of this Directive by supplementing it, shall be carried out in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).';

(c) the third sentence of paragraph 4 shall be replaced by the following:

'Such provisions shall be adopted by the Commission. That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).';

4. Article 8 shall be amended as follows:

(a) the third subparagraph of paragraph 4 shall be replaced by the following:

'This list may be supplemented by the Commission. That measure, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).';

(b) paragraph 6 shall be replaced by the following:

'6. The Community provisions referred to in paragraphs 1, second subparagraph, 2(b) and (d) and 5, second subparagraph, shall be adopted by the Commission. That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).';

5. in Article 11(2), the third subparagraph shall be replaced by the following:

'The Community provisions referred to in this paragraph shall be adopted by the Commission. That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).';

6. in Article 12, the second paragraph shall be replaced by the following:

'In the case of other beverages containing more than 1,2 % by volume of alcohol, these rules shall be laid down by the Commission.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).';

7. Article 16(1) shall be replaced by the following:

'1. Member States shall ensure that the sale is prohibited within their own territories of foodstuffs for which the particulars provided for in Article 3 and Article 4(2) do not appear in a language easily understood by the consumer, unless the consumer is in fact informed by means of other measures, determined as regards one or more labelling particulars. Determination of such measures, being a measure designed to amend non-essential elements of this Directive by supplementing it, shall be carried out in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).';

8. Article 20 shall be amended as follows:

(a) paragraph 3 shall be replaced by the following:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

(b) the following paragraph shall be added:

'4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

9. Article 21 shall be replaced by the following:

'*Article 21*

The Commission shall adopt temporary measures, if these prove necessary in order to facilitate the application of this Directive.

Temporary measures of general scope designed to amend non-essential elements of this Directive, including those supplementing it with new non-essential elements, in particular further specifications of the requirements laid down in the provisions of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(3).

Other temporary measures may be adopted in accordance with the regulatory procedure referred to in Article 20(2).'.

5.7. **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** [1]

As regards Directive 2001/37/EC, the Commission should be empowered in particular to adopt rules for the use of colour photographs or the illustrations on tobacco products and to adapt the provisions on the measurement methods and on the health warnings to scientific and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2001/37/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2001/37/EC is hereby amended as follows:

1. the first subparagraph of Article 5(3) shall be replaced by the following:

'3. The rules for the use of colour photographs or other illustrations to depict and explain the health consequences of smoking shall be adopted by the Commission with a view to ensuring that internal market provisions are not undermined. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).';

2. Article 9 shall be replaced by the following:

'*Article 9*

Adaptations

1. The adaptation to scientific and technical progress of the measurement methods laid down in Article 4 and the definitions relating thereto shall be decided by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).

2. The adaptation to scientific and technical progress of health warnings to be shown on unit packets of tobacco products as set out in Annex I and the frequency of rotation of the health warnings shall be decided by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).

3. The Commission shall, in accordance with the procedure laid down in Article 10(2), adapt to scientific and technical progress the marking for identification and tracing purposes of tobacco products.';

[1] OJ L 194, 18.7.2001, p. 26.

3. Article 10 shall be replaced by the following:

'*Article 10*

Committee procedure

1. The Commission shall be assisted by a committee.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

5.8. **Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety** [1]

As regards Directive 2001/95/EC, the Commission should be empowered in particular to set out and adapt the principal rules and procedures of notification of serious risks from products. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2001/95/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

On grounds of efficiency and in particular because the adequacy of the principal rules and procedures regarding notifications of serious risks from products is a precondition for the proper functioning of the rapid alert system, the time-limits for the regulatory procedure with scrutiny should be curtailed.

Accordingly, Directive 2001/95/EC is hereby amended as follows:

1. Article 4(1)(a) shall be replaced by the following:

'(a) the requirements intended to ensure that products which conform to those standards satisfy the general safety requirement shall be determined by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(4);';

2. the second subparagraph of Article 5(3) shall be replaced by the following:

'The Commission shall adapt the specific requirements relating to the obligation to provide information laid down in Annex I. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(5).';

3. Article 12(3) shall be replaced by the following:

'3. Detailed procedures for RAPEX are set out in Annex II. They shall be adapted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(5).';

4. Article 15 shall be replaced by the following:

'*Article 15*

1. The Commission shall be assisted by a Committee.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

[1] OJ L 11, 15.1.2002, p. 4.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.

3. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time-limits laid down in Article 5a(3)(c) and (4)(b) and (e) of Decision 1999/468/EC shall be set at two months, one month and two months respectively.'.

5.9. **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** [1]

As regards Regulation (EC) No 178/2002, the Commission should be empowered in particular to adopt provisions relating to the number and names of the Scientific Panels, the rules of procedure for submitting a request for an opinion to the Authority and the criteria for inclusion of an institute on the list of competent organisations designated by the Member States. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 178/2002, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 178/2002 is hereby amended as follows:

1. the second subparagraph of Article 28(4) shall be replaced by the following:

'The number and names of the Scientific Panels may be adapted in the light of technical and scientific development by the Commission, at the Authority's request. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 58(3).';

2. Article 29(6) shall be replaced by the following:

'6. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority. Those rules shall specify in particular:

(a) the procedure to be applied by the Authority to the requests referred to it;

(b) the guidelines governing the scientific evaluation of substances, products or processes which are subject under Community legislation to a system of prior authorisation or entry on a positive list, in particular where Community legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant.

The measure referred to in point (a), designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 58(3).

The guidelines referred to in point (b) shall be adopted in accordance with the regulatory procedure referred to in Article 58(2).';

[1] OJ L 31, 1.2.2002, p. 1.

3. Article 36(3) shall be replaced by the following:

'3. The Commission, after consulting the Authority, shall lay down rules establishing the criteria for inclusion of an institute on the list of competent organisations designated by the Member States, arrangements for setting out harmonised quality requirements and the financial rules governing any financial support. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 58(3).

Other implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the regulatory procedure referred to in Article 58(2).';

4. paragraphs 2 and 3 of Article 58 shall be replaced by the following:

'2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

5.10. **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** ([1])

As regards Regulation (EC) No 1774/2002, the Commission should be empowered in particular to establish rules on the disposal, processing, importation/exportation and transformation of Category 1, 2 and 3 material of animal by-products, as well as rules on the placing on the market of animal by-products coming from territories subject to animal health restrictions and of organic fertilisers and soil improvers; to define the conditions for the importation from third countries of petfood and raw material for petfood production; and to define specific or alternative hygiene requirements laid down in the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1774/2002, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of the rules regarding the placing on the market of animal by-products, or products deriving therefrom, coming from territories subject to animal health restrictions, for the adoption of alternative rules for specific situations regarding the placing on the market of animal by-products, or products deriving therefrom, coming from territories subject to animal health restrictions and for amendment of the Annexes.

Accordingly, Regulation (EC) No 1774/2002 is hereby amended as follows:

1. Article 3(2) shall be replaced by the following:

'2. However, Member States may regulate under national law the importation and placing on the market of products not referred to in Annexes VII and VIII, pending the adoption of a decision by the Commission. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Member States shall immediately inform the Commission of the use that they make of this possibility.';

([1]) OJ L 273, 10.10.2002, p. 1.

2. Article 4 shall be amended as follows:

(a) paragraph 2(e) shall be replaced by the following:

'(e) in the light of developments in scientific knowledge, disposed of by other means that are approved by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Those means may either supplement or replace those provided for in points (a) to (d) of this paragraph.';

(b) the first sentence of paragraph 4 shall be replaced by the following:

'Category 1 material shall not be imported or exported except in accordance with this Regulation or with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

3. Article 5 shall be amended as follows:

(a) paragraph 2 shall be amended as follows:

(i) in point (c), point (i) shall be replaced by the following:

'(i) in the case of resulting proteinaceous material, used as an organic fertiliser or soil improver in compliance with requirements, if any, laid down by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3),';

(ii) point (d) shall be replaced by the following:

'(d) in the case of material of fish origin, ensiled or composted in compliance with rules adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3);';

(iii) in point (e), point (iii) shall be replaced by the following:

'(iii) transformed in a biogas plant or composted in accordance with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3);';

(iv) point (g) shall be replaced by the following:

'(g) disposed of by other means, or used in other ways, in accordance with rules laid down by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Those means or ways may either supplement or replace those provided for in points (a) to (f) of this paragraph.';

(b) paragraph 4 shall be replaced by the following:

'4. Category 2 material shall not be placed on the market or exported except in accordance with this Regulation or with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

4. points (g), (h) and (i) of Article 6(2) shall be replaced by the following:

'(g) in the case of catering waste referred to in paragraph 1(l), transformed in a biogas plant or composted in accordance with rules laid down by the Commission, or, pending the adoption of such rules, in accordance with national law. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3);

(h) in the case of material of fish origin, ensiled or composted in accordance with rules laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3); or

(i) disposed of by other means, or used in other ways, in accordance with rules laid down by the Commission after consultation of the appropriate scientific committee; those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). Those means or ways may either supplement or replace those provided for in points (a) to (h).';

5. Article 12(5) shall be replaced by the following:

'5. The requirements of paragraphs 2 and 3 may be amended by the Commission in the light of developments in scientific knowledge, after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

6. Article 16(3) shall be amended as follows:

(a) point (d) shall be replaced by the following:

'(d) comply with the requirements laid down in Annexes VII and VIII, or with detailed rules to be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 33(4).';

(b) the first sentence of the second subparagraph shall be replaced by the following:

'Conditions alternative to those set out in the first subparagraph may be laid down in specific situations by decisions adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 33(4).';

7. Article 20(2) shall be replaced by the following:

'2. Member States shall ensure that organic fertilisers and soil improvers produced from processed products, other than those produced from manure and digestive tract content, are placed on the market or exported only if they meet requirements, if any, laid down by the Commission after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3)';

8. Article 22(2) shall be replaced by the following:

'2. The Commission shall establish rules concerning control measures. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

Other rules for the implementation of this Article shall be adopted in accordance with the regulatory procedure referred to in Article 33(2).

Derogations from paragraph 1(a) may be granted in relation to fish and fur animals, after consultation of the appropriate scientific committee. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

9. Article 23 shall be amended as follows:

(a) paragraph 2(d) shall be replaced by the following:

'(d) In addition, Member States may authorise the use, under the supervision of the competent authorities, of Category 1 material referred to in Article 4(1)(b)(ii) for the feeding of endangered or protected species of necrophagous birds in accordance with rules laid down by the Commission after consultation of the European Food Safety Authority. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

(b) paragraph 5 shall be replaced by the following:

'5. Detailed rules concerning verification measures may be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

10. Article 25(3) shall be replaced by the following:

'3. The Commission may lay down rules concerning the frequency of checks and reference methods for microbiological analyses. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

Any other detailed arrangements for implementing this Article may be laid down under the regulatory procedure referred to in Article 33(2).';

11. Article 26(5) shall be replaced by the following:

'5. The Commission may lay down rules concerning the frequency of checks and reference methods for microbiological analyses. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).

Any other detailed arrangements for implementing this Article may be laid down under the regulatory procedure referred to in Article 33(2).';

12. the second paragraph of Article 28 shall be replaced by the following:

'However, the importation from third countries of petfood and raw material for petfood production, derived from animals which have been treated with certain substances prohibited in accordance with Directive 96/22/EC, shall be permitted provided that such raw material is permanently marked and under specific conditions laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

13. Article 32(1) shall be replaced by the following:

'1. After consultation of the appropriate scientific committee on any question that could have an impact on animal or public health, the Annexes may be amended or supplemented and any appropriate transitional measures may be adopted by the Commission.

Transitional measures and measures amending or supplementing the Annexes, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, in particular further specifications of the requirements laid down in this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 33(4).

Other transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 33(2).';

14. Article 33 shall be replaced as follows:

'*Article 33*

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, hereinafter referred to as 'the Committee'.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

15. in Annex III, Chapter II, Part B, point 11 shall be replaced by the following:

'11. Waste water must be treated to ensure, as far as is reasonably practicable, that no pathogens remain. Specific requirements for the treatment of waste water from Category 1 and Category 2 intermediate plants may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

16. Annex V shall be amended as follows:

(a) point 4 of Chapter II shall be replaced by the following:

'4. Waste water originating in the unclean sector must be treated to ensure, as far as is reasonably practicable, that no pathogens remain. Specific requirements for the treatment of waste water from processing plants may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

(b) point 5 of Chapter V shall be replaced by the following:

'5. Validation procedures based on testing methods may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

17. Annex VI shall be amended as follows:

(a) point 8 in Part C of Chapter I shall be replaced by the following:

'8. Processed products derived from Category 1 or 2 material, with the exception of liquid products destined for biogas or composting plants, must be permanently marked, where technically possible with smell, using a system approved by the competent authority. Detailed rules for such marking may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

(b) point 2(b) of Chapter III shall be replaced by the following:

'(b) in a continuous process at 140 °C 2 bars (2 000 hPa) for eight minutes, or under equivalent conditions laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

18. Annex VII shall be amended as follows:

(a) point 13(b) in Part C of Chapter II shall be replaced by the following:

'(b) reprocessed in a processing plant approved pursuant to this Regulation or decontaminated by a treatment authorised by the competent authority. A list of permitted treatments may be established by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3). The consignment must not be released until it has been treated, tested for salmonella by the competent authority in accordance with Chapter I, paragraph 10, and a negative result obtained.';

(b) Chapter V shall be amended as follows:

(i) point 5 of Part A shall be replaced by the following:

'5. Raw milk and colostrum must be produced under conditions offering adequate guarantees as regards animal health. Such conditions may be established by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

(ii) point 3 of Part B shall be replaced by the following:

'3. Where a risk of introduction of an exotic disease or any other risk to animal health is identified, additional conditions for the protection of animal health may be established by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

(c) point 3(c) in Part B of Chapter VI shall be replaced by the following:

'(c) an equivalent production process approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

(d) point 1 in Part A of Chapter VII shall be replaced by the following:

'1. Dicalcium phosphate must be produced by a process that:

(a) ensures that all Category 3 bone-material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at a minimum concentration of 4 % and a pH of less than 1,5) over a period of at least two days;

(b) following the procedure provided for in point (a), applies a treatment of the obtained phosphoric liquor with lime, resulting in a precipitate of dicalcium phosphate at pH 4 to 7; and

(c) finally, air-dries the precipitate of dicalcium phosphate with inlet temperature of 65 °C to 325 °C and end temperature between 30 °C and 65 °C, or

by an equivalent process approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

(e) point 1 in Part A of Chapter VIII shall be replaced by the following:

'1. Tricalcium phosphate must be produced by a process that ensures:

(a) that all Category 3 bone-material is finely crushed and degreased in counter-flow with hot water (bone chips less than 14 mm);

(b) continuous cooking with steam at 145 °C during 30 minutes at 4 bars;

(c) separation of the protein broth from the hydroxyapatite (tricalcium phosphate) by centrifugation; and

(d) granulation of the tricalcium phosphate after drying in a fluid bed with air at 200 °C; or

by an equivalent production process approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

19. Annex VIII shall be amended as follows:

(a) point 2(e) in Part A of Chapter VI shall be replaced by the following:

'(e) preserved by a process other than tanning specified by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).';

(b) point 4(a)(iii) in Part A of Chapter VII shall be replaced by the following:

'(iii) preserved by a treatment other than tanning approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 33(3).'.

5.11. **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** ([1])

As regards Directive 2002/98/EC, the Commission should be empowered in particular to adapt the technical requirements set out in Annexes I to IV to technical and scientific progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2002/98/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

([1]) OJ L 33, 8.2.2003, p. 30.

In the event that scientific and technical developments indicate that additional information should be provided to or obtained from donors, in order, for instance, to exclude donors presenting a health risk to others, an adaptation should be made without delay. Similarly, if scientific progress suggests new eligibility criteria concerning the suitability of blood and plasma donors, new deferral criteria should be added to the list immediately. When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adaptation to scientific and technical progress of the technical requirements concerning information to be provided to or obtained from donors, as well as requirements related to the suitability of blood and plasma donors, set out in Annexes I to IV.

Accordingly, Directive 2002/98/EC is hereby amended as follows:

1. Article 28 shall be replaced by the following:

'*Article 28*

Committee procedure

1. The Commission shall be assisted by a Committee.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

2. Article 29 shall be amended as follows:

(a) the first paragraph shall be replaced by the following:

'The adaptation of the technical requirements set out in Annexes I to IV to technical and scientific progress shall be decided by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 28(4) as regards technical requirements set out in Annexes III and IV.';

(b) the introductory wording in the second paragraph shall be replaced by the following:

'The following technical requirements and their adaptation to technical and scientific progress shall be decided by the Commission:';

(c) the following paragraphs are added:

'Technical requirements referred to in points (a) to (i) of the second paragraph, being measures designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(3).

On imperative grounds of urgency the Commission may have recourse to the urgency procedure referred to in Article 28(4) as regards technical requirements referred to in points (b), (c),(d), (e), (f) and (g) of the second paragraph.'.

5.12. **Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition** [1]

As regards Regulation (EC) No 1831/2003, the Commission should be empowered in particular to establish, as a result of technological progress or scientific development, additional feed additive categories and functional groups, to adopt amendments to Annex III and to the general conditions of Annex IV to take technological progress and scientific development into account and to adopt amendments to Annex II. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1831/2003, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 1831/2003 is hereby amended as follows:

1. Article 3(5) shall be replaced by the following:

'5. Where necessary, as a result of technological progress or scientific development, the Commission may adapt the general conditions set out in Annex IV. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).';

2. Article 6(3) shall be replaced by the following:

'3. Where necessary, as a result of technological progress or scientific development, the Commission shall establish additional feed additive categories and functional groups. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).';

3. the second subparagraph of Article 7(5) shall be replaced by the following:

'After the Authority has been consulted, further rules for the implementation of this Article may be established.

Rules to allow for simplified provisions for the authorisation of additives which have been authorised for use in food shall be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).

Other implementing rules may be adopted in accordance with the regulatory procedure referred to in Article 22(2). Those rules should, where appropriate, differentiate between requirements for feed additives in respect of food-producing animals and requirements in respect of other animals, in particular pets.';

4. Article 16(6) shall be replaced by the following:

'6. The Commission may adopt amendments to Annex III to take technological progress and scientific development into account. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).';

5. the third paragraph of Article 21 shall be replaced by the following:

'Detailed rules for implementing Annex II shall be adopted in accordance with the regulatory procedure referred to in Article 22(2).

[1] OJ L 268, 18.10.2003, p. 29.

