

Council of the European Union

> Brussels, 21 December 2017 (OR. en)

15950/17 ADD 10

Interinstitutional File: 2017/0353 (COD)

> ENT 276 MI 987 CONSOM 410 COMPET 895 UD 309 CHIMIE 110 COMER 132 CODEC 2130 IA 225

## PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	20 December 2017
То:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2017) 469 final PART 3/3
Subject:	<ul> <li>COMMISSION STAFF WORKING DOCUMENT REFIT EVALUATION</li> <li>Accompanying the document Proposal for a Regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council</li> </ul>

Delegations will find attached document SWD(2017) 469 final PART 3/3.

Encl.: SWD(2017) 469 final PART 3/3



EUROPEAN COMMISSION

> Brussels, 19.12.2017 SWD(2017) 469 final

PART 3/3

# COMMISSION STAFF WORKING DOCUMENT

# **REFIT EVALUATION**

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council

{COM(2017) 795 final} - {SWD(2017) 466 final} - {SWD(2017) 467 final} - {SWD(2017) 468 final} - {SWD(2017) 470 final}

#### ANNEX 5: UNION HARMONISATION LEGISLATION AND OVERVIEW OF APPLICABLE EU MARKET SURVEILLANCE PROVISIONS

#### 1. UNION HARMONISATION LEGISLATION

- (1) Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass;
- (2) Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles;
- (3) Council Directive 75/107/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers;
- (4) Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers;
- (5) Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products;
- (6) Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC;
- (7) Council Directive 92/23/EEC of 31 March 1992 relating to tyres for motor vehicles and their trailers and to their fitting (*valid until 31 October 2017*);
- (8) Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hotwater boilers fired with liquid or gaseous fuels;
- (9) Directive 94/11/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer;
- (10) Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery;
- (11) Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC;
- (12) Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors;
- (13) Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers;

- (14) Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;
- (15) Directive 2004/52/EC of the European Parliament and of the Council of 29 April 2004 on the interoperability of electronic road toll systems in the Community;
- (16) Regulation (EC) No 552/2004 of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network (the interoperability Regulation);
- (17) Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents;
- (18) Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC;
- (19) Directive 2005/64/EC of the European Parliament and of the Council of 26 October 2005 on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability and amending Council Directive 70/156/EEC;
- (20) Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 relating to emissions from air conditioning systems in motor vehicles and amending Council Directive 70/156/EEC;
- (21) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery;
- (22) Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC;
- (23) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;
- (24) Directive 2007/45/EC of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for pre-packed products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC;
- (25) Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles;
- (26) Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger

and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information;

- (27) Directive 2008/2/EC of the European Parliament and of the Council of 15 January 2008 on the field of vision and windscreen wipers for wheeled agricultural or forestry tractors (Codified version);
- (28) Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community;
- (29) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;
- (30) Directive 2009/34/EC of the European Parliament and of the Council of 23 April 2009 relating to common provisions for both measuring instruments and methods of metrological control;
- (31) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys;
- (32) Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products;
- (33) Regulation (EC) No 78/2009 of the European Parliament and of the Council of 14 January 2009 on the type-approval of motor vehicles with regard to the protection of pedestrians and other vulnerable road users, amending Directive 2007/46/EC and repealing Directives 2003/102/EC and 2005/66/EC;
- (34) Regulation (EC) No 79/2009 of the European Parliament and of the Council of 14 January 2009 on type-approval of hydrogen-powered motor vehicles, and amending Directive 2007/46/EC;
- (35) Regulation (EC) No 595/2009 of the European Parliament and of the Council of 18 June 2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC;
- (36) Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor;
- (37) Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer;
- (38) Regulation (EC) No 1222/2009 of the European Parliament and of the Council of 25 November 2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters;

- (39) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products;
- (40) Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel;
- (41) Directive 2010/30/EU of the European Parliament and of the Council of 19 May 2010 on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products;
- (42) Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment;
- (43) Regulation (EU) No 1007/2011 of the European Parliament and of the Council of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products and repealing Council Directive 73/44/EEC and Directives 96/73/EC and 2008/121/EC of the European Parliament and of the Council;
- (44) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment;
- (45) Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC;
- (46) Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE);
- (47) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products;
- (48) Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles;
- (49) Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles;
- (50) Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles;
- (51) Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC;
- (52) Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses;

- (53) Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels;
- (54) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility;
- (55) Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments;
- (56) Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments;
- (57) Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts;
- (58) Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres;
- (59) Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits;
- (60) Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC;
- (61) Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment;
- (62) Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC;
- (63) Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006;
- (64) Regulation (EU) No 540/2014 of the European Parliament and of the Council of 16 April 2014 on the sound level of motor vehicles and of replacement silencing systems, and amending Directive 2007/46/EC and repealing Directive 70/157/EEC;
- (65) Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC;

- (66) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC;
- (67) Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC;
- (68) Directive (EU) 2016/802 of the European Parliament and of the Council of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels.
- 2. OVERVIEW OF EU MARKET SURVEILLANCE PROVISIONS APPLICABLE TO HARMONISED PRODUCTS

MARKET SURVEILLANCE PROVISIONS IN EU LEGISLATION			
MARKET SURVEILLANCE MEASURES AND STRUCTURES	REGULATION (EC) No 765/2008	SECTOR LEGISLATION	
MARKET SURVEILLANCI	E PROCEDURES		
Obligations of economic operators vis-à-vis market surveillance authorities	No	Yes	
Cases in which obligations of manufacturers apply to importers and distributors	No	Yes	
Identification of economic operators	No	Yes	
Definition of formal non-compliance	No	Yes	
Procedures for dealing with products presenting a risk at national level	No	Yes	
Market surveillance measures	Yes	No but legislation refers to Regulation (EC) No 765/2008	
Products presenting a serious risk			
Restrictive measures			
Exchange of information — Rapid Information System			
General information support system (ICSMS)			
Union safeguard procedure	No	Yes	
Procedure for compliant products which present a risk to health and safety	No	Yes	
MARKET SURVEILLANC	E STRUCTURES		
General requirements for market surveillance			
Information obligations about market surveillance authorities	Yes	No but legislation refers to Regulation	
Obligations of the Member States as regards organisation of market surveillance	(EC) No 765/20		

MARKET SURVEILLANCE PROVISIONS IN EU LEGISLATION		
MARKET SURVEILLANCE MEASURES AND STRUCTURES	REGULATION (EC) No 765/2008	SECTOR LEGISLATION
Principles of cooperation between the Member States and the Commission		
Sharing of resources		
Cooperation with the competent authorities of third countries		
Controls of products entering the Union market		
Release of products		
National measures on products entering the Union market		
Financing provisions for market surveillance	Yes	No
Penalties	Penalties for economic operators applicable to infringements of the provisions of the Regulation	Penalties for economic operators applicable to infringements of the provisions of sector legislation

#### ANNEX 6: FEEDBACK ON MARKET SURVEILLANCE IN THE EU [SWD(2014)23]

#### 1. CHALLENGES FACING MARKET SURVEILLANCE AUTHORITIES

#### EQ17: What are the main challenges facing market surveillance authorities?

Market surveillance is a Member State responsibility, although the Commission has an important overall monitoring and coordination role. Effective market surveillance and regulatory enforcement is a crucial mechanism for ensuring the efficient and effective implementation of IM legislation for industrial products. It is vital for ensuring product safety and health and for promoting fair competition and a level playing field among economic operators. In order to strengthen the current approach to market surveillance, the EU adopted Regulation 765/2008 setting out common market surveillance rules and the Commission has proposed a Regulation on Market Surveillance as part of the wider Product Safety and Market Surveillance Package (PSMSP).

As noted earlier, market surveillance is inherently challenging and is considered by many stakeholders (e.g. 60.6% of NBs responding to our survey) to be the most problematic part of the IM regime for industrial products. Indeed, the impact assessment accompanying the PSMSP highlights a number of challenges, which have also been confirmed by the research undertaken for this evaluation.

A first challenge is the relatively **high levels of non-compliant products** entering the market, although instances of non-compliance often relate to minor administrative irregularities rather than to serious breaches of the essential requirements. There is evidently a balance to be struck between preventing non-compliant products from entering the market and avoiding the imposition of unreasonable requirements on responsible economic operators. It is also reported that there are relatively **few withdrawals of non-compliant products** from the market, although the RAPEX information systems has helped to raise awareness of high-risk products. However, the 2006 public consultation on the New Legislative Framework (NLF) found that 87% of operators considered there to be unfair competition due to the presence of non-compliant products on the internal market<sup>1</sup>. Evidence from a number of evaluations and impact assessments suggests that non-compliant products account for a sizeable share of the market in certain sectors. This is confirmed in data provided by market surveillance authorities<sup>2</sup>.

For example, the impact assessment<sup>3</sup> on the proposed "Radio Equipment Directive" to replace the R&TTE Directive cited evidence from European Market Surveillance Authorities (MSAs) that presently between as little as an estim ated 28% and 56% of products were fully compliant with the essential requirements. Administrative compliance has been estimated at an even lower level by MSAs at about 20%. In the case of the Ecodesign Directive, noncompliance was estimated to be 10-  $20\%^4$ . In other areas (e.g. Gas Appliances, Personal protective equipment) the existing studies indicate non-compliance levels of no more than 5- $10\%^5$  and there are also cases – such as explosives – where, according to the relevant

<sup>1</sup> EC (2012), Product Safety and Market Surveillance Package - COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=swd:2013:0033(51):FIN:EN:PDF

<sup>2</sup> EC (2012), Commission Staff Working Document, Annexes to the Impact Assessment, <u>http://eur-</u>

lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2013:0033(52):FIN:en:PDF

<sup>3</sup> Proposal for a Directive of the European Parliament and of the Council on the harmonisation of laws of the Member States to the making available on the market of radio equipment

<sup>4</sup> Evaluation of the Ecodesign Directive (2009/125/EC) - Final Report

<sup>5</sup> Impact assessment study on the review of the Gas Appliances Directive 2009/142/EC

evaluation study<sup>6</sup>, there are very few cases of non-compliance.

