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PRODUCT SAFETY AND MARKET SURVEILLANCE PACKAGE

COMMISSION STAFF WORKING DOCUMENT
Accompanying

the 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 for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

Organisation of market surveillance in the Member States

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Organisation of market surveillance in the Member States

1. INTRODUCTION

Regulation (EC) No 765/2008 establishes specific requirements for the organisation of market surveillance by Member States. Most of them have then fine-tuned their administrative structures and put in place specific solutions to ensure the fulfilment of those requirements.

In view of the preparation of the accompanying report on the implementation of the Regulation (EC) No 765/2008, the Commission requested from Member States a contribution regarding the implementation of the Regulation at national level.

This Commission Staff Working Document gives an overview of the replies of sixteen Member States. The other Member States did not reply.

2. RESPONSES

2.1. FRANCE

France has not communicated any shortcomings in the market surveillance area. The coordination between market surveillance authorities is done by the Directorate-General for Competitiveness and Services (DGCIS), which also centralizes data from different French authorities monitoring the market to develop the national market surveillance. It also organizes several annual meetings to exchange views on the implementation of Regulation (EC) 765/2008 by different authorities.

2.2. UNITED KINGDOM

2.2.1. Market Surveillance

Before the Regulation (EC) 765/2008 came into force, Market Surveillance Authorities in UK have already existed and been indicated for each EU legislation. UK Market Surveillance Co-ordination Committee was established which includes all UK market surveillance authorities (and also business interaction). The implementation of ICSMS in all market surveillance authorities is required.

The Regulation has not directly led to any adjustments to procedures to follow-up complaints, because the UK has had effective systems in place for many years. These systems are reviewed and amended on a regular basis to ensure that they are fit for purpose e.g. consumer complaints via Consumer Direct are now made through the Citizens Advice Bureau which has stronger brand recognition amongst consumers.

No adjustments have been made to the existing systems on procedures to follow-up complaints, to monitor accidents and harm to health. The UK also continues to feed into the EU's Injuries Database. UK believes that a system for the collection of comprehensive accident data is needed and should be based on the existing EU's Injuries Database and that policy decisions to strengthen this (particularly the causal linkages between accidents and products) and over increased levels of participation needs to be taken at the Union level.

No changes were considered necessary to strengthen market surveillance authorities' powers, because existing UK enforcement powers are considered to be broadly compatible to those required by the Regulation.

No major adjustments to the UK's market surveillance system were considered necessary to strengthen market surveillance authorities' financial and human resources as a direct result of Regulation (EC) No 765/2008. Measures to avoid multiple inspections and to maintain competencies of the market surveillance officials will deliver greater effectiveness and efficiency. Given the current economic climate, public authority budgets will remain a challenge.

Penalties for economic operators have remained unchanged because UK implementing legislation already meets the relevant requirements of 765/2008.

2.2.2. Customs

A sub-group of the Market Surveillance Co-ordination Committee has been established involving representatives from the customs authorities and the market surveillance authorities. This has established a protocol for the exchange of information and developed policy for how border controls will be carried out in the UK.

The UK has also worked collaboratively with NED (co-operation project on best practices with the Netherlands (VWA) at their largest ports (Felixstowe in the UK and Rotterdam in the Netherlands) to develop best practices.

A new law has also been made to protect customs information from misuse when disclosed for the purposes of 765/2008 (SI 2012/1848). The ongoing work is required to ensure that the border controls work is broadened to cover more points of entry beyond the major container ports. In addition, the identification of priorities and the management of risk based profiles is a continuous work in progress to ensure that border controls are properly targeted and that trade facilitation is not adversely affected. The main challenges that remain are operational rather than issues revolving around co-operation.

2.3. CZECH REPUBLIC

2.3.1. Market Surveillance

The responsibility and identity of the CTI (***Czech Trade Inspection***) was set out by the Act No. 64/1996 Coll., on the Czech Trade Inspection, as amended and further responsibilities were identified by the Act No. 634/1992 Coll., on consumer protection, as amended, Act No. 22/1997 Coll., on technical requirements of products, as amended, Act No. 102/2001 Coll., on general product safety, as amended and by related government regulations. Act No. 22/1997 Coll. and Act No. 102/2001 Coll. was amended, namely in relation to the protective measures extension and producers, importers and distributors obligations. The form of national communication and co-ordination responsibility setting needs to be introduced.

The attribution of responsibilities and the identity of ***State Energy Inspection*** (SEI) authorities were achieved in Act on business Conditions and Public Administration in the Energy Sector No. 458/2000 Sb. and in Act on Energy Management No. 406/2000 Sb. in valid version at the time of entry into force of Regulation 765/2008. SEI was, on the basis of these two acts, authorized to perform market surveillance on Energy using Products (EuP). Since 2009 SEI is responsible also for market surveillance on Energy related Products (ErP**)**, in the field of implementation Directive 2010/30/EU on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products and Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products.

The attribution of responsibilities and the identity of ***Czech Proof House for Arms and Ammunition*** authorities were achieved in Act on business Conditions and Public Administration in the Energy Sector No. 458/2000 Sb. and in Act on Energy Management No. 406/2000 Sb. in valid version at the time of entry into force of Regulation 765/2008.

Communication and coordination between ***CTI*** authorities and between ***Czech Proof House for Arms and Ammunition*** authorities is based on optional mutual agreements only. The communication and coordination mechanisms between ***CMA (Czech Mining Authority***) market surveillance authorities were modified by Act No. 490/2009 Coll.

Follow-up complaints procedure is set out sufficiently within the ***CTI***. Accidents and harm to health monitoring procedure has not been set out in Czech Republic yet. There is a negotiation between MTI (Ministry of Trade and Industry) and CTI on harm and health accidents monitoring procedure, therefore an appropriate procedure on accidents and harm to health needs to be established.

In ***SEI*** the establishment of procedure to follow-up complaints was solved in accordance with provision of the Act on State Inspection No. 552/1991 Sb. and No. 458/2000 Sb. The complaints are properly checked and if necessary the fines are put on the account of legal persons according to Administrative Procedure Code No. 500/2004 Sb. SEI is not authorized to inspect and monitor accidents and harm to health caused by products. Accidents and harm to health monitoring procedure is not set out yet for ***Czech Proof House for Arms and Ammunition***. The obligation

regarding the procedure to monitor accidents and harm to health has been already established in ***CMA***.

In ***CTI*** the financial and human sources as a whole were reduced due to the budget cut, thus the reorganization ensured current capacities of human resources. Their goal is to acquire additional human and financial resources.

Strengthening ***SEI*** market surveillance powers is currently enlarged on the base of ongoing implementation of Directive 2009/125/EC and Directive 2010/30/EU on the different ErP according to issued Commission Regulations.

Strengthening market surveillance authorities' financial and human resources properly depended and depends on ***SEI*** budget. The ongoing provisions on state budget savings invoke very strict behaviour for market surveillance activities. Market surveillance goals are ensured with existing human and financial resources.

In ***CMA***, strengthening market surveillance authorities' powers was adjusted by Act No. 490/009 Coll, competency ultra vires Act No. 61/1988 Coll and Act No. 552/1991 Coll. In CMA due to the state budget cut there was no strengthening of market surveillance authorities' financial and human resources.

