PRODUCT SAFETY AND MARKET SURVEILLANCE PACKAGE

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

(Text with EEA relevance)

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1. **INTRODUCTION**

   This report gives an overview of the implementation of Regulation (EC) No 765/2008 (also 'the Regulation') setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93. This Regulation applies from 1 January 2010. Its main objective is to ensure that products on the Single Market covered by Union legislation fulfil the applicable requirements, which provide a high level of protection of health and safety and other public interests. To this purpose the Regulation establishes a framework for accreditation and market surveillance.

   The report was prepared in cooperation with the Member States through the 'SOGS', i.e. the Senior Officials Group for Standardisation and Conformity Assessment Policy and the ad hoc market surveillance group called 'SOGS-MSG'. This report also evaluates the relevance of the conformity assessment, accreditation and market surveillance activities that receive Union financing in the light of the requirements of EU policies and legislation.

2. **ACCREDITATION**

2.1. **National accreditation bodies**

   Regulation (EC) No 765/2008 introduces for the first time a legal framework for accreditation. It applies in both the voluntary and regulated sectors. The purpose is to strengthen accreditation as the last level of control in the conformity assessment system and to enhance trust in conformity assessment results while responding to the needs of markets and public authorities alike.

   The Regulation introduces a number of general principles and requirements for national accreditation bodies[1]. These requirements are in line with the globally accepted requirements laid down in the relevant ISO/IEC international standards, although some of them can be perceived as being more rigorous, going beyond the requirements set out in the applicable standards. This is the case of the requirements according to which there is only one accreditation body per Member State,

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   [1]   See Articles 4, 6 and 8 of the Regulation.

accreditation is performed as a public authority activity, accreditation is operated on a non-commercial and non- profit basis and accreditation bodies do not compete with conformity assessment bodies or amongst each other.

In order to meet the requirements of the Regulation Member States had to introduce changes to their national accreditation systems to a varying degree. While for some Member States only some or minor changes were needed, others had to substantially overhaul their national accreditation system. In some cases, it was necessary to merge a number of accreditation bodies. All Member States as well as EFTA countries and Turkey have set up national accreditation bodies[2].

The process of restructuring and adaptation to the Regulation is now largely completed, while consolidation is still on-going, and in some cases national accreditation bodies still need to be strengthened within their national context.

2.2. Cross-border accreditation

The Regulation foresees that conformity assessment bodies should seek accreditation in the Member State where they are established. However, there are three scenarios in which a conformity assessment body may seek accreditation elsewhere:

(1)   The first is that the Member State in question has not set up a national accreditation body.

(2)   The second scenario is that the national accreditation body does not perform accreditation for the activity for which accreditation is sought.

(3)   The third scenario is that the relevant national accreditation body has not successfully undergone peer evaluation.

So far the first scenario did not materialise as all member States have set up a national accreditation body. The second and third scenarios are more frequent as not all national accreditation bodies perform the full scope of activities.

While these provisions on cross-border accreditation proved to be relatively straight forward, an issue that has become increasingly important in recent years is that of multi-site international conformity assessment bodies and subcontracting. The Commission has, in consensus with the Member States, adopted a policy document that explains how accreditation bodies should proceed in such cases with the aim to avoid multiple accreditations[3]. The European Cooperation for Accreditation, EA (see section on accreditation infrastructure), has then provided guidelines on how to put into practice these policy principles. Some fine-tuning of the implementation of these policy principles may still be required after better experience with these guidelines has been gathered.

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[2]   Their contact details are available on the Commission website at the following address: http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=ab.main

[3]   CERTIF 2009-06 Rev. 6.0 Cross Border Accreditation Activities (See accompanying Commission staff working document).

2.3. Peer evaluation

Peer evaluation is possibly the most essential tool in ensuring that the European accreditation system meets expectations of ensuring the quality of the European conformity assessment system. A successful peer evaluation is the prerequisite for the mutual recognition of accreditation certificates.

Therefore a rigorous peer evaluation mechanism between national accreditation bodies is central to the good implementation of the Regulation. It ensures a continuous control of the quality of the work of the national accreditation bodies, while also providing a learning process not only of those who are assessed but also of those who are doing the assessment. It is the peer evaluation that distinguishes and singles accreditation out in comparison to other means of assessing the competence and performance of conformity assessment bodies. The next objective is to further strengthen the peer evaluation process, to enhance the availability of trained and experienced peer evaluators and to further harmonise approaches particularly in the regulated sector.