However, this is also a possible illustration of authorities giving a higher priority to products more directly linked to public safety issues. Estimates from market surveillance authorities and enterprises collected in 2006 also ranged from 1% for recreational craft to 30% for the Electrotechnical sector and even up to 50% for luminaires. Similar findings were obtained in three market surveillance campaigns carried out by the Administrative Cooperation group (ADCO) for the implementation of the Electro-magnetic Compatibility Directive focusing on Energy Saving Lamps, Power Tools and Consumer Entertainment Electronic Products. The level of technical non-compliance was 23% for the Energy Saving Lamps, 20% for the Power Tools and 50% for the Consumer Entertainment Electronic Products while according to the ADCO machinery NOMAD study around 80% of products do not comply with noise requirements.

A second challenge, related to the first, is the difficulty in **ensuring the traceability of products**, which was stressed by a number of interviewees, so that market surveillance authorities can obtain technical documentation not only at the point when products are placed on the market but for up to 10 years following their placement on the market. The limited traceability of products and of manufacturers strongly hinders market surveillance authorities in carrying out their work and improvements in this area would help to strengthen the efficiency and effectiveness of MSAs. However, it should be noted that economic operators were not generally favourable towards traceability requirements, and in particular, were against the introduction of requirements to register in databases. A major EU industry compliance and for producing the DoC to achieve presumption of conformity. Traceability has become a religion and imposes unnecessary administrative burdens on economic operators, such as compulsory registration schemes and the requirement to put the address of the responsible economic operator on the label."

A market surveillance authority in the UK commented that concerns about the administrative burdens of registration schemes extend beyond industry to some public authorities. "The proposed new registration scheme under the new R&TTE is intended to improve the traceability of products. However, it risks causing a bigger divide between good and bad providers; by creating more hoops to jump through, it will discourage some economic operators from complying and could also give greater competitive advantage to noncompliant providers".

A Product Contact Point in **Sweden** pointed out that, although there has been a lot of discussion about traceability in the context of the Alignment Package, its value and importance depends on the type of product concerned, the directive or regulation in question and whether it is a professional or a consumer product. "When we refer to professional products where economic operators are known to one another, the extent to which there is really a need for traceability requirements should be reconsidered since this imposes unnecessary administrative requirements".

A third challenge is the **difference in approaches taken to market surveillance in different countries**, for example, how likely MSAs are to carry out testing themselves, as opposed to requesting technical information from economic operators. Such differences may undermine the internal market since there could be variations for economic operators in their

<sup>6</sup> Evaluation on dg enterprise and industry legislation – Cosmetics and Explosives Directives

experiences, for instance, the type and frequency of requests for information from market surveillance authorities, the likelihood of having products tested, etc. Different approaches to market surveillance often reflect different levels of resources and technical expertise available to MSAs in each country; some stakeholders were of the view that the level of resources and expertise was insufficient in some countries.

One MSA in **Sweden** noted that "We test a broad selection of products ourselves and do not only ask manufactures to submit papers on the use of products. We also test a broad selection of products from different geographic origins both within and outside the EU. We do identify dangerous products and even where products are generally compliant, remarks are made for three-quarters of products tested". Another MSA in **Romania** noted that market surveillance needs to be "highly coordinated and capable of reacting rapidly. However, market surveillance has not kept pace with developments in the Union's regulatory framework, which could be overcome through the use of an "intelligent" model. This means that "random checking" will not be mathematically random, but will instead be focused on a risk-based approach and the identification of potential problem products and economic operators that have previously been non-compliant. Wholesalers, distributors etc. who are known by experience to comply with the rules may therefore expect a fewer inspection visits".

Encouragingly, stakeholders reported that market surveillance had improved and become more consistent across different Member States through the measures included in the NLF and, in particular the common rules on market surveillance set out in Regulation 765/2008. Some Member States (e.g. Greece, Ireland, Slovenia) had made significant changes to their market surveillance systems, such as the creation of national market surveillance authorities and the development of market surveillance programmes, as a direct response to the requirements of Regulation 765/2008.

#### **Research Findings (RFs)**

- (RF60) Market surveillance is considered to be the weakest part of the implementation system, partly due to the inherently difficult nature of the task and in part due to varying levels of resources and technical expertise available in different countries. (Stakeholder interviews; Survey of NBs)
- (RF61) There are high levels of non-compliance for some products, low levels of product withdrawals and a need to strengthen the traceability of products. However, there is the need for MSAs to differentiate between minor instances of non-compliance with administrative requirements and serious instances of non-compliance with essential safety requirements. (Data from previous studies; Stakeholder interviews)

# 2. CO-OPERATION AND INFORMATION SHARING BETWEEN MARKET SURVEILLANCE AUTHORITIES

## EQ18: How effective is the co-operation between market surveillance authorities?

Through the evaluation, we also assessed the extent to which mechanisms and tools put in place to facilitate cooperation between market surveillance authorities and information sharing are working effectively, notably the Rapid Alert Information System (RAPEX) and the "ICSMS" tool (Information and Communication System for Market Surveillance.

Regulation 765/2008 includes a reference in the Regulation to the RAPEX system and has highlighted the importance of this exchange information mechanism for market surveillance in the Single Market. The report on the implementation of Regulation 765/2008 provides feedback on the added value of RAPEX. "Reference to the RAPEX system in the Regulation

has extended 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 etc.). This has contributed to the protection of workers and the environment, although the total number of new notifications has been limited during the first two years of implementation".

However, a market surveillance authority in **Ireland** noted that "RAPEX has not led to many notifications for harmonised products for professional users and the ICSMS has been more useful in practice". Whereas RAPEX was viewed as being useful in informing market surveillance authorities and the Commission about high-risk products, and the database is useful for reporting purposes on products presenting serious risks, **ICSMS**<sup>7</sup>, the general information support system for market surveillance also has an important contribution in ensuring that there are mechanisms in place for exchanging information between market surveillance authorities, joint working and for virtual communication and cooperation.

The tool provides a single portal containing information on specific products (product description, test results, in cases of non-compliance identified any remedial measures taken etc.). Two of the actions set out in the Multi-annual plan for market surveillance refer to ICSMS (Action 2: Maximise the benefits of ICSMS and Action 3: Create synergies between GRAS-RAPEX and ICSMS). A small number of stakeholders referred to ICSMS during the interview programme.

A market surveillance authority in **Germany** stressed the importance of the need for greater synergies between RAPEX and ICSMS. "ICSMS is a great operational tool to communicate with different market surveillance authorities in other EU Member States. Among the advantages of using the system are that it is available in all languages across EU28. Documents can be uploaded and although there is no automatic translation of all documents, most phrases are translated. This solves one of the practical difficulties in ensuring effective market surveillance - language problems can be a barrier to finding out about dangerous products and for avoiding duplication of effort between market surveillance authorities in different countries".

ICSMS was not seen as duplicating RAPEX but rather complementing it. It was pointed out that it is only available in EN and it does not provide a tool for communicating and collaborative working between market surveillance authorities, which ICSMS does.

The need to examine the scope to converge different databases on market surveillance that feed into Member State reporting requirements to the Commission was highlighted. For example, a market surveillance authority in **Belgium** noted that "Each year, Member States have to prepare a report on market surveillance carried out and set out the plan for the coming year. There are several databases that are useful, such as Circa, RAPEX, ICSMS. The Commission should investigate whether merging of databases is possible and should study the value added of each database".

<sup>7</sup> 

ICSMS provides an internet-based platform for the comprehensive exchange of information between all the market surveillance bodies. The tool has an internal area for the use of market surveillance authorities that can also be used by customs authorities and EU officials.

#### **Research Findings (RFs)**

- (RF62) RAPEX and ISCSMS are viewed as useful in informing market surveillance authorities. (Interviews of MSAs)
- (RF63) There is scope to increase the complementarity and synergy between RAPEX and ISCMS. (Interviews of MSAs)

#### 3. **RISK-BASED AND SYSTEMS-BASED AUTHORITIES**

The proposed Market Surveillance Regulation is based on a risk-based approach to market surveillance (of both harmonised and non-harmonised products). One of the criticisms made by stakeholders is that there is no definition in the Regulation of what constitutes risk, and the criteria to assess it. A market surveillance authority in **Germany** commented that "Market surveillance authorities should focus on checking non-conformity, since this is easier to perform against the regulatory requirements. If instances of product non-conformity are identified, and it is judged that these are likely to lead to a risk or to a serious risk, then these products should be alerted through the RAPEX system. Although they were in favour of having common elements in Union harmonisation legislation built into a horizontal regulation, market surveillance should continue to be based on an assessment of product compliance with IM regulations.

However, the report on the implementation of Regulation (EC) No 765/2008 published in February 2013 as part of the PSMSP asserted that progress has already been made in the development of a **risk assessment methodology**. It was noted that the existing RAPEX Guidelines already provide for the risk assessment methodology for consumer goods, and are an important reference point for Member States. Moreover, in 2011, the Commission set up a Risk Assessment Task Force composed of Member States' experts whose role was 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.

Through the research, we reviewed good practice in carrying out market surveillance (given the broad focus of our study, only selected examples are possible). In the **Netherlands**, a systems-based approach to market surveillance based on risk has been adopted. This was recognised by interviewees in other countries such as **Latvia**, as being an interesting, and potentially transferable example. An explanation as to how the system works is provided below:

# Table 6-1: A systems-based and horizontal approach to market surveillance and regulatory enforcement<sup>8</sup>

In the Netherlands, the government adopted the "Vernieuwd Toezicht" (Renewed Surveillance Programme) in 2008. The aim is to strengthen the efficiency and effectiveness of market surveillance activities by fostering better relationships with economic operators and by raising awareness among enterprises about their legal obligations under product safety and environmental legislation.

A distinction is made between (i) horizontal enforcement and (ii) system-based enforcement. These two different types of enforcement are already being applied by some government inspections agencies. *Horizontal enforcement* involves combining regulatory enforcement with horizontal activities and support actions for enterprises.