Effective and dissuasive penalties for economic operators were established sufficiently for the ***CTI*** by relevant national legislation Act No. 22/1997 Coll. was amended in relation to the serious and non-serious violation sanctions. ***SEI*** is authorized to put and administrate the penalties during the process of ErP pursuant to listed act. In ***CMA***, penalties for economic operators were modified by Act No. 490/2009 Coll – partial extension in comparison with Act No. 61/1988 Coll.

2.3.2. Customs

Cooperation between customs and ***CTI*** was set-out by the Act No. 64/1996 Coll. The CTI is represented in the Working Group on import controls in the area of product safety and compliance, organised by the Directorate-general Taxation and Customs Union (DG TAXUD) and coordinates the horizontal cooperation on the national level simultaneously. A number of agreements between Customs and CTI directorates have been signed.

The cooperation between ***SEI*** and customs in the scope of ErP has not been established yet.

Cooperation between ***CMA***s and customs has been already set up by common cooperation (Act No. 500/2004 Coll).

2.4. FINLAND

2.4.1. Market surveillance

Communication and coordination mechanisms between market surveillance authorities in Finland were adapted by:

- setting up a working group (NLF-national working group);

- the act on the Information Exchange in Market Surveillance (1197/2009);
- modifications to the Market Surveillance Information Exchange Network.

Finish authorities are still in preparation of the general market surveillance programme and in the future they will set up an official body to carry out coordination tasks.

Strengthening of the market surveillance authorities' powers was adjusted by Section 36 of the Consumer Safety Act (920/2011) regarding non-compliance related to CE marking.

Penalties for economic operators were modified by the Act on CE marking Infringement (187/2010) and by the Consumer safety Act (920/2011), Section 52.

2.4.2. Customs

Discussions and information exchange are still ongoing regarding cooperation between market surveillance authorities and customs.

2.5. IRELAND

2.5.1. Market surveillance

In Ireland responsibilities for sectoral market surveillance had already been assigned to various market surveillance authorities through transposition of Directives into national law. Since the Regulation 765/2008 came into force, the Irish Medicines Board (IMB) was nominated as Competent Authority for cosmetics in October 2010. The role of Market Surveillance Authority for cosmetics was transferred from the Department of Health to the IMB in October 2010. A new section on Recreational Craft is being added to the Marine Survey Office (MSO), section of the Department of Transport, Tourism and Sports' (DTTAS) website and updated by the MSO. The IMB is seeking clarification on need to implement national legislation to formalise its nomination as the market Surveillance Authority for cosmetics and medical devices.

The system for communication with other market surveillance authorities is in place which continues to be developed and enhanced. The IMB has actively participated in the EU working group PEMSAC (Platform of European Market Surveillance Authorities for cosmetics) since becoming the Competent Authority for cosmetic products. This group continues to include improvements on increasing cooperation between market surveillance authorities within its work programme.

Training for GRAS-RAPEX was organised for Market Surveillance Authorities (MSAs) by the National Consumer Agency (NCA), which is the national contact point for IT system GRAS-RAPEX[1].Training for ICSMS was organised for MSAs by the Health & Safety Authority (HSA), the national contact point for ICSMS.

[1] General Rapid Alert System used for the Member states to submit RAPEX notifications. GRAS-RAPEX replaced the old IT system RAPEX-REIS and extended the scope of RAPEX to professional products and to other risks than health and safety.

A Market Surveillance Forum (comprised of MSAs and Customs) meets quarterly to exchange information and to keep abreast of developments. It is chaired by the Department of Jobs, Enterprise and Innovation. More specifically, the IMB has established a National Cosmetics Surveillance Forum consisting of representatives of IMB and Health Service Executive (HSE) involved in the operational aspects of cosmetic product market surveillance. The IMB also participates in the European PEMSAC working group establishing a national work programme on a two-yearly basis. In the medical devices sector, the IMB is an active participant at the Compliance and Enforcement Working Group (COEN) and currently holds the position of co-chair of the Group.

Irish authorities still need to ensure that all projects and activities agreed through SOGS-MSG are communicated to the relevant directorates-general of the Commission for each sector.(e.g. projects undertaken by DG TAXUD to be communicated and agreed with DG SANCO for inclusion into specific annual programme of work for PEMSAC (cosmetics market surveillance authorities)). Likewise, at the COEN Group, similar challenges exist to ensure that relevant projects are communicated at a cross-sectoral level.

Procedures for collection of national accident data in relation to persons at work were already in place. Compliance checks undertaken have been based on alerts, complaints, inspections and accident reports. More specifically, the Recreational Craft Directive ADCO Group use agreed ADM forms (RCDADM) to request information or action from other market surveillance authorities. Marine Casualty Investigation Board (MCIB) carries out investigations into marine casualties that take place in Irish waters or involve Irish registered vessels. Reports are produced on accidents investigated by the MCIB which include recommendations for appropriate action to be taken by relevant parties. The IMB manages the medical device vigilance system for Ireland managing all incidents that occur in Ireland, monitoring all field safety actions in Ireland and taking the lead role in a European vigilance cases as appropriate. This is all completed in line with Meddev 2.12-1 Guidelines on a medical device Vigilance System. The scope, management and guidance in the area of medical device vigilance is continuously being expanded and improved.

A new section on Recreational Craft will be added to the MSO section of the DTTAS website and updated by the MSO – this will include information on recent relevant RAPEX alerts and follow-up. Marine Notices are issued where considered relevant on the DTTAS website. Marine Notices are information notices that are issued to publicise important safety, regulatory and other relevant information relating to maritime affairs in Ireland. They are circulated to a wide range of individuals and organisations, ranging from State agencies and the fishing industry, to international shipping and water-based recreational interests. The IMB has established a cosmeto-vigilance system for reporting by healthcare professionals and consumers. With the implementation of Regulation 1223/2009 in July 2013, which introduces mandatory vigilance reporting requirements for cosmetics, a more formal process will be adopted. IMB is currently monitoring undesirable effects associated with the use of cosmetic products.

There has been still lack of existing infrastructure and resources to monitor consumer accidents and harm to health. The medical devices legislation is currently undergoing a substantial revision in Europe. It is anticipated that vigilance data will be collated

and trend analysis conducted to detect safety signals sooner. Current cosmetics legislation does not provide for mandatory reporting requirements (Cosmetics Directive 76/768/EEC). However with the implementation of Regulation 1223/2009 mandatory reporting requirements are introduced.

While Regulation 765/2008 clarifies the powers for market surveillance authorities, many enforcement powers were already in place under extant legislation. With the implementation of Regulation 1223/2009 the Competent Authority will have powers to recall and withdraw products posing a risk to consumers. In the interim solution, the market surveillance authority only has powers to recall products in case of a serious risk.

Irish authorities would like to have in the future the ability to request those, who place substances, mixtures or articles, to undertake a product recall. The medical devices legislation is currently undergoing revision and it is anticipated that proposals will place greater responsibility on the economic operators within the supply chain.

Since 2001 there has been a consistent increasing trend of market surveillance reports being received, and is increasing year by year. With the implementation of the new cosmetics legislation in July 2013 (Regulation 1223/2009) there will be an increase in the scope for Competent Authorities in terms of monitoring vigilance activities including increased communication and reporting requirements.

Both human and financial resources were assigned to the extent possible given restrictions and cut-backs in public sector numbers. Where staff numbers had increased to deal with the work load, the volume of reports currently being received continues to make this a challenge to achieve. A risk based approach is currently adopted by the IMB medical devices section to deal with this challenge.

In many cases, an increase in financial and human resources is not planned due to financial constraints. However, financial resources are being assigned to cover cost of product testing in respect of chemical related issues.