2.4. European accreditation infrastructure

As set out in the Regulation, the Commission recognised the European Cooperation for Accreditation (EA) as the European accreditation infrastructure[4]. It then concluded an agreement that specifies the detailed tasks of EA, funding provisions and provisions for its supervision.

In April 2009, the Commission, EFTA, Member States and EA signed general cooperation guidelines that emphasise their political commitment to work closely together on a successful implementation of the accreditation chapter of the Regulation[5]. They express a common understanding of the importance of accreditation for the European economy as well as its supporting role for several European policies and corresponding legislation. The guidelines lay down the specific policy objectives for accreditation so that it may fulfil its goals expressed in the Regulation.

In June 2010, the Commission and EA signed a framework partnership agreement for the period of 2010-2014. This framework partnership agreement allows financial support for EA in fulfilling its tasks as foreseen by the Regulation and meeting the objectives detailed in the guidelines. The EA activities eligible for EU funding include technical work linked to the peer evaluation system, information of interested parties and participation in the international organisations in the field of accreditation, drawing up and updating of contributions to guidelines related to accreditation, notification of conformity assessment bodies, conformity assessment and market surveillance, activities of assistance to third countries[6].

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[4]   See Article 14 of the Regulation.

[5]   General guidelines for the cooperation between the European Cooperation for Accreditation and the European Commission, the European Free Trade Association and the competent national authorities. OJ 2009/C 116/04: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:116:0006:0011:EN:PDF

[6]   See Article 32 of the Regulation.

The framework partnership agreement stipulates the possibility of an annual operational grant for the on-going work of EA and its secretariat. At the time of writing this report, two annual operational grants amounting to 375,000€ and approximately 40% of the overall EA budget have been disbursed.

The grant has supported work related to the operation and management of the peer evaluation system which in 2010 and 2011 included 32 evaluations - including pre-evaluations, initial evaluations, re-evaluations and extraordinary evaluations of national accreditation bodies - and 8 trainings of evaluators. The activities in this area also include the launch of an overall process of enhancing the peer evaluation system that has produced a number of proposals currently under discussion.

Furthermore the EA's horizontal harmonisation committee as well as the laboratory, certification and inspection committees have been working on furthering a common understanding on how to perform accreditation and also on supporting accreditation in the relevant regulated sectors. This has resulted in a number of guidance documents[7].

EA has also been very active in fulfilling its tasks of providing technical expertise to different Commission services for the inclusion of accreditation in legislative projects or in terms of implementing existing sectoral legislation[8].

In addition, EA has been working with interested stakeholders through its EA Advisory Board and has fulfilled its obligations to participate in the international accreditation organisations ILAC/IAF by participating in their peer evaluation process and in their different working groups. It has also consolidated relations with third countries by accepting national accreditation bodies of EFTA and candidate countries as full members and by signing association agreements with national accreditation bodies of countries participating in the European neighbourhood policy. EA currently counts 35 full members and 13 associate members[9].

Besides the annual operational grant, the framework partnership agreement with EA also stipulates the possibility of action grants for specific projects. So far, no use has been made of this possibility.

Cooperation with EA has been very fruitful on the whole. Considerable efforts have been made to meet the changed circumstances for accreditation with the entry into force of the Regulation and EA's new role as the European accreditation infrastructure within this context. The progress made so far should be further consolidated to continue enhancing accreditation's role as the last level of control in the European conformity assessment system. As accreditation is increasingly being

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[7]   http://www.european-accreditation.org/content/publications/pub.htm.

[8]   Activities have not been limited to the services of the Directorate-General "Enterprise and Industry" but have spanned to other Directorates-General (amongst others DG SANCO, DG AGRI, DG ENV, DG MOVE, DG CLIMA). A prime example would be cooperation on the new European Emission Trading (ETS) Accreditation and Verification Regulation, where EA cooperated closely with DG ENTR and DG CLIMA in order to come up with a solution that meets the needs of this legislation. (Commission Regulation (EU) No 600/2012 of 21 June 2012 on the verification of greenhouse gas emission reports and tonne-kilometre reports and the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council Text with EEA relevance).

[9]   http://www.european-accreditation.org/content/ea/members.htm

used for the purposes of EU legislation, this may also entail a review of the resources and financial support available to EA.