Annex II may be amended by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 22(3).';

6. Article 22(3) shall be replaced by the following:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

5.13. **Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods** [1]

As regards Regulation (EC) No 2065/2003, the Commission should be empowered in particular to adopt amendments to the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2065/2003, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 2065/2003 is hereby amended as follows:

1. Article 17(3) shall be replaced by the following:

'3. If necessary, the Commission shall, after requesting scientific and technical assistance from the Authority, adopt quality criteria for validated analytical methods proposed in accordance with point 4 of Annex II, including substances to be measured.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).';

2. Article 18 shall be replaced by the following:

'*Article 18*

Amendments

1. Amendments to the Annexes shall be adopted by the Commission following a request to the Authority for scientific and/or technical assistance. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).

2. Amendments to the list referred to in Article 6(1) shall be adopted in accordance with the regulatory procedure referred to in Article 19(2) following a request to the Authority for scientific and/or technical assistance.';

3. Article 19(3) shall be replaced by the following:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

5.14. **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** [2]

As regards Regulation (EC) No 2160/2003, the Commission should be empowered in particular to adopt Community targets for the reduction of the prevalence of zoonoses and zoonotic agents, specific control methods and specific rules concerning the criteria for the evaluation of the testing methods, and to lay down the responsibilities and tasks of the reference laboratories and the rules for the implementation of Community controls. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2160/2003, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

[1] OJ L 309, 26.11.2003, p. 1.
[2] OJ L 325, 12.12.2003, p. 1.

Accordingly, Regulation (EC) No 2160/2003 is hereby amended as follows:

1. Article 4 shall be amended as follows:

(a) the second subparagraph of paragraph 1 shall be replaced by the following:

'The targets, and any amendments thereto, shall be established by the Commission. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

(b) paragraph 6(a) shall be replaced by the following:

'(a) Annex I may be amended by the Commission for the purposes listed in point (b), after taking account in particular of the criteria listed in point (c). Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

(c) paragraph 7 shall be replaced by the following:

'7. Annex III may be amended or supplemented by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

2. Article 5(6) shall be replaced by the following:

'6. The requirements and minimum sampling rules laid down in Annex II may be amended, adapted or supplemented by the Commission, after taking account in particular of the criteria listed in Article 4(6)(c). Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

3. Article 8(1) shall be amended as follows:

(a) the introductory words shall be replaced by the following:

'At the initiative of the Commission or at the request of a Member State:';

(b) the following subparagraph shall be added:

'Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

4. Article 9(4) shall be replaced by the following:

'4. Without prejudice to Article 5(6), specific rules concerning the setting by Member States of the criteria referred to in Article 5(5) and in paragraph 2 of this Article may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

5. Article 10(5) shall be replaced by the following:

'5. The Member State of final destination may be authorised, in accordance with the regulatory procedure referred to in Article 14(2), to require for a transitional period that the results of the testing referred to in paragraph 4 of this Article fulfil the same criteria as those laid down under its national programme, in accordance with Article 5(5). The authorisation may be withdrawn and, without prejudice to Article 5(6), specific rules concerning such criteria may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

6. Article 11 shall be amended as follows:

(a) paragraph 2 shall be replaced by the following:

'2. The responsibilities and tasks of the Community reference laboratories, in particular with regard to coordination of their activities and those of the national reference laboratories, shall be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

(b) paragraph 4 shall be replaced by the following:

'4. Certain responsibilities and tasks of the national reference laboratories, in particular with regard to coordination of their activities and those of the relevant laboratories in the Member States designated under Article 12(1)(a), may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

7. the third subparagraph of Article 12(3) shall be replaced by the following:

'Where necessary, other methods for testing may be approved by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).';

8. Article 13 shall be replaced by the following:

'*Article 13*

Implementing and transitional measures

Appropriate transitional or implementing measures, including the necessary amendments to the relevant health certificates, may be adopted by the Commission. Transitional measures of general scope designed to amend non-essential elements of this Regulation, including those supplementing it with new non-essential elements, in particular further specifications of the requirements laid down in the provisions of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Other implementing or transitional measures may be adopted in accordance with the regulatory procedure referred to in Article 14(2).';

9. Article 14(3) shall be replaced by the following:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

10. Article 17(2) shall be replaced by the following:

'2. Practical arrangements for the implementation of this Article, in particular those governing the procedure for cooperation with national competent authorities, shall be laid down under the regulatory procedure referred to in Article 14(2).'.

5.15. **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** [1]

As regards Directive 2004/23/EC, the Commission should be empowered in particular to establish traceability requirements for tissues and cells and the related procedures of enforcement as well as certain technical requirements regarding, *inter alia*, an accreditation system for tissue establishments and the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/32/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

[1] OJ L 102, 7.4.2004, p. 48.

In the event that scientific and technical developments on selection criteria and laboratory tests for donors provide for new evidence of diseases transmissible through donation, prompt adaptation of Community legislation should follow consequently. When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of decisions concerning the criteria for selection of the donor of tissues and/or cells and the laboratory tests required for donors.

Accordingly, Directive 2004/23/EC is hereby amended as follows:

1. Article 8 shall be amended as follows:

   (a) paragraph 5 shall be replaced by the following:

   '5. The traceability requirements for tissues and cells, as well as for products and materials coming into contact with those tissues and cells and having an effect on their quality and safety, shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(3).';

   (b) paragraph 6 shall be replaced by the following:

   '6. The procedures for ensuring traceability at Community level shall be established by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(3).';

2. Article 9(4) shall be replaced by the following:

   '4. The procedures for verifying the equivalent standards of quality and safety in accordance with paragraph 1 shall be established by the Commission Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(3).';

3. Article 28 shall be amended as follows:

   (a) the introductory wording shall be replaced by the following:

   'The following technical requirements and their adaptation to scientific and technical progress shall be decided by the Commission:';

   (b) the following paragraphs shall be added:

   'Technical requirements referred to in points (a) to (i), being measures designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(3).

   On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 29(4) as regards technical requirements referred to in points (d) and (e) of this Article.';

4. Article 29 shall be amended as follows:

   (a) paragraph 3 shall be replaced by the following:

   '3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

(b) the following paragraph shall be added:

'4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

5.16. **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** ([1])

As regards Regulation (EC) No 882/2004, the Commission should be empowered in particular to adopt implementing measures concerning methods of sampling and analysis, to lay down the conditions in which special treatment may take place, to update the minimum rates for any fees or charges, to determine the circumstances in which official certification is required, to amend and update the lists of Community reference laboratories, and to lay down the criteria for assessing the risk of products exported to the Community and specific import conditions. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 882/2004, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 882/2004 is hereby amended as follows:

1. Article 11(4) shall be amended as follows:

(a) the introductory wording shall be replaced by the following:

'The following implementing measures may be taken by the Commission:';

(b) the following subparagraph shall be added:

'Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).';

2. Article 20(2) shall be replaced by the following:

'2. The competent authority shall ensure that special treatment takes place in establishments under its control, or under the control of another Member State, and in accordance with conditions laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4). In the absence of such conditions, the special treatment shall take place in accordance with national rules.';

3. the second subparagraph of Article 27(3) shall be replaced by the following:

'The rates in Annex IV, Section B and Annex V, Section B shall be updated by the Commission at least every two years, in particular to take account of inflation. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).';

4. Article 30(1) shall be amended as follows:

(a) the introductory wording shall be replaced by the following:

'Without prejudice to requirements concerning official certification adopted for animal health or animal welfare purposes, requirements may be adopted by the Commission concerning:';

([1]) OJ L 165, 30.4.2004, p. 1.

(b) the following subparagraphs are added:

'The measures referred to in point (a), designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).

The measures referred to in points (b) to (g) shall be adopted in accordance with the regulatory procedure referred to in Article 62(3).';

5. Article 32 shall be amended as follows:

(a) paragraph 5 shall be replaced by the following:

'5. Other Community reference laboratories relevant to the areas referred to in Article 1 may be included in Annex VII by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4). In accordance with the same procedure, Annex VII may be updated.';

(b) paragraph 6 shall be replaced by the following:

'6. Additional responsibilities and tasks for Community reference laboratories may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).';

6. Article 33(6) shall be replaced by the following:

'6. Additional responsibilities and tasks for national reference laboratories may be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).';

7. the second subparagraph of Article 46(3) shall be replaced by the following:

'The criteria for determining risk for the purpose of the risk assessment referred to in point (a) shall be decided by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).';

8. Article 48(1) shall be replaced by the following:

'1. To the extent that the conditions and detailed procedures to be respected when importing goods from third countries or their regions are not provided for by Community law and in particular by Regulation (EC) No 854/2004, they shall, if necessary, be laid down by the Commission. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).';

9. Article 62(4) shall be replaced by the following:

'4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

10. Article 63 shall be replaced by the following:

'*Article 63*

Implementing and transitional measures

1. Transitional measures of general scope, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it with new non-essential elements, in particular

— any modification of the standards referred to in Article 12(2),

— a definition of what feed is to be regarded as feed of animal origin for the purpose of this Regulation,

and further specifications of the requirements laid down in the provisions of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).

Other transitional and implementing measures necessary in order to ensure the uniform application of this Regulation may be laid down in accordance with the regulatory procedure referred to in Article 62(3). This applies in particular to:

— the delegation of control tasks to control bodies referred to in Article 5, where those control bodies were already in operation before the entry into force of this Regulation,

— non-compliance as referred to in Article 28 which gives rise to expense arising from additional official controls,

— expenditure incurred pursuant to Article 54,

— rules on microbiological, physical and/or chemical analysis in official controls, in particular in cases involving a suspicion of risk and including the surveillance of the safety of products imported from third countries,

2. In order to take account of the specificity of Regulations (EEC) No 2092/91, (EEC) No 2081/92 and (EEC) No 2082/92, specific measures to be adopted by the Commission may provide for the necessary derogations from, and adjustments to, the rules laid down in this Regulation. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).';

11. Article 64 shall be replaced by the following:

'*Article 64*

Amendment of Annexes and references to European standards

The following measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4):

(1) the Annexes to this Regulation may be updated, except for Annex I, Annex IV and Annex V, without prejudice to Article 27(3), in particular in order to take account of administrative changes and scientific and/or technological progress;

(2) the references to the European standards mentioned in this Regulation may be updated in the event that CEN amends those references.'.

5.17. **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** [1]

As regards Regulation (EC) No 1935/2004, the Commission should be empowered in particular to adopt specific measures for groups of materials and articles, Community authorisation of a substance, and the modification, suspension or revocation of such authorisation. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 1935/2004, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

In order to strengthen the competitiveness and innovation of the European industry, materials and articles intended to come into contact with food should be marketed as soon as possible once their safety has been established. On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the adoption of a list of substances authorised for use in the manufacturing of materials and articles; list(s) of authorised substances incorporated in active or intelligent food contact materials and articles, list(s) of active or intelligent materials and articles and, when necessary, special conditions of use for those substances and/or the materials and articles in which they are incorporated; purity standards; special conditions of use for certain substances and/or the materials and articles in which they are used; specific limits on the migration of certain constituents or groups of constituents into or on to food; amendments of existing specific directives on materials and articles; Community authorisations and the modification, suspension or revocation thereof.

When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to have recourse to the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of specific measures regarding the modification, suspension or revocation of Community authorisations.

Accordingly, Regulation (EC) No 1935/2004 is hereby amended as follows:

1. Article 5 shall be amended as follows:

(a) the first subparagraph of paragraph 1 shall be replaced by the following:

'For the groups of materials and articles listed in Annex I and, where appropriate, combinations of those materials and articles or recycled materials and articles used in the manufacture of those materials and articles, specific measures may be adopted or amended by the Commission.';

(b) the following subparagraphs shall be added to paragraph 1:

'The specific measures referred to in point (m) shall be adopted by the Commission in accordance with the regulatory procedure referred to in Article 23(2).

The specific measures referred to in points (f), (g), (h), (i), (j), (k), (l) and (n), designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(3).

The specific measures referred to in points (a) to (e), designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(4).';

(c) paragraph 2 shall be replaced by the following:

'2. The Commission may amend the existing specific directives on materials and articles. Those measures, designed to amend the non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(4).';

[1] OJ L 338, 13.11.2004, p. 4.

2. Article 11(3) shall be replaced by the following:

'3. Community authorisation in the form of specific measure, as referred to in paragraph 1, shall be adopted by the Commission. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(4).';

3. Article 12(6) shall be replaced by the following:

'6. A final specific measure on the modification, suspension or revocation of the authorisation shall be adopted by the Commission. That measure, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 23(5).';

4. Article 22 shall be replaced by the following:

'Article 22

Amendments to Annexes I and II shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 23(3).';

5. Article 23 shall be amended as follows:

(a) paragraph 3 shall be replaced by the following:

'3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

(b) the following paragraphs shall be added:

'4. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time-limits laid down in Article 5a(3)(c), (4)(b) and (4(e) of Decision 1999/468/EC shall be set at two months, one month and two months respectively.

5. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

6. ENERGY AND TRANSPORT

6.1. **Council Directive 96/98/EC of 20 December 1996 on marine equipment** [1]

As regards Directive 96/98/EC, the Commission should be empowered in particular to adopt testing standards where international organisations fail or refuse to adopt them within a reasonable time, to transfer equipment from Annex A.2 to Annex A.1, and to authorise, in exceptional circumstances, the placing on board of technically innovative equipment. The Commission should also be empowered to apply, for the purposes of that Directive, subsequent amendments of international instruments, to update Annex A, to add the possibility of using certain modules for equipment listed in Annex A.1, to amend the columns for the conformity assessment modules, and to include standardisation organisations in the definition of 'testing standards' in Article 2. Since those measures are of general scope and are designed to amend non-essential elements of Directive 96/98/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

[1] OJ L 46, 17.2.1997, p. 25.

Accordingly, Directive 96/98/EC is hereby amended as follows:

1. Article 7(5) and (6) shall be replaced by the following:

'5. Should the international organisations, including the IMO, fail or refuse to adopt appropriate testing standards for a specific item of equipment within a reasonable time, standards based on the work of the European standardisation organisations may be adopted. That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).

6. When the testing standards referred to in paragraphs 1 or 5 are adopted or enter into force, as appropriate, for a specific item of equipment, that equipment may be transferred from Annex A.2 to Annex A.1. That measure, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).

Article 5 shall apply to that equipment from the date of that transfer.';

2. in Article 13(2), the first indent shall be replaced by the following:

'— the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is attributed to shortcomings in the testing standards, the Commission shall, after consulting the parties concerned, bring the matter before the Committee referred to in Article 18(1) within two months if the Member State which has taken the decision intends to maintain it, and shall initiate the regulatory procedure referred to in Article 18(2).';

3. Article 14(5) shall be replaced by the following:

'5. Equipment such as is referred to in paragraph 1 shall be added to Annex A.2. That measure, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

4. the first paragraph of Article 17 shall be replaced by the following:

'This Directive may be amended in order:

(a) to apply subsequent amendments of international instruments for the purposes of this Directive;

(b) to update Annex A, both by introducing new equipment and by transferring equipment from Annex A.2 to Annex A.1 and vice versa;

(c) to add the possibility of using modules B + C and module H for equipment listed in Annex A.1, and by amending the columns for the conformity assessment modules;

(d) to include other standardisation organisations in the definition of 'testing standards' in Article 2.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 18(3).';

5. Article 18 shall be replaced by the following:

'*Article 18*

1. The Commission shall be assisted by the Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) created by Article 3 of Regulation (EC) No 2099/2002 of the European Parliament and of the Council (*).

2. Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC (**) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at two months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 324, 29.11.2002, p. 1.
(**) OJ L 184, 17.7.1999, p. 23.'.

6.2. **Regulation (EC) No 2099/2002 of the European Parliament and of the Council of 5 November 2002 establishing a Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) and amending the Regulations on maritime safety and the prevention of pollution from ships** [1]

As regards Regulation (EC) No 2099/2002, the Commission should be empowered in particular to amend Article 2(2) in order to include a reference to the Community acts conferring implementing powers on COSS that have entered into force following the adoption of this Regulation. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2099/2002, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 2099/2002 is hereby amended as follows:

1. Article 3 shall be replaced by the following:

'*Article 3*

Establishment of a Committee

1. The Commission shall be assisted by a Committee on Safe Seas and the Prevention of Pollution from Ships (hereinafter called COSS).

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at one month.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

2. Article 7 shall be replaced by the following:

'*Article 7*

Powers of COSS

COSS shall exercise the powers conferred on it by virtue of the Community legislation in force. Article 2(2) may be amended in accordance with the regulatory procedure with scrutiny referred to in Article 3(3) in order to include a reference to the Community acts conferring implementing power on COSS that have entered into force following the adoption of this Regulation. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the procedure referred to in Article 3(3).'.

[1] OJ L 324, 29.11.2002, p. 1.

6.3. **Directive 2003/42/EC of the European Parliament and of the Council of 13 June 2003 on occurrence reporting in civil aviation** [1]

As regards Directive 2003/42/EC, the Commission should be empowered in particular to amend the Annexes in order to expand upon, or change, the examples, to facilitate the exchange of information and to adopt measures for the dissemination to interested parties of the information. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2003/42/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2003/42/EC is hereby amended as follows:

1. Article 3(2) shall be replaced by the following:

'2. The Commission may decide to amend the Annexes in order to expand upon, or change, the examples. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).';

2. Article 7(2) shall be replaced by the following:

'2. Without prejudice to the public's right of access to the Commission's documents as laid down in Regulation (EC) No 1049/2001 of the European Parliament and the Council (*), the Commission shall adopt on its own initiative measures for the dissemination to interested parties of the information referred to in paragraph 1 and the associated conditions. Those measures, which may be general or individual, shall be based on the need:

— to provide persons and organisations with the information they need to improve civil aviation safety,

— to limit the dissemination of information to what is strictly required for the purpose of its users, in order to ensure appropriate confidentiality of that information,

The individual measures shall be adopted in accordance with the regulatory procedure referred to in Article 10(2).

The general measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).

The decision to disseminate information under this paragraph shall be limited to what is strictly required for the purpose of its user, without prejudice to the provisions of Article 8.

(*) OJ L 145, 31.5.2001, p. 43.';

3. Article 10 shall be replaced by the following:

'*Article 10*

1. The Commission shall be assisted by the committee established by Article 12 of Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonisation of technical requirements and administrative procedures in the field of civil aviation (*).

[1] OJ L 167, 4.7.2003, p. 23.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 373, 31.12.1991, p. 4.'.