Implementing a horizontal approach refers to the development of mutual cooperation between

<sup>8</sup> Source: Systeemtoezicht en Horizontaal Toezicht, conceptleidraad voor de Rijksinspecties, Begrippen en randvoorwaarden, December 2012 http://www.inspectieloket.nl/vernieuwing\_toezicht/programma\_systeemtoezicht/

government and society. Horizontal enforcement is based on building mutual trust and a working relationship between government and economic operators based on the development and implementation of quality management systems to strengthen regulatory compliance. The agreements are set out in a covenant based on a partnership-based approach which is published on the inspection agency's website. The provision of relevant information, the exchange of knowledge, and if relevant the monitoring of business activities are sufficient to consolidate compliance.

System enforcement focuses on the enforcement of quality and assurance systems and more specifically on the development of a strategy for companies to set up robust regulatory compliance procedures, documentation to measure the results achieved, interventions committed and the defects. Surveillance in general takes place on the basis of periodical (administrative) inspections. Surveillance is not aimed at checking whether individual regulations have been complied with. The confidentiality of the government in the enterprise is still based on inspection.

The application of horizontal and system-based approaches means that that one agency may apply the horizontal system and another may apply a system-based approach, while others adopt elements of both approaches. Through the application of a horizontal and system-based approach, the inspection can reduce the administrative burdens for enterprises/institutions which take their responsibility and do not injure the confidentiality received from the government. In addition the surveillance institutions are in the position to focus their capacity to enterprises performing not correctly.

An example of a surveillance authority that applies the system approach is the Food and Consumer Product Safety Authority (Voedsel en Warenautoriteit). The systems-based approach is targeted at larger manufactures and EU importers based on the following criteria: position in the value chain (manufacturer, EU importer or major distributor); they must have a relatively large share of the market;, regularly included on RAPEX or often having defects found during product inspections; their willingness to invest in strengthening business-processes aimed at ensuring the safety of products.

#### **Research Findings (RFs)**

- (RF64) There is a need for better definition and clarification of risk and how to assess it in the proposed Market Surveillance Regulation, building on the proposed risk assessment methodology in the PMSP. (Analysis of legal text; Interviews of MSAs)
- (RF65) There is a need for guidance on the relative merits of the alternative approaches to market surveillance and the circumstances under which each type of approach should be adopted. (Analysis of legal text; Interviews of MSAs)

# ANNEX 7: REVIEW AND ASSESSMENT OF MARKET SURVEILLANCE ON NON-FOOD PRODUCTS IN THE EU

#### **1. INTRODUCTION**

In the framework 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, Member States must periodically review and assess the functioning of their market surveillance activities. Article 18(6) of the Regulation requires such reviews to be carried out at least every four years and stipulates that the results are to be communicated to the other Member States and the Commission and made available to the public.

As Regulation (EC) No 765/2008 has been applicable since 1 January 2010, the first round of reviews and assessments communicated by the Member States relate to market surveillance activities carried out between 1 January 2010 and 31 December 2013.

In order to facilitate their compilation and transmission of the information, the Commission prepared – with the help of the members of the Internal Market for Products Expert Group, IMP-MSG – a template that Member States could use to structure the relevant information. Among other things, the template establishes a reference list of 29 sectors falling within the scope of the Regulation that should be included in the Member States' reviews and assessment (hereinafter 'the reference list of sectors').<sup>9</sup> Market surveillance carried out under Directive 2001/95/EC (General Product Safety Directive or GPSD) could be optionally included. At the same time, the template left Member States free to determine the relevant criteria for the assessment of the different (general/sectoral) market surveillance activities.

The reviews and assessments prepared by each Member states are available on the following page (under the section "List of national reviews and assessments of the functioning of market surveillance activities"): <u>http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index\_en.htm</u>. The reports have also been published by Member States<sup>10</sup>.

This annex gives a combined overview of the Member States' own reviews and the assessments of market surveillance activities, and attempts to present main findings on the implementation of the EU requirements for market surveillance.

In particular, the remainder of the document is structured as follows:

- (a) A snapshot of the information provided by each Member State by explaining the approach taken when collecting and assessing the functioning of market surveillance activities, the general organisation of market surveillance and the resources available to it, the sectors covered by the national report and the conclusions drawn.
- (b) The main findings on the implementation of the Regulation at national level in the 2010-2013 period and points to challenges faced. Finally it contains some considerations on the results of this first application of Article 18(6) of the Regulation.

<sup>9</sup> The template also clarifies that market surveillance activities conducted under REACH and CLP Regulations fall within the scope of Regulation 765/2008. However, since they are already the subject matter of specific reports available to the public, they could be excluded from the reviews and assessment carried out pursuant to Article 18(6) of the Regulation.

<sup>10</sup> However at the time of writing the Commission is still awaiting for confirmation of publication by one Member State.

(c) A more detailed analysis of information provided by Member States for a specific sector (Toys).

# 2. OVERVIEW AND ASSESSMENT

All Member States, have communicated to the Commission their review and assessments of market surveillance activities during the 2010-2013 period. The majority of Member States chose to follow the common template prepared by the Commission, while Germany, Croatia, Lithuania, the Netherlands and the UK chose a different format for their report.

Overall, most Member States provided a considerable amount of data and other information on their activities. This section summarises the information provided by each Member State by organising it according to the following scheme:

## General market surveillance activities

- <u>General organisation</u>: this part sums up the way market surveillance responsibilities are distributed among different authorities and the main tools for cooperation and coordination between them, as well as with customs in a given Member State. The information contained in Member States' reports according to Article 18(6) of the Regulation should be integrated with the information already provided in national market surveillance programmes<sup>11</sup> and in the Report on the implementation of Regulation (EC) No 765/2008<sup>12</sup>.
- <u>Resources</u>: this part indicates the overall resources made available to market surveillance, if mentioned in Member States' reports.
- <u>Own assessment:</u> this part contains each Member State's own assessment of the distribution of responsibilities, cooperation and coordination between national authorities, as well as of the total resources available to them.

## Market surveillance in specific sectors

- <u>Coverage:</u> this part explains how many of the 29 sectors (plus 1 optional sector) that the Commission recommended to include in the national reviews and assessments are covered in each Member State's report.
- <u>Distribution of resources:</u> this section indicates those sectors in which a given Member State concentrates most of the available resources and those where resources are lacking according to the national report.
- <u>Own assessment:</u> this part summarises each Member State's own assessment of the functioning of market surveillance sectoral activities in the 2010-2013.

# 2.1 Belgium

## General market surveillance activities

General organisation: Belgium refers to the information on the general organisation of market

<sup>11</sup> See the section "National market surveillance programmes " on the following page: <u>http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index\_en.htm</u>

<sup>12</sup> COM(2013)77.

surveillance provided in the national programmes. \_Market Surveillance pursuant to Regulation (EC) No 765/2008 is handled at national level (with voluntary contributions from individual regions) and is carried out by several federal government departments, agencies and institutes. The majority of products covered by the harmonised European legislation fall under the responsibility of the Federal Public Service (FPS) for Economy, SMEs, Self-employed and Energy.

FPS for Economy, SMEs, Self-	Toys
employed and Energy	Machinery
	Cableway installations
	Personal protective equipment
	Lifts
	Equipment for use in explosive atmospheres
	Pressure equipment
	Pressure receptacles
	Household appliances measuring energy consumption
	Central-heating boilers
	Gas appliances
	Low voltage electrical equipment
	Electromagnetic compatibility
	Non-automatic weighing instruments
	Explosives for civil use
	Pyrotechnic articles
	Construction products
	Pre-packaged products
FPS Health, Food Chain Safety	Chemical products
and the Environment	Cosmetic products
	Electrical and electronic equipment
	Noise emissions of equipment used outdoors
Scientific Institute for Public Health	In vitro diagnostic medical devices
FPS Finance	Customs activities
Federal Agency for Medicines and	Pharmaceutical products
Health Products	Medical devices
	Active implantable medical devices

Table 7-1: Distribution Market Surveillance Responsibility in Belgiun	1
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FPS Mobility and Transport	Motorised vehicles Transportable pressure equipment Recreational craft Railway systems Marine equipment
Federal Agency for the safety of the Food Chain	Fertilisers
Belgian Institute for Postal services and Telecommunications	Radio equipment and telecommunications terminal equipment Electromagnetic compatibility Eco-design and energy labelling
Federal Agency for Nuclear Control	Medical devices and similar products Radiopharmaceuticals Dosimeters

In cases where several authorities have responsibility for a particular area, the area is assigned to the authority with primary responsibility.

There is no national body to coordinate market surveillance activities but for the purpose of Article 18(5) (national programmes) and Article 22 (RAPEX) of the Regulation, a coordinator role has been assigned to the Interministerial Economic Commission (IEC) within the Federal Public Service for Economy for the exchange of information.

Overall resources: Belgium does not provide this resource information.

<u>Own assessment:</u> The report does not provide an assessment of the effectiveness or efficiency of the general market surveillance organisation.

## Market surveillance in specific sectors

<u>Coverage:</u> The Belgian report covers most sectors indicated in the reference list (including non-harmonised consumer products falling under the GPSD) with the exception of medical devices, cosmetics, transportable pressure equipment, cableways, pyrotechnics, explosives for civil uses, recreational crafts and marine equipment.

<u>Distribution of resources:</u> Belgium provides information on resources for the period 2010-2013 on market surveillance for some of the various federal government departments and product sectors.

Resources for market surveillance for the FPS Economy decreased from 1.1 million EUR in 2010 to 0.8 million EUR in 2013, coupled with a decline in the number of inspectors from 11 to 7.5 full-time equivalent unit (FTEs) staff.

The FPS Public Health, Food Chain Safety and Environment is responsible for enforcing the national Products Standards Act of 21 December 1998, checking a wide range of consumer products for the possible presence of dangerous substances. A yearly budget of 425 000 EUR (not including staff members) has been allocated for market surveillance, with 16 FTEs' staff

availability of which 13 inspectors.