Increased economic pressures have an impact on the funding available for market surveillance activities within Ireland. Irish authorities will continue to secure funding for purchase, transport and testing, especially of complex articles. The IMB is currently investigating the funding structure for medical devices both at a national and European level. Optimising funding and resourcing of market surveillance authorities for medical devices remains a key challenge. A robust funding model based on periodic fees for surveillance activity may be the best means to secure funding and allow appropriate development of robust medical device market surveillance at each national level.

In most cases, penalties already existed under extant legislation. In cosmetics legislation, with the implementation of Regulation 1223/2009, national implementing provisions will be applied to address penalties for economic operators. The medical devices legislation is currently undergoing substantial revision in Europe. This may have an impact on penalties.

2.5.2. Customs

Customs and many market surveillance authorities have signed Data Exchange Agreements and/or Memoranda of Understanding (MOU). A Market Surveillance Forum (comprised of MSAs and Customs) meets quarterly to exchange information and to keep abreast of developments. It is chaired by the Department of Jobs, Enterprise and Innovation.

The process on signing of MOUs and/or Data Exchange Agreements between Customs and remaining MSAs is on-going. Training and development of procedures and the use of check lists is also in progress.

In the future Irish authorities would like to concentrate on co-operation with other market surveillance authorities where products originate in another EU Member State. Resource challenges are in terms of inspection including at ports.

2.6. POLAND

2.6.1. Market surveillance

In Poland all minor adjustments were implemented by the Act of 15 April 2011 on amendments of the conformity assessment system act and some other acts (OJL of 2011 No. 102, item 586).

2.6.2. Customs

Under articles 27-29 of Regulation 765/2008, customs authorities have the powers to stop import of dangerous/non-compliant goods and consult relevant competent authorities if import of such goods is in breach of the legislation on general product safety or conformity of goods. Accordingly, in Poland:

- customs authorities contact national competent authorities in various sectoral fields when they find out that there is a reason to believe that goods that are placed under customs procedure of release for free circulation do not fulfill requirements of the relevant legislation;

- national market surveillance authorities are obliged to advise customs whether goods mee tthe relevant requirements if their release for free circulation has been suspended and they should provide their opinion within three working days;

- lack of such an opinion means that the goods may be released for free circulation on condition that they fulfill other relevant import requirements;

- in the case of non-compliance, indicated by market surveillance authorities, customs authorities, if possible, seek voluntary compliance from an economic operator when a product is found not to comply with the relevant legislation. However, once a market surveillance authority (MSA) indicates that it is not possible to apply corrective measures, customs authorities ban release for free circulation of such products;

- customs authorities are obliged by national law to inform the Office of Competition and Consumer Protection, the authority monitoring the market surveillance system, on actions undertaken with regard to products which do not meet requirements, i.e. customs authorities inform on the customs procedure that was assigned to the products, which most often involve re-export or customs warehouse procedure (if there is a possibility to apply corrective measures with regard to the product, e.g. labeling, attaching the CE marking);

- the Polish customs authorities take a risk based approach in the area of market surveillance checks. Customs officials have unique access to the documentation relating to imports from third countries, consequently, the information contained in customs declarations and the supporting documents is profiled in order to target products that are likely to present a risk to users. Risk analysis involves a combination of central and local intelligence. Risk analysis is assisted by electronic customs systems and RAPEX.

Customs authorities co-operate with MSAs, particularly in the cases of:

- specific actions, such as joint actions with other Member States and/or market surveillance authorities (e.g. the PROSAFE projects on lighters or toys), or

- a need to implement uniform and/or stricter measures for a given period of time, or

- an implementation of a new checklist.

In all of the regional customs offices (16 Customs Chambers), there have been designated so called ”co-ordinators for product safety issues”. These are customs officials who are responsible for providing assistance to customs officers who perform customs controls, maintaining contacts with the central authority (Ministry of Finance), carrying out or assisting in risk analysis, helping to harmonize customs actions, and training customs officers. A systematic increase in the number of actions undertaken by customs authorities has been noticed and high efficiency of customs actions, which is confirmed by a significant number of negative opinions issued by MSAs.

2.7. THE NETHERLANDS

2.7.1. Market surveillance

Dutch authorities created a national coordination platform where all market surveillance authorities (MSAs) in the field of EU non-food legislation and Customs participate (Alliance group market surveillance and border controls EU legislation non-foods). Amongst others the task of this group is to discuss and adopt the Dutch position in the SOGS-MSG group and in general to improve the information flow, share strategies, tactics and knowledge (for instance on e-commerce, risk assessment and relations with Asia) and concrete cooperation between the MSA’s and with customs.

In certain domains (e.g. the equipment for professional use) the current procedure to follow up complaints was improved by appointing sections/units where a complaint

can be filed and investigated by the inspectorate. For professional products the current procedure to monitor accidents will be further developed in order to investigate them more systematically.

Priorities were re-organized and resources in some domains have or are being strengthened. In the future it will be important to find more financial resources (e.g. by introducing fees for certain inspections and controls).

Penalties for economic operators have been already established prior to Regulation 765/2008, but in future perspectives penalties should be increased which will have a more deterrent effect. There is also a need for more uniformity of penalties.

2.7.2. Customs

Several MSAs have established written agreements with customs to strengthen cooperation in the field of border controls. These agreements, including roles and responsibilities, differ depending on the domain in question. Other MSAs are working on improving co-operation with customs.

The future challenge is to enlarge the number of concrete market surveillance and border controls projects in which a large number of MSAs and customs authorities participate. There is a need for improving information sharing between market surveillance and customs authorities as well as for intensifying cooperation with MSAs of third countries. Another challenging task for the future is also functioning of the ICSMS system.

2.8. SLOVENIA

2.8.1. Market surveillance

In March 2011 Slovenia adopted new "Act regulating the technical requirements for products and the conformity assessment" for designation of the competent market surveillance authorities.

The communication and coordination mechanisms between market surveillance authorities were intensified and strengthened through existing channels. Ministry of the economic development and technology, as responsible ministry for the implementation of the Regulation 765/2008, chairs a "765 Coordinative working group" composed of all market inspectorates and customs authorities. The work of this group was adjusted to the requirements of the Article 18 of Regulation 765/2008.

There were no changes in the existing Slovenian system concerning complaints. Slovenia is a member of Injury Data Base (IDB) since 2006, which includes the injury registries in hospitals. There is no other systematic monitoring of accidents and harm caused by products.

Powers of Slovenian market surveillance authorities were strengthened through more precise legal base for market surveillance measures. In March 2011 Slovenian Parliament adopted new "Act regulating the technical requirements for products and the conformity assessment". Act for the purpose of implementing Regulation 765/2008 designates the competent market surveillance authorities and penal provisions.

The entry into force of the Regulation 765/2008 requires strengthening of market surveillance authorities' financial and human resources. Due to crisis in Slovenia MSAs are not able to earmark more financial and human resources for more effective implementation. They oriented all powers for optimisation of the work in the competent market surveillance authority.

Establishment of effective and dissuasive penalties for economic operators were necessary. This was done through the new "Act regulating the technical requirements for products and the conformity assessment", where chapter IV (Penalties provisions) precisely defines the level of fine for the offences.