2.5.   Accreditation in support of notification

The Regulation is very clear in its preference of accreditation as the means for demonstrating the technical competence of a conformity assessment body for the purposes of 'notification' under specific legislation, i.e. ultimately to acknowledge the body's ability to assess product compliance with the requirements of a given regulation or directive.

Accreditation has the benefit of being a transparent, standard-based activity, while the peer evaluation process is in place to ensure that comparable levels of quality are maintained. This is not the case for notifications that are not based on accreditation. The Commission has therefore, in consensus with the Member States, issued a guidance document on the kind of information that a non-accredited notification should carry[10]. As unaccredited notifications are not always accompanied by the appropriate documentation and Member States and the Commission have a longer time frame to raise objections, the notification process can in these cases become rather drawn-out and cumbersome.

The use of accreditation for notification purposes differs across Member States and across sectors. While some Member States have made accreditation for notification purposes compulsory, this is not the case in others that apply a rather mixed approach. It is a fact that at the end of 2009, before the entry into force of the Regulation, out of 2249 notifications 1089 were not accredited and 1118 accredited, while until June 2012 there were 3106 notifications of which 861 were not accredited and 2196 were accredited. Accreditation is thus successfully taking on its role in support of notification. A closer communication between national authorities and the accreditation body is therefore warranted.

2.6.   Guidance documents

The Commission has, in consensus with the Member States, issued guidance documents which are set out in the accompanying Commission staff working document.

2.7.   Challenges

While the Regulation has set a solid legal framework for accreditation, the major challenges in the implementation of the accreditation chapter of the Regulation for the coming years will be to consolidate and strengthen the system as well as raising awareness and a better understanding of accreditation's benefits. Apart from a number of legal questions surrounding accreditation, this will require a further strengthening of the peer evaluation system as the main tool for ensuring a continued quality of certificates throughout the EU. Furthermore accreditation for notification purposes will need to be given greater prominence and it will have to be used more systematically in EU legislation where the latter provides for conformity assessment and the designation of conformity assessment bodies. This may also require that the

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[10]   CERTIF 2010-08 Rev.1 Notification without Accreditation (Art. 5(2) of Regulation (EC) No 765/2008).

Commission and EA develop sectoral accreditation schemes to ensure that conformity assessment bodies meet the level of competence required by Union harmonisation legislation in fields with specific requirements[11].

3.   UNION MARKET SURVEILLANCE FRAMEWORK FOR PRODUCTS

This section summarises the state of play of the implementation of the main provisions of Regulation (EC) No 765/2008 concerning the establishment of a market surveillance framework for all harmonised products in the single market. This chapter complements the information contained in the impact assessment accompanying the Commission's proposals for a Consumer Products Safety Regulation and for a Market Surveillance Regulation.

3.1.   Requirements for the organisation of market surveillance by Member States

The Regulation establishes specific requirements for the organisation of market surveillance by Member States since 2010. Most of them have then fine-tuned their administrative structures and put in place specific solutions to ensure the fulfilment of those requirements. The replies of the Member States to a questionnaire on the implementation of the Regulation can be summarized[12] as follows:

- *Responsibility and identity of authorities*: in most Member States, the Regulation only required some small adjustments to pre-existing market surveillance activities (e.g. establishing a programme for the enhancement of market surveillance) as Member States have had already set up market surveillance procedures by relevant national legislation.

- *The communication and coordination mechanism between market surveillance authorities* varies amongst Member States: communication channels are sometimes based on an informal agreement, or communication takes place via a coordination body for market surveillance, through a Working Group responsible for implementation of New Legislative Framework or through a Market Surveillance Committee.

- *Procedure to follow up complaints*: before the Regulation, most Member States had already set up systems for complaints. Although these systems are updated on a regular basis, the majority of Member States indicate that they can be improved further.

- *Procedure to monitor accidents and harm to health*: some Member States believe that an improved system for accident data is needed and could be based on the current EU Injuries Database.

- *Strengthen market surveillance authorities' powers*: there were some minor adjustments in Member States as the enforcement powers have been mostly compatible to those required by the Regulation. Some Member States had to amend existing national legislation to comply with the Regulation (EC).

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[11]   See Article 13(3) of the Regulation.
[12]   A full overview of the replies can be found in the accompanying Commission staff working document.