The information on the amount of resources dedicated to market surveillance by the FPS Mobility shows an increase in the period 2010-2013 from around 133 000 EUR to 206 000 EUR, with an increase in FTE availability from 1 to 2.5 (1.5 FTEs for inspectors).

The report stipulates allocation of resources on market surveillance on electrical appliances and equipment falling under the low voltage directive (0.7-0.5 mln EUR; 0.6-0.4 staff), appliances burning gaseous fuels (102 000-217 000 EUR; 1.0 staff) and eco-design and energy labelling with a budget of 73 000 EUR over 2013 and 1 FTE for staff available.

Other indicated sectors are electrical equipment with a budget of 40 000 EUR over 2013 and 0.7 FTEs, electrical equipment falling under the Electromagnetic Compatibility Directive (48 000-40 000 EUR; 0.7 staff) and efficiency requirements for hot-water boilers (26 500 EUR-28 600 EUR; 0.2 staff). Coverage also extends to the construction products sector where 1.5 FTEs are allocated to market surveillance activities

<u>Own assessment</u>: The Belgian report provides information on enforcement and communication activities carried out in most sectors. The results of some inspection campaigns can be found on the responsible authorities' websites. In general the report does not provide for an assessment of the effectiveness or efficiency of these sector-specific activities.

## 2.2 Bulgaria

## General market surveillance activities

<u>General organisation</u>: Market surveillance authorities within the meaning of Regulation (EC) No 765/2008 are the following institutions:

- the State Agency for Metrological and Technical Supervision (DAMTN), which carries out market surveillance activities for products covered by the New Approach directives (except Medical Devices), for eco-design requirements, for energy-related products, on waste from electrical and electronic equipment and restriction of hazardous substances;
- the Consumer Protection Commission (KZP), which is the specialized state authority in Bulgaria dealing with the problems of consumer protection. It is also one of the main internal market surveillance authorities. Its main activities relate to the surveillance of the safety of general products and services on the Bulgarian market, the protection of the main consumer rights, trade practices and methods of sale, etc. In addition KZP is the Bulgarian contact point for the RAPEX system;
- the Executive Agency for Medicines (IAL) to which are assigned the market surveillance activities for medical devices;
- the Regional Health Inspectorates (RZI) responsible for cosmetics and chemicals;
- the Bulgarian Food Safety Agency (BABH), responsible for fertilisers;
- the Technical Control Inspectorate (KTI) responsible for agricultural and forestry machinery and

- the Regional Inspectorates for the Environment and Water (RIOSV) responsible for surveillance of fluorinated greenhouse gases and ozone depleting substances.

The market surveillance authorities function according to the distribution of competences between four ministries, namely the Ministry of the Economy and Energy, the Ministry of Health, the Ministry of Agriculture and Food and the Ministry of the Environment and Water.

Coordination and exchange of information between market surveillance authorities in Bulgaria takes place by means of a Council established by a governmental act in 2005.

<u>Overall resources</u>: Bulgaria provides information on the resources of the two major market surveillance authorities. From the total budget of DAMNT between 2010 and 2013, about 2.3 million EUR were dedicated each year to market surveillance related to the New Approach directives<sup>13</sup> (except for Medical Devices), eco-design and waste of electrical and electronic equipment . Furthermore, the authority employed each year 275 full-time equivalent unit (FTE) staff (out of which about 150 inspectors). During the same period, the market surveillance budget of KZP decreased from 1 to 0.7 million per year<sup>14</sup> and the authority employed about 130 FTEs for staff (of which about 110 inspectors).

<u>Own assessment</u>: Bulgaria assesses the functioning of the main market surveillance authorities (see section below). No specific assessment of general organisation (e.g. cooperation and coordination) is provided.

#### Market surveillance in specific sectors

<u>Coverage</u>: The Bulgarian report covers all sectors in the reference list, except cosmetics, efficiency requirements for hot-water boilers and marine equipment, as well as non-harmonised consumer goods. It also includes, leather labelling, crystal glass, food-imitating products, packaging, liquid fuels and wheeled tractors.

<u>Distribution of resources</u>: One third of DAMNT financial resources were dedicated to market surveillance of products put into operation (industrial use) such as pressure equipment, transportable pressure equipment, machinery, lifts, and cableways; about 25% was allocated to market surveillance of products placed on the market like toys, personal protective equipment, construction products, noise emissions, ATEX, pyrotechnics, civil explosives, radio equipment and telecommunications terminal equipment, restriction of hazardous substances and waste from electrical and electronic equipment, eco-design; about 13% to market surveillance of measuring instruments.

More than two-thirds of the resources available for market surveillance to KZP were dedicated to the enforcement of the Packaging Directive<sup>15</sup> (0.3-0.4 million EUR per year) and the safety of non-harmonised consumer products (0.2-0.3 million EUR per EUR), followed by leather, textile and energy labelling (respectively up to 80 000, 70 000 and 60 000 EUR/year during the reporting period).

<u>Own assessment</u>: according to the Bulgarian report in the period 2010-2013 DAMTN succeeded in achieving the general objectives laid down in the sectoral programmes by applying the requirements of Regulation (EC) No 765/2008. On the other hand, difficulties

<sup>13</sup> The budget also covers inspections of industrial equipment during use, as well as quality control of liquid fuels.

<sup>14</sup> Correspondingly, the share of KZP's resources dedicated to market surveillance went down from 62% to 40%.

<sup>15</sup> Directive 94/62/EC.

experienced in market surveillance relate in particular to the lack of information in tracing products back along the distribution chain to the producer or the responsible economic operator, lack of cooperation by certain economic operators, e-commerce challenges, high cost of tests in some sectors, unavailability of expert staff to carry out assessment of compliance in certain sectors (e.g. personal protective equipment).

KZP is also considered to have achieved good results, despite an insufficient number of staff having to deal with an increasing volume of activities. The same inspectors carry out market surveillance activities in all sectors falling within the competence of the KZP. A lack of material and financial resources hampers work relating to the outsourcing of laboratory analyses establishing product compliance with safety requirements or the conformity and reliability of information provided by economic operators in labels or advertising messages.

The Bulgarian report contains information on the way the other authorities work in their respective areas. A specific assessment of their activities is not systematically provided.

## 2.3 Czech Republic

## General market surveillance activities

<u>General organisation</u>: market surveillance in the Czech Republic is carried out by various central government bodies – authorities subordinated to specific ministries with specific powers. Coordination among authorities and with customs is ensured by bilateral agreements.

The report from the Czech Republic does not provide an overview of the general organisation of market surveillance at national level. On the other hand, it refers to the detailed annual reports prepared by some of these authorities, notably by the Trade Inspectorate Authority (CTIA), which assumes overall responsibility for the vast majority of the product areas mentioned in the reference list of sectors (medical devices, toys, protective equipment, aerosol, machinery, lifts, noise emissions, equipment for use in potentially explosive atmospheres, gas appliances, electromagnetic compatibility, low voltage electrical products and appliances, radio equipment and telecommunications terminal equipment, measuring instruments, recreational crafts, as well as timber, batteries and novelty lighters.

<u>Overall resources</u>: the total national resources for market surveillance cannot be estimated because the budget of the relevant authorities does not distinguish between funds earmarked for market surveillance and other tasks. The same can be said for staff. However as CTIA carries out almost exclusively market surveillance its total budget<sup>16</sup> (on average around 9.5 million EUR per year between 2010 and 2013) provides a good indication of resources for market surveillance for most sectors.

The total number full-time equivalent units (FTE) for staff employed in market surveillance was between 940 and 1090 per year<sup>17</sup>, out of which between 415 and 445 inspectors. Resources decreased over the 2010-2013 period.

Own assessment: According to the national report the functioning of market surveillance in

<sup>16</sup> The figure excludes the wages of personnel not directly involved in markets surveillance.

<sup>17</sup> Between 415 and 460 staff was employed by CTIA, 414-479 for the Environmental Inspectorate (chemicals and consumer products under the GPSD), 50-60 people worked for the Energy Inspectorate (competent for the area of ecodesign and energy labelling), 47 for the Health Ministry (cosmetics, products for children up to three years and food contact materials), 35 for the Rail Authority (interoperability, simple pressure vessels, transportable pressure equipment and cableways),5 for the Arms and Ammunition Authority (pyrotechnics, firearms and ammunitions) and 0.5 or the Mining Authority (civil explosives and mining machinery.

the Czech Republic can generally be considered effective. The level of cooperation between surveillance authorities is very good. In areas where the powers of certain supervisory authorities overlap, rules are in place to ensure effective coordination of the surveillance.

Individual surveillance authorities carry out specifically-focused inspections, the results of which are then used both to set priorities for further surveillance activities and to enhance the efficiency of surveillance authorities' activities. Various surveillance authorities keep their own databases of monitored products, and this undoubtedly has a positive impact on the overall success of surveillance activities.

The representatives of the various market surveillance authorities regularly attend European and international meetings; relevant market surveillance information is then shared with other surveillance authorities.

The main problems encountered by surveillance authorities relate to:

- The persistent problem lack of funds and material resources to ensure the truly effective implementation of surveillance activities.
- The lack of an accident and injury database (IDB) to determine surveillance priorities.
- Frequent difficulties in tracking and tracing products/manufacturers throughout the supply chain (particularly from third countries), which is naturally reflected in the overall efficiency and effectiveness of market surveillance. The sale of products via e-shops further contributes to this.
- The proportion of poor-quality, high-risk products from third countries that reach the market via informal supply channels (e.g. marketplaces), where the efficiency of surveillance remains questionable.

## Market surveillance in specific sectors

<u>Coverage</u>: the Czech report includes all sectors in the reference list, plus timber products, mining machinery, batteries, blasting technology resources and food contact materials.

<u>Distribution of resources</u>: There is no information on the distribution of financial resources. As to the staff figures reported in the section above on overall resources, it is noted that about 75% of total inspectors were employed by CTIA, slightly less than 10% by the Energy Inspectorate competent for eco-design and energy labelling and a further 5% by the Environmental Inspectorate competent for chemicals.