2.8.2. Customs

Slovenia reports effective cooperation between Slovenian Market Surveillance Inspectorate and Slovenian Customs Office. This cooperation is based on the bilateral agreement between the Slovenian Market Surveillance Inspectorate and Slovenian Customs Office (signed in 2003). Since Regulation 765/2008 entered into force, special agreements for cooperation between market surveillance and customs authorities are not necessary. Horizontal exchange of information is done through the "765 Coordinative working group" chaired by the Ministry of the economic development and technology. Sector specific issues are discussed on a bilateral level between customs authority and different inspectorates. The future challenge is to strengthen the cooperation between customs authority and other inspectorate while following the good practice in the case of cooperation between Customs Office and Market Inspectorate

2.9. SWEDEN

2.9.1. Market surveillance

Responsibilities and identity of authorities were adapted to Regulation 765/2008 by Law and Regulation on Accreditation and CE-marking (SFS 2011:791 and SFS 2011:811). Market surveillance provisions adjusting Swedish law to Regulation 765/2008 have been adopted in some sectors by:

- Law and Regulation on explosive products (SFS 2010:1011) and (SFS 2010:1075).
- Law and Regulation on safety of toys (SFS 2011:579) and (SFS 2011:703).

Sweden is in a phase of adjusting national regulations concerning market surveillance to the Regulation 765/2008. Most Swedish rules concerning responsibilities for market surveillance are found in national regulations transposing harmonisation directives (or complementing EU-regulations). Some aspects of market surveillance are covered by a horizontal regulation (SFS 2005:893), concerning e.g. cooperation and reporting obligations, which is currently being updated.

The future task of Swedish MSA is to update all Swedish regulations to avoid duplications or even conflicts between national rules and Regulation 765/2008. In many cases legislation will be updated to nine directives in the Alignment package.

Sweden has had a coordination body for market surveillance since 2005, designated as the Market Surveillance Council. Its duties and responsibilities are regulated (e.g. to establish a national action plan for market surveillance and a yearly report to the government). The council meets four to five times a year and represents fifteen MSAs and the Customs. Brand and consumer organisations are invited on a regular basis and working groups have been established for different issues, e.g. guidelines for publication of information on dangerous products, guidelines on how to plan and form the sector specific action plans. In addition, an external website and an exchange and information system were set up in 2010 (www.marknadskontroll.se). The Swedish Agency for Accreditation and Conformity Assessment (Swedac) holds the secretariat and chairmanship of the Council.

The procedure to follow-up complaints, monitor accidents and harm to health was adapted by Law and Regulation on explosive products (SFS 2010:1011) and (SFS 2010:1075), Law and Regulation on safety of toys (SFS 2011:579) and (SFS 2011:703). There is a room for improvements by using more statistics in order to monitor accidents and a more systematic approach might be also needed.

Powers of market surveillance authorities are complemented with national legislation which is being updated. Financial resources for market surveillance are handled as a part of the ordinary Swedish budgetary process for public authorities.

Penalties for economic operators were adapted to Regulation 765/2008 by:

- Law and Regulation on explosive products (SFS 2010:1011) and (SFS 2010:1075);
- Law and Regulation on explosive products (SFS 2010:1011) and (SFS 2010:1075).
- Law and Regulation on safety of toys (SFS 2011:579) and (SFS 2011:703).

The legal support for the duties of MSA (e.g. penalties/sanctions) varies from sector to sector. All MSAs should have the same possibilities which will be taken care of when updating national legislation.

2.9.2. Customs

In 2008 a national cooperation model/flowchart was set up between the Customs and all MSAs. The aim was to clarify the distribution of responsibilities between Customs and MSAs. Routines for contact were made between MSAs and Customs. The model was updated to adapt to Regulation 765/2008. The model is a "living" document and will be updated as a result of the new DG TAXUD guidelines. In addition, a working group was established within the Market Surveillance Council in 2011 for all customs related issues.

2.10. SLOVAKIA

2.10.1. Market surveillance

Responsibilities and identity of authorities in Slovakia are governed by the horizontal law[2] that refers to the specific regulations governing the procedures for the respective NMSA (supervisory authorities). Responsibilities of ***STI***[3] result from the Act No.128/2002 Coll. on State control of the internal market in consumer protection matters, and amending certain laws as amended. Responsibilities of ***SMA***[4] result from the Act No. 51/1988 Coll. on mining activity, as amended. Responsibilities of ***PHA***[5] result from the Act No. 355/2007 Coll. on the protection, promotion and development of public health and amending certain laws, as amended, and Government Regulation No. 658/2005 Coll. laying down requirements for cosmetic products, as amended. Responsibilities of ***SIDC***[6] result from the Act No. 362/2011 Coll. on drugs and medical devices, as amended. Responsibilities of ***SMI***[7] result from the Act No. 142/2000 Coll. on metrology, as amended. Responsibilities of ***RTRA***[8] result from the Act No. 513/2009 Coll. on railways, as amended. Responsibilities of ***TO SR***[9] concerning products covered by the R&TTE and EMC Directive result from the Act No. 351/2011 Coll. on Electronic Communications (especially article 38, article 36 paragraph 1, article 39 paragraph 2 and article 73), by which the previous Act No. 610/2003 Coll. was canceled and Act No. 264/1999 Coll. (article 30 and related articles) on Technical Requirements for Products and on Conformity Assessment, as amended. Responsibilities of ***LI***[10] concerning determined products[11] result from the Act No. 125/2006 Coll. on Labour Inspection, as amended (amendment of the law with effect from 1.7.2012 in the context of Regulation 765/2008) and Act No. 264/1999 Coll. (article 30 and related articles) on Technical Requirements for Products and on Conformity Assessment, as amended. There is a new text of horizontal law on technical requirements for products and on conformity assessment which should replace the Act. No. 264/1999 Coll.[12]

Communication and coordination mechanisms between market surveillance authorities were created from January 2009 through inter-departmental Working group (WG), coordinated by ***SOSMT***[13], as the leader of the implementation of NLF in Slovakia. WG consists of representatives of the Slovak market surveillance authorities, relevant ministries and the Custom Department of the Financial Directorate SR. ***PHI*** Cooperation Agreement is signed between the PHI SVFA and

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2 Act No. 264/1999 Coll. on technical requirements for products and on conformity assessment as amended

3 **STI** - Slovak Trade Inspection

4 **SMA** - State Mining Authority

5 **PHA** - Public Health Authority of SR

6 **SIDC** - State Institute for Drugs Control

7 **SMI** - Slovak Metrology Inspection

8 **RTRA** - Railways Transport Regulation Authority

9 **TO SR** - Telecommunication Office SR

10 **LI** - Labour Inspectorates

11 Determined products are such products that represent higher risk of jeopardy to justified concern

12 Act No. 264/1999 Coll. on technical requirements for products and on conformity assessment as amended

13 **SOSMT** - Slovak Office of Standards, Metrology and Testing

STI in the field of control of food and cosmetic products. ***PHA*** made amendment to the Act 355/2007 Coll.[14]

There were no major adjustments made concerning procedure to follow-up complaints. Among other provisions of sectoral regulations or the horizontal act, there is an Act No. 9/2010 on complaints which refers to follow-up process of complaints in general. This Act regulates the procedure for applying, accepting, recording, investigation and written notification of the result of the investigation of a complaint or its checkup. No major adjustments were performed to procedure to monitor accidents and harm to health. In ***LI*** complaints are regulated by the Act No. 125/2006 Coll. on Labour Inspection, as amended and Act. No. 124/2006 Coll. on Occupational Safety and Health. In ***STI*** info system ECHO was introduced in 2008.