6.4. **Directive 2004/36/EC of the European Parliament and of the Council of 21 April 2004 on the safety of third-country aircraft using Community airports** [1]

As regards Directive 2004/36/EC, the Commission should be empowered in particular to adopt measures for the dissemination to interested parties of the information obtained through ramp inspections conducted under the European Community (EC) SAFA Programme, and measures amending the Annexes to the Directive, laying down the elements of technical procedures for the conduct and reporting of SAFA ramp inspections. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/36/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2004/36/EC is hereby amended as follows:

1. Article 6(3) shall be replaced by the following:

'3. Without prejudice to the public's right of access to the Commission's documents as laid down in Regulation (EC) No 1049/2001, the Commission shall adopt, on its own initiative, measures for the dissemination to interested parties of the information referred to in paragraph 1 and the associated conditions. Those measures, which may be general or individual, shall be based on the need:

— to provide persons and organisations with the information they need to improve civil aviation safety,

— to limit the dissemination of information to what is strictly required for the purposes of its users, in order to ensure appropriate confidentiality of that information,

The individual measures shall be adopted in accordance with the advisory procedure referred to in Article 10(3).

The general measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(4).';

2. Article 8(2) shall be replaced by the following:

'2. On the basis of the information collected under paragraph 1, the Commission may

(a) in accordance with the regulatory procedure referred to in Article 10(2), take any appropriate measures to facilitate the implementation of Articles 3, 4 and 5, such as:

— define the format for the storage and dissemination of data,

— create or support the appropriate bodies for managing or operating the tools necessary for the collection and exchange of information,

[1] OJ L 143, 30.4.2004, p. 76.

(b) detail conditions for conducting ramp inspections, including systematic ones, and establish the list of information to be collected. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(4).';

3. Article 10 shall be replaced by the following:

'*Article 10*

1. The Commission shall be assisted by the committee set up by Article 12 of Regulation (EEC) No 3922/91.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5. The Committee may furthermore be consulted by the Commission on any other matter concerning the application of this Directive.';

4. Article 12 shall be replaced by the following:

'*Article 12*

The Commission may amend the Annexes to this Directive.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(4).'.

6.5. **Regulation (EC) No 868/2004 of the European Parliament and of the Council of 21 April 2004 concerning protection against subsidisation and unfair pricing practices causing injury to Community air carriers in the supply of air services from countries not members of the European Community** [1]

As regards Regulation (EC) No 868/2004, the Commission should be empowered in particular to develop a detailed methodology for determining the existence of unfair pricing practices. This methodology should cover, *inter alia*, the manner in which normal competitive pricing, actual costs and reasonable profit margins are to be assessed in the specific context of the aviation sector. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 868/2004 by supplementing it, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Regulation (EC) No 868/2004 is hereby amended as follows:

1. Article 5(3) shall be replaced by the following:

'3. The Commission shall develop a detailed methodology for determining the existence of unfair pricing practices. This methodology shall cover, *inter alia*, the manner in which normal competitive pricing, actual costs and reasonable profit margins are to be assessed in the specific context of the aviation sector. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(4).';

[1] OJ L 162, 30.4.2004, p. 1.

2. Article 15 shall be replaced by the following:

'*Article 15*

Committee procedure

1. The Commission shall be assisted by the Committee established by Article 11 of Council Regulation (EEC) No 2408/92 of 23 July 1992 on access for Community air carriers to intra-Community air routes (*).

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

(*) OJ L 240, 24.8.1992, p. 8.'.

6.6. **Directive 2004/54/EC of the European Parliament and of the Council of 29 April 2004 on minimum safety requirements for tunnels in the Trans-European Road Network** [1]

As regards Directive 2004/54/EC, the Commission should be empowered in particular to make the necessary amendments to adapt the Annexes to technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2004/54/EC, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Accordingly, Directive 2004/54/EC is hereby amended as follows:

1. Article 13(3) shall be replaced by the following:

'3. By 30 April 2009 the Commission shall publish a report on the practice followed in the Member States. Where necessary, it shall make recommendations for the adoption of a common harmonised risk analysis methodology in accordance with the regulatory procedure referred to in Article 17(2).';

2. Article 16 shall be replaced by the following:

'*Article 16*

Adaptation to technical progress

The Commission shall adapt to technical progress the Annexes to this Directive. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 17(3).';

3. Article 17 shall be replaced by the following:

'*Article 17*

Committee procedure

1. The Commission shall be assisted by a committee.

[1] OJ L 167, 30.4.2004, p. 39.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

6.7. **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** [1]

As regards Regulation (EC) No 2111/2005, the Commission should be empowered in particular to modify the common criteria for imposing an operating ban on an air carrier in order to take account of scientific and technical developments. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 2111/2005, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the modification of the Annex setting out the common criteria for consideration of an operating ban for safety reasons at Community level.

Accordingly, Regulation (EC) No 2111/2005 is hereby amended as follows:

1. Article 3(2) shall be replaced by the following:

'2. The common criteria for imposing an operating ban on an air carrier, which shall be based on the relevant safety standards, are set out in the Annex (and are hereinafter referred to as the common criteria). The Commission may modify the Annex, in particular in order to take account of scientific and technical developments. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(4).';

2. Article 8(1) shall be replaced by the following:

'1. The Commission shall, where appropriate, adopt implementing measures in order to lay down detailed rules in respect of the procedures referred to in this Chapter. Those measures, designed to amend non-essential elements of this regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(4).';

3. Article 15 shall be replaced by the following:

'*Article 15*

1. The Commission shall be assisted by the Committee referred to in Article 12 of Regulation (EEC) No 3922/91 (hereinafter referred to as the Committee).

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

[1] OJ L 344, 27.12.2005, p. 15.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time-limits laid down in Article 5a(3)(c), (4)(b) and (4)(e) of Decision 1999/468/EC shall be one month, one month and two months respectively.

5. The Commission may consult the Committee on any other matter concerning the application of this Regulation.'.

Chronological index

(1) Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food.

(2) Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes.

(3) Council Regulation (EC) No 2494/95 of 23 October 1995 concerning harmonized indices of consumer prices.

(4) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and products.

(5) Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls.

(6) Council Directive 96/98/EC of 20 December 1996 on marine equipment.

(7) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

(8) Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 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.

(9) Council Regulation EC) No 577/98 of 9 March 1998 on the organisation of a labour force sample survey in the Community.

(10) Council Regulation (EC) No 1165/98 of 19 May 1998 concerning short-term statistics.

(11) Decision 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.

(12) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

(13) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

(14) Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity.

(15) Council Regulation (EC) No 530/1999 of 9 March 1999 concerning structural statistics on earnings and on labour costs.

(16) Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.

(17) Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.

(18) Regulation (EC) No 2037/2000 of the European Parliament and of the Council of 29 June 2000 on substances that deplete the ozone layer.

(19) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

(20) 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.

(21) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.

(22) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.

(23) 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.

(24) 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.

(25) Regulation (EC) 2099/2002 of the European Parliament and of the Council of 5 November 2002 establishing a Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) and amending the Regulations on maritime safety and the prevention of pollution from ships.

(26) Regulation (EC) No 2195/2002 of the European Parliament and of the Council of 5 November 2002 on the Common Procurement Vocabulary (CPV).

(27) 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.

(28) Regulation (EC) No 450/2003 of the European Parliament and of the Council of 27 February 2003 concerning the labour cost index.

(29) Directive 2003/42/EC of the European Parliament and of the Council of 13 June 2003 on occurrence reporting in civil aviation.

(30) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition.

(31) Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods.

(32) 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.

(33) Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors.

(34) Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts.

(35) 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.

(36) Directive 2004/36/EC of the European Parliament and of the Council of 21 April 2004 on the safety of third-country aircraft using Community airports.

(37) Regulation (EC) No 868/2004 of the European Parliament and of the Council of 21 April 2004 concerning protection against subsidisation and unfair pricing practices causing injury to Community air carriers in the supply of air services from countries not members of the European Community.

(38) Directive 2004/54/EC of the European Parliament and of the Council of 29 April 2004 on minimum safety requirements for tunnels in the Trans-European Road Network.

(39) 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.

(40) 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.

(41) Regulation (EC) No 1552/2005 of the European Parliament and of the Council of 7 September 2005 on statistics relating to vocational training in enterprises.

(42) 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.

(43) 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.

(44) Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality.

(45) Directive 2006/21/EC of the European Parliament and of the Council of 15 March 2006 on the management of waste from extractive industries.

(46) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery.

COUNCIL REGULATION (EC) No 597/2009

of 11 June 2009

on protection against subsidised imports from countries not members of the European Community

(Codified version)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 thereof,

Having regard to the Regulations establishing the common organisation of agricultural markets and the Regulations adopted pursuant to Article 308 of the Treaty applicable to goods manufactured from agricultural products, and in particular the provisions of those Regulations which allow for derogation from the general principle that protective measures at frontiers may be replaced solely by the measures provided for in those Regulations,

Having regard to the proposal from the Commission,

Whereas:

(1) Council Regulation (EC) No 2026/97 of 6 October 1997 on protection against subsidised imports from countries not members of the European Community [1] has been substantially amended several times [2]. In the interests of clarity and rationality the said Regulation should be codified.

(2) The conclusion of the Uruguay Round of multilateral trade negotiations led to the establishment of the World Trade Organisation (WTO).

(3) Annex 1A to the Agreement establishing the WTO (hereinafter referred to as the WTO Agreement), approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986 to 1994) [3], contains, inter alia, the General Agreement on Tariffs and Trade 1994 (hereinafter referred to as the GATT 1994), an Agreement on Agriculture (hereinafter referred to as the Agreement on Agriculture), an Agreement on implementation of Article VI of the GATT 1994 (hereinafter referred to as the 1994 Anti-Dumping Agreement) and an Agreement on Subsidies and Countervailing Measures (hereinafter referred to as the Subsidies Agreement).

(4) In order to reach greater transparency and effectiveness in the application by the Community of the rules laid down in the 1994 Anti-Dumping Agreement and the Subsidies Agreement respectively, the adoption of two separate Regulations which would lay down in sufficient detail the requirements for the application of each of these commercial defence instruments has been considered as necessary.

(5) In order to ensure an adequate and transparent implementation of the rules provided for in those two Agreements, it is appropriate to transpose their language into Community legislation to the best extent possible.

(6) Furthermore, it seems advisable to explain, in adequate detail, when a subsidy shall be deemed to exist, according to which principles it shall be countervailable (in particular whether the subsidy has been granted specifically), and according to which criteria the amount of the countervailable subsidy is to be calculated.

(7) In determining the existence of a subsidy, it is necessary to demonstrate that there has been a financial contribution by a government or any public body within the territory of a country, or that there has been some form of income or price support within the meaning of Article XVI of the GATT 1994, and that a benefit has thereby been conferred on the recipient enterprise.

(8) For the calculation of the benefit to the recipient, in cases where a market benchmark does not exist in the country concerned the benchmark should be determined by adjusting the terms and conditions prevailing in the country concerned on the basis of actual factors available in that country. If this is not practicable because, inter alia, such prices or costs do no exist or are unreliable, then the appropriate benchmark should be determined by resorting to terms and conditions in other markets.

(9) It is desirable to lay down clear and detailed guidance as to the factors which may be relevant for the determination of whether the subsidised imports have caused material injury or are threatening to cause injury. In demonstrating that the volume and price levels of the imports concerned are responsible for injury sustained by a Community industry, attention should be given to the effect of other factors and in particular prevailing market conditions in the Community.

[1] OJ L 288, 21.10.1997, p. 1.
[2] See Annex V.
[3] OJ L 336, 23.12.1994, p. 1.

(10) It is advisable to define the term 'Community industry' and to provide that parties related to exporters may be excluded from such industry, and to define the term 'related'. It is also necessary to provide for countervailing duty action to be taken on behalf of producers in a region of the Community and to lay down guidelines on the definition of such region.

(11) It is necessary to lay down who may lodge a countervailing duty complaint, including the extent to which it should be supported by the Community industry, and the information on countervailable subsidies, injury and causation which such complaint should contain. It is also expedient to specify the procedures for the rejection of complaints or the initiation of proceedings.

(12) It is necessary to lay down the manner in which interested parties should be given notice of the information which the authorities require, and should have ample opportunity to present all relevant evidence and to defend their interests. It is also desirable to set out clearly the rules and procedures to be followed during the investigation, in particular the rules whereby interested parties are to make themselves known, present their views and submit information within specified time limits, if such views and information are to be taken into account. It is also appropriate to set out the conditions under which an interested party may have access to, and comment on, information presented by other interested parties. There should also be cooperation between the Member States and the Commission in the collection of information.

(13) It is necessary to lay down the conditions under which provisional duties may be imposed, including conditions whereby they may be imposed no earlier than 60 days from initiation and no later than nine months thereafter. Such duties may in all cases be imposed by the Commission only for a four-month period.

(14) It is necessary to specify procedures for the acceptance of undertakings eliminating or offsetting the countervailable subsidies and injury in lieu of the imposition of provisional or definitive duties. It is also appropriate to lay down the consequences of breach or withdrawal of undertakings and that provisional duties may be imposed in cases of suspected violation or where further investigation is necessary to supplement the findings. In accepting undertakings, care should be taken that the proposed undertakings, and their enforcement, do not lead to anti-competitive behaviour.

(15) It is considered appropriate to allow withdrawal of an undertaking and application of the duty by one single legal act. It is also necessary to ensure that the withdrawal procedure is terminated within a time limit of normally six months and in no case more than nine months in order to ensure a proper enforcement of the measure in force.

(16) It is necessary to provide that the termination of cases should, irrespective of whether definitive measures are adopted or not, normally take place within 12 months and in no case later than 13 months, from the initiation of the investigation.

(17) An investigation or proceedings should be terminated whenever the amount of the subsidy is found to be *de minimis* or if, particularly in the case of imports originating in developing countries, the volume of subsidised imports or the injury is negligible, and it is appropriate to define those criteria. Where measures are to be imposed, it is necessary to provide for the termination of investigations and to lay down that measures should be less than the amount of countervailable subsidies if such lesser amount would remove the injury, and also to specify the method of calculating the level of measures in cases of sampling.

(18) It is necessary to provide for the retroactive collection of provisional duties if that is deemed appropriate and to define the circumstances which may trigger the retroactive application of duties in order to avoid the undermining of the definitive measures to be applied. It is also necessary to provide that duties may be applied retroactively in cases of breach or withdrawal of undertakings.

(19) It is necessary to provide that measures are to lapse after five years unless a review indicates that they should be maintained. It is also necessary to provide, in cases where sufficient evidence is submitted of changed circumstances, for interim reviews or for investigations to determine whether refunds of countervailing duties are warranted.

(20) Even though the Subsidies Agreement does not contain provisions concerning circumvention of countervailing measures, the possibility of such circumvention exists, in terms similar, albeit not identical, to the circumvention of anti-dumping measures. It appears therefore appropriate to enact an anti-circumvention provision in this Regulation.

(21) It is desirable to clarify which parties have the right to request the initiation of anti-circumvention investigations.

(22) It is also desirable to clarify which practices constitute circumvention of the measures in place. Circumvention practices may take place either inside or outside the Community. It is consequently necessary to provide that exemptions from the extended duties which may be granted to importers may also be granted to exporters when duties are being extended to address circumvention taking place outside the Community.

(23) It is expedient to permit the suspension of countervailing measures where there is a temporary change in market conditions which makes the continued imposition of such measures temporarily inappropriate.

(24) It is necessary to provide that imports under investigation may be made subject to registration upon importation in order to enable measures to be subsequently applied against such imports.

(25) In order to ensure proper enforcement of measures, it is necessary that Member States monitor, and report to the Commission, the import trade in products subject to investigation or subject to measures, and also the amount of duties collected under this Regulation. It is also necessary to provide for the possibility for the Commission to request Member States to supply, subject to the respect of confidentiality rules, information to be used for monitoring price undertakings and verifying the level of effectiveness of the measures in force.

(26) It is necessary to provide for consultation of an Advisory Committee at regular and specified stages of the investigation. The Committee should consist of representatives of Member States with a representative of the Commission as chairman.

(27) It is expedient to provide for verification visits to check information submitted on countervailable subsidies and injury, such visits being, however, conditional on proper replies to questionnaires being received.

(28) It is essential to provide for sampling in cases where the number of parties or transactions is large in order to permit completion of investigations within the appointed time limits.

(29) It is necessary to provide that, where parties do not cooperate satisfactorily, other information may be used to establish findings and that such information may be less favourable to the parties than if they had cooperated.

(30) Provision should be made for the treatment of confidential information so that business or governmental secrets are not divulged.

(31) It is essential that provision be made for proper disclosure of essential facts and considerations to parties which qualify for such treatment and that such disclosure be made, with due regard to the decision-making process in the Community, within a time period which permits parties to defend their interests.

(32) It is prudent to provide for an administrative system under which arguments can be presented as to whether measures are in the Community interest, including the interests of consumers, and to lay down the time periods within which such information has to be presented, together with the disclosure rights of the parties concerned.

(33) In applying the rules of the Subsidies Agreement it is essential, in order to maintain the balance of rights and obligations which this Agreement sought to establish, that the Community take account of their interpretation by the Community's major trading partners, as reflected in legislation or established practice,

HAS ADOPTED THIS REGULATION:

Article 1

Principles

1. A countervailing duty may be imposed for the purpose of offsetting any subsidy granted, directly or indirectly, for the manufacture, production, export or transport of any product whose release for free circulation in the Community causes injury.

2. Notwithstanding paragraph 1, where products are not directly imported from the country of origin but are exported to the Community from an intermediate country, the provisions of this Regulation shall be fully applicable and the transaction or transactions shall, where appropriate, be regarded as having taken place between the country of origin and the Community.

Article 2

Definitions

For the purpose of this Regulation:

(a) a product is considered to be subsidised if it benefits from a countervailable subsidy as defined in Articles 3 and 4. Such subsidy may be granted by the government of the country of origin of the imported product, or by the government of an intermediate country from which the product is exported to the Community, known for the purpose of this Regulation as 'the country of export';

(b) 'government' means a government or any public body within the territory of the country of origin or export;

(c) 'like product' shall be interpreted to mean a product which is identical, that is to say, alike in all respects, to the product under consideration, or in the absence of such a product, another product which, although not alike in all respects, has characteristics closely resembling those of the product under consideration;

(d) 'injury', unless otherwise specified, means material injury to the Community industry, threat of material injury to the Community industry or material retardation of the establishment of such an industry, and shall be interpreted in accordance with the provisions of Article 8.