<u>Own assessment</u>: the Czech Republic provides extensive information on enforcement and communication activities carried out in most sectors and points to challenges faced; furthermore, additional information can be found in some of the annual reports produced by Czech authorities<sup>18</sup>. On the other hand, the report does not provide for a more general assessment of the effectiveness or efficiency of these sector specific activities.

For instance the latest CTIA annual report indicates that in 2013, the Czech Trade Inspection Authority carried out a total of 37,299 inspections, which was 23% less than in the previous years. However, the rate of inspections with findings increased from 28.6% in 2012 to 35.5% in 2013.

## 2.4 Denmark

#### General market surveillance activities

<u>General organisation</u>: Denmark refers to the information on the general organisation of markets surveillance provided in the national programmes. Due to the decentralised organisation of market surveillance in Denmark, the Market Surveillance Committee established in 2010 has the task of contributing to the exchange of information about initiatives and strategic projects, to disseminate best practices (e.g. to ensure that the authorities make the best possible use of the tools available for exchanging information) and to help to clarify the boundaries between authorities and create opportunities for collaboration in overlapping areas. The Committee is chaired by the Danish Business Authority. The latter authority and the Danish Safety Technology Authority serve jointly as the Secretariat. Compliance with the Regulation's requirement largely depends on the active commitment of the authorities to the work of the Market Surveillance Committee.

<u>Overall resources</u>: Between 2010 and 2013, Denmark devoted between 8.2 and 8.6 million EUR per year to market surveillance. Overall staff available to market surveillance can be estimated at around 72-78 full-time equivalent units (FTE) (among which between 30 and 35 inspectors<sup>19</sup>). Data show that the budget and staff for the market surveillance authorities remained fairly constant over the 2010-2013 period. The figures are largely based on estimates and therefore have some uncertainty associated with them.

<u>Own assessment</u>: According to the Danish report, market surveillance in Denmark is working well overall, and collaboration between the relevant authorities is satisfactory. Danish authorities also participate actively in relevant European fora, including the ADCO groups (administrative collaboration). None of the authorities have reported any problems in relation to collaboration with the notified bodies.

The following challenges are identified:

- The need to always prioritise initiatives and optimise the use of resources in order to implement comprehensive, effective market surveillance.
- The ineffectiveness of surveillance and penalties in respect of e-commerce businesses that sell to Danish consumers, but are situated in third countries or merely act as intermediaries.
- Businesses' lack of knowledge and guidance concerning the legislation.
- Examples of cases where authorities in the Member States take contradictory decisions despite harmonised legislation.

## Market surveillance in specific sectors

<u>Coverage</u>: The Danish report covers almost all sectors indicated in the reference list (including non-harmonised consumer products), the only exception being explosives for civil uses and efficiency requirements for hot-water boilers. It also includes food contact materials

<sup>19</sup> The proportion of staff who are inspectors may be slightly greater, since some authorities have not classified their staff in more detail.

and some national legislation.

<u>Distribution of resources</u>: The sectors to which the greatest part of resources was allocated are medical devices (1.5-2 mln EUR; 9-11 staff), machinery (1.3-1 mln EUR; 11.3-8.8 staff), electrical appliances and equipment falling under the low voltage directive (1-1.2 mln EUR; 10.7-12.3 staff).

The report notes that no ad hoc resources were allocated to market surveillance in the areas of noise emissions and recreational craft.

<u>Own assessment</u>: Demark provides extensive information on enforcement and communication activities carried out in most sectors and points to challenges faced. In general the Danish report does not provide an assessment of the effectiveness or efficiency of these sector specific activities.

# 2.5 Germany

## General market surveillance activities

<u>General organisation</u>: Information on the general organisation of market surveillance in Germany can be found in the national programme for 2014. In Germany the responsibility for market surveillance falls within the remit of the Länder. Since 2000, the coordination of activities of the individual Länder is ensured by the Working Committee on Market Surveillance (AAMÜ). AAMÜ also decides on inter-regional focus initiatives in Germany as part of proactive market surveillance. This Committee also includes representatives from customs authorities and other sectors, e.g. the Federal Network Agency (electromagnetic compatibility and R&TTE directives) and the German Institute for Construction Technology (construction products).

From 1 January 2013 the coordination tasks of the Länder market surveillance authorities, as in Article 18(5) (national programmes), Article 22 (RAPEX) and Article 23 (ICSMS) of Regulation (EC) No 765/2008, were transferred to the Central Authority of the Länder for Safety (ZLS). In certain cases ZLS also has the power of enforcement in relation to a specific product. The new set up has improved coordination.

<u>Overall resources</u>: Germany has omitted information on financial resources and staff as it believes that it would not contribute towards any conclusion on the effectiveness or efficiency of market surveillance activities.

<u>Own assessment</u>: The national report does not provide an assessment of the general organisation of market surveillance in Germany.

## Market surveillance in specific sectors

Germany's report under Article 18(6) of the Regulation follows a different approach from that proposed in the common template. Germany summarises the results of the market surveillance actions included in the four-year programme established in 2010. Exceptions are made for the Electrical products under electromagnetic compatibility and the radio equipment and telecommunications terminal equipment sectors for which more specific information has been provided (see below).

<u>Coverage</u>: In general, the German report concerns the sectors covered by the national Product

Safety Act which transposed the General Product Safety Directive and 12<sup>20</sup> other directives among the 29 included in the reference list of products. In addition the Product Safety Act covers non-harmonised non-consumer products.

The report focuses on the 11 target areas for proactive market surveillance mentioned in the programme for sectors covered by the Product Safety Act. Some of these areas are based on hazard presented by products, while others are of a more horizontal nature. The majority of these action areas cannot be linked directly to specific product sectors. The table below shows the number of market surveillance campaigns<sup>21</sup> implemented under each area.

Action area	Number of market surveillance campaigns
Area 1: Optimisation of target group-specific information	94
Area 2: Uniform application of revised RAPEX guidelines	4
Area 3: Cooperation with customs authorities	166
Area 4: Electronic sales channels	247
Area 5: Safety through standardisation	33
Area 6: Hot surfaces	95
Area 7: Electrical fire hazards	127
Area 8: Closing forces	5
Area 9: Market surveillance and operational safety	408
Area 10: Safety of products for children	158
Area 11: Cheap products from non-EU countries	631

Furthermore, Germany reports the following information on specific sampling and testing activities conducted under the Product Safety Act:

Overall the market surveillance authorities of the Länder performed approx. 78 000 checks in total from 2010 to 2013, in which around 138 000 products were inspected with regard to their conformity;. 4 761 products were tested in laboratories.

It was found that 47 % (65299) of the products inspected did not comply with requirements22. By contrast, the proportion of those products that presents a serious risk is only 0.7 % (1032 cases).

Aerosol dispensers (75/324/EEC), Simple pressure vessels (2009/105/EC), Personal protective equipment (89/686/EEC), Appliances burning gaseous fuels (2009/142/EC), 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).

<sup>21</sup> This may either consists in sampling and testing, or also encompass activities such as collecting, processing and editing of information (e.g. on categories of potential users).

<sup>22</sup> The percentage of rejected products does not indicate a representative value for the entire market; it is due to the fact that official investigations are initiated primarily in those cases where it can be assumed there is a high probability that non-compliant products are being placed on the market

About 15% (2930) of the overall measures (17969) were taken by market surveillance authorities, while the rest was taken voluntarily by companies.

Following those measures, 562 products were withdrawn from the market, 100 products were recalled from consumers, 8863 products were destroyed and 206 sanctions were imposed.

<u>Distribution of resources:</u> The report mentions resource allocation to Electrical products under electromagnetic compatibility and the radio equipment and telecommunications terminal equipment sectors. In total and between 2010 and 2013  $\in$  12.1 million to  $\in$  11.6 million were available to the market surveillance authorities with a staff allocation of a consistent 85 full-time equivalent units (FTE).

<u>Own assessment:</u> Germany considers that setting priorities in the form of action areas proved useful in a context of limited resources, although experience suggests that certain action areas should be adjusted or discontinued and new action areas added (e.g. market surveillance at trade fairs, involvement in standardisation). No assessment of the effectiveness or efficiency of market surveillance activities in specific sectors is provided. Improvements in market surveillance are needed to address the challenge of on-line sales where the relevant economic operator is often outside the EU and border controls are performed by customs, for which product specific-specialist knowledge must be available.

# 2.6 Estonia

## General market surveillance activities

<u>General organisation</u>: Market surveillance is carried out by seven authorities: the Consumer Protection Board, the Health Board, the Technical Surveillance Authority, the Labour Inspectorate, the Maritime Administration, the Environmental Inspectorate and the Agricultural Board.

To facilitate cooperation and exchange of information between the authorities, a market surveillance council has been set up at the Ministry of Economic Affairs and Communications, made up of representatives from all market surveillance authorities, including the Tax and Customs Board, and from the ministries under whose jurisdiction they operate. Exchange of information between market surveillance authorities also takes place bilaterally.

<u>Overall resources:</u> Estonia states that it is not possible to indicate financial resources that are dedicated solely to market surveillance, since this is only a part of the responsible authorities' activities. It is possible to indicate the operating expenses of the authorities as a share of the total national budget. This translates into 29.7 million EUR in 2010 (0.53% of 5.6 billion EUR) and increasing to 35.4 million EUR in 2013 (0.46% of 7.7 billion EUR).

Further, the number of staff available to market surveillance authorities ranged from 1354 full-time equivalent units (FTE) in 2010 to 1360 FTEs in 2013, of which 43 to 41 were dedicated to inspectors.

<u>Own assessment:</u> The report indicates that the results of Estonia's market surveillance activities are good and the functioning of the country's organisation and infrastructure is qualified as efficient. The taking part in international cooperation projects by some market surveillance authorities has provided a good overview of practices in other countries. In the same way the exchanges of officials programme financed by the European Commission has

also been assessed as useful.