The procedure to follow-up complaints, to monitor accidents and harm to health of ***RTRA*** is set out in article 19 of the Act No. 513/2009 Coll. on Railways: the operator of the determined technical equipment[15] (DTE) is obliged to report to RTRA (Security Authority) the emergence of incident in operation. In ***PHI*** - under "enforcement of preventive measures in the field of cosmetic products with a particular focus on consumer education" the procedure for electronic notification of serious adverse effects of cosmetic products on public health will be developed by the end of 2013.

No major adjustments were made regarding strengthening of market surveillance authorities' powers apart from Safety of toys Directive (2009/48/EC). **STI** issued a new Act No. 78/2012 Coll. on Safety of toys and on amending of the Act No. 128/2002 Coll. on State control of the internal market in consumer protection matters. **PHA** amended the Act. No. 355/2007 Coll.[16] (Addition of competence in the field of state health supervision in the field of cosmetic products: impose an obligation for natural or legal person to take corrective action if product does not comply with the specific regulation, including withdrawal or recall, impose withdrawal of the product from the consumer, if product presents a serious risk.).

No major adjustments were executed to strengthen market surveillance authorities' financial and human resources. It is necessary to strengthen market surveillance authorities' financial and human resources. ***LI*** believes that it is necessary to provide funds to verify the safe condition of the determined product[17], or clearly define who is required to pay for the costs related to physical and laboratory tests (under § 7 of the Act No. 125/2006 Coll. on Labour Inspection, as amended). According to **RTRA** strengthening of market surveillance authorities' financial and human resources is required only in case of an extension beyond the activities carried out so far.

No major adjustments were done on penalties for economic operators. Act No. 264/1999 Coll. (article 32) on Technical Requirements for Products and on Conformity Assessment, as amended. In ***RTTA*** penalties are regulated according to

14 Act. 355/2007 Coll. on protection, promotion and development of public health and amending certain laws under preparation

15 Determined technical equipment is such equipment that represent higher risk of jeopardy to justified concern (Act. No. 264/1999 Coll.)

16 Act No. 355/2007 Coll. on protection, promotion and development of public health and amending certain laws under preparation

17 Determined product is such product that represent higher risk of jeopardy to justified concern (Act No. 264/1999 Coll.)

articles 103 and 109 of the Act No. 513/2009 Coll. on Railways, as amended. In ***PHA*** penalties are regulated in amended Act No. 355/2007 Coll. (Change of penalties for natural or legal person depending on the deficiencies found in the field of cosmetic products.).

2.10.2. Customs

Customs Administration SR and NMSA cooperate on a base of bilateral agreements following the Articles 27-29 of the Regulation 765/2008. Until now cooperation agreements have been concluded between the Customs Directorate of SR and:

- Central Inspectorate of the Slovak Trade Inspection,
- State Institute for Drugs Control,
- Department of State Control of Veterinary Biological Products and Drugs,
- State Veterinary and Food Administration of SR.

In ***STI*** cooperation Agreements were concluded with the Public Health Authority SR (control of health safety of toys, childcare products and products containing the detected volume of chemicals) and the State Veterinary and Food Administration (control of general food sales requirements).

Other cooperation is organised on the basis of oral agreements and it is applied to case-by-case issues.

According to Regulation 765/2008 (articles 27–29), STI extended "Exchange of information and cooperation within Working group", coordinated by SOSMT[18].

Negotiations for the conclusion of other cooperation agreements have already started. ***PHA*** made an amendment to the Act 355/2007 Coll.[19]

There is also an addition of competencies - cooperation of public health authorities with the Customs in the area of inspection of products imported from third countries.

The cooperation between different NMSA and the cooperation with customs still need to be improved. There are two ongoing projects: the preparation of the opening of the ICSMS system in Slovakia and training of NMSA in 2013.

2.11. GERMANY

2.11.1. Market surveillance

The measures described below refer in the first line only to market surveillance in the area of the German Product Safety Act and specified market surveillance activities do not apply to all sectors. This legal act transposes the General Product Safety Directive and the following twelve New Approach Directives into German national law:

[18] **SOSMT -** Slovak Office of Standards, Metrology and Testing

[19] Act No. 355/2007 Coll. on protection, promotion and development of public health and amending certain laws

- General Product Safety (2001/95/EC),
- Aerosol dispensers (75/324/EEC),
- Simple pressure vessels (2009/105/EC),
- Personal protective equipment (89/686/EEC),
- Appliances burning gaseous fuels (90/396/EEC),
- Equipment and protective systems intended for use in potentially explosive atmospheres (94/9/EC),
- Recreational craft (94/25/EC),
- Lifts (95/16/EC),
- Pressure equipment (97/23/EC),
- Machinery (2006/42/EC),
- Low voltage (2006/95/EC),
- Toys (2009/48/EC),
- Noise emission in the environment by equipment for use outdoors (2000/14/EC).
- The entry into force of the Regulation 765/2008 did not require changes/adjustments in the administrative structure of market surveillance in the area of the German Product Safety Act. However, as one result of the MATTEL case (toys recall in 2007) the Federal Government together with the German Länder (German Federal States) established a programme for the enhancement of market surveillance (Common Strategy of the Federal and State Governments to strengthen market surveillance in the area of the Equipment and Product Safety Act - *http://www.baua.de/de/Produktsicherheit/Marktueberwachung/pdf/Eckpunkte.pdf?__blob=publicationFile&v=1*). One important step in this programme is the attribution of certain enforcement responsibilities and coordination tasks to the Zentralstelle der Länder für Sicherheitstechnik – ZLS (Central Authority of the German Federal States for Safety).

In special cases (e.g. two or more local market surveillance authorities involved – diverging risk assessment and therefore diverging measures) the enforcement competence will pass to the ZLS. The ZLS could also take over a case by order of the majority of the German Länder. Changes/adjustments were partially necessary in the area of Energy Efficiency. The pressure to streamline responsibilities results in the area of energy labelling, however, rather from the increasing number of covered products and the increasing workload.

As regards communication and coordination, special tasks were assigned to the ZLS. Changes/adjustments were partially necessary in the area of Energy Efficiency. In this field a committee on market surveillance for the coordination between the national level and the level of the Federal States was established in June 2012. The committee covers market surveillance in the areas of energy labelling (Directive 2010/30/E) and ecodesign (Directive 2009/125/EC).

No special measures were created to the procedure to follow-up complaints in the area of the German Product Safety Act. In the area of Energy Efficiency there was a need to establish a procedure on how to react on notices on non-compliance with energy labelling rules. It was not necessary to establish a new procedure in terms of administrative law since existing administrative law covers also administrative decision in terms of market surveillance activities.

No special measures were created for the procedure to follow-up complaints, to monitor accidents and harm to health in the area of the German Product Safety Act and also not in the area of Energy Efficiency, because energy labelling has no effects on product safety and human health.

Since the revision of the Product Safety Act (entry into force in December 2011), there are provisions for higher fines. Besides this authorities have to charge economic operators for their testing and enforcement activities when they find non-compliant products. In the area of Energy Efficiency, new competences of market surveillance authorities were introduced, when adapting national energy labelling law to the Regulation 765/2008.

Due to the important role of market surveillance in the area of the German Product Safety Act for both, businesses and consumers, there is no further staff reduction in this area. In the area of Energy Efficiency it can only be remarked that financial and human resources of market surveillance authorities are within the competence of the Länder, not within the competence at the national level.