Article 3

Definition of a subsidy

A subsidy shall be deemed to exist if:

1. (a) there is a financial contribution by a government in the country of origin or export, that is to say, where:

(i) a government practice involves a direct transfer of funds (for example, grants, loans, equity infusion), potential direct transfers of funds or liabilities (for example, loan guarantees);

(ii) government revenue that is otherwise due is forgone or not collected (for example, fiscal incentives such as tax credits). In this regard, the exemption of an exported product from duties or taxes borne by the like product when destined for domestic consumption, or the remission of such duties or taxes in amounts not in excess of those which have been accrued, shall not be deemed to be a subsidy, provided that such an exemption is granted in accordance with the provisions of Annexes I, II and III;

(iii) a government provides goods or services other than general infrastructure, or purchases goods;

(iv) a government:

— makes payments to a funding mechanism, or

— entrusts or directs a private body to carry out one or more of the type of functions illustrated in points (i), (ii) and (iii) which would normally be vested in the government, and the practice, in no real sense, differs from practices normally followed by governments;

or

(b) there is any form of income or price support within the meaning of Article XVI of the GATT 1994; and

2. a benefit is thereby conferred.

Article 4

Countervailable subsidies

1. Subsidies shall be subject to countervailing measures only if they are specific, as defined in paragraphs 2, 3 and 4.

2. In order to determine whether a subsidy is specific to an enterprise or industry or group of enterprises or industries (hereinafter referred to as certain enterprises) within the jurisdiction of the granting authority, the following principles shall apply:

(a) where the granting authority, or the legislation pursuant to which the granting authority operates, explicitly limits access to a subsidy to certain enterprises, such subsidy shall be specific;

(b) where the granting authority, or the legislation pursuant to which the granting authority operates, establishes objective criteria or conditions governing the eligibility for, and the amount of, a subsidy, specificity shall not exist, provided that the eligibility is automatic and that such criteria and conditions are strictly adhered to;

(c) if, notwithstanding any appearance of non-specificity resulting from the application of the principles laid down in points (a) and (b), there are reasons to believe that the subsidy may in fact be specific, other factors may be considered. Such factors are: use of a subsidy programme by a limited number of certain enterprises; predominant use by certain enterprises; the granting of disproportionately large amounts of subsidy to certain enterprises; and the manner in which discretion has been exercised by the granting authority in the decision to grant a subsidy. In this regard, information on the frequency with which applications for a subsidy are refused or approved and the reasons for such decisions shall, in particular, be considered.

For the purpose of point (b), 'objective criteria or conditions' means criteria or conditions which are neutral, which do not favour certain enterprises over others, and which are economic in nature and horizontal in application, such as number of employees or size of enterprise.

The criteria or conditions must be clearly set out by law, regulation, or other official document, so as to be capable of verification.

In applying point (c) of the first subparagraph, account shall be taken of the extent of diversification of economic activities within the jurisdiction of the granting authority, as well as of the length of time during which the subsidy programme has been in operation.

3. A subsidy which is limited to certain enterprises located within a designated geographical region within the jurisdiction of the granting authority shall be specific. The setting or changing of generally applicable tax rates by all levels of government entitled to do so shall not be deemed to be a specific subsidy for the purposes of this Regulation.

4. Notwithstanding paragraphs 2 and 3, the following subsidies shall be deemed to be specific:

(a) subsidies contingent, in law or in fact, whether solely or as one of several other conditions, upon export performance, including those illustrated in Annex I;

(b) subsidies contingent, whether solely or as one of several other conditions, upon the use of domestic over imported goods.

For the purposes of point (a), subsidies shall be considered to be contingent in fact upon export performance when the facts demonstrate that the granting of a subsidy, without having been made legally contingent upon export performance, is in fact tied to actual or anticipated exportation or export earnings. The mere fact that a subsidy is accorded to enterprises which export shall not, for that reason alone, be considered to be an export subsidy within the meaning of this provision.

5. Any determination of specificity under the provisions of this Article shall be clearly substantiated on the basis of positive evidence.

Article 5

Calculation of the amount of the countervailable subsidy

The amount of countervailable subsidies shall be calculated in terms of the benefit conferred on the recipient which is found to exist during the investigation period for subsidisation. Normally this period shall be the most recent accounting year of the beneficiary, but may be any other period of at least six months prior to the initiation of the investigation for which reliable financial and other relevant data are available.

Article 6

Calculation of benefit to the recipient

As regards the calculation of benefit to the recipient, the following rules shall apply:

(a) government provision of equity capital shall not be considered to confer a benefit, unless the investment can be regarded as inconsistent with the usual investment practice, including for the provision of risk capital, of private investors in the territory of the country of origin and/or export;

(b) a loan by a government shall not be considered to confer a benefit, unless there is a difference between the amount that the firm receiving the loan pays on the government loan and the amount that the firm would pay for a comparable commercial loan which the firm could actually obtain on the market. In that event the benefit shall be the difference between these two amounts;

(c) a loan guarantee by a government shall not be considered to confer a benefit, unless there is a difference between the amount that the firm receiving the guarantee pays on a loan guaranteed by the government and the amount that the firm would pay for a comparable commercial loan in the absence of the government guarantee. In this case the benefit shall be the difference between these two amounts, adjusted for any differences in fees;

(d) the provision of goods or services or purchase of goods by a government shall not be considered to confer a benefit, unless the provision is made for less than adequate remuneration or the purchase is made for more than adequate remuneration. The adequacy of remuneration shall be determined in relation to prevailing market conditions for the product or service in question in the country of provision or purchase, including price, quality, availability, marketability, transportation and other conditions of purchase or sale.

If there are no such prevailing market terms and conditions for the product or service in question in the country of provision or purchase which can be used as appropriate benchmarks, the following rules shall apply:

(i) the terms and conditions prevailing in the country concerned shall be adjusted, on the basis of actual costs, prices and other factors available in that country, by an appropriate amount which reflects normal market terms and conditions; or

(ii) when appropriate, the terms and conditions prevailing in the market of another country or on the world market which are available to the recipient shall be used.

Article 7

General provisions on calculation

1. The amount of the countervailable subsidies shall be determined per unit of the subsidised product exported to the Community.

In establishing this amount the following elements may be deducted from the total subsidy:

(a) any application fee, or other costs necessarily incurred in order to qualify for, or to obtain, the subsidy;

(b) export taxes, duties or other charges levied on the export of the product to the Community specifically intended to offset the subsidy.

Where an interested party claims a deduction, it must prove that the claim is justified.

2. Where the subsidy is not granted by reference to the quantities manufactured, produced, exported or transported, the amount of countervailable subsidy shall be determined by allocating the value of the total subsidy, as appropriate, over the level of production, sales or exports of the products concerned during the investigation period for subsidisation.

3. Where the subsidy can be linked to the acquisition or future acquisition of fixed assets, the amount of the countervailable subsidy shall be calculated by spreading the subsidy across a period which reflects the normal depreciation of such assets in the industry concerned.

The amount so calculated which is attributable to the investigation period, including that which derives from fixed assets acquired before this period, shall be allocated as described in paragraph 2.

Where the assets are non-depreciating, the subsidy shall be valued as an interest-free loan, and be treated in accordance with Article 6(b).

4. Where a subsidy cannot be linked to the acquisition of fixed assets, the amount of the benefit received during the investigation period shall in principle be attributed to this period, and allocated as described in paragraph 2, unless special circumstances arise justifying attribution over a different period.

Article 8

Determination of injury

1. A determination of injury shall be based on positive evidence and shall involve an objective examination of:

(a) the volume of the subsidised imports and the effect of the subsidised imports on prices in the Community market for like products; and

(b) the consequent impact of those imports on the Community industry.

2. With regard to the volume of the subsidised imports, consideration shall be given to whether there has been a significant increase in subsidised imports, either in absolute terms or relative to production or consumption in the Community. With regard to the effect of the subsidised imports on prices, consideration shall be given to whether there has been significant price undercutting by the subsidised imports as compared with the price of a like product of the Community industry, or whether the effect of such imports is otherwise to depress prices to a significant degree or prevent price increases which would otherwise have occurred, to a significant degree. No one or more of these factors can necessarily give decisive guidance.

3. Where imports of a product from more than one country are simultaneously subject to countervailing duty investigations, the effects of such imports shall be cumulatively assessed only if it is determined that:

(a) the amount of countervailable subsidies established in relation to the imports from each country is more than *de minimis* as defined in Article 14(5) and that the volume of imports from each country is not negligible; and

(b) a cumulative assessment of the effects of the imports is appropriate in light of the conditions of competition between imported products and the conditions of competition between the imported products and the like Community product.

4. The examination of the impact of the subsidised imports on the Community industry concerned shall include an evaluation of all relevant economic factors and indices having a bearing on the state of the industry, including: the fact that an industry is still in the process of recovering from the effects of past subsidisation or dumping; the magnitude of the amount of countervailable subsidies; actual and potential decline in sales, profits, output, market share, productivity, return on investments, utilisation of capacity; factors affecting Community prices; actual and potential negative effects on cash flow, inventories, employment, wages, growth, ability to raise capital or investments and, in the case of agriculture, whether there has been an increased burden on government support programmes. This list is not exhaustive, nor can any one or more of these factors necessarily give decisive guidance.

5. It must be demonstrated, from all the relevant evidence presented in relation to paragraph 1, that the subsidised imports are causing injury. Specifically, this shall entail a demonstration that the volume and/or price levels identified pursuant to paragraph 2 are responsible for an impact on the Community industry as provided for in paragraph 4, and that this impact exists to a degree which enables it to be classified as material.

6. Known factors, other than the subsidised imports which are injuring the Community industry at the same time, shall also be examined to ensure that injury caused by these other factors is not attributed to the subsidised imports pursuant to paragraph 5. Factors which may be considered in this respect include the volume and prices of non-subsidised imports, contraction in demand or changes in the patterns of consumption, restrictive trade practices of, and competition between, third country and Community producers, developments in technology and the export performance and productivity of the Community industry.

7. The effect of the subsidised imports shall be assessed in relation to the production of the Community industry of the like product when available data permit the separate identification of that production on the basis of such criteria as the production process, producers' sales and profits. If such separate identification of that production is not possible, the effects of the subsidised imports shall be assessed by examination of the production of the narrowest group or range of products including the like product, for which the necessary information can be provided.

8. A determination of a threat of material injury shall be based on facts and not merely on allegations, conjecture or remote possibility. The change in circumstances which would create a situation in which the subsidy would cause injury must be clearly foreseen and imminent.

In making a determination regarding the existence of a threat of material injury, consideration should be given to, inter alia, such factors as:

(a) the nature of the subsidy or subsidies in question and the trade effects likely to arise there from;

(b) a significant rate of increase of subsidised imports into the Community market indicating the likelihood of substantially increased imports;

(c) sufficient freely disposable capacity of the exporter or an imminent substantial increase in such capacity indicating the likelihood of substantially increased subsidised exports to the Community, account being taken of the availability of other export markets to absorb any additional exports;

(d) whether imports are entering at prices that would, to a significant degree, depress prices or prevent price increases which otherwise would have occurred, and would probably increase demand for further imports; and

(e) inventories of the product being investigated.

Not one of the factors listed above by itself can necessarily give decisive guidance but the totality of the factors considered must lead to the conclusion that further subsidised exports are imminent and that, unless protective action is taken, material injury will occur.

Article 9

Definition of Community industry

1. For the purposes of this Regulation, the term 'Community industry' shall be interpreted as referring to the Community producers as a whole of the like products or to those of them whose collective output of the products constitutes a major proportion, as defined in Article 10(6), of the total Community production of those products, except that:

(a) when producers are related to the exporters or importers, or are themselves importers of the allegedly subsidised product, the term 'Community industry' may be interpreted as referring to the rest of the producers;

(b) in exceptional circumstances the territory of the Community may, for the production in question, be divided into two or more competitive markets and the producers within each market may be regarded as a separate industry if:

(i) the producers within such a market sell all or almost all of their production of the product in question in that market; and

(ii) the demand in that market is not to any substantial degree met by producers of the product in question located elsewhere in the Community.

In such circumstances, injury may be found to exist even where a major portion of the total Community industry is not injured, provided that there is a concentration of subsidised imports into such an isolated market and provided further that the subsidised imports are causing injury to the producers of all or almost all of the production within such a market.

2. For the purpose of paragraph 1, producers shall be considered to be related to exporters or importers only if:

(a) one of them directly or indirectly controls the other; or

(b) both of them are directly or indirectly controlled by a third person; or

(c) together they directly or indirectly control a third person, provided that there are grounds for believing or suspecting that the effect of the relationship is such as to cause the producer concerned to behave differently from non-related producers.

For the purpose of this paragraph, one producer shall be deemed to control another when the former is legally or operationally in a position to exercise restraint or direction over the latter.

3. Where the Community industry has been interpreted as referring to the producers in a certain region, the exporters or the government granting countervailable subsidies shall be given an opportunity to offer undertakings pursuant to Article 13 in respect of the region concerned. In such cases, when evaluating the Community interest of the measures, special account shall be taken of the interest of the region. If an adequate undertaking is not offered promptly or if the situations set out in Article 13(9) and (10) apply, a provisional or definitive countervailing duty may be imposed in respect of the Community as a whole. In such cases the duties may, if practicable, be limited to specific producers or exporters.

4. The provisions of Article 8(7) shall apply to this Article.

Article 10

Initiation of proceedings

1. Except as provided for in paragraph 8, an investigation to determine the existence, degree and effect of any alleged subsidy shall be initiated upon a written complaint by any natural or legal person, or any association not having legal personality, acting on behalf of the Community industry.

The complaint may be submitted to the Commission, or to a Member State, which shall forward it to the Commission. The Commission shall send Member States a copy of any complaint it receives. The complaint shall be deemed to have been lodged on the first working day following its delivery to the Commission by registered mail or the issuing of an acknowledgement of receipt by the Commission.

Where, in the absence of any complaint, a Member State is in possession of sufficient evidence of subsidisation and of resultant injury to the Community industry, it shall immediately communicate such evidence to the Commission.

2. A complaint, as referred to in paragraph 1, shall include sufficient evidence of the existence of countervailable subsidies (including, if possible, of their amount), injury and a causal link between the allegedly subsidised imports and the alleged injury. The complaint shall contain such information as is reasonably available to the complainant on the following:

(a) the identity of the complainant and a description of the volume and value of the Community production of the like product by the complainant. Where a written complaint is made on behalf of the Community industry, the complaint shall identify the industry on behalf of which the complaint is made by a list of all known Community producers of the like product (or associations of Community producers of the like product) and, to the extent possible, a description of the volume and value of Community production of the like product accounted for by such producers;

(b) a complete description of the allegedly subsidised product, the names of the country or countries of origin and/or export in question, the identity of each known exporter or foreign producer and a list of known persons importing the product in question;

(c) evidence with regard to the existence, amount, nature and countervailability of the subsidies in question;

(d) information on changes in the volume of the allegedly subsidised imports, the effect of those imports on prices of the like product in the Community market and the consequent impact of the imports on the Community industry, as demonstrated by relevant factors and indices having a bearing on the state of the Community industry, such as those listed in Article 8(2) and (4).

3. The Commission shall, as far as possible, examine the accuracy and adequacy of the evidence provided in the complaint, in order to determine whether there is sufficient evidence to justify the initiation of an investigation.

4. An investigation may be initiated in order to determine whether or not the alleged subsidies are 'specific' within the meaning of Article 4(2) and (3).

5. An investigation may also be initiated in respect of measures of the type listed in Annex IV, to the extent that they contain an element of subsidy as defined by Article 3, in order to determine whether the measures in question fully conform to the provisions of that Annex.

6. An investigation shall not be initiated pursuant to paragraph 1 unless it has been determined, on the basis of an examination as to the degree of support for, or opposition to, the complaint expressed by Community producers of the like product, that the complaint has been made by or on behalf of the Community industry. The complaint shall be considered to have been made by or on behalf of the Community industry if it is supported by those Community producers whose collective output constitutes more than 50 % of the total production of the like product produced by that portion of the Community industry expressing either support for or opposition to the complaint. However, no investigation shall be initiated when Community producers expressly supporting the complaint account for less than 25 % of total production of the like product produced by the Community industry.

7. The authorities shall, unless a decision has been made to initiate an investigation, avoid any publicising of the complaint seeking the initiation of an investigation. However, as soon as possible after receipt of a properly documented complaint pursuant to this Article, and in any event before the initiation of an investigation, the Commission shall notify the country of origin and/or export concerned, which shall be invited for consultations with the aim of clarifying the situation as to matters referred to in paragraph 2 and arriving at a mutually agreed solution.

8. If, in special circumstances, the Commission decides to initiate an investigation without having received a written complaint by or on behalf of the Community industry for the initiation of such investigation, this shall be done on the basis of sufficient evidence of the existence of countervailable subsidies, injury and causal link, as described in paragraph 2, to justify such initiation.

9. The evidence both of subsidies and of injury shall be considered simultaneously in the decision on whether or not to initiate an investigation. A complaint shall be rejected where there is insufficient evidence of either countervailable subsidies or of injury to justify proceeding with the case. Proceedings shall not be initiated against countries whose imports represent a market share of below 1 %, unless such countries collectively account for 3 % or more of Community consumption.

10. The complaint may be withdrawn prior to initiation, in which case it shall be considered not to have been lodged.

11. Where, after consultation, it is apparent that there is sufficient evidence to justify initiating proceedings, the Commission shall do so within 45 days of the lodging of the complaint and shall publish a notice in the *Official Journal of the European Union*. Where insufficient evidence has been presented, the complainant shall, after consultation, be so informed within 45 days of the date on which the complaint is lodged with the Commission.

12. The notice of initiation of the proceedings shall announce the initiation of an investigation, indicate the product and countries concerned, give a summary of the information received, and provide that all relevant information is to be communicated to the Commission.

It shall state the periods within which interested parties may make themselves known, present their views in writing and submit information, if such views and information are to be taken into account during the investigation. It shall also state the period within which interested parties may apply to be heard by the Commission in accordance with Article 11(5).

13. The Commission shall advise the exporters, importers and representative associations of importers or exporters known to it to be concerned, as well as the country of origin and/or export and the complainants, of the initiation of the proceedings and, with due regard to the protection of confidential information, provide the full text of the written complaint referred to in paragraph 1 to the known exporters and to the authorities of the country of origin and/or export, and make it available upon request to other interested parties involved. Where the number of exporters involved is particularly high, the full text of the written complaint may instead be provided only to the authorities of the country of origin and/or export or to the relevant trade association.

14. A countervailing duty investigation shall not hinder the procedures of customs clearance.

Article 11

The investigation

1. Following the initiation of the proceedings, the Commission, acting in cooperation with the Member States, shall commence an investigation at Community level. Such investigation shall cover both subsidisation and injury, and these shall be investigated simultaneously.