The main challenges for market surveillance authorities derive from:

- The plurality of sectors and responsibilities coupled with limited human resources, training and in-service training opportunities. The lack of resources pushes Estonia towards a more risk- and project-based surveillance, but awareness of regulations among economic operators is described as poor, meaning that there is additional pressure on resources for starting awareness-raising campaigns.
- Increase of e-commerce and catalogue sales that make it difficult for the authorities to perform checks.
- Non-existence of test laboratories and notified bodies making the assessment of conformity in major technical sectors very difficult.
- Carrying out market surveillance and the harmonisation of customs procedures. Problems have been noted in cases where an economic operator wants to import a product with no CE marking and bring it into conformity with the requirements at a later stage. In these types of situations Estonia mentions that surveillance authorities have difficulties reconciling the concepts of "placing on the market" and "release for free circulation" as defined in Regulation (EC) No 765/2008. It has not always been possible to carry out these operations in the customs zone.
- Perceived shortcomings in national legislation. Estonia's market surveillance authorities report that the wording of legal acts is often perceived as ambiguous for economic operators. Further, cooperation between authorities has on occasion been suspended since it was not clear how they should divide the responsibility for surveillance on certain products. Estonia found a solution to this through mutual agreements and amendments to legal acts.

## Market surveillance in specific sectors

<u>Coverage:</u> The Estonian report covers most sectors indicated in the reference list (including non-harmonised consumer products falling under the GPSD such as lighters and children's clothing) with the exception of eco-design and energy labelling, efficiency requirements for hot-water boilers fired with liquid or gaseous fuels and non-road mobile machinery.

Distribution of resources: No information on the distribution of resources is provided.

<u>Own assessment</u>: Estonia provides extensive information on enforcement and communication activities carried out in most sectors, and points to the challenges faced. The report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

# 2.7 Ireland

## General market surveillance activities

<u>General organisation</u>: Market surveillance is dispersed across various Government Departments and State Agencies and responsibility for Community harmonisation legislation

is allocated according to competence. The responsibilities of market surveillance authorities are conferred through primary legislation in the case of chemicals and secondary legislation implementing Community harmonisation legislation for the other sectors.

There is no national body to coordinate market surveillance activities nor does a single piece of overarching market surveillance legislation exist. Under Regulation (EC) No 765/2008 the Department of Jobs, Enterprise and Innovation coordinates Ireland's notifications.

<u>Overall resources:</u> Ireland does not provide specific resource information and states that there is no specific budget to fund market surveillance authorities since they are part of larger organisations. It is estimated that approximately 4.8 million EUR is available to authorities for market surveillance activities. The number of staff available to market surveillance authorities remained somewhat stable from 41.7 full-time equivalent units (FTE) in 2010 to 41.6 FTEs in 2013 in total.

<u>Own assessment:</u> The Irish report identifies the following issues in the functioning of market surveillance:

- The resources of the HSA have been reduced in recent years which impact negatively the ability to engage in market surveillance. Further the absence of independent test laboratories\_renders assessing of conformity very difficult and costly. Problems also arise on the reporting and recording of accidents that occur outside the workplace since there is no state supported system in place.
- The NCA has been operating with 7 to 8 FTEs in the Product Safety Unit. The report mentions significant budgetary and staffing constraints.

## Market surveillance in specific sectors

<u>Coverage</u>: Ireland reports on most of the sectors from the reference list (including nonharmonised consumer products falling under the GPSD) with the exception of construction products, aerosol dispensers, cableways, noise emissions for outdoor equipment, radio and telecom equipment under electromagnetic compatibility and radio equipment and telecommunications terminal equipment, efficiency requirements for hot-water boilers, recreational crafts, marine equipment and non-road mobile machinery.

<u>Distribution of resources:</u> Information on the distribution of resources is provided for the medical devices sector with a stable budget of 1.4 million EUR for 2010-2013 and a full-time equivalent unit (FTE) availability of 15.8 to 17.3, with 1.5 FTEs for inspectors. Eco-design and labelling had a budget of 150 000 EUR allocated with 1 FTE available in 2013 and 4 FTEs for inspectors.

The electrical and electronic equipment sector under restriction of hazardous substances, waste from electrical and electronic equipment and batteries directives had a budget allocated of approximately 37 000 EUR with a spike of 64 500 EUR in 2012 (between 0.25 and 0.20 FTEs staff available). The chemicals sector had a budget available from around 44 300 EUR in 2010 to 25 500 EUR in 2013, with 0.14 to 0.05 FTE staff availability in the same period.

No financial budget is indicated for the cosmetics sector but between 6.25 and 7.25 FTEs was available for market surveillance activities between 2010 and 2013 (5.25 FTEs for inspectors). For fertilisers these were 2 FTEs available for market surveillance activities between 2010 and 2013 (1.5 FTEs for inspectors).

<u>Own assessment:</u> In the area of medical devices, the HPRA does not have any legislative powers over distribution or distributors apart from the provisions set out in the New Approach legislation.\_Concern is particularly on the device management, storage and traceability throughout the distribution chain. Legislative powers are being sought to request distributors to conduct appropriate follow-up and be required to request an audit of their quality systems.

Further, on the specific sector of medical devices and cosmetics, Ireland's report on its market surveillance activities notes that enforcing compliance on medical devices and cosmetics sold through online web shops is challenging due to issues around traceability. Concerning medical devices the HPRA is actively involved in developing the framework for implementing a unique device identifiers (UDI) system. Applying a harmonised market surveillance approach and action effectively is seen as problematic when different Member States take varying positions in the qualification and classification of products as medical devices.

Issuing alerts on hazards is required under the EU legislation, but not specifically addressed under national legislation which is seen as problematic. Furthermore, in the event a serious issue arises and action is taken under the medical device legislation, the penalties are deemed as minor when the potentially serious nature of the offence is considered.

# 2.8 Greece

## General market surveillance activities

<u>General organisation:</u> Market surveillance pursuant to Regulation (EC) No 765/2008 is handled at national level. Greece reports that in 2012 a new legal framework was developed, with the General Secretariat for Industry of the Ministry of Development and Competitiveness as the country's National Market Surveillance Authority. The body is responsible for coordinating the other market surveillance authorities already in place, and for streamlining communication. The report mentions that an audit methodology has been developed for each product, at manufacturers' premises and at product operating, distribution and storage sites. An electronic national information exchange system has been put in place that should back the market surveillance procedure.

<u>Overall resources:</u> Greece does not provide general resource information per market surveillance authority since they have not been identified separately. An amount of 50 000 EUR (excluding wage costs) is estimated for the General Secretariat for Industry.

<u>Own assessment:</u> The report does not provide an assessment of the effectiveness or efficiency of the general market surveillance organisation. It identifies the lack of financial resources as a challenge, particularly with regard to the costs of laboratory tests and the transportation of inspectors. Other challenges mentioned are:

- The lack of traceability of information during laboratory tests in some sectors.
- The lack of having specialised inspectors in place for certain sectors (e.g. lifts).
- The lack of consistency in imposing sanctions.
- The difficulty of locating the responsible person in the supply chain.

- The overlap of responsibilities in certain sectors (e.g. noise emissions).

## Market surveillance in specific sectors

<u>Coverage:</u> The Greek report covers most sectors indicated in the reference list (including nonharmonised consumer products falling under the GPSD) with the exception of medical devices, cosmetics, noise emissions for outdoor equipment, equipment and protective systems intended for use in potentially explosive atmospheres, marine equipment, motor vehicles and tyres and non-road mobile machinery.

<u>Distribution of resources:</u> No information on the distribution of financial resources per sector has been provided, with the exception of the radio equipment and telecommunications terminal equipment sector with a budget of around 33 000 EUR allocated in 2010 and 8 500 EUR in 2013. 5 full-time equivalent units (FTE) have been attributed in this period (from 2 to 4 FTEs for inspectors). In general 0.2 to 2.5 FTEs of staff are allocated to most sectors with chemicals being the exception counting 90 FTEs of staff of which 65 FTEs of inspectors available to market surveillance authorities.

<u>Own assessment:</u> Greece provides extensive information on enforcement and communication activities carried out in most sectors and points to challenges faced that reflect those mentioned previously. In general the report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

## 2.9 Spain

## General market surveillance activities

<u>General organisation</u>: Market surveillance is coordinated at national level by the Spanish Consumer Affairs, Food Safety and Nutrition Agency (which acts on rare occasions as a surveillance authority) and is carried out by various authorities who are organised on either a national or regional level. Only in very special cases involving imports or products controlled by the customs authorities does it act as a market surveillance authority.

The customs authorities are part of the Tax Agency but border controls also involve another body called SOIVRE (the Official Service of Surveillance, Certification and Technical Assistance of Foreign Trade). It monitors a series of products before they reach the customs offices. It conducts surveillance activities with regard to documents, inspections and testing. For the sectors of products, toys, textiles, shoes, some personal protective equipment, some electrical products and wood products and their derivatives, a safety certificate must be obtained in advance from SOIVRE so that customs can release them for free circulation. The Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) acts as a market surveillance authority only in cases where the customs authorities ask for support on the basis of Articles 27-29 of Regulation (EC) No 765/2008 (The report mentions it carries out 80 exercises each year). It is also the contact point for RAPEX.

Furthermore, the Ministry of Industry, Energy and Tourism examines the extent of legislative compliance of the industrial products placed on the markets (1349 industrial products were inspected in 2013). The main lines of action that are described in the report focus on the inspection of distribution centres (through reactive and proactive compliance assessment) and the testing on products in accordance with the legislation in force.

<u>Overall resources:</u> No general resource information per market surveillance authority is specified but the combined estimated budget of the consumer affairs authorities is mentioned. Approximately 26.7 million EUR was available to authorities in 2010 to 20.7 million EUR in 2013, which is approx. 0.025% of the national budget. The number of staff available to market surveillance authorities counted 312 full-time equivalent units (FTE) in 2010 and dropped to 208 FTEs in 2013 in total. Between 212 and 125 FTEs were available for inspectors.