In the area of Energy Efficiency, resulting from the additional competences on market surveillance, there are additional possibilities for penalties. Administrative offences and administrative fines are, however, no new instruments in the area of energy labelling.

2.11.2. Customs

The ZLS will become in 2013 the "contact point" for the German customs. Nevertheless the cooperation according to articles 27 to 29 of Regulation 765/2008 will still exist at a local level.

The guidelines for cooperation between customs and market surveillance authorities are currently being revised and updated in the area of the German Product Safety Act.

2.12. BULGARIA

2.12.1. Market surveillance

Communication and coordination mechanisms between market surveillance authorities were adjusted by Amendments of a Decree No. 180 of the Council of Ministers from 1 August 2005 for the establishment of a Council for coordination and exchange of information between market surveillance authorities. The main aims of the amendments are to clarify the functions, tasks and the composition of the Council and to move the secretariat of the Council into the Ministry of Economy, Energy and Tourism.

The procedure to follow-up complaints is being updated. There is a need to develop a procedure/national system to follow-up complaints, to monitor accidents and harm to health caused by products.

2.13. DENMARK

2.13.1. Market surveillance

There are no major adjustments in responsibilities and identity of authorities, strengthening of market surveillance authorities' powers and strengthening of market surveillance authorities' financial and human resources.

Regarding communication and coordination mechanisms between market surveillance authorities, a market surveillance committee has been set up to facilitate coordination. Several initiatives on coordination are ongoing: exchange of experiences on enforcement, including alternative enforcement mechanisms and formal exchange of officials between authorities. A main challenge will be to avoid a 'one size fits all' approach but to encompass all authorities in activities in the market surveillance committee.

Denmark improved procedure to follow-up complaints, monitor accidents and harm to health following implementation of Regulation 765/2008. A couple of Danish Authorities already has completed a procedure to follow-up complaints, several authorities have already set up procedures to monitor accidents and are in the progress of setting up procedures to monitor harm to health. But there are still a couple of authorities which have not fully implemented a procedure for monitoring accident, while others do not deem it relevant.

Penalties for economic operators were partly adjusted to Regulation 765/2008 and as an ongoing process - one authority is currently changing its penalties.

2.13.2. Customs

Some authorities are still in process of drafting formal cooperation agreements between market surveillance authorities and customs. Formal cooperation agreement with tax authorities are being drafted for other authorities.

2.14. ITALY

2.14.1. Market surveillance

Following authorities in Italy contributed to the reply:

- Ministry of Health, Department of Public Health and Innovation, Directorate General for Prevention, REACH Office;
- Ministry of Infrastructure and Transport, Port General Command;
- Department for Transport, Navigation and Information Systems and Statistics, Directorate General for Rail Transport;
- Directorate General for Maritime and Inland Waterways;
- Ministry of Economy and Finance, Independent Administration of State Monopolies (AAMS);
- Customs agency, Central Directorate for Verifications and Controls, Office for methodology and control of trade in the field of customs and taxation;
- Ministry of Interior, Department of Public Safety, Office of the General Administration, Affairs Office of the Social and Administrative Policy;
- Fire Department of Public Assistance and Civil Defense, Central Directorate for Prevention and Technical Safety, Area II - Standardization notification and control;
- Ministry of Economic Development, Department of Communications and the Regional Inspectorates, Directorate General for Planning and spectrum management;
- Department for Enterprise Internationalization, Directorate General for industrial policy and competitiveness;
- Directorate General for the Market, Competition, Consumer, Supervisory Board and the Technical Regulations, Security and Compliance of Products Division;
- National Union Chamber of Commerce.

1) Responsibility and identity of authorities: Articles 20 and 50 of the National Decree of 31 March 1998 - attributed to the ***Chambers of Commerce***, Industry, Crafts and Agriculture the functions performed by the Metric Offices and the provincial offices for industry, trade and craft (UPICA). This Decree transferred to the Chamber skills inspections competences, the control of conformity of products, measurement tools and skills to any sanctions. The aim was to enhance the role of the chamber as well as to point out the reference for the business system subject to market regulation, consumer protection and public confidence. The national legislation of 15 February 2010 re-defined the institutional and organizational skills of the Chamber of Commerce and the chamber system as a whole by strengthening

the function of supervision and control. The competent chamber offices comply with the rules of the industry for:

- Legal metrology;
- Electrical low voltage;
- Products subject to electromagnetic compatibility;
- Toys;
- Personal protective equipment of the first category (eg, sunglasses, ski goggles, etc.);
- Labeling of footwear;
- Labeling of textile products; and in the following aspects:
- Safety aspects of products (pursuant to legislative decree of 6 September 2005, No. 206, Part IV, Title I - articles 102 to 113);
- Fuel consumption and emissions of carbon dioxide (CO2) of the various models of new cars;
- Domestic consumption of products related to the use of energy. Control activities include the operation of inspections and sanctions according to the competency of the following:
- Control of visual products: these are undertaken by all operators in the industry and are designed to verify compliance with formal regulations.
- Controls type of document on technical dossiers relating to food or metric tools: these checks are intended to ensure compliance of the products with respect to the technical requirements laid down by the legislation which is binding and voluntary.
- Laboratory tests: these controls are designed to ensure the physical and chemical characteristics of the products complying with the operation of testing laboratories.

The investigative powers of the Chambers of Commerce are governed not only by the national transposition of EU directives, but also by national legislation No. 689 of 1981.

Ministry of Health: the authorities' control is subject to the enforcement forum of ECHA (The European Chemical Agency Helsinki).

Ministry of Health, Directorate General for Prevention: responsibility and identity of authorities is in accordance with Legislative Decree No. 54/2011, Article 29, paragraph 5.

Supervisory Authority, General Command of the body of the Harbor - 6th Ward is responsible for Council Directive 96/98/EC by performing a reacting monitoring (complaints, specific incidents on board, inspections' national units which issue certification of ship safety). They check product certification on-board, perform operational testing on-board and laboratory tests on the product. They also establish the plan for the activities, cooperate with competent authorities and have available resources for proactive surveillance.

The Ministry of Economic Development, Department for Enterprise and Internationalization, Directorate General for Market, Competition, Consumer, Supervision and Technical Regulations, Security and Compliance Division: article 14 of Legislative Decree 58 of 4 April 2010 implementing Directive 2007/23/EC on the placing on the market of pyrotechnic products provides supervision to ensure that these items are safe, properly stored and used for purposes which they are intended for.

Ministry of infrastructure and transport, Department for transport navigation, information systems and statistics, Directorate-General for maritime transport and inland waterways: the Directive 94/25/EC was amended by Directive 2003/44/EC, which is implemented by the Legislative Decree No. 171 of 18 July 2005. Article 11, Paragraph 1 of the Legislative Decree No. 171 provides that the supervisory activities on recreational craft are carried out in coordination with the Ministry of Economic Development and the Ministry of Infrastructure and Transport and within their respective competences. In the legislative context described above, it should be noted that, with regard to the responsibility of the Department of Infrastructure and Transport, DG Maritime transport and inland waterways, the market surveillance of recreational craft is one of the duties of the Division 5. The performance of office tasks consists of the verification of conformity of recreational craft and components to the requirements of the aforementioned Decree, through specific checks and targeted checks on the market, even with sampling basis (Article 11, paragraph 3) and of the control of the technical documentation referred to in Annex IX of the Decree, that the manufacturer or his authorized representative, established in the territory, are required to keep for ten years (Article 11, paragraph 5). This Office is working with the relevant sectoral group created in the RCD ADCO for the preparation of a document "Risk Assessment".