For the purpose of a representative finding, an investigation period shall be selected which, in the case of subsidisation shall, normally, cover the investigation period provided for in Article 5.

Information relating to a period subsequent to the investigation period shall not, normally, be taken into account.

2. Parties receiving questionnaires used in a countervailing duty investigation shall be given at least 30 days to reply. The time limit for exporters shall be counted from the date of receipt of the questionnaire, which for this purpose shall be deemed to have been received one week from the day on which it was sent to the respondent or transmitted to the appropriate diplomatic representative of the country of origin and/or export. An extension to the 30-day period may be granted, due account being taken of the time limits of the investigation, provided that the party shows due cause for such extension, in terms of its particular circumstances.

3. The Commission may request Member States to supply information, and Member States shall take whatever steps are necessary in order to give effect to such requests.

They shall send to the Commission the information requested together with the results of all inspections, checks or investigations carried out.

Where this information is of general interest or where its transmission has been requested by a Member State, the Commission shall forward it to the Member States, provided it is not confidential, in which case a non-confidential summary shall be forwarded.

4. The Commission may request Member States to carry out all necessary checks and inspections, particularly amongst importers, traders and Community producers, and to carry out investigations in third countries, provided that the firms concerned give their consent and that the government of the country in question has been officially notified and raises no objection.

Member States shall take whatever steps are necessary in order to give effect to such requests from the Commission.

Officials of the Commission shall be authorised, if the Commission or a Member State so requests, to assist the officials of Member States in carrying out their duties.

5. The interested parties which have made themselves known in accordance with the second subparagraph of Article 10(12), shall be heard if they have, within the period prescribed in the notice published in the *Official Journal of the European Union*, made a written request for a hearing showing that they are an interested party likely to be affected by the result of the proceedings and that there are particular reasons why they should be heard.

6. Opportunities shall, on request, be provided for the importers, exporters and the complainants, which have made themselves known in accordance with the second subparagraph of Article 10(12), and the government of the country of origin and/or export, to meet those parties having adverse interests, so that opposing views may be presented and rebuttal arguments offered.

Provision of such opportunities must take account of the need to preserve confidentiality and of the convenience to the parties.

There shall be no obligation on any party to attend a meeting, and failure to do so shall not be prejudicial to that party's case.

Oral information provided under this paragraph shall be taken into account by the Commission in so far as it is subsequently confirmed in writing.

7. The complainants, the government of the country of origin and/or export, importers and exporters and their representative associations, users and consumer organisations, which have made themselves known in accordance with the second subparagraph of Article 10(12), may, upon written request, inspect all information made available to the Commission by any party to an investigation, as distinct from internal documents prepared by the authorities of the Community or its Member States, which is relevant to the presentation of their cases and is not confidential within the meaning of Article 29, and is used in the investigation.

Such parties may respond to such information and their comments shall be taken into consideration wherever they are sufficiently substantiated in the response.

8. Except in circumstances provided for in Article 28, the information which is supplied by interested parties and upon which findings are based shall be examined for accuracy as far as possible.

9. For proceedings initiated pursuant to Article 10(11), an investigation shall, whenever possible, be concluded within one year. In any event, such investigations shall in all cases be concluded within 13 months of their initiation, in accordance with the findings made pursuant to Article 13 for undertakings or the findings made pursuant to Article 15 for definitive action.

10. Throughout the investigation, the Commission shall afford the country of origin and/or export a reasonable opportunity to continue consultations with a view to clarifying the factual situation and arriving at a mutually agreed solution.

Article 12

Provisional measures

1. Provisional duties may be imposed if:

(a) proceedings have been initiated in accordance with Article 10;

(b) a notice has been given to that effect and interested parties have been given adequate opportunities to submit information and make comments in accordance with the second subparagraph of Article 10(12);

(c) a provisional affirmative determination has been made that the imported product benefits from countervailable subsidies and of consequent injury to the Community industry; and

(d) the Community interest calls for intervention to prevent such injury.

The provisional duties shall be imposed no earlier than 60 days from the initiation of the proceedings but no later than nine months from the initiation of the proceedings.

The amount of the provisional countervailing duty shall not exceed the total amount of countervailable subsidies as provisionally established but it should be less than this amount, if such lesser duty would be adequate to remove the injury to the Community industry.

2. Provisional duties shall be secured by a guarantee and the release of the products concerned for free circulation in the Community shall be conditional upon the provision of such guarantee.

3. The Commission shall take provisional action after consultation or, in cases of extreme urgency, after informing the Member States. In this latter case, consultations shall take place 10 days, at the latest, after notification to the Member States of the action taken by the Commission.

4. Where a Member State requests immediate intervention by the Commission and where the conditions of the first and second subparagraphs of paragraph 1 are met, the Commission shall, within a maximum of five working days from receipt of the request, decide whether a provisional countervailing duty shall be imposed.

5. The Commission shall forthwith inform the Council and the Member States of any decision taken under paragraphs 1 to 4. The Council, acting by a qualified majority, may decide differently.

6. Provisional countervailing duties shall be imposed for a maximum period of four months.

Article 13

Undertakings

1. Upon condition that a provisional affirmative determination of subsidisation and injury has been made, the Commission may accept satisfactory voluntary undertakings offers under which:

(a) the country of origin and/or export agrees to eliminate or limit the subsidy or take other measures concerning its effects; or

(b) any exporter undertakes to revise its prices or to cease exports to the area in question as long as such exports benefit from countervailable subsidies, so that the Commission, after specific consultation of the Advisory Committee, is satisfied that the injurious effect of the subsidies is thereby eliminated.

In such a case and as long as such undertakings are in force, the provisional duties imposed by the Commission in accordance with Article 12(3) and the definitive duties imposed by the Council in accordance with Article 15(1) shall not apply to the relevant imports of the product concerned manufactured by the companies referred to in the Commission decision accepting undertakings and in any subsequent amendment of such decision.

Price increases under such undertakings shall not be higher than is necessary to offset the amount of countervailable subsidies, and should be less than the amount of countervailable subsidies if such increases would be adequate to remove the injury to the Community industry.

2. Undertakings may be suggested by the Commission, but no country or exporter shall be obliged to enter into such an undertaking. The fact that countries or exporters do not offer such undertakings, or do not accept an invitation to do so, shall in no way prejudice consideration of the case.

However, it may be determined that a threat of injury is more likely to be realised if the subsidised imports continue. Undertakings shall not be sought or accepted from countries or exporters unless a provisional affirmative determination of subsidisation and injury caused by such subsidisation has been made.

Save in exceptional circumstances, undertakings may not be offered later than the end of the period during which representations may be made pursuant to Article 30(5).

3. Undertakings offered need not be accepted if their acceptance is considered impractical, such as where the number of actual or potential exporters is too great, or for other reasons, including reasons of general policy. The exporter and/or the country of origin and/or export concerned may be provided with the reasons for which it is proposed to reject the offer of an undertaking and may be given an opportunity to make comments thereon. The reasons for rejection shall be set out in the definitive decision.

4. Parties which offer an undertaking shall be required to provide a non-confidential version of such undertaking, so that it may be made available to interested parties to the investigation.

5. Where undertakings are, after consultation, accepted, and where there is no objection raised within the Advisory Committee, the investigation shall be terminated. In all other cases, the Commission shall submit to the Council forthwith a report on the results of the consultation, together with a proposal that the investigation be terminated. The investigation shall be deemed terminated if, within one month, the Council, acting by qualified majority, has not decided otherwise.

6. If the undertakings are accepted, the investigation of subsidisation and injury shall normally be completed. In such a case, if a negative determination of subsidisation or injury is made, the undertaking shall automatically lapse, except in cases where such a determination is due in large part to the existence of an undertaking. In such cases, it may be required that an undertaking be maintained for a reasonable period.

In the event that an affirmative determination of subsidisation and injury is made, the undertaking shall continue consistent with its terms and the provisions of this Regulation.

7. The Commission shall require any country or exporter from whom undertakings have been accepted to provide, periodically, information relevant to the fulfilment of such undertaking, and to permit verification of pertinent data. Non-compliance with such requirements shall be construed as a breach of the undertaking.

8. Where undertakings are accepted from certain exporters during the course of an investigation, they shall, for the purpose of Articles 18, 19, 20 and 22, be deemed to take effect from the date on which the investigation is concluded for the country of origin and/or export.

9. In case of breach or withdrawal of undertakings by any party to the undertaking, or in case of withdrawal of acceptance of the undertaking by the Commission, the acceptance of the undertaking shall, after consultation, be withdrawn by Commission Decision or Commission Regulation, as appropriate, and the provisional duty which has been imposed by the Commission in accordance with Article 12 or the definitive duty which has been imposed by the Council in accordance with Article 15(1), shall apply, provided that the exporter concerned, or the country of origin and/or export has, except in the case of withdrawal of the undertaking by the exporter or such country, been given an opportunity to comment.

Any interested party or Member State may submit information, showing prima facie evidence of a breach of an undertaking. The subsequent assessment of whether or not a breach of an undertaking has occurred shall normally be concluded within six months, but in no case later than nine months following a duly substantiated request.

The Commission may request the assistance of the competent authorities of the Member States in the monitoring of undertakings.

10. A provisional duty may, after consultation, be imposed in accordance with Article 12 on the basis of the best information available, where there is reason to believe that an undertaking is being breached, or in case of breach or withdrawal of an undertaking where the investigation which led to the undertaking has not been concluded.

Article 14

Termination without measures

1. Where the complaint is withdrawn, the proceedings may be terminated unless such termination would not be in the Community interest.

2. Where, after consultation, protective measures are unnecessary and there is no objection raised within the Advisory Committee, the investigation or proceedings shall be terminated. In all other cases, the Commission shall submit to the Council forthwith a report on the results of the consultation, together with a proposal that the proceedings be terminated. The proceedings shall be deemed terminated if, within one month, the Council, acting by a qualified majority, has not decided otherwise.

3. There shall be immediate termination of the proceedings where it is determined that the amount of countervailable subsidies is *de minimis*, in accordance with paragraph 5, or where the volume of subsidised imports, actual or potential, or the injury, is negligible.

4. For proceedings initiated pursuant to Article 10(11), injury shall normally be regarded as negligible where the market share of the imports is less than the amounts set out in Article 10(9). With regard to investigations concerning imports from developing countries, the volume of subsidised imports shall also be considered negligible if it represents less than 4 % of the total imports of the like product in the Community, unless imports from developing countries whose individual shares of total imports represent less than 4 % collectively account for more than 9 % of the total imports of the like product in the Community.

5. The amount of the countervailable subsidies shall be considered to be *de minimis* if such amount is less than 1 % *ad valorem*, except where, as regards investigations concerning imports from developing countries, the *de minimis* threshold shall be 2 % *ad valorem*, provided that it is only the investigation that shall be terminated where the amount of the countervailable subsidies is below the relevant *de minimis* level for individual exporters, which shall remain subject to the proceedings and may be reinvestigated in any subsequent review carried out for the country concerned pursuant to Articles 18 and 19.

Article 15

Imposition of definitive duties

1. Where the facts as finally established show the existence of countervailable subsidies and injury caused thereby, and the Community interest calls for intervention in accordance with Article 31, a definitive countervailing duty shall be imposed by the Council, acting on a proposal submitted by the Commission after consultation of the Advisory Committee.

The proposal shall be adopted by the Council unless it decides by a simple majority to reject the proposal, within a period of one month after its submission by the Commission.

Where provisional duties are in force, a proposal regarding definitive action shall be submitted no later than one month before the expiry of such duties.

No measures shall be imposed if the subsidy or subsidies are withdrawn or it has been demonstrated that the subsidies no longer confer any benefit on the exporters involved.

The amount of the countervailing duty shall not exceed the amount of countervailable subsidies established but it should be less than the total amount of countervailable subsidies if such lesser duty would be adequate to remove the injury to the Community industry.

2. A countervailing duty shall be imposed in the appropriate amounts in each case, on a non-discriminatory basis, on imports of a product from all sources found to benefit from countervailable subsidies and causing injury, except for imports from those sources from which undertakings under the terms of this Regulation have been accepted. The regulation imposing the duty shall specify the duty for each supplier, or, if that is impracticable, the supplying country concerned.

3. When the Commission has limited its examination in accordance with Article 27, any countervailing duty applied to imports from exporters or producers which have made themselves known in accordance with Article 27 but were not included in the examination shall not exceed the weighted average amount of countervailable subsidies established for the parties in the sample.

For the purpose of this paragraph, the Commission shall disregard any zero and *de minimis* amounts of countervailable subsidies and amounts of countervailable subsidies established in the circumstances referred to in Article 28.

Individual duties shall be applied to imports from any exporter or producer for which an individual amount of subsidisation has been calculated as provided for in Article 27.

Article 16

Retroactivity

1. Provisional measures and definitive countervailing duties shall only be applied to products which enter free circulation after the time when the measure taken pursuant to Article 12(1) or Article 15(1), as the case may be, enters into force, subject to the exceptions set out in this Regulation.

2. Where a provisional duty has been applied and the facts as finally established show the existence of countervailable subsidies and injury, the Council shall decide, irrespective of whether a definitive countervailing duty is to be imposed, what proportion of the provisional duty is to be definitively collected.

For this purpose, 'injury' shall not include material delay of the establishment of a Community industry, nor threat of material injury, except where it is found that this would, in the absence of provisional measures, have developed into material injury. In all other cases involving such threat or delay, any provisional amounts shall be released and definitive duties can only be imposed from the date on which a final determination of threat or material delay is made.

3. If the definitive countervailing duty is higher than the provisional duty, the difference shall not be collected. If the definitive duty is lower than the provisional duty, the duty shall be recalculated. Where a final determination is negative, the provisional duty shall not be confirmed.

4. A definitive countervailing duty may be levied on products which were entered for consumption no more than 90 days prior to the date of application of provisional measures but not prior to the initiation of the investigation.

The first subparagraph shall apply, provided that:

(a) the imports have been registered in accordance with Article 24(5);

(b) the importers concerned have been given an opportunity to comment by the Commission;

(c) there are critical circumstances where for the subsidised product in question injury which is difficult to repair is caused by massive imports in a relatively short period of a product benefiting from countervailable subsidies under the terms of this Regulation; and

(d) it is deemed necessary, in order to preclude the recurrence of such injury, to assess countervailing duties retroactively on those imports.

5. In cases of breach or withdrawal of undertakings, definitive duties may be levied on goods entered for free circulation no more than 90 days before the application of provisional measures, provided that the imports have been registered in accordance with Article 24(5) and that any such retroactive assessment shall not apply to imports entered before the breach or withdrawal of the undertaking.

Article 17

Duration

A countervailing measure shall remain in force only as long as, and to the extent that, it is necessary to counteract the countervailable subsidies which are causing injury.

Article 18

Expiry reviews

1. A definitive countervailing measure shall expire five years from its imposition or five years from the date of the most recent review which has covered both subsidisation and injury, unless it is determined in a review that the expiry would be likely to lead to a continuation or recurrence of subsidisation and injury. Such an expiry review shall be initiated on the initiative of the Commission, or upon a request made by or on behalf of Community producers, and the measure shall remain in force pending the outcome of such review.

2. An expiry review shall be initiated where the request contains sufficient evidence that the expiry of the measures would be likely to result in a continuation or recurrence of subsidisation and injury. Such a likelihood may, for example, be indicated by evidence of continued subsidisation and injury or evidence that the removal of injury is partly or solely due to the existence of measures or evidence that the circumstances of the exporters, or market conditions, are such that they would indicate the likelihood of further injurious subsidisation.

3. In carrying out investigations under this Article, the exporters, importers, the country of origin and/or export and the Community producers shall be provided with the opportunity to amplify, rebut or comment on the matters set out in the review request, and conclusions shall be reached with due account taken of all relevant and duly documented evidence presented in relation to the question as to whether the expiry of measures would be likely, or unlikely, to lead to the continuation or recurrence of subsidisation and injury.

4. A notice of impending expiry shall be published in the *Official Journal of the European Union* at an appropriate time in the final year of the period of application of the measures as defined in this Article. Thereafter, the Community producers shall, no later than three months before the end of the five-year period, be entitled to lodge a review request in accordance with paragraph 2. A notice announcing the actual expiry of measures under this Article shall also be published.

Article 19

Interim reviews

1. The need for the continued imposition of measures may also be reviewed, where warranted, on the initiative of the Commission or at the request of a Member State or, provided that a reasonable period of time of at least one year has elapsed since the imposition of the definitive measure, upon a request by any exporter, importer or by the Community producers or the country of origin and/or export which contains sufficient evidence substantiating the need for such an interim review.

2. An interim review shall be initiated where the request contains sufficient evidence that the continued imposition of the measure is no longer necessary to offset the countervailable subsidy and/or that the injury would be unlikely to continue or recur if the measure were removed or varied, or that the existing measure is not, or is no longer, sufficient to counteract the countervailable subsidy which is causing injury.

3. Where the countervailing duties imposed are less than the amount of countervailable subsidies found, an interim review may be initiated if the Community producers or any other interested party submit, normally within two years from the entry into force of the measures, sufficient evidence that, after the original investigation period and prior to or following the imposition of measures, export prices have decreased or that there has been no movement, or insufficient movement of resale prices of the imported product in the Community. If the investigation proves the allegations to be correct, countervailing duties may be increased to achieve the price increase required to remove injury. However, the increased duty level shall not exceed the amount of the countervailable subsidies.

The interim review may also be initiated, under the conditions set out above, at the initiative of the Commission or at the request of a Member State.

4. In carrying out investigations pursuant to this Article, the Commission may, *inter alia*, consider whether the circumstances with regard to subsidisation and injury have changed significantly, or whether existing measures are achieving the intended results in removing the injury previously determined under Article 8. In these respects, account shall be taken in the final determination of all relevant and duly documented evidence.

Article 20

Accelerated reviews

Any exporter whose exports are subject to a definitive countervailing duty but which was not individually investigated during the original investigation for reasons other than a refusal to cooperate with the Commission, shall be entitled, upon request, to an accelerated review in order that the Commission may promptly establish an individual countervailing duty rate for that exporter.

Such a review shall be initiated after consultation of the Advisory Committee and after Community producers have been given an opportunity to comment.

Article 21

Refunds

1. Notwithstanding Article 18, an importer may request reimbursement of duties collected where it is shown that the amount of countervailable subsidies, on the basis of which duties were paid, has been either eliminated or reduced to a level which is below the level of the duty in force.

2. In requesting a refund of countervailing duties, the importer shall submit an application to the Commission. The application shall be submitted via the Member State in the territory of which the products were released for free circulation, within six months of the date on which the amount of the definitive duties to be levied was duly determined by the competent authorities or of the date on which a decision was made definitively to collect the amounts secured by way of provisional duty. Member States shall forward the request to the Commission forthwith.