<u>Own assessment:</u> The report does not provide an assessment of the effectiveness or efficiency of the general market surveillance organisation but points to challenges faced. In particular, the shortage of resources is a main cause of lack of monitoring of imports and problems with traceability of products. It also mentions that penalties laid down in national law might not be a sufficient deterrent for larger companies trying to market non-compliant products. The country aims to increase the use of ICSMS.

## Market surveillance in specific sectors

<u>Coverage:</u> The Spanish report provides some information on enforcement activities (i.e. number inspections, tests performed, finding of non-compliance and restrictive measures taken) on the sectors that fall under the responsibility of the Subdirectorate-General for Quality and Industrial Safety of the Ministry of Industry, Energy and Tourism only i.e. list, electrical appliances and equipment under the low voltage directive, radio and telecoms equipment under electromagnetic compatibility directive, machinery, pressure equipment, construction products, chemicals and lifts.

<u>Distribution of resources</u>: No information on the distribution of financial resources per sector has been reported.

<u>Own assessment:</u> In general the report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

## 2.10 France

## General market surveillance activities

<u>General organisation</u>: France refers to the information on the general organisation of markets surveillance provided in the national programmes. In France, market surveillance is mainly performed by officials of the Directorate-General for Competition, Consumer Affairs and Fraud Repression (DGCCRF) and, for products imported from countries outside the European Union, the Directorate-General for Customs and Indirect Taxation (DGDDI) which is a surveillance authority for the entire market so that customs officials may collect samples of products, have them tested by a laboratory and, depending on the test results, decide on any action to be taken. The DGCCRF and DGDDI have a territorial network at their disposal. For laboratory tests they can use the Joint Laboratory Service (SCL) and can also call upon private laboratories.

Other services also contribute to market surveillance<sup>23</sup>, either by carrying out checks

<sup>23</sup> They include the: Direction Générale de la Compétitivité, de L'industrie et des Services (DGCIS), for measuring instruments; Direction Générale de la Prévention des Risques (DGPR) for gas appliances, pressure equipment, chemical products, explosives and materials for use in potentially explosive atmospheres; Direction des Affaires Maritimes (DAM) for recreational craft and marine equipment; Direction Générale du Travail (DGT) for machinery and equipment, and personal protective equipment; Service Technique des Remontées Mécaniques et des Transports Guidés (STRMTG) for cableway installations used to transport persons;

themselves or with the help of services on the ground.

The Ministry of Economy, Directorate-General for Competitiveness, Industry and Services (DGCIS) DGCIS, ensures coordination of the application of Regulation (EC) No 765/2008

<u>Overall resources:</u> In the 2010-2013 period between 2.5 and 2.9 million EUR per year were dedicated to testing of toys, cosmetics and professional products, while around a further 1.5 million EUR per year were dedicated to testing of equipment for use in potentially explosive atmospheres, pyrotechnical articles, radio equipment and telecommunications terminal equipment and, to a lesser extent, to pressure equipment, gas appliances and civil explosives. <sup>24</sup> In addition to these figures, the report mentions about 13.5 million EUR (excluding testing activities) allocated to market surveillance authorities in a number of (mainly consumer product) sectors.<sup>25</sup> In various sectors resources declined over the 2010-2013 period. No specific details on resources for market surveillance are given for medical devices, professional machinery, lifts, cableways, noise emissions and products falling under restriction of hazardous substances, waste from electrical and electronic equipment and batteries legislation. Overall over 260 full-time equivalent units (FTE) are reported for all the sectors mentioned above for both testing and other activities. These figures do not include customs budget and staff for market surveillance.

<u>Own assessment:</u> The French report does not contain an assessment of the general organisation of market surveillance.

#### Market surveillance in specific sectors

<u>Coverage:</u> The French report covers all sectors in the reference list (including non-harmonised consumer products), except eco-design, efficiency requirements for boilers and non-road mobile machinery.

<u>Distribution of resources:</u> By looking at the overall resources mentioned in the above sections, between 2010 and 2013 the biggest share of resources (about 25%) was allocated to non-harmonised consumer goods, about 10% each respectively to toys, cosmetics and radio equipment and telecommunications terminal equipment, 5% respectively to low voltage electrical products and energy labelling<sup>26</sup>.

<u>Own assessment</u>: According to the French report overall market surveillance activities functioned satisfactorily in France, and products covered by harmonised European regulations were subject to appropriate inspection. Apart from a few exceptions, such as cosmetics products, a more specific assessment of the activities carried out in a given sector is not provided.

In some sectors (i.e. equipment for use in potentially explosive atmospheres, pyrotechnical articles, civil explosives and gas appliances), insufficient cross-border cooperation is mentioned as a difficulty to tackle when relevant economic operators are located abroad. In others (radio equipment and telecommunications terminal equipment) it is noted that control procedures are not adequate to handle products sold on line.

Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM) for medical devices and cosmetics; Agence Nationale des Fréquences (ANFR) for radio equipment.

<sup>24</sup> Budget including both tests carried out by State laboratory and tests subcontracted to private laboratories.

<sup>25</sup> Toys, cosmetics, consumer machinery, non harmonised consumer goods, construction products, electromagnetic compatibility, radio and telecommunications, low voltage electrical products, chemicals, energy labelling, recreational craft, motor vehicles, fertilisers.

<sup>26</sup> The percentage mentioned here are very rough and purely indicative estimates.

## 2.11 Croatia

#### General market surveillance activities

<u>General organisation</u>: The report covers the period 1 July 2013 to 31 December 2013 and mentions that the overall responsibility for market surveillance was with the State Inspectorate until the end of that year. Upon becoming a Member State of the European Union a contact point was set up in the Inspectorate for the exchange of official notifications on measures and actions (through RAPEX). The Inspectorate conducted inspections with the Customs Administration of the Ministry of Finance implementing Articles 27 to 29 of Regulation (EC) No 765/2008. A Commission that was set up in 2009, and that had ceased its activities by the end of 2013, coordinated and communicated between inspectorates responsible for controls of products placed on and/or made available to the market.

As of 1 January 2014 the Ministry of the Economy took over the tasks of the State Inspectorate, namely the protection of consumers, product safety and pressure equipment and the tasks of the mining and electricity inspectorate.

Other authorities are the State Office for Metrology (measuring instruments, non-automatic weighing instruments and pre-packaged products), the Ministry of the Interior (pyrotechnical articles), the Croatian Regulatory Authority for Network Industries (radio equipment and telecommunications terminal equipment), the Ministry of Agriculture (fertilisers) and the Ministry of Health (cosmetic products, toys and chemical products)

Overall resources: No further general resource information is specified.

<u>Own assessment:</u> The report does not provide an assessment of the effectiveness or efficiency of the overall market surveillance organisation.

#### *Market surveillance in specific sectors*

<u>Coverage:</u> For the period indicated above, the Croatian report covers: (i) the sectors under the responsibility of the State Inspectorate, i.e. personal protective equipment, construction products, machinery, electrical appliances and equipment under the low voltage directive, other consumer products under GPSD (lighters and children's clothing with drawstrings) and textile products and footwear in accordance with Regulation (EC) No 1007/2011 and Directive No 94/11/EC; (ii) other sectors covered by the State Office for Metrology (measuring instruments, non-automatic weighing instruments and pre-packaged products), the Ministry of the Interior (pyrotechnical articles), the Croatian Regulatory Authority for Network Industries (radio equipment and telecommunications terminal equipment), the Ministry of Agriculture (fertilisers) and the Ministry of Health (cosmetic products, toys and chemical products);

<u>Distribution of resources</u>: No information on the distribution of financial resources per sector has been reported.

<u>Own assessment:</u> In general the report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

## 2.12 Italy

#### General market surveillance activities

<u>General organisation</u>: Italy refers to the information on the general organisation of markets surveillance provided in the national programmes for the 2010-2013 periods. It also recalls that a least 7 Ministries are responsible for market surveillance activities under the scope of the report, in addition to Guardia di Finanza, which carries out product safety controls in the national territory, and the Customs Agency, responsible for product checks at the border.

<u>Overall resources</u>: In the section on overall resources, Italy mentions about 1.5 mln EUR per year; however this budget actually coincides almost entirely with the budget of the Ministry of Economic Development which is responsible for many - but not all, and not exclusively<sup>27</sup> - of the product areas falling under the scope of the Regulation (i.e. personal protective equipment, electromagnetic compatibility, low voltage electrical products and appliances, radio equipment and telecommunications terminal equipment, measuring instruments, eco-design and energy labelling legislation, labelling of textiles and footwear), as well as for general product safety.

The section also mentions about 1 100 full-time equivalent units for staff (FTE) (of which 100 customs staff, about 100 staff units of various ministries<sup>28</sup>that carry out documentary checks, and more than 900 inspectors<sup>29</sup>that carry out field work) for market surveillance in the areas of responsibility of the Ministry of Economic Development (see above), the Ministry of Health (toys, consumer goods, medical devices and cosmetics), the Employment Ministry (machinery) and the Environment Ministry (noise emissions).

<u>Own assessment</u>: According to the national report, the entry into force of the Regulation helped the development of market surveillance in Italy. The practice of national programmes has helped to focus controls on products intended for vulnerable consumers (children and elderly), and has brought about several restrictive measures of both a voluntary and mandatory nature. Italy's report considers that market surveillance conducted between 2010 and 2013 has been effective overall, in particular due to the importance given to the training of inspectors. The lack of resources however limits the ability to ensure continuity in training, as well as to increase the number of (proactive) inspections and laboratory checks.

#### Market surveillance in specific sectors

<u>Coverage</u>: Italy's report covers 15 of the 29 sectors indicated in the reference list. Excluded from the report are, in particular, construction products, pressure equipment, lifts, gas appliances, electrical equipment falling under the electromagnetic compatibility directive, certain chemicals, motor vehicles, recreational craft, equipment for use in potentially explosive atmospheres and non-road mobile machinery. On the other hand, Italy's report includes non-harmonised consumer products, tobacco products and the labelling of footwear.