Circulation tobacco, Directorate for Excise: Following the correspondence with the Ministry of Economic Development, this directorate was identified as the authority responsible for the supervision on fire protection requirements of the cigarettes referred to the Commission Decision No. 264 of 25 March 2008.

2) Communication and coordination mechanisms between market surveillance authorities: In order to support the supervisory activities of the ***Chambers of Commerce*** for the Inspection Campaign National Memorandum of Understanding MED/Unioncamere 2009, the Information System VIMER was created. VIMER is a database that allows to record all data of Chambers of Commerce and to report on the inspections carried out on the field. The data collection and consultation by Chambers and MED allows monitoring in real time the control activities which are carried out by the authorities in order to better coordinate the activities throughout the country in accordance with national surveillance programs and to avoid duplication in controls. The system also provides reporting for any notifications in

the RAPEX system. In the VIMER system information is collected and managed on the control activities carried out by the Chambers of Commerce relating to: Safety of products (toys, electrical products, personal protective equipment), labeling products (shoes, textiles) and MID surveillance tools.

Ministry of Health: communication and coordination mechanisms between market surveillance authorities are proceeded through websites and via e-mail.

National Administration Ministry of Health, Directorate General for Prevention created a network of territorial and central units of NAS (Police Unit for the Protection of health and safety of products) with the Ministry of Health. The Communication is provided by electronic mail and paper mail PEC.

Circulation tobacco, Directorate for Excise: Participation in the seminars for the management of RAPEX and ICSMS platforms.

3) Procedure to follow-up complaints, to monitor accidents and harm to health: ***Chambers of Commerce*** - Information System VIMER collects, among others, information regarding non-conforming products and when data are available, it collects also information on incidents, risk categories and measures taken as a result of the inspection.

Ministry of Health: Procedure to follow-up complaints, to monitor accidents and harm to health exists in Legislative Decree of 9 April 2008 No. 81 on Law safety at workplace.

National Administration Ministry of Health, Directorate General for Prevention established a network between the Emergency Hospital, the Authorities of territorial control, the headquarters of Police Unit for the Protection of Health and the Ministry of Health.

Responsible national administration for Directive 1999/5/EC (Radio and Telecommunications Terminal Equipment) enhance communication with other supervisory authorities (Department of Business and Internationalization MISE) through representation in the National Advisory Committee which meets twice per month. Territorial Inspectorates are involved for products that are potentially harmful to health and results are submitted to Competent Authority to input data in RAPEX system.

4) Strengthen market surveillance authorities' powers:

Ministry of Health: not necessary.

National Administration Ministry of Health, Directorate General for Prevention: An agreement signed with the Region Piemonte: monitoring and evaluation of the toxicity of cosmetic products and those used in tattoo parlors, the amount allocated 40,000 EUR. An agreement signed with the Institute ISS: Identification of volatile organic compounds produced by the combustion of incense on a scientific basis to promote evaluation and limitations of use, the amount allocated 55,141,34 EUR. An agreement signed with the National Institute of Health: Support Action for interventions of Rapid Alert System (RAPEX) and Remediation of Soils and groundwater which are contaminated, the amount allocated 250,000 EUR.

5) Strengthen market surveillance authorities' financial and human resources: in order to strengthen the supervisory activities of the market surveillance authorities and to adapt to Regulation 765/2008, the Ministry of Economic Development and Union Chamber signed in June 2009 a Memorandum of Understanding that provides the allocation of resources for strengthening of monitoring on the field by the ***Chambers of Commerce***. The initial term of this protocol has been extended until 31 December 2012. The signature of the new Memorandum of Understanding for the rest of the activities is an ongoing project. The Protocol provides means to create a network of services, integrated and in connection with the MED and a tool that contributes to the creation of a harmonized surveillance system in the European single market for the benefit of the health and safety of consumers and the public interests. This plan involved eighty three chambers of commerce across Italy. Under the Protocol there are also following activities carried out:

- Technology Platform for the national information system that manages controls: an information system has been set up to collect information on security controls and labeling. The information system is used to track and manage the control plan at national and local level and to avoid duplication of controls in this area.

- Operating procedures for the conduct of audits: operating procedures and related forms are defined for each supervision and monitoring arrangement in order to define a common reference framework for the conduct of audits and facilitate the role of officials in the chamber and ensure uniformity of behavior in the country.

- Training of personnel involved in the activities of the Chamber of Control: general education and studies on supervisory activities. The training provided useful insights for the Chamber personnel to carry out the checks in various areas.

- Communication plan dedicated to consumers and businesses: the project specific support for managing information programs directed to the consumer and information/training directed to economic operators who are potential recipients of control activities.

Ministry of Health: There are currently 220 inspectors on the field for REACH and CLP. The central surveillance will have about 40 inspectors.

The Ministry of Economic Development, Department for Enterprise and Internationalization, Directorate General for Market, Competition, Consumer, Supervision and Technical Regulations, Security and Compliance Division: There are currently 220 inspectors available in the domain of the REACH Regulation and CLP Regulation (classification, labeling, packaging). In the current situation of economic difficulty, it is necessary to implement the resources which have not been adequately sufficient, in order to prepare and ensure that the audit work is efficient and effective.

Circulation tobacco, Directorate for Excise: They have implemented tools and professional resources of the laboratory of analysis for the implementation of

controls, according to ISO standards, of the fire-prevention requirements of cigarettes.

The Ministry of Economic Development, Department for Enterprise and Internationalization, Directorate-General for Market, Competition, Consumer, Supervision and Technical Regulations, Security and Compliance Division: In this situation of economic difficulty, it is necessary to implement the resources which have not been adequately sufficient, in order to prepare and ensure that the audit work is efficient and effective.

6) Penalties for economic operators: each ***Chamber of Commerce*** established an Office for Penalties for the adoption of sanctions as a result of the administrative offenses. These offices shall examine the fines ticket provided by control bodies (Municipal Police, State Police, Finance etc.) for the violation of standards in various sectors, including security and products' compliances.

Ministry of Health: Penalties for economic operator are regulated by: Legislative Decree No. 133/2009 laying down "Sanctioning discipline for violation of the provisions of Regulation 1907/2006, which establishes principles and requirements for registration, evaluation, authorisation and restriction of chemical substances"; by Legislative Decree 186/2011 laying down "Discipline penalties for violation of the provisions of Regulation 1272/2008 on the classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation 1907/2006 "; by Legislative Decree 200/2011 laying down "Discipline penalties for violation of the provisions of Regulation 689/2008 on the export and import of dangerous chemicals" and by Legislative Decree 266/2006 laying down "Discipline penalties for violation of the provisions of Regulation 648/2004 on detergents".

National Administration Ministry of Health, Directorate General for Prevention: Penalties for economic operator are regulated by: Legislative Decree No. 14 of 13 September 2009 (article 16) in relation to violations of Article 67 of REACH Regulation 1907/2006 as amended by the Regulation 552/2009; by Legislative Decree No. 54 of 11 April 2011 implementing Directive 2009/48/EC on the safety of toys (article 31) and by Consumer Code of 6 September 2005 (article 206).

The Ministry of Economic Development, Department for Enterprise and Internationalization, Directorate General for Market, Competition, Consumer, Supervision and Technical Regulations, Security and Compliance Division: The rules on penalties are regulated by article 17 of national legislation No. 58/2010.