3. An application for refund shall be considered to be duly supported by evidence only where it contains precise information on the amount of refund of countervailing duties claimed and all customs documentation relating to the calculation and payment of such amount. It shall also include evidence, for a representative period, of the amount of countervailable subsidies for the exporter or producer to which the duty applies. In cases where the importer is not associated with the exporter or producer concerned and such information is not immediately available, or where the exporter or producer is unwilling to release it to the importer, the application shall contain a statement from the exporter or producer that the amount of countervailable subsidies has been reduced or eliminated, as specified in this Article, and that the relevant supporting evidence will be provided to the Commission. Where such evidence is not forthcoming from the exporter or producer within a reasonable period of time the application shall be rejected.

4. The Commission shall, after consultation of the Advisory Committee, decide whether and to what extent the application should be granted, or it may decide at any time to initiate an interim review, whereupon the information and findings from such review, carried out in accordance with the provisions applicable for such reviews, shall be used to determine whether and to what extent a refund is justified.

Refunds of duties shall normally take place within 12 months and in no circumstances more than 18 months after the date on which a request for a refund, duly supported by evidence, has been made by an importer of the product subject to the countervailing duty.

The payment of any refund authorised should normally be made by Member States within 90 days of the decision referred to in the first subparagraph.

Article 22

General provisions on reviews and refunds

1. The relevant provisions of this Regulation with regard to procedures and the conduct of investigations, excluding those relating to time limits, shall apply to any review carried out pursuant to Articles 18, 19 and 20.

Reviews carried out pursuant to Articles 18 and 19 shall be carried out expeditiously and shall normally be concluded within 12 months of the date of initiation of the review. In any event, reviews pursuant to Articles 18 and 19 shall in all cases be concluded within 15 months of initiation.

Reviews pursuant to Article 20 shall in all cases be concluded within nine months of the date of initiation.

If a review carried out pursuant to Article 18 is initiated while a review under Article 19 is ongoing in the same proceedings, the review pursuant to Article 19 shall be concluded at the same time as foreseen above for the review pursuant to Article 18.

The Commission shall submit a proposal for action to the Council no later than one month before the expiry of the above deadlines.

If the investigation is not completed within the above deadlines, the measures shall:

(a) expire in investigations pursuant to Article 18;

(b) expire in the case of investigations carried out pursuant to Articles 18 and 19 in parallel, where either the investigation pursuant to Article 18 was initiated while a review under Article 19 was ongoing in the same proceedings or where such reviews were initiated at the same time; or

(c) remain unchanged in investigations pursuant to Articles 19 and 20.

A notice announcing the actual expiry or maintenance of the measures pursuant to this paragraph shall be published in the *Official Journal of the European Union*.

2. Reviews pursuant to Articles 18, 19 and 20 shall be initiated by the Commission after consultation of the Advisory Committee.

3. Where warranted by reviews, measures shall be repealed or maintained pursuant to Article 18, or repealed, maintained or amended pursuant to Articles 19 and 20, by the Community institution responsible for their introduction.

4. Where measures are repealed for individual exporters, but not for the country as a whole, such exporters shall remain subject to the proceedings and may be reinvestigated in any subsequent review carried out for that country pursuant to this Article.

5. Where a review of measures pursuant to Article 19 is in progress at the end of the period of application of measures as defined in Article 18, the measures shall also be investigated under the provisions of Article 18.

6. In all review or refund investigations carried out pursuant to Articles 18 to 21, the Commission shall, provided that circumstances have not changed, apply the same methodology as in the investigation which led to the duty, with due account being taken of Articles 5, 6, 7 and 27.

Article 23

Circumvention

1. Countervailing duties imposed pursuant to this Regulation may be extended to imports from third countries, of the like product, whether slightly modified or not, or to imports of the slightly modified like product from the country subject to measures, or to parts thereof, when circumvention of the measures in force is taking place.

2. Countervailing duties not exceeding the residual countervailing duty imposed in accordance with Article 15(2) may be extended to imports from companies benefiting from individual duties in the countries subject to measures when circumvention of the measures in force is taking place.

3. Circumvention shall be defined as a change in the pattern of trade between third countries and the Community or between individual companies in the country subject to measures and the Community, which stems from a practice, process or work for which there is insufficient due cause or economic justification other than the imposition of the duty, and where there is evidence of injury or that the remedial effects of the duty are being undermined in terms of the prices and/or quantities of the like product and that the imported like product and/or parts thereof still benefit from the subsidy.

The practice, process or work referred to in the first subparagraph includes, inter alia:

(a) the slight modification of the product concerned to make it fall under customs codes which are normally not subject to the measures, provided that the modification does not alter its essential characteristics;

(b) the consignment of the product subject to measures via third countries; and

(c) the reorganisation by exporters or producers of their patterns and channels of sales in the country subject to measures in order to eventually have their products exported to the Community through producers benefiting from an individual duty rate lower than that applicable to the products of the manufacturers.

4. Investigations shall be initiated pursuant to this Article on the initiative of the Commission or at the request of a Member State or of any interested party on the basis of sufficient evidence regarding the factors set out in paragraphs 1, 2 and 3. Initiations shall be made, after consultation of the Advisory Committee, by Commission Regulation which may also instruct the customs authorities to make imports subject to registration in accordance with Article 24(5) or to request guarantees.

Investigations shall be carried out by the Commission, which may be assisted by customs authorities and shall be concluded within nine months.

If the facts as finally ascertained justify the extension of measures, this shall be done by the Council, acting on a proposal submitted by the Commission after consultation of the Advisory Committee. The proposal shall be adopted by the Council unless it decides by a simple majority to reject the proposal, within a period of one month after its submission by the Commission.

The extension shall take effect from the date on which registration was imposed pursuant to Article 24(5) or on which guarantees were requested. The relevant procedural provisions of this Regulation with regard to initiations and the conduct of investigations shall apply pursuant to this Article.

5. Imports shall not be subject to registration pursuant to Article 24(5) or measures where they are traded by companies which benefit from exemptions.

6. Requests for exemptions duly supported by evidence shall be submitted within the time limits established in the Commission Regulation initiating the investigation.

Where the circumventing practice, process or work takes place outside the Community, exemptions may be granted to producers of the product concerned that can show that they are not related to any producer subject to the measures and that are found not to be engaged in circumvention practices as defined in paragraph 3.

Where the circumventing practice, process or work takes place inside the Community, exemptions may be granted to importers that can show that they are not related to producers subject to the measures.

These exemptions are granted by decision of the Commission after consultation of the Advisory Committee or decision of the Council imposing measures and shall remain valid for the period and under the conditions set down therein.

Provided that the conditions set in Article 20 are met, exemptions may also be granted after the conclusion of the investigation leading to the extension of the measures.

7. Provided that at least one year has lapsed from the extension of the measures, and in case the number of parties requesting or potentially requesting an exemption is significant, the Commission may decide to initiate a review of the extension of the measures. Any such review shall be conducted in accordance with the provisions of Article 22(1) as applicable to reviews under Article 19.

8. Nothing in this Article shall preclude the normal application of the provisions in force concerning customs duties.

Article 24

General provisions

1. Provisional or definitive countervailing duties shall be imposed by Regulation, and collected by Member States in the form, at the rate specified and according to the other criteria laid down in the Regulation imposing such duties. Such duties shall also be collected independently of the customs duties, taxes and other charges normally imposed on imports.

No product shall be subject to both anti-dumping and countervailing duties for the purpose of dealing with one and the same situation arising from dumping or from export subsidisation.

2. Regulations imposing provisional or definitive countervailing duties, and Regulations or Decisions accepting undertakings or terminating investigations or proceedings, shall be published in the *Official Journal of the European Union*.

Such Regulations or Decisions shall contain in particular, and with due regard to the protection of confidential information, the names of the exporters, if possible, or of the countries involved, a description of the product and a summary of the facts and considerations relevant to the subsidy and injury determinations. In each case, a copy of the Regulation or Decision shall be sent to known interested parties. The provisions of this paragraph shall apply *mutatis mutandis* to reviews.

3. Special provisions, in particular with regard to the common definition of the concept of origin, as contained in Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code [1], may be adopted pursuant to this Regulation.

4. In the Community interest, measures imposed pursuant to this Regulation may, after consultation of the Advisory Committee, be suspended by a decision of the Commission for a period of nine months. The suspension may be extended for a further period, not exceeding one year, if the Council so decides, acting on a proposal from the Commission.

The proposal shall be adopted by the Council unless it decides by a simple majority to reject the proposal, within a period of one month after its submission by the Commission.

Measures may only be suspended where market conditions have temporarily changed to an extent that injury would be unlikely to resume as a result of the suspension, and provided that the Community industry has been given an opportunity to comment and these comments have been taken into account. Measures may, at any time and after consultation, be reinstated if the reason for suspension is no longer applicable.

5. The Commission may, after consultation of the Advisory Committee, direct the customs authorities to take the appropriate steps to register imports, so that measures may subsequently be applied against those imports from the date of such registration.

Imports may be made subject to registration following a request from the Community industry which contains sufficient evidence to justify such action.

Registration shall be introduced by Regulation which shall specify the purpose of the action and, if appropriate, the estimated amount of possible future liability. Imports shall not be made subject to registration for a period longer than nine months.

6. Member States shall report to the Commission every month on the import trade of products subject to investigation and to measures, and on the amount of duties collected pursuant to this Regulation.

[1] OJ L 302, 19.10.1992, p. 1.

7. Without prejudice to paragraph 6, the Commission may request Member States, on a case-by-case basis, to supply information necessary to monitor efficiently the application of measures. In this respect, the provisions of Articles 11(3) and (4) shall apply. Any data submitted by Member States pursuant to this Article shall be covered by the provisions of Article 29(6).

Article 25

Consultations

1. Any consultations provided for in this Regulation, except those referred to in Articles 10(7) and 11(10), shall take place within an Advisory Committee, which shall consist of representatives of each Member State, with a representative of the Commission as chairman. Consultations shall be held immediately on request by a Member State or on the initiative of the Commission, and in any event within a period of time which allows the time limits set by this Regulation to be adhered to.

2. The Committee shall meet when convened by its chairman. He shall provide the Member States, as promptly as possible, but no later than 10 working days before the meeting, with all relevant information.

3. Where necessary, consultation may be in writing only. In that event, the Commission shall notify the Member States and shall specify a period within which they shall be entitled to express their opinions or to request an oral consultation which the chairman shall arrange, provided that such oral consultation can be held within a period of time which allows the time limits set by this Regulation to be adhered to.

4. Consultation shall cover, in particular:

(a) the existence of countervailable subsidies and the methods of establishing their amount;

(b) the existence and extent of injury;

(c) the causal link between the subsidised imports and injury;

(d) the measures which, in the circumstances, are appropriate to prevent or remedy the injury caused by the countervailable subsidies and the ways and means of putting such measures into effect.

Article 26

Verification visits

1. The Commission shall, where it considers it appropriate, carry out visits to examine the records of importers, exporters, traders, agents, producers, trade associations and organisations, to verify information provided on subsidisation and injury. In the absence of a proper and timely reply a verification visit may not be carried out.

2. The Commission may carry out investigations in third countries as required, provided that it obtains the agreement of the firms concerned, that it notifies the country in question and that the latter does not object to the investigation. As soon as the agreement of the firms concerned has been obtained the Commission should notify the country of origin and/or export of the names and addresses of the firms to be visited and the dates agreed.

3. The firms concerned shall be advised of the nature of the information to be verified during verification visits and of any further information which needs to be provided during such visits, though this should not preclude requests made during the verification for further details to be provided in the light of information obtained.

4. In investigations carried out pursuant to paragraphs 1, 2 and 3, the Commission shall be assisted by officials of those Member States which so request.

Article 27

Sampling

1. In cases where the number of complainants, exporters or importers, types of product or transactions is large, the investigation may be limited to:

(a) a reasonable number of parties, products or transactions by using samples which are statistically valid on the basis of information available at the time of the selection; or

(b) the largest representative volume of the production, sales or exports which can reasonably be investigated within the time available.

2. The selection of parties, types of products or transactions made under this Article shall rest with the Commission, though preference shall be given to choosing a sample in consultation with, and with the consent of, the parties concerned, provided that such parties make themselves known and make sufficient information available, within three weeks of initiation of the investigation, to enable a representative sample to be chosen.

3. In cases where the examination has been limited in accordance with this Article, an individual amount of countervailable subsidisation shall be calculated for any exporter or producer not initially selected who submits the necessary information within the time limits provided for in this Regulation, except where the number of exporters or producers is so large that individual examinations would be unduly burdensome and would prevent completion of the investigation in good time.

4. Where it is decided to sample and there is a degree of non-cooperation by some or all of the parties selected which is likely to materially affect the outcome of the investigation, a new sample may be selected.

However, if a material degree of non-cooperation persists or there is insufficient time to select a new sample, the relevant provisions of Article 28 shall apply.

Article 28

Non-cooperation

1. In cases in which any interested party refuses access to, or otherwise does not provide necessary information within the time limits provided in this Regulation, or significantly impedes the investigation, provisional or final findings, affirmative or negative, may be made on the basis of the facts available.

Where it is found that any interested party has supplied false or misleading information, the information shall be disregarded and use may be made of the facts available.

Interested parties should be made aware of the consequences of non-cooperation.

2. Failure to give a computerised response shall not be deemed to constitute non-cooperation, provided that the interested party shows that presenting the response as requested would result in an unreasonable extra burden or unreasonable additional cost.

3. Where the information submitted by an interested party is not ideal in all respects it should nevertheless not be disregarded, provided that any deficiencies are not such as to cause undue difficulty in arriving at a reasonably accurate finding and that the information is appropriately submitted in good time and is verifiable, and that the party has acted to the best of its ability.

4. If evidence or information is not accepted, the supplying party shall be informed forthwith of the reasons therefore and shall be granted an opportunity to provide further explanations within the time limit specified. If the explanations are considered unsatisfactory, the reasons for rejection of such evidence or information shall be disclosed and given in published findings.

5. If determinations, including those regarding the amount of countervailable subsidies, are based on the provisions of paragraph 1, including the information supplied in the complaint, it shall, where practicable and with due regard to the time limits of the investigation, be checked by reference to information from other independent sources which may be available, such as published price lists, official import statistics and customs returns, or information obtained from other interested parties during the investigation. Such information may include relevant data pertaining to the world market or other representative markets, where appropriate.

6. If an interested party does not cooperate, or cooperates only partially, so that relevant information is thereby withheld, the result may be less favourable to the party than if it had cooperated.

Article 29

Confidentiality

1. Any information which is by nature confidential (for example, because its disclosure would be of significant competitive advantage to a competitor or would have a significantly adverse effect upon a person supplying the information or upon a person from whom he has acquired the information), or which is provided on a confidential basis by parties to an investigation shall, if good cause is shown, be treated as such by the authorities.

2. Interested parties providing confidential information shall be required to furnish non-confidential summaries thereof. Those summaries shall be in sufficient detail to permit a reasonable understanding of the substance of the information submitted in confidence. In exceptional circumstances, such parties may indicate that such information is not susceptible of summary. In such exceptional circumstances, a statement of the reasons why summarisation is not possible must be provided.

3. If it is considered that a request for confidentiality is not warranted and if the supplier of the information is either unwilling to make the information available or to authorise its disclosure in generalised or summary form, such information may be disregarded unless it can be satisfactorily demonstrated from appropriate sources that the information is correct. Requests for confidentiality shall not be arbitrarily rejected.

4. This Article shall not preclude the disclosure of general information by the Community authorities, and in particular of the reasons on which decisions taken pursuant to this Regulation are based, nor disclosure of the evidence relied on by the Community authorities in so far as is necessary to explain those reasons in court proceedings. Such disclosure must take into account the legitimate interests of the parties concerned that their business or governmental secrets should not be divulged.

5. The Council, the Commission and the Member States, or the officials of any of these, shall not reveal any information received pursuant to this Regulation for which confidential treatment has been requested by its supplier, without specific permission from the supplier. Exchanges of information between the Commission and Member States, or any information relating to consultations made pursuant to Article 25, or consultations described in Articles 10(7) and 11(10), or any internal documents prepared by the authorities of the Community or its Member States, shall not be divulged except as specifically provided for in this Regulation.

6. Information received pursuant to this Regulation shall be used only for the purpose for which it was requested.

This provision shall not preclude the use of information received in the context of one investigation for the purpose of initiating other investigations within the same proceedings concerning the same like product.

Article 30

Disclosure

1. The complainants, importers and exporters and their representative associations, and the country of origin and/or export, may request disclosure of the details underlying the essential facts and considerations on the basis of which provisional measures have been imposed. Requests for such disclosure shall be made in writing immediately following the imposition of provisional measures, and the disclosure shall be made in writing as soon as possible thereafter.

2. The parties mentioned in paragraph 1 may request final disclosure of the essential facts and considerations on the basis of which it is intended to recommend the imposition of definitive measures, or the termination of an investigation or proceedings without the imposition of measures, particular attention being paid to the disclosure of any facts or considerations which are different from those used for any provisional measures.

3. Requests for final disclosure shall be addressed to the Commission in writing and be received, in cases where a provisional duty has been applied, no later than one month after publication of the imposition of that duty. Where a provisional duty has not been imposed, parties shall be provided with an opportunity to request final disclosure within time limits set by the Commission.

4. Final disclosure shall be given in writing. It shall be made, with due regard to the protection of confidential information, as soon as possible and, normally, not later than one month prior to a definitive decision or the submission by the Commission of any proposal for final action pursuant to Articles 14 and 15. Where the Commission is not in a position to disclose certain facts or considerations at that time, they shall be disclosed as soon as possible thereafter.

Disclosure shall not prejudice any subsequent decision which may be taken by the Commission or the Council but where such decision is based on any different facts and considerations they shall be disclosed as soon as possible.

5. Representations made after final disclosure is given shall be taken into consideration only if received within a period to be set by the Commission in each case, which shall be at least 10 days, due consideration being given to the urgency of the matter.

Article 31

Community interest

1. A determination as to whether the Community interest calls for intervention should be based on an appraisal of all the various interests taken as a whole, including the interests of the domestic industry and users and consumers. A determination pursuant to this Article shall be made only where all parties have been given the opportunity to make their views known pursuant to paragraph 2. In such an examination, the need to eliminate the trade-distorting effects of injurious subsidisation and to restore effective competition shall be given special consideration. Measures, as determined on the basis of subsidisation and injury found, may not be applied where the authorities, on the basis of all the information submitted, can clearly conclude that it is not in the Community interest to apply such measures.