- *Strengthen market surveillance authorities' financial and human resources*: the financial and human resources for market surveillance were reduced due to budgetary constraints in the majority of Member States, while in a minority of Member States no major adjustments were considered necessary until now.

- *Penalties for economic operators*: penalties for non-compliant economic operators existed already before the Regulation came into force, but were slightly amended in certain Member States as a consequence of the new competences for market surveillance authorities.

At the beginning of 2010 all Member States, Iceland and Turkey, informed the Commission of their market surveillance authorities and their areas of competence as specifically requested by the Regulation[13]. These communications provide a good overview of the distribution of tasks and responsibilities in the area of market surveillance for harmonised goods, including relevant contact details. They were published on the website of the Commission[14] and certainly contribute to transparency on national market surveillance authorities in the EU.

3.2. The national market surveillance programmes

According to the Regulation[15] Member States must establish, implement and update their market surveillance programmes. They must also communicate the programmes to other Member States and to the Commission and make them accessible to the public via internet. The purpose of these programmes is to allow the other countries' authorities, as well as citizens in general, to understand how, when, where and in which areas market surveillance is carried out. National programmes then contain information on the general organisation of market surveillance at national level (e.g. mechanisms of coordination between different authorities, resources attributed to them, working methods, etc.) and on specific areas of intervention (e.g. product categories, risk categories, types of users, etc.).

The majority of Member States communicated their national (general or sectoral) programmes and any necessary revision to the Commission in 2010, 2011 and 2012 (see Table 1). In 2012, the Commission published on its website a non-confidential original and translated version of the latest national programmes received from Member States, Iceland and Turkey[16].

The assessment of the efforts made by Member States is overall very positive, despite the fact that some countries have put more emphasis on information concerning the general organisation of market surveillance, while others have chosen to privilege information on sector activities, so the information is not always fully comparable. The clarity on how Member States have organised cooperation and coordination among different authorities and with customs could be improved.

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[13] See Article 17.
[14] http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/market-surveillance-authorities/index_en.htm.
[15] See Article 18(5).
[16] http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/national-market-surveillance-programmes/index_en.htm.

The Commission helped Member States' implementation of these provisions of the Regulation in particular by proposing a common template to lay out their sector programmes. This now greatly facilitates the comparability of national information in specific product or legislation areas and makes it possible for market surveillance authorities to plan cross-border cooperation in areas of common interest**.**

Table 1: National Market Surveillance Programmes (NMSP) – state of play 2010-2012

Country	*Type of programme*[17]	*2010*	*2011*	*2012*
Austria	General and Sectoral	x	x	x
Belgium	General *	x	x	x
Bulgaria	General *	x	x	x
Cyprus	General and Sectoral	x	x	x
Czech Republic	Sectoral	x	x	x
Denmark	General and Sectoral	x	x	x
Estonia	General and Sectoral	x	x	x
Finland	Sectoral	x	x	x
France	General and Sectoral	x	x	x
Germany	General *	x	x	x
Greece	General	x	x	x
Hungary	Sectoral	x	x	x
Ireland	General *	x	x	x
Italy	General	x	x	x
Latvia	General and sectoral	x	x	x
Lithuania	Sectoral	x	x	x
Luxembourg	General and Sectoral	x	x	x
Malta	Sectoral	x	x	x
Netherlands	Sectoral	x	x	x
Poland	General and Sectoral	x	x	x
Portugal	General and Sectoral	x	x	x
Romania	General and Sectoral	x	x	x
Slovakia	General and Sectoral	x	x	x

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[17]   The situation reflects in particular the approach followed for year 2012.

Country	Type of programme[17]	2010	2011	2012
Slovenia	General and Sectoral	x	x	x
Spain	Sectoral	--	x[18]	x
Sweden	General and Sectoral	x	x	x
United Kingdom	General and Sectoral	x	x	x
Iceland	General	x	x	x
Turkey	General	x	x	x

* The programme covers also some information on specific sectors, although this is not detailed

3.3. Products presenting a serious risk

The Regulation establishes a general obligation for Member States to ensure that the goods liable to compromise the health or safety of users (consumers and workers) or in any case non-compliant with product requirements set out in the EU harmonisation legislation are withdrawn, prohibited or their supply restricted[19]. Moreover, it sets out that when products – on the basis of an appropriate risk assessment – are considered to present a serious risk, Member States must also inform the Commission without delay of the measures taken by using the rapid information system "RAPEX"[20].