2.14.2. Customs

Ministry of Health created a monitoring network with all customs ports and airports by signing the Memorandum of Understanding between the Customs Agency and the Ministry of Health on 23 March 2007.

Control activities are in accordance with articles 27, 28 and 29 of Regulation 765/2008 and the Code of Consumption:

- Joint projects carried out: "Safe Christmas" 2007, "STOP, Only Safe Toys Please" 2008-2009, Conventions "For a safer market" 2010-2013, "Safe Toy"

2011-2102 on the strengthening of the audit - when imported - of the compliance of toys and electrical products suspected not to satisfy the requirements laid down in Union legislation on "Updating the procedural manual for customs inspections in the field of product safety" - December 2009.

- Joint participation on the preparation of "Guidelines for import controls in the area of product safety and compliance",

- Joint training activities on Directive 2009/48/EC (Toys Safety Directive) and in cooperation with Assogiocattoli and, in security and counterfeiting, with National Federation of Electrotechnical and Electronics (ANIE).

- Exchange of information for monitoring of market control activities in the product safety area.

- Participation in events organized by national associations. Periodic meetings of coordination on emerging issues.

- Convention "Secure Toy 2012" on the strengthening of the audit - import - the compliance of toys and electrical products suspected of not satisfying the requirements laid down in Union legislation.

- Joint actions for the strengthening of the surveillance of imports of products that may be harmful to the health and safety of consumers.

- Joint training activities and seminars.

- Revision of the procedural manual for customs inspections in the field of the product safety.

The Ministry of Economic Development, Department for Enterprise and Internationalization, Directorate General for Market, Competition, Consumer, Supervision and Technical Regulations, Security and Compliance of Products Division carried out a procedural work for the realization of the provisions in Tables A and B of the Prime Minister's Decree No. 242/2010, implementing article 4 of Law 350/2003 on the establishment of a single customs.

National administration responsible for Directive 1999/5/EC on Radio and Telecommunication Equipment was engaged in a direct exchange with some customs offices to receive news on non-conforming products and requiring the destination of the product in order to proceed with further checks involving the competent Territorial Inspectorates.

Ministry of Economic Development Department for the Enterprise and Internationalization signed the Convention MISE with Customs Agency ISS-IMQ for Toy Fair 2012 and in September 2012 they signed the Convention MISE with Customs Agency ISS-IMQ for Toy Fair 2013-2014.

Chambers of Commerce cooperates through specific agreements with other supervisory authorities (Customs Agency, the Financial Supervision), committed in the area of the same interests.

2.15. LITHUANIA

2.15.1. Market surveillance

1) Responsibilities and identity of authorities: There were no major adjustments in all Lithuanian market surveillance authorities. Responsibilities and identity of authorities are set out in the following legal acts:

- Law on the State Labour Inspectorate (Official Gazette, 2008, No. 137-5385).
- Law on the Weaponry Fund of the Republic of Lithuania under the Ministry of Interior of the Republic of Lithuania (Official Gazette, 1996, No. 71-1717; 2005, No. 67-2396, 2010 and No. 13-612).
- Regulation on the State Non Food Products Inspectorate under the Ministry of Economy (Official Gazette, 2000, No. 53-1558, 2006 and No.14-485).
- Regulation of the Communications Regulatory Authority (Official Gazette, 2004, No.131-4734).
- Regulation of the State Health Care Accreditation Agency under the Ministry of Health (Official Gazette, 2011, No. 112-5279).
- Regulation of the Lithuanian Metrology Inspectorate (Official Gazette, 2011; No. 69-3308). Regulation of the Lithuanian Maritime Safety Administration (Official Gazette, 2010, 77-3982).

2) Communication and coordination mechanisms between market surveillance authorities: In 2002 the State Labour Inspectorate and the State Non Food Inspectorate signed a cooperation agreement. In 2003 the Communications Regulatory Authority and State Non Food Products Inspectorate signed a cooperation agreement.

3) Procedure to follow-up complaints, monitor accidents and harm to health: Lithuanian market surveillance authorities have internal data bases. The State Non Food Inspectorate and the State Labour Inspectorate use the RAPEX system for registration and announcement of dangerous consumer goods. The Lithuanian Maritime Safety Administration participates in the GRAS-RAPEX system.

4) Strengthen market surveillance authorities' powers: The powers, which are granted to Lithuanian market surveillance authorities, are sufficient to fulfill their functions and tasks described in the legal acts mentioned in point 1. The provisions regarding strengthening of institution‘s powers will be foreseen in the Draft of Law on State Labour Inspectorate.

5) Strengthen market surveillance authorities' financial and human resources: The seminar on CE marking was held on 15 December 2011. The training on the use of ICSMS took place on 18-20 September 2012. The annual budget of the State Non Food Inspectorate in 2010 was 8.515.000 LTL and 118 people were employed. In 2012 number of personnel was reduced to 100 and the budget was reduced to 5.228.000 LTL.

The annual budget of the Lithuanian Metrology Inspectorate was reduced from 3.713.000 LTL in 2008 to 2.236.000 LTL in 2012 (number of personnel was reduced from 58 to 43). The reform of institutions supervising economic entities has been implemented in Lithuania since 2009. The main purpose of the reform is the effectiveness of supervisory institutions.

6) Penalties for economic operators: The penalty exemption is foreseen in the Administrative Code (Art. 30(2) of Official Gazette, 1992, No. 21-610, 2010 and No. 142-7257).

2.15.2. Customs

The Agreement on Cooperation between the State Non Food Products Inspectorate and the Customs was signed in 2002. The Agreement on Cooperation between the Communications Regulatory Authority and the Customs was signed in 2003. The Agreement on Exchange of Data between the State Non Food Products Inspectorate and the Customs was signed in 2004.

The Lithuanian Metrology Inspectorate provides the Customs with the relevant information.

The Agreement on Cooperation between the Lithuanian Maritime Safety Administration and the Customs is under the consideration.

The Agreement on Cooperation between the State Health Care Accreditation Agency under the Ministry of Health and Customs is under the consideration.

2.16. LUXEMBOURG

2.16.1. Market Surveillance

The authorities in Luxembourg are clearly identified and their responsibilities are defined. However a new law on the restructuring of ILNAS[20] foresees some changes in the responsibilities and identity of these authorities. The State Council has expressed its advice and the Ministry of Economy and Foreign trade is now waiting that the Parliament will start to work on the document.

The law of 20 May 2008 on the creation of ILNAS puts in place a communication and coordination structure. A national committee was created under the responsibility of ILNAS.

The new law on the restructuring of ILNAS clearly covers the procedure to follow-up, to monitor accidents and harm to health.

The ILNAS law of 20 May 2008 covers the obligation on strengthening of market surveillance authorities' powers. The new legislation on the restructuring of ILNAS is also strengthening the authorities' power.

At the moment a new legislation is on the way regarding strengthening of market surveillance authorities' financial and human resources. It will reinforce ILNAS'

[20] Institut luxembourgeois de la normalisation, de l'accréditation, de la sécurité et qualité des produits et services.

human resources. Personnel and financial reinforcement of the market surveillance department is an ongoing challenge.

The ILNAS law of 20 May 2008 covers the penalties for economic operators. The new legislation on the restructuring of ILNAS will strengthen this obligation, after its adoption.

2.16.2. Customs

A cooperation agreement, signed between market surveillance authorities, has been in place since 1998. To be in line with the Regulation 765/2008, the agreement was amended in 2011.