2. In order to provide a sound basis on which the authorities can take account of all views and information in the decision as to whether or not the imposition of measures is in the Community interest, the complainants, importers and their representative associations, representative users and representative consumer organisations may, within the time limits specified in the notice of initiation of the countervailing duty investigation, make themselves known and provide information to the Commission. Such information, or appropriate summaries thereof, shall be made available to the other parties specified in this paragraph, and they shall be entitled to respond to such information.

3. The parties which have acted in conformity with paragraph 2 may request a hearing. Such requests shall be granted when they are submitted within the time limits set in paragraph 2, and when they set out the reasons, in terms of the Community interest, why the parties should be heard.

4. The parties which have acted in conformity with paragraph 2 may provide comments on the application of any provisional duties imposed. Such comments shall be received within one month of the application of such measures if they are to be taken into account and they, or appropriate summaries thereof, shall be made available to other parties who shall be entitled to respond to such comments.

5. The Commission shall examine the information which is properly submitted and the extent to which it is representative, and the results of such analysis, together with an opinion on its merits, shall be transmitted to the Advisory Committee. The balance of views expressed in the Committee shall be taken into account by the Commission in any proposal made pursuant to Articles 14 and 15.

6. The parties which have acted in conformity with paragraph 2 may request that the facts and considerations on which final decisions are likely to be taken be made available to them. Such information shall be made available to the extent possible and without prejudice to any subsequent decision taken by the Commission or the Council.

7. Information shall be taken into account only where it is supported by actual evidence which substantiates its validity.

Article 32

Relationships between countervailing duty measures and multilateral remedies

If an imported product is made subject to any countermeasures imposed following recourse to the dispute settlement procedures of the Subsidies Agreement, and such measures are appropriate to remove the injury caused by the countervailable subsidies, any countervailing duty imposed with regard to that product shall immediately be suspended, or repealed, as appropriate.

Article 33

Final provisions

This Regulation shall not preclude the application of:

(a) any special rules laid down in agreements concluded between the Community and third countries;

(b) the Community Regulations in the agricultural sector and Council Regulations (EEC) No 2783/75 [1], (EC) No 3448/93 [2] and (EC) No 1667/2006 [3]. This Regulation shall operate by way of complement to those regulations and in derogation from any provisions thereof which preclude the application of countervailing duties;

(c) special measures, provided that such action does not run counter to obligations under the GATT.

Article 34

Repeal

Regulation (EC) No 2026/97 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and be read in accordance with the correlation table set out in Annex VI.

Article 35

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Luxembourg, 11 June 2009.

For the Council
The President
G. SLAMEČKA

[1] OJ L 282, 1.11.1975, p. 104.
[2] OJ L 318, 20.12.1993, p. 18.
[3] OJ L 312, 11.11.2006, p. 1.

ANNEX I

ILLUSTRATIVE LIST OF EXPORT SUBSIDIES

(a) The provision by governments of direct subsidies to a firm or an industry contingent upon export performance.

(b) Currency retention schemes or any similar practices which involve a bonus on exports.

(c) Internal transport and freight charges on export shipments, provided or mandated by governments, on terms more favourable than for domestic shipments.

(d) The provision by governments or their agencies either directly or indirectly through government-mandated schemes, of imported or domestic products or services for use in the production of exported goods, on terms or conditions more favourable than for provision of like or directly competitive products or services for use in the production of goods for domestic consumption, if (in the case of products) such terms or conditions are more favourable than those commercially available [1] on world markets to their exporters.

(e) The full or partial exemption, remission, or deferral specifically related to exports, of direct taxes [2] or social welfare charges paid or payable by industrial or commercial enterprises [3].

(f) The allowance of special deductions directly related to exports or export performance, over and above those granted in respect of production for domestic consumption, in the calculation of the base on which direct taxes are charged.

(g) The exemption or remission, in respect of the production and distribution of exported products, of indirect taxes [4] in excess of those levied in respect of the production and distribution of like products when sold for domestic consumption.

(h) The exemption, remission or deferral of prior-stage cumulative indirect taxes [5] on goods or services used in the production of exported products in excess of the exemption, remission or deferral of like prior-stage cumulative indirect taxes on goods or services used in the production of like products when sold for domestic consumption; provided, however, that prior-stage cumulative indirect taxes may be exempted, remitted or deferred on exported products even when not exempted, remitted or deferred on like products when sold for domestic consumption, if the prior-stage cumulative indirect taxes are levied on inputs that are consumed in the production of the exported product (making normal allowance for waste) [6]. This item shall be interpreted in accordance with the guidelines on consumption of inputs in the production process contained in Annex II.

---

[1] 'Commercially available' means that the choice between domestic and imported products is unrestricted and depends only on commercial considerations.

[2] For the purpose of this Regulation:
- 'direct taxes' means taxes on wages, profits, interests, rents, royalties, and all other forms of income, and taxes on the ownership of real property,
- 'import charges' means tariffs, duties, and other fiscal charges not elsewhere enumerated in this note that are levied on imports,
- 'indirect taxes' means sales, excise, turnover, value added, franchise, stamp, transfer, inventory and equipment taxes, border taxes and all taxes other than direct taxes and import charges,
- 'prior-stage' indirect taxes are those levied on goods or services used directly or indirectly in making the product,
- 'cumulative' indirect taxes are multi-staged taxes levied where there is no mechanism for subsequent crediting of the tax if the goods or services subject to tax at one stage of production are used in a succeeding state of production,
- 'remission' of taxes includes the refund or rebate of taxes,
- 'remission or drawback' includes the full or partial exemption or deferral of import charges.

[3] Deferral may not amount to an export subsidy where, for example, appropriate interest charges are collected.

[4] See footnote 2.

[5] See footnote 2.

[6] Point (h) does not apply to value added tax systems and border-tax adjustment in lieu thereof; the problem of the excessive remission of value added taxes is exclusively covered by point (g).

(i) The remission or drawback of import charges ([7]) in excess of those levied on imported inputs that are consumed in the production of the exported product (making normal allowance for waste); provided, however, that in particular cases a firm may use a quantity of home market inputs equal to, and having the same quality and characteristics as, the imported inputs as a substitute for them in order to benefit from this provision if the import and the corresponding export operations both occur within a reasonable time period, not to exceed two years. This item shall be interpreted in accordance with the guidelines on consumption of inputs in the production process contained in Annex II and the guidelines in the determination of substitution drawback systems as export subsidies contained in Annex III.

(j) The provision by governments (or special institutions controlled by governments) of export credit guarantee or insurance programmes, of insurance or guarantee programmes against increases in the cost of exported products or of exchange risk programmes, at premium rates which are inadequate to cover the long-term operating costs and losses of the programmes.

(k) The grant by governments (or special institutions controlled by and/or acting under the authority of governments) of export credits at rates below those which they actually have to pay for the funds so employed (or would have to pay if they borrowed on international capital markets in order to obtain funds of the same maturity and other credit terms and denominated in the same currency as the export credit), or the payment by them of all or part of the costs incurred by exporters or financial institutions in obtaining credits, in so far as they are used to secure a material advantage in the field of export credit terms.

Provided, however, that if a Member of the WTO is a party to an international undertaking on official export credits to which at least 12 original such Members are parties as of 1 January 1979 (or a successor undertaking which has been adopted by those original Members), or if in practice a Member of the WTO applies the interest rates provisions of the relevant undertaking, an export credit practice which is in conformity with those provisions shall not be considered an export subsidy.

(l) Any other charge on the public account constituting an export subsidy in the sense of Article XVI of the GATT 1994.

([7]) See footnote 2.

ANNEX II

GUIDELINES ON CONSUMPTION OF INPUTS IN THE PRODUCTION PROCESS [1]

I

1. Indirect tax rebate schemes can allow for exemption, remission or deferral of prior-stage cumulative indirect taxes levied on inputs that are consumed in the production of the exported product (making normal allowance for waste). Similarly, drawback schemes can allow for the remission or drawback of import charges levied on inputs that are consumed in the production of the exported product (making normal allowance for waste).

2. The illustrative list of export subsidies in Annex I makes reference to the term 'inputs that are consumed in the production of the exported product' in points (h) and (i). Pursuant to point (h), indirect tax rebate schemes can constitute an export subsidy to the extent that they result in exemption, remission or deferral of prior-stage cumulative indirect taxes in excess of the amount of such taxes actually levied on inputs that are consumed in the production of the exported product. Pursuant to point (i), drawback schemes can constitute an export subsidy to the extent that they result in a remission or drawback of import charges in excess of those actually levied on inputs that are consumed in the production of the exported product. Both points stipulate that normal allowance for waste must be made in findings regarding consumption of inputs in the production of the exported product. Point (i) also provides for substitution, where appropriate.

II

3. In examining whether inputs are consumed in the production of the exported product, as part of a countervailing duty investigation pursuant to this Regulation, the Commission must normally proceed on the following basis.

4. Where it is alleged that an indirect tax rebate scheme, or a drawback scheme, conveys a subsidy by reason of over-rebate or excess drawback of indirect taxes or import charges on inputs consumed in the production of the exported product, the Commission must normally first determine whether the government of the exporting country has in place and applies a system or procedure to confirm which inputs are consumed in the production of the exported product and in what amounts. Where such a system or procedure is determined to be applied, the Commission must normally then examine the system or procedure to see whether it is reasonable, effective for the purpose intended, and based on generally accepted commercial practices in the country of export. The Commission may deem it necessary to carry out, in accordance with Article 26(2), certain practical tests in order to verify information or to satisfy itself that the system or procedure is being effectively applied.

5. Where there is no such system or procedure, where it is not reasonable, or where it is instituted and considered reasonable but is found not to be applied or not to be applied effectively, a further examination by the exporting country based on the actual inputs involved will normally need to be carried out in the context of determining whether an excess payment occurred. If the Commission deems it necessary, a further examination may be carried out in accordance with point 4.

6. The Commission must normally treat inputs as physically incorporated if such inputs are used in the production process and are physically present in the product exported. An input need not be present in the final product in the same form in which it entered the production process.

7. In determining the amount of a particular input that is consumed in the production of the exported product, a 'normal allowance for waste' must normally be taken into account, and such waste must normally be treated as consumed in the production of the exported product. The term 'waste' refers to that portion of a given input which does not serve an independent function in the production process, is not consumed in the production of the exported product (for reasons such as inefficiencies) and is not recovered, used or sold by the same manufacturer.

8. The Commission's determination of whether the claimed allowance for waste is 'normal' must normally take into account the production process, the average experience of the industry in the country of export, and other technical factors, as appropriate. The Commission must bear in mind that an important question is whether the authorities in the exporting country have reasonably calculated the amount of waste, when such an amount is intended to be included in the tax or duty rebate or remission.

---

[1] Inputs consumed in the production process are inputs physically incorporated, energy, fuels and oil used in the production process and catalysts which are consumed in the course of their use to obtain the exported product.

ANNEX III

GUIDELINES IN THE DETERMINATION OF SUBSTITUTION DRAWBACK SYSTEMS AS EXPORT SUBSIDIES

I

Drawback systems can allow for the refund or drawback of import charges on inputs which are consumed in the production process of another product and where the export of this latter product contains domestic inputs having the same quality and characteristics as those submitted for the imported inputs. Pursuant to point (i) of Annex I, substitution drawback systems can constitute an export subsidy to the extent that they result in an excess drawback of the import charges levied initially on the imported inputs for which drawback is being claimed.

II

In examining any substitution drawback system as part of a countervailing duty investigation pursuant to this Regulation, the Commission must normally proceed on the following basis:

1. point (i) of Annex I stipulates that home market inputs may be substituted for imported inputs in the production of a product for export provided such inputs are equal in quantity to, and have the same quality and characteristics as, the imported inputs being substituted. The existence of a verification system or procedure is important because it enables the government of the exporting country to ensure and demonstrate that the quantity of inputs for which drawback is claimed does not exceed the quantity of similar products exported, in whatever form, and that there is not drawback of import charges in excess of those originally levied on the imported inputs in question;

2. where it is alleged that a substitution drawback system conveys a subsidy, the Commission must normally first proceed to determine whether the government of the exporting country has in place and applies a verification system or procedure. Where such a system or procedure is determined to be applied, the Commission shall normally then examine the verification procedures to see whether they are reasonable, effective for the purpose intended, and based on generally accepted commercial practices in the country of export. To the extent that the procedures are determined to meet this test and are effectively applied, no subsidy will be presumed to exist. It may be deemed necessary by the Commission to carry out, in accordance with Article 26(2), certain practical tests in order to verify information or to satisfy itself that the verification procedures are being effectively applied;

3. where there are no verification procedures, where they are not reasonable, or where such procedures are instituted and considered reasonable but are found not to be actually applied or not to be applied effectively, there may be a subsidy. In such cases, further examination by the exporting country based on the actual transactions involved would need to be carried out to determine whether an excess payment occurred. If the Commission deems it necessary, a further examination may be carried out in accordance with point 2;

4. the existence of a substitution drawback provision under which exporters are allowed to select particular import shipments on which drawback is claimed should not of itself be considered to convey a subsidy;

5. an excess drawback of import charges within the meaning of point (i) of Annex I would be deemed to exist where governments paid interest on any monies refunded under their drawback schemes, to the extent of the interest actually paid or payable.

ANNEX IV

(This Annex reproduces Annex 2 to the Agreement on Agriculture. Any terms or expressions which are not explained herein or which are not self-explanatory are to be interpreted in the context of that Agreement.)

DOMESTIC SUPPORT: THE BASIS OF EXEMPTION FROM THE REDUCTION COMMITMENTS

1. Domestic support measures for which exemption from the reduction commitments is claimed shall meet the fundamental requirement that they have no, or at most minimal, trade-distorting effects or effects on production. Accordingly, all measures for which exemption is claimed shall conform to the following basic criteria:

   (a) the support in question shall be provided through a publicly-funded government programme (including government revenue foregone) not involving transfers from consumers; and

   (b) the support in question shall not have the effect of providing price support to producers;

   plus policy-specific criteria and conditions as set out below.

Government service programmes

2. General services

   Policies in this category involve expenditures (or revenue foregone) in relation to programmes which provide services or benefits to agriculture or the rural community. They shall not involve direct payments to producers or processors. Such programmes, which include but are not restricted to the following list, shall meet the general criteria in point 1 and policy-specific conditions where set out below:

   (a) research, including general research, research in connection with environmental programmes, and research programmes relating to particular products;

   (b) pest and disease control, including general and product-specific pest and disease control measures, such as early-warning systems, quarantine and eradication;

   (c) training services, including both general and specific training facilities;

   (d) extension and advisory services, including the provision of means to facilitate the transfer of information and the results of research to producers and consumers;

   (e) inspection services, including general inspection services and the inspection of particular products for health, safety, grading or standardisation purposes;

   (f) marketing and promotion services, including market information, advice and promotion relating to particular products but excluding expenditure for unspecified purposes that could be used by sellers to reduce their selling price or confer a direct economic benefit to purchasers; and

   (g) infrastructural services, including: electricity reticulation, roads and other means of transport, market and port facilities, water supply facilities, dams and drainage schemes, and infrastructural works associated with environmental programmes. In all cases the expenditure shall be directed to the provision or construction of capital works only, and shall exclude the subsidised provision of on-farm facilities other than for the reticulation of generally available public utilities. It shall not include subsidies to inputs or operating costs, or preferential user charges.

3. Public stockholding for food security purposes [1]

   Expenditures (or revenue foregone) in relation to the accumulation and holding of stocks of products which form an integral part of a food security programme identified in national legislation. This may include government aid to private storage of products as part of such a programme.

[1] For the purpose of point 3 of this Annex, governmental stockholding programmes for food security purposes in developing countries whose operation is transparent and conducted in accordance with officially published objective criteria or guidelines shall be considered to be in conformity with the provisions of this point, including programmes under which stocks of foodstuffs for food security purposes are acquired and released at administered prices, provided that the difference between the acquisition price and the external reference price is accounted for in the AMS.

The volume and accumulation of such stocks shall correspond to predetermined targets related solely to food security. The process of stock accumulation and disposal shall be financially transparent. Food purchases by the government shall be made at current market prices and sales from food security stocks shall be made at no less than the current domestic market price for the product and quality in question.

4. Domestic food aid [1]

Expenditure (or revenue foregone) in relation to the provision of domestic food aid to sections of the population in need.

Eligibility to receive the food aid shall be subject to clearly-defined criteria related to nutritional objectives. Such aid shall be in the form of direct provision of food to those concerned or the provision of means to allow eligible recipients to buy food either at market or at subsidised prices. Food purchases by the government shall be made at current market prices and the financing and administration of the aid shall be transparent.

5. Direct payments to producers

Support provided through direct payments (or revenue foregone, including payments in kind) to producers for which exemption from reduction commitments as claimed shall meet the basic criteria set out in point 1, plus specific criteria applying to individual types of direct payment as set out in points 6 to 13. Where exemption from reduction is claimed for any existing or new type of direct payment other than those specified in points 6 to 13, it shall conform to criteria set out in points 6(b) to (e), in addition to the general criteria set out in point 1.

6. Decoupled income support

(a) Eligibility for such payments shall be determined by clearly-defined criteria such as income, status as a producer or landowner, factor use or production level in a defined and fixed base period.

(b) The amount of such payments in any given year shall not be related to, or based on, the type or volume of production (including livestock units) undertaken by the producer in any year after the base period.

(c) The amount of such payments in any given year shall not be related to, or based on, the prices, domestic or international, applying to any production undertaken in any year after the base period.

(d) The amount of such payments in any given year shall not be related to, or based on, the factors of production employed in any year after the base period.

(e) No production shall be required in order to receive such payments.

7. Government financial participation in income insurance and income safety-net programmes

(a) Eligibility for such payments shall be determined by an income loss, taking into account only income derived from agriculture, which exceeds 30 % of average gross income or the equivalent in net income terms (excluding any payments from the same or similar schemes) in the preceding three-year period or a three-year average based on the preceding five-year period, excluding the highest and the lowest entry. Any producer meeting this condition shall be eligible to receive the payments.

(b) The amount of such payments shall compensate for less than 70 % of the producer's income loss in the year the producer becomes eligible to receive this assistance.

(c) The amount of any such payments shall relate solely to income; it shall not relate to the type or volume of production (including livestock units) undertaken by the producer; or to the prices, domestic or international, applying to such production; or to the factors of production employed.

(d) Where a producer receives in the same year payments pursuant to this point and pursuant to point 8 (relief from natural disasters), the total of such payments shall be less than 100 % of the producer's total loss.