The inclusion in the Regulation of a reference to the RAPEX system has acknowledged the importance of this exchange information mechanism for market surveillance in the Single Market and the link of this mechanism to product-specific regulations. The reference to the RAPEX system has also had the effect of extending the obligation to send RAPEX notifications to all goods falling within the scope of EU harmonisation legislation, including products for use in a professional context (e.g. industrial machinery) and products which may harm public interests other than health and safety (e.g. environment, security, fairness of commercial transactions, etc.).

This extension has contributed particularly to the protection of workers[21] and the protection of the environment[22], although the total number of new notifications has been rather limited during the first two years of implementation of the Regulation. Besides the RAPEX notifications pursuant to the General Products Safety Directive, the Commission received, in 2010, 20 notifications under Regulation (EC) No 765/2008 (7 of them presenting a serious risk); in 2011 it received 25 such

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[18] Only for a limited number of products.
[19] See Article 16.
[20] See Articles 20 and 22. RAPEX is an alert system already established under Article 12 of the GPSD.
[21] Examples are the notification of a feed mixer used in agriculture that was found not to comply with the Machinery Directive 2006/42/EC after having caused a fatal accident in the notifying country and of various dangerous professional tools found not to comply with the Low Voltage Directive 2006/95/EC.
[22] Examples are the notifications on various consumer protective equipment and packages of toys containing a quantity of cadmium exceeding the limit allowed in the REACH Regulation (EC) 1907/2006 and the notifications of fireworks containing persistent organic pollutants.

notifications (17 of them presenting a serious risk)[23]. Overall, 9 Member States transmitted notifications on professional goods and products which may harm public interests other than health and safety.

More recent patterns show an increase in the number of communications received as in 2012 the Commission validated altogether 37 new notifications, 31 of which presented a serious risk. In the same period an additional Member State started to notify. These figures are expected to definitely go up overtime as Member States become more proactive in the area of professional products and fully adjust their practice to the broader scope of RAPEX.

On the side of the Commission the implementation of the Regulation has required some efforts to coordinate the expertise necessary to assess the new notifications and to adjust the operational procedures to the system's wider scope. The completion of the new IT platform for RAPEX notifications, called GRAS-RAPEX[24], was a major step forward for the handling of new notifications.

3.4.   An appropriate risk assessment methodology

As part of implementation of the Regulation carried out through the 'SOGS' groups, the Commission set up in 2011 a Risk Assessment Task Force composed of Member States' experts. The mission of the task force was to advice on appropriate means of carrying out risk assessment for all non-food products and all risks falling within the harmonisation legislation. The existing RAPEX Guidelines[25] already provide for the risk assessment methodology for consumer goods, which certainly constitute an important reference for Member States. The task force was then asked to assess: (i) whether the existing methodology, whose main focus is on non-harmonised products, could suitably take into account the legal requirements of harmonised goods; (ii) how to address the need to assess risks to public interests other than health and safety, which are not taken on board by this methodology.

At the end of the project the Risk Assessment Task Force concluded that the methodology referred to by the RAPEX Guidelines represents a good basis, however its suitability to the harmonised area should be improved by including explicit references to the product essential requirements and to the relevant harmonised standards. Furthermore, the language of the methodology should be adjusted to a broader set of public interests by focusing on the concept of 'harm' instead of that of 'injury'[26].

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[23]   More details on these notifications (notifying Member States, product categories, etc.) can be found in chapter 2.3 of the RAPEX Annual Reports for 2010 and 2011 available at: http://ec.europa.eu/consumers/safety/rapex/key_docs_en.htm.

[24]   GRAS-RAPEX has replaced the RAPEX-REIS application on 29 May 2012. The new IT platform contains more advanced functionalities among which drop down menus allowing RAPEX Contact Points to upload information on professional products and other risks than health and safety.

[25]   Adopted by Commission Decision 2010/15/EU of 16 December 2009, OJ L 22, 26.1.2010, p. 1, http://ec.europa.eu/consumers/safety/rapex/docs/rapex_guid_26012010_en.pdf

[26]   Document SOGS-MSG N031Rev1 or CERTIF 2012-01 Rev1.

3.5. **General information support system - ICSMS**

According to the Regulation, the Commission must develop and maintain a general archiving and exchange of information system, on issues relating to market surveillance activities[27].