Distribution of resources: Italy's report does not contain information on the overall amount of

<sup>27</sup> E.g. the Health Ministry, the Carabinieri's specialised territorial cells called NAS and the regional offices share responsibility for conducting inspections in the area of some consumer products, including toys. Furthermore, Guardia di Finanza verifies the execution of restrictive measures issued by the Ministry of Economic Development. The resources of these other entities involved in market surveillance are not included.

<sup>28 63</sup> people from the Ministry of Economic Development, around 25-30 from the Ministry of Health dealing with certain aspects of toys, consumer goods; medical devices and cosmetics and a few units from the Employment and Environment Ministries dealing respectively with machinery and noise emission legislation.

<sup>29</sup> This figure includes 500 FTEs from Guardia di Finanza, 275 from Chambers of Commerce, 100 Carabinieri NAS.

resources dedicated to market surveillance and its distribution across sectors. The figure of 1.5 million EUR is provided for market surveillance carried out by the Ministry of Economic Development notably in relation to a range of consumer goods and to eco-design/energy labelling legislation.

The report notes that no ad hoc financial resources are attributed to market surveillance in the areas of maritime equipment, pyrotechnics and civil explosives, where only some limited reactive surveillance activity is carried out<sup>30</sup>.

The figures on staff are covered in the previous section on overall resources.

<u>Own assessment:</u> Italy provides quite extensive information on enforcement and communication activities carried out in several sectors, and points to challenges faced (notably the lack of resources); however in general the Italian report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities. The report points to the best practice established in the sector of medical devices where market surveillance relies on the use of an extensive database covering more than 500 000 products and allowing information-sharing with healthcare agencies and businesses.

# 2.13 Cyprus

## General market surveillance activities

<u>General organisation</u>: Cyprus refers to information reported in the 2014 national market surveillance programme.

<u>Overall resources:</u> Cyprus does not report overall resources available, however the report mentions between 200 and 290 000 EUR per year and slightly less than 5 full-time equivalent units for staff (FTE) for low voltage electrical products, 150 000 EUR per year and 8 FTEs for construction products. Lower resources are reported for eco-design and energy labelling (increasing from 4 500 up to 39 000 EUR per year during the period), civil explosives (33 000 EUR per year), electronic magnetic compatibility (between 20 and 30 000 EUR per year), pyrotechnical articles (22 000 EUR per year), aerosol dispensers (5-15 000 EUR per year) and gas appliances (10 000 EUR per year). No resources were attributed for market surveillance of radio and telecommunications equipment.

<u>Own assessment:</u> No specific assessment of the general organisation (e.g. cooperation and coordination) is provided.

## Market surveillance in specific sectors

<u>Coverage:</u> the Cyprus report covers about two-thirds of the products in the reference list. Sectors excluded are: cosmetics, noise emissions for outdoor equipment, measuring instruments, electronic and electronic equipment under restriction of hazardous substances, waste from electrical and electronic equipment and batteries, chemicals, efficiency requirements for hot-water boilers, recreational craft, marine equipment, non-road mobile machinery, motor vehicles and fertilisers.

Distribution of resources: See section on resources above.

<sup>30</sup> However pyrotechnics and civil explosives also come under the responsibility of the police.

<u>Own assessment:</u> the Cyprus report contains an assessment of market surveillance carried out by the Department of Labour Inspection of the Ministry of Labour in the sectors of personal protective equipment, pressure equipment, machinery, lifts and equipment for use in potentially explosive atmospheres, for which checks performed on products imported from third countries are considered satisfactory. At the same time the these sectors are said to face difficulties due to lack of traceability, mismatch between the customs product classification and the nomenclature used by market surveillance authorities, a lack of financial resources to conduct checks, and time-consuming procedures for imposing penalties.

Furthermore, market surveillance of radio and telecommunications equipment is considered as inadequate due to underfinancing and understaffing of the Department of Electronic Communications of the Ministry of Communications.

## 2.14 Latvia

## General market surveillance activities

<u>General organisation</u>: Market surveillance in Latvia is handled by 11 different authorities<sup>31</sup> subordinated to 7 different ministries. To facilitate cooperation and exchange of information between the authorities, a Market Surveillance Council was set up in 2000 at the Ministry of Economics, and it meets twice a year. It is made up of representatives from all market surveillance authorities and from the ministries under whose jurisdiction they operate.

<u>Overall resources:</u> The report provides estimates since it is not possible to indicate financial resources dedicated to market surveillance because this is only a part of the responsible authorities' activities. It is estimated that approximately 1.6 million EUR was available to authorities in 2010 to 2.2 million EUR in 2013, which is a stable 0.03% of the national budget. The number of full-time equivalent units for staff (FTE) available to market surveillance authorities counted 101.3 FTEs in 2010 to 117.8 FTEs in 2013 in total. Between 74.5 and 83 FTEs were available for inspectors.

Own assessment: The Latvian report identifies the following challenges:

- A lack of coordination of activities among Member States surveillance authorities with respect to the release of goods for free circulation leading to situations where goods that were not released onto the market in one Member State enter the market through another one.
- Insufficient cooperation with the Member States market surveillance authorities in cases where the compliance of goods is being assessed or where irregularities have been identified.
- In practice there is not always cooperation between the market surveillance authorities and the notified bodies.
- A lack of resources to fully implement the EU's legal acts governing non-food goods.
- A large number of importers are not aware of the requirements for imported goods.

<sup>31</sup> The Consumer Rights Protection Centre (CRPC), State Labour Inspectorate, Health Inspectorate, State Agency for Technical Surveillance, State Plant Protection Service, State Environment Service, Excise Goods Department of the State Revenue Service, Customs Board of the State Revenue Service, Assay Office of Latvia, State Police, the Food and Veterinary Service (FVS).

- The requirements are not differentiated for EU-manufactured or imported goods, leading to situations where it is simpler to manufacture goods outside the EU as the amount of checks that the surveillance authorities can perform on imported goods is small.
- Restricted resources lead to insufficient laboratory controls.
- Inspectors find it challenging to ensure the fulfilment of the registration requirements of chemical substances as stipulated in the REACH Regulation.

## Market surveillance in specific sectors

<u>Coverage:</u> The Latvian report covers all sectors in the reference list (including non-harmonised consumer products).

Distribution of resources: In general no information on the distribution of financial resources per sector has been provided, with the exception of the chemical substances sector with a budget of around 300 000 EUR and a staff availability of 12 full-time equivalent units (FTE) in 2010 and 9.5 in 2013. The number of inspectors in the period has been fairly consistent of around 8 FTEs with a drop in 2013 to 5.5 FTEs. The medical devices sector is mentioned with a budget of approx. 37 000 EUR allocated in 2010 and 21 000 EUR in 2013. 2.5 FTEs have been attributed in this period which went down to 1.5 in 2013. A consistent 1.5 FTEs to inspectors has been available. Lastly the sector of electrical and electronic goods subject to the low voltage directive is mentioned with figures ranging from 30 000 EUR to 31 000 EUR for the years 2011 to 2013, with a consistent staff availability of 2 FTEs.

<u>Own assessment:</u> The report provides information on enforcement and communication activities carried out in several sectors, and points to challenges faced. It does not provide for an assessment of the effectiveness or efficiency of these sector specific-activities.

# 2.15 Lithuania

## General market surveillance activities

Lithuania's report under Article 18(6) of the Regulation follows a different approach than the one proposed by the Commission, as an extensive study to evaluate the national legal framework was already launched in 2013.

<u>General organisation</u>: the Lithuanian report focuses on the legal framework for market surveillance. This is characterised by the existence of: (ii) the Product Safety Law that acts as a general 'umbrella' legal instrument regulating, among other aspects, market surveillance for both (non-food<sup>32</sup>) products and services; (ii) special law regulating market surveillance for certain product areas (e.g. metrology, pharmaceuticals) or certain specific aspects (e.g. accidents at work, electronic communications, implementation of RAPEX system); (iii) by-laws regulating in detail specific matters (e.g. rules on the application of restrictions on marketing of products).

Overall resources: The Lithuanian study does not cover this information.

Own assessment: The purpose of Lithuania's study is to evaluate whether national law has

<sup>32</sup> According to the Lithuanian study that the scope of the Product Safety Law in respect of foodstuff is unclear.

properly implemented the provisions of the Regulation. The study concludes that certain aspects of the national legal framework should be improved. In particular, it notes that:

- as the Product Safety Law only applies to consumer products, certain non-consumer products may fall outside the scope of control powers. Furthermore, the legal technique of resorting to by-laws to regulate powers to apply restrictive measures and sanctions are not efficient: although the provisions of the EU Regulation apply directly, they are not referred to in Lithuanian market surveillance legislation.
- the legislation does not contain an approved and exhaustive list of market surveillance authorities. In practice, the fact that the State Non-Food Product Inspectorate under the Ministry of Economy is treated (except for products regulated by special laws) as an 'umbrella' market surveillance authority should help avoiding "grey areas" (i.e. cases where the safety of consumer products is not controlled by any authority). However, this responsibility of the Non-Food Product Inspectorate should be regulated by law. Furthermore, there is no similar 'umbrella' authority in the area of non-consumer goods.
- the legal framework regulating the function of coordination among authorities is defective and could be improved by clearly clarifying and aligning the responsibilities of both the ministries involved in the process and the market surveillance authorities, and at the same time by establishing a model for cooperation (activity coordination).
- the lack of clarity of the EU framework also create confusion. More detailed legislation would be needed to clarify and regulate specific functions (e.g. authorities' obligation to cooperate, accumulate scientific knowledge, monitor accidents) of the market surveillance systems established by the EU Regulation.

## Market surveillance in specific sectors

The Lithuanian study does not include information on enforcement and communication activities carried out in specific sectors.

# 2.16 Luxembourg

## General market surveillance activities

<u>General organisation</u>: In Luxembourg there are eight market surveillance authorities<sup>33</sup>. The "Institut Luxembourgeois de la Normalisation, de l'Accréditation, de la Sécurité et qualité des produits et services", ILNAS, is, since 2008, the market surveillance authority responsible for the bulk of consumer products