8. Payments (made either directly or by way of a government financial participation in crop insurance schemes) for relief from natural disasters

(a) Eligibility for such payments shall arise only following a formal recognition by government authorities that a natural or like disaster (including disease outbreaks, pest infestations, nuclear accidents, and war on the territory of the Member concerned) has occurred or is occurring; and shall be determined by a production loss which exceeds 30 % of the average of production in the preceding three-year period or a three-year average based on the preceding five-year period, excluding the highest and the lowest entry.

[1] For the purposes of points 3 and 4 of this Annex, the provision of foodstuffs at subsidised prices with the objective of meeting food requirements of urban and rural poor in developing countries on a regular basis at reasonable prices shall be considered to be in conformity with the provisions of this point.

(b) Payments made following a disaster shall be applied only in respect of losses of income, livestock (including payments in connection with the veterinary treatment of animals), land or other production factors due to the natural disaster in question.

(c) Payments shall compensate for not more than the total cost of replacing such losses and shall not require or specify the type or quantity of future production.

(d) Payments made during a disaster shall not exceed the level required to prevent or alleviate further loss as defined in criterion set out in point (b).

(e) Where a producer receives in the same year payments pursuant to this point and pursuant to point 7 (income insurance and income safety-net programmes), the total of such payments shall be less than 100 % of the producer's total loss.

9. Structural adjustment assistance provided through producer retirement programmes

(a) Eligibility for such payments shall be determined by reference to clearly defined criteria in programmes designed to facilitate the retirement of persons engaged in marketable agricultural production, or their movement to non-agricultural activities.

(b) Payments shall be conditional upon the total and permanent retirement of the recipients from marketable agricultural production.

10. Structural adjustment assistance provided through resource retirement programmes

(a) Eligibility for such payments shall be determined by reference to clearly defined criteria in programmes designed to remove land or other resources, including livestock, from marketable agricultural production.

(b) Payments shall be conditional upon the retirement of land from marketable agricultural production for a minimum of three years, and in the case of livestock on its slaughter or definitive permanent disposal.

(c) Payments shall not require or specify any alternative use for such land or other resources which involves the production of marketable agricultural products.

(d) Payments shall not be related to either type or quantity of production or to the prices, domestic or international, applying to production undertaken using the land or other resources remaining in production.

11. Structural adjustment assistance provided through investment aids

(a) Eligibility for such payments shall be determined by reference to clearly-defined criteria in government programmes designed to assist the financial or physical restructuring of a producer's operations in response to objectively demonstrated structural disadvantages. Eligibility for such programmes may also be based on a clearly defined government programme for the reprivatisation of agricultural land.

(b) The amount of such payments in any given year shall not be related to, or based on, the type or volume of production (including livestock units) undertaken by the producer in any year after the base period other than as provided for under criterion (e).

(c) The amount of such payments in any given year shall not be related to, or based on, the prices, domestic or international, applying to any production undertaken in any year after the base period.

(d) The payments shall be given only for the period of time necessary for the realisation of the investment in respect of which they are provided.

(e) The payments shall not mandate or in any way designate the agricultural products to be produced by the recipients except to require them not to produce a particular product.

(f) The payments shall be limited to the amount required to compensate for the structural disadvantage.

12. Payments under environmental programmes

(a) Eligibility for such payments shall be determined as part of a clearly-defined government environmental or conservation programme and be dependent on the fulfilment of specific conditions under the government programme, including conditions related to production methods or inputs.

(b) The amount of payment shall be limited to the extra costs or loss of income involved in complying with the government programme.

13. Payments under regional assistance programmes

(a) Eligibility for such payments shall be limited to producers in disadvantaged regions. Each such region must be a clearly designated contiguous geographical area with a definable economic and administrative identity, considered as disadvantaged on the basis of neutral and objective criteria clearly spelt out in a law or regulation and indicating that the region's difficulties arise out of more than temporary circumstances.

(b) The amount of such payments in any given year shall not be related to, or based on, the type or volume of production (including livestock units) undertaken by the producer in any year after the base period other than to reduce that production.

(c) The amount of such payments in any given year shall not be related to, or based on, the prices, domestic or international, applying to any production undertaken in any year after the base period.

(d) Payments shall be available only to producers in eligible regions, but generally available to all producers within such regions.

(e) Where related to production factors, payments shall be made at a degressive rate above a threshold level of the factor concerned.

(f) The payments shall be limited to the extra costs or loss of income involved in undertaking agricultural production in the prescribed area.

ANNEX V

Repealed Regulation with list of its successive amendments

Council Regulation (EC) No 2026/97 (OJ L 288, 21.10.1997, p. 1)	
Council Regulation (EC) No 1973/2002 (OJ L 305, 7.11.2002, p. 4)	
Council Regulation (EC) No 461/2004 (OJ L 77, 13.3.2004, p. 12)	Only Article 2

ANNEX VI

CORRELATION TABLE

Regulation (EC) No 2026/97	This Regulation
Article 1(1)	Article 1(1)
Article 1(2), introductory wording	Article 2, introductory wording
Article 1(2), final wording	Article 2(a), initial sentence
Article 1(3), first subparagraph	Article 2(a), final sentence
Article 1(3), second subparagraph	Article 2(b)
Article 1(4)	Article 1(2)
Article 1(5)	Article 2(c)
Article 2	Article 3
Article 3(1)	Article 4(1)
Article 3(2), first subparagraph, introductory wording	Article 4(2), first subparagraph, introductory wording
Article 3(2), first subparagraph, point (a)	Article 4(2), first subparagraph, point (a)
Article 3(2), first subparagraph, point (b), first sentence	Article 4(2), first subparagraph, point (b)
Article 3(2), first subparagraph, point (b), second sentence	Article 4(2), second subparagraph
Article 3(2), first subparagraph, point (b), third sentence	Article 4(2), third subparagraph
Article 3(2), first subparagraph, point (c)	Article 4(2), first subparagraph, point (c)
Article 3(2), second subparagraph	Article 4(2), fourth subparagraph
Article 3(3)	Article 4(3)
Article 3(4), first subparagraph, introductory wording	Article 4(4), first subparagraph, introductory wording
Article 3(4), first subparagraph, point (a), first sentence	Article 4(4), first subparagraph, point (a)
Article 3(4), first subparagraph, point (a), second and third sentences	Article 4(4), second subparagraph
Article 3(4), first subparagraph, point (b)	Article 4(4), first subparagraph, point (b)
Article 3(5)	Article 4(5)
Article 5	Article 5
Article 6	Article 6
Article 7(1) and (2)	Article 7(1) and (2)
Article 7(3), first subparagraph, first sentence	Article 7(3), first subparagraph
Article 7(3), first subparagraph, second sentence	Article 7(3), second subparagraph
Article 7(3), second subparagraph	Article 7(3), third subparagraph
Article 7(4)	Article 7(4)
Article 8(1)	Article 2(d)
Article 8(2) to (9)	Article 8(1) to (8)
Article 9	Article 9
Article 10(1) to (4)	Article 10(1) to (4)
Article 10(7) to (13)	Article 10(5) to (11)
Article 10(14), first sentence	Article 10(12), first subparagraph
Article 10(14), second and third sentences	Article 10(12), second subparagraph
Article 10(15), and (16)	Article 10(13) and (14)
Article 11(1), first and second sentences	Article 11(1), first subparagraph
Article 11(1), third sentence	Article 11(1), second subparagraph
Article 11(1), fourth sentence	Article 11(1), third subparagraph
Article 11(2)	Article 11(2)

Regulation (EC) No 2026/97	This Regulation
Article 11(3), first sentence	Article 11(3), first subparagraph
Article 11(3), second sentence	Article 11(3), second subparagraph
Article 11(3), third sentence	Article 11(3), third subparagraph
Article 11(4), first sentence	Article 11(4), first subparagraph
Article 11(4), second sentence	Article 11(4), second subparagraph
Article 11(4), third sentence	Article 11(4), third subparagraph
Article 11(5)	Article 11(5)
Article 11(6), first sentence	Article 11(6), first subparagraph
Article 11(6), second sentence	Article 11(6), second subparagraph
Article 11(6), third sentence	Article 11(6), third subparagraph
Article 11(6), fourth sentence	Article 11(6), fourth subparagraph
Article 11(7), first sentence	Article 11(7), first subparagraph
Article 11(7), second sentence	Article 11(7), second subparagraph
Article 11(8), (9) and (10)	Article 11(8), (9) and (10)
Article 12	Article 12
Article 13(1)	Article 13(1)
Article 13(2), first and second sentences	Article 13(2), first subparagraph
Article 13(2), third and fourth sentences	Article 13(2), second subparagraph
Article 13(2), fifth sentence	Article 13(2), third subparagraph
Article 13(3), (4) and (5)	Article 13(3), (4) and (5)
Article 13(6), first, second and third sentences	Article 13(6), first subparagraph
Article 13(6), fourth sentence	Article 13(6), second subparagraph
Article 13(7) and (8)	Article 13(7) and (8)
Article 13(9), first subparagraph	Article 13(9), first subparagraph
Article 13(9), second subparagraph, first and second sentences	Article 13(9), second subparagraph
Article 13(9), second subparagraph, third sentence	Article 13(9), third subparagraph
Article 13(10)	Article 13(10)
Article 14(1) to (4)	Article 14(1) to (4)
Article 14(5) introductory wording	Article 14(5) first part of the sentence
Article 14(5)(a)	Article 14(5), second part of the sentence, from 'as regards' to '*ad valorem*'
Article 14(5)(b)	—
Article 14(5), final wording	Article 14(5), last part of the sentence
Article 15(1), first sentence	Article 15(1), first subparagraph
Article 15(1), second sentence	Article 15(1), second subparagraph
Article 15(1), third sentence	Article 15(1), third subparagraph
Article 15(1), fourth sentence	Article 15(1), fourth subparagraph
Article 15(1), fifth sentence	Article 15(1), fifth subparagraph
Article 15(2)	Article 15(2)
Article 15(3), first sentence	Article 15(3), first subparagraph
Article 15(3), second sentence	Article 15(3), second subparagraph
Article 15(3), third sentence	Article 15(3), third subparagraph
Article 16(1)	Article 16(1)
Article 16(2), first sentence	Article 16(2), first subparagraph
Article 16(2), second and third sentences	Article 16(2), second subparagraph

Regulation (EC) No 2026/97	This Regulation
Article 16(3)	Article 16(3)
Article 16(4), introductory wording, first part	Article 16(4), first subparagraph
Article 16(4), introductory wording, second part	Article 16(4), second subparagraph, introductory wording and points (a) and (b)
Article 16(4)(a) and (b)	Article 16(4), second subparagraph, points (c) and (d)
Article 16(5)	Article 16(5)
Article 17	Article 17
Article 18	Article 18
Article 19	Article 19
Article 20, first sentence	Article 20, first paragraph
Article 20, second sentence	Article 20, second paragraph
Article 21(1), (2) and (3)	Article 21(1), (2) and (3)
Article 21(4), first sentence	Article 21(4), first subparagraph
Article 21(4), second sentence	Article 21(4), second subparagraph
Article 21(4), third sentence	Article 21(4), third subparagraph
Article 22(1), first subparagraph, first sentence	Article 22(1), first subparagraph
Article 22(1), first subparagraph, second and third sentences	Article 22(1), second subparagraph
Article 22(1), first subparagraph, fourth sentence	Article 22(1), third subparagraph
Article 22(1), first subparagraph, fifth sentence	Article 22(1), fourth subparagraph
Article 22(1), second subparagraph	Article 22(1), fifth subparagraph
Article 22(1), third subparagraph, introductory wording	Article 22(1), sixth subparagraph, introductory wording
Article 22(1), third subparagraph, first, second and third indents	Article 22(1), sixth subparagraph, points (a), (b) and (c)
Article 22(1), fourth subparagraph	Article 22(1), seventh subparagraph
Article 22(2), first sentence	Article 22(2)
Article 22(2), second sentence	Article 22(3)
Article 22(2), third sentence	Article 22(4)
Article 22(3)	Article 22(5)
Article 22(4)	Article 22(6)
Article 23(1), first subparagraph, first sentence	Article 23(1)
Article 23(1), first subparagraph, second sentence	Article 23(2)
Article 23(1), first subparagraph, third sentence	Article 23(3), first subparagraph
Article 23(1), second subparagraph, from 'The practice' to 'inter alia'	Article 23(3), second subparagraph, initial wording
Article 23(1), second subparagraph, from 'the slight modification' to 'the manufacturers'	Article 23(3), second subparagraph, points (a), (b) and (c)
Article 23(2), first and second sentences	Article 23(4), first subparagraph
Article 23(2), third sentence	Article 23(4), second subparagraph
Article 23(2), fourth and fifth sentences	Article 23(4), third subparagraph
Article 23(2), sixth and seventh sentences	Article 23(4), fourth subparagraph
Article 23(3), first subparagraph, first sentence	Article 23(5)
Article 23(3), first subparagraph, second sentence	Article 23(6), first subparagraph
Article 23(3), first subparagraph, third sentence	Article 23(6), second subparagraph
Article 23(3), first subparagraph, fourth sentence	Article 23(6), third subparagraph
Article 23(3), second subparagraph	Article 23(6), fourth subparagraph
Article 23(3), third subparagraph	Article 23(6), fifth subparagraph

Regulation (EC) No 2026/97	This Regulation
Article 23(3), fourth subparagraph	Article 23(7)
Article 23(4)	Article 23(8)
Article 24(1), first and second sentences	Article 24(1), first subparagraph
Article 24(1), third sentence	Article 24(1), second subparagraph
Article 24(2), first sentence	Article 24(2), first subparagraph
Article 24(2), second and third sentences	Article 24(2), second subparagraph
Article 24(3)	Article 24(3)
Article 24(4), first and second sentences	Article 24(4) first subparagraph
Article 24(4), third sentence	Article 24(4) second subparagraph
Article 24(4), fourth and fifth sentences	Article 24(4) third subparagraph
Article 24(5), first sentence	Article 24(5) first subparagraph
Article 24(5), second sentence	Article 24(5), second subparagraph
Article 24(5), third and fourth sentences	Article 24(5), third subparagraph
Article 24(6) and (7)	Article 24(6) and (7)
Article 25	Article 25
Article 26	Article 26
Article 27(1), (2) and (3)	Article 27(1), (2) and (3)
Article 27(4), first sentence	Article 27(4), first subparagraph
Article 27(4), second sentence	Article 27(4), second subparagraph
Article 28	Article 28
Article 29(1) to (5)	Article 29(1) to (5)
Article 29(6), first sentence	Article 29(6), first subparagraph
Article 29(6), second sentence	Article 29(6), second subparagraph
Article 30(1), (2) and (3)	Article 30(1), (2) and (3)
Article 30(4), first, second and third sentences	Article 30(4), first subparagraph
Article 30(4), final sentence	Article 30(4), second subparagraph
Article 30(5)	Article 30(5)
Article 31	Article 31
Article 32	Article 32
Article 33	Article 33
Article 34	—
—	Article 34
Article 35	Article 35
Annexes I to IV	Annexes I to IV
—	Annex V
—	Annex VI

CORRIGENDA

Corrigendum to Regulation (EC) No 444/2009 of the European Parliament and of the Council of 28 May 2009 amending Council Regulation (EC) No 2252/2004 on standards for security features and biometrics in passports and travel documents issued by Member States

(Official Journal of the European Union L 142 of 6 June 2009)

On the cover and on page 1, the title should read as follows:

for: 'Regulation (EC) No 444/2009 of the European Parliament and of the Council of 28 May 2009 amending Council Regulation (EC) No 2252/2004 on standards for security features and biometrics in passports and travel documents issued by Member States',

read: 'Regulation (EC) No 444/2009 of the European Parliament and of the Council of 6 May 2009 amending Council Regulation (EC) No 2252/2004 on standards for security features and biometrics in passports and travel documents issued by Member States'.

2009 SUBSCRIPTION PRICES (excluding VAT, including normal transport charges)

EU Official Journal, L + C series, paper edition only	22 official EU languages	EUR 1 000 per year (*)
EU Official Journal, L + C series, paper edition only	22 official EU languages	EUR 100 per month (*)
EU Official Journal, L + C series, paper + annual CD-ROM	22 official EU languages	EUR 1 200 per year
EU Official Journal, L series, paper edition only	22 official EU languages	EUR 700 per year
EU Official Journal, L series, paper edition only	22 official EU languages	EUR 70 per month
EU Official Journal, C series, paper edition only	22 official EU languages	EUR 400 per year
EU Official Journal, C series, paper edition only	22 official EU languages	EUR 40 per month
EU Official Journal, L + C series, monthly CD-ROM (cumulative)	22 official EU languages	EUR 500 per year
Supplement to the Official Journal (S series), tendering procedures for public contracts, CD-ROM, two editions per week	multilingual: 23 official EU languages	EUR 360 per year (= EUR 30 per month)
EU Official Journal, C series — recruitment competitions	Language(s) according to competition(s)	EUR 50 per year

(*) Sold in single issues: up to 32 pages: EUR 6
from 33 to 64 pages: EUR 12
over 64 pages: Priced individually.

Subscriptions to the *Official Journal of the European Union*, which is published in the official languages of the European Union, are available for 22 language versions. The Official Journal comprises two series, L (Legislation) and C (Information and Notices).

A separate subscription must be taken out for each language version.

In accordance with Council Regulation (EC) No 920/2005, published in Official Journal L 156 of 18 June 2005, the institutions of the European Union are temporarily not bound by the obligation to draft all acts in Irish and publish them in that language. Irish editions of the Official Journal are therefore sold separately.

Subscriptions to the Supplement to the Official Journal (S Series — tendering procedures for public contracts) cover all 23 official language versions on a single multilingual CD-ROM.

On request, subscribers to the *Official Journal of the European Union* can receive the various Annexes to the Official Journal. Subscribers are informed of the publication of Annexes by notices inserted in the *Official Journal of the European Union*.

Sales and subscriptions

Priced publications issued by the Publications Office are available from our commercial distributors. The list of commercial distributors is available at:

http://publications.europa.eu/others/agents/index_en.htm

EUR-Lex (http://eur-lex.europa.eu) offers direct access to European Union legislation free of charge. The *Official Journal of the European Union* can be consulted on this website, as can the Treaties, legislation, case-law and preparatory acts.

For further information on the European Union, see: http://europa.eu

Publications Office
Publications.europa.eu

OFFICE FOR OFFICIAL PUBLICATIONS OF THE EUROPEAN COMMUNITIES
L-2985 LUXEMBOURG

EN