Commission experts examined possible alternatives (acquire an existing tool, develop a new tool etc.) and came to the conclusion that the most appropriate solution was to acquire the "ICSMS" tool (Information and Communication System for Market Surveillance), which is the only information system of its nature currently already operating. At that moment, ICSMS was used by 12 EU/EFTA Member States (Austria, Belgium, Cyprus, Estonia, Germany, Luxemburg, Malta The Netherlands, Slovenia, Sweden, Switzerland and UK) as communication means for market surveillance authorities to exchange information on investigations of specific products and related activities.

In November 2011, the Commission agreed with ICSMS-AISBL (the body regrouping market surveillance authorities in the EU/EFTA Member States that are ICSMS users) and LUBW (Agency for environmental measurements depending on the Ministry of Environment and Transport of Baden-Wuerttemberg that hosts physically ICSMS) to purchase ICSMS for €1,940,940. Under the contract, ICSMS-AISBL and LUBW undertook to:

– transfer the IPRs of the ICSMS tool to the Commission;

– integrate Member States not yet ICSMS members and provide training to users of the new ICSMS member countries. The first trainings have taken place in May-June 2012;

– provide technical support and assistance to all ICSMS users (including help desk);

– manage ICSMS on a daily basis and ensure quality of service;

– transfer the know-how of ICSMS to the Commission.

Supported by the internet, ICSMS enables a comprehensive exchange of information between all the market surveillance bodies. The system allows to quickly and efficiently share between its users test results, product identification data, photographs, economic operator information, risk assessments including hazard data, accident information, and measures taken by surveillance authorities.

ICSMS consists of an internal and a public area. The internal area is for the use of market surveillance authorities. It can also be used by customs authorities and EU officials. It contains all information available (product description, test results, measures taken etc.). The public area is for the use of consumers and economic operators. The information which is visible to the public provides only the data, which references the product and its non-compliance and not any internal documents (i.e. between authority and manufacturer/importer etc.).

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[27] See Article 23 of the Regulation.

ICSMS already gathers test results on more than 47,500 products and lists more than 650 authorities in all EEA countries for more than 45 directives. The number of user accounts is 3,600. ICSMS enables all internal and public users to carry out a specific search. A search can be made, for example, according to individual products, and according to test results for entire product groups. Test results can be obtained for products from specific countries. Information can be obtained for products coming under certain directives, safeguard clause notifications, information about RAPEX notifications, for manufacturers, importers and dealers. Confidentiality aspects are protected by a system of access authorisations.

Each market surveillance authority can input data about investigated products, which are not yet in the database and add comments to an already existing product information file, i.e. feedback about the activities of market surveillance authorities with regard to investigated products. Furthermore the possibility to transfer the responsibility for a product from one authority to another (so called "baton passing") exists and is extensively used.

An evaluation of the ICSMS contract is premature as it was signed in November 2011 and as the roll-out of the system to EU countries which were not already members has just started. However, in view of the potential of ICSMS, the contract offers good "value for money" for the Commission and all concerned stakeholders (national authorities, manufacturers, citizens). The general information support system established under the Regulation is meant to be a policy tool that facilitates market surveillance across the European Union, in particular by increasing the effectiveness and coherence of investigations carried out at national level.

According to the experts who use ICSMS, the exchange of information on test results and investigations offers advantages for market surveillance authorities such as:

– Prompt intervention: information on unsafe products can be announced immediately and immediate measures may be taken;

– Deterrence: "black sheep" among manufacturers will be detected earlier and punished more effectively;

– Avoiding duplication of work: Test results by one surveillance authority will be immediately made available to all other Member States;

– Possibility to generate statistics by sector, product, etc.;

– Coverage of all issues concerning non-compliance of products.

In addition, ICSMS provides a valuable platform for the implementation of the European market surveillance policy by creating the basis for:

– the coordination of wide-scale market interventions against suspicious products;

– the elaboration of best practices, the exchange of general knowledge and experience;

–   the adoption of a common approach to market surveillance in different countries (thus avoiding distortion to competition);

–   the availability of an encyclopaedia of EU market surveillance intelligence;

–   the information of citizens about non-compliant products and the contact details of the competent authorities[28].

3.6.   Support to administrative cooperation

Regulation (EC) No 765/2008 gives the Commission the legal basis to assist with financial aid and support to the Member States in relation to ADCO (Administrative Co-operation on Market Surveillance) groups' activities[29].

The main objective of the Administrative Co-operation groups on Market Surveillance is to guarantee proper, uniform application of the technical provisions of the directives (certification procedures) and thus limit the use by the Member States of restrictions on the placing on the market of products certified to be in conformity.

There are currently twenty ADCO groups. They hold, in general, about 40 meetings a year covering areas such as construction, safety of toys, noise emissions, pyrotechnics, radio and telecommunication terminal equipment, electromagnetic compatibility, low voltage equipment, medical devices, equipment and protective systems intended for use in explosive atmospheres, pressure and transportable pressure equipment, machinery, lifts, cableways, personal protective equipment, eco-design, energy labelling, measuring and non-automatic weighing instruments or recreational crafts. The participants are officials of national market surveillance authorities who also ensure the chairmanship of the meetings. The Commission is also represented in the groups.

However, different levels of attendance to ADCO groups meetings, from one sector to another, have been noticed. The main reason of the weak attendance of several groups seems to be the lack of financial resources for travel and accommodation of the representatives. On the other hand, some market surveillance authorities do not apply for the chairmanship of the group because of the same financial problem in organising meetings.

4.   CONTROLS OF PRODUCTS ENTERING THE EU MARKET

In addition, Regulation (EC) No 765/2008 sets out a regulatory framework for external border controls[30]. The overall objective of these provisions is to ensure that Member States have appropriate control mechanisms in place in order to verify that products originating from third countries and entering the EU market comply with the requirements set out in Union legislation. To this end the Regulation establishes basic principles on the operation of external border controls, on the authorisation or not of the release of the goods for free circulation and on the cooperation of all

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[28]   See Article 19(2).
[29]   See Article 32(1)(e).
[30]   See Articles 27, 28 and 29.

authorities involved in relation to both tasks. These provisions build on Council Regulation (EEC) No 339/93[31], which was repealed by the Regulation.

4.1. Implementation by Member States

Therefore the Member States implemented specific provisions on border controls by:

- establishing a single point of contact in order to develop effective and efficient border controls;
- making available funding for border controls;
- developing policy on how border controls should be carried out;
- broadening border controls in order to cover more points of entry;
- ensuring that border controls are properly targeted and that trade facilitation is not adversely affected;
- establishing written agreements between customs and market surveillance authorities to strengthen cooperation in the area of border controls;
- improving cooperation between customs and market surveillance authorities (e.g. improving information sharing, intensifying cooperation with market surveillance authorities of third countries);
- providing assistance to custom officers who perform custom controls;
- carrying or assisting in risk analyses;
- harmonizing customs actions;
- training customs officers.

4.2. Guidance by the Commission

In order to facilitate the implementation of Regulation (EC) No 765/2008 the Commission, together with the Member States, has drafted the Guidelines for imports controls in the area of product safety and compliance[32]. The Guidelines are intended as an instrument to assist customs and market surveillance authorities in improving cooperation methods and good administrative practice. At the same time, the Guidelines focus on the practical questions customs are faced with when performing controls related to product safety and compliance.

The Guidelines consist of a Generic and a Specific Part. The generic part is essential to understand the overall relevant applicable EU legislation and in particular the obligations on safety and compliance controls and the cooperation between the relevant national authorities. The specific part of the Guidelines consists of practical tools for customs officers, i.e. information sheets and check lists for individual product groups intended to facilitate controls.

The Commission is coordinating Member States' efforts to disseminate and use the Guidelines at national level. It is also engaged in an extensive programme of country visits to provide as wide as possible guidance to national officials and to address specific questions they may have.

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[31] Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries (OJ L 40, 17.2.1993, p.1).

[32] http://ec.europa.eu/taxation_customs/resources/documents/common/publications/info_docs/customs/product_safety/guidelines_en.pdf.

All these initiatives have been financed through the Customs 2013 programme[33].

5. CE MARKING AND CONFORMITY ASSESSMENT

The Commission has in the past detected a lack of understanding of what CE marking means amongst economic operators, in particular SMEs. For this reasons, Regulation (EC) No 765/2008 lays down the general principles underlying the CE marking. In this respect, upon request by the European Parliament and as part of the Regulation implementation, the Commission committed itself to carry out an information campaign on CE marking addressed in particular to economic operators (with focus on SMEs) but also to public authorities and consumers.

5.1. The CE Marking information campaign

The CE Marking information campaign was intended to raise the stakeholders' knowledge regarding CE marking. It was financed by the Entrepreneurship and Innovation Programme in 2009 and cost in total 2 million EUR. The campaign started in the 1st quarter of 2010 and lasted until March 2012.

The outputs of the campaign include:

– the creation of a dedicated website in all EU/EFTA languages that serves as a one-stop-shop for information on CE marking (http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/)

– the development of a stand for presence at commercial fairs[34]; educational seminars in all EU/EFTA Member States (for Switzerland and Lichtenstein there was one joint seminar);

– the production of leaflets and brochures in all EU/EFTA languages for professionals and consumers; the production of two videos and promotional material; the production of factsheets describing the situation regarding CE Marking in various sectors in all EU/EFTA languages and various articles in the specialised press.

The campaign appears to have fulfilled its goals. The feed-back from the seminars and the fairs (the high number of participants[35] and their positive written evaluations), the high demand for informational material[36] and the strong interest of print and on-line media[37] show the success of the campaign.

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[33] Decision No 624/2007/EC of the European Parliament and of the Council of 23 May 2007 establishing an action programme for customs in the Community.

[34] Presence at the following fairs: Hannover Messe 2010 (April 2010), Paris Hopital Expo (May 2010), London CEDIA EXPO (June 2010), Berlin IFA (September 2010), Madrid Orto Pro Care (September-October 2010), Krakow Eurotool (October 2010), Nuernberg International Toy fair (February 2011), Milano fair (January 2011), Hannover Cebit (March 2011), Brno (Czech Republic) Amper fair (March-April 2011), Hannover Messe (April 2011).

[35] Almost two thousand stakeholders have followed the seminars. At some fairs, more than two thousand people visited the campaign stand, while more than two hundred visitors participated in deeper discussions with the stand personnel.

[36] Sixty thousand copies of leaflets and brochures already distributed.

[37] Over one hundred and forty press clippings/publications in magazines, newsletters and on specialised websites.

Furthermore the majority of the questions being asked by stakeholders on the CE Marking demonstrate that the stakeholders are now more familiar with the meaning of the CE Marking and are more aware of their rights and obligations. The number of the written questions from the stakeholders to the Commission has increased over the period of the campaign. The questions themselves became more complex and refined, demonstrating a much better knowledge of the CE Marking than before. In addition the guidance provided by the website reduces the risk of possible mistakes and misunderstandings.

5.2.   Guidance to sectoral legislator and other stakeholders

The correct use of the CE marking presupposes a good understanding of conformity assessment procedures applicable to different products. In order to help legislators, national authorities, Accreditation Bodies, Conformity Assessment Bodies, operators and other stakeholders to select the correct assessment procedures, the Commission provided specific guidance through policy documents:

- SOGS-N593 EN or CERTIF 2009-03 "Orientations for selecting and implementing the modules of Decision 768/2008 and SMEs specificities in the area of conformity assessment" provides guidance to the sectoral legislator how to select conformity assessment modules from the "menu" of the Decision No 768/2008/EC. Furthermore it provides guidance to Notified Bodies performing conformity assessment. In line with the better regulation objectives, the legislator must take into account the complexity of the product, the size of the undertakings operating in the sector addressed (e.g. SMEs) the technology in question, the risk for the public interest, the mass or serial nature of the production process. Notified bodies must, in a similar way, avoid unnecessary burden for the economic operators, maintaining however the required high level of protection of the public interest.

- SOGS-N594 EN or CERTIF 2009-04 "Introduction to conformity assessment of the New Legislative Framework as laid down in Decision 768/2008" is addressed to newcomers (legislator, Notified Bodies, manufacturers) into conformity assessment. It explains what conformity assessment is and describes its mechanisms and its role in the supply chain of a product. Furthermore it explains the role of the stakeholders involved and provides a detailed analysis of the conformity assessment procedures as defined in Decision 768/2008.

- SOGS N612 EN or CERTIF 2009–08 "Using Harmonised Standards to assess the competence of Conformity Assessment Bodies in the context of the New Legislative Framework" is addressed mainly to Accreditation Bodies and describes for every conformity assessment module which of the Harmonised Standards published in the Official Journal of the EU reflect the criteria Conformity Assessment Bodies must fulfil in order to be notified for the module in question.

The documents are available on the Commission's website[38].

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[38]   http://ec.europa.eu/enterprise/policies/single-market-goods/documents/certif_doc_en.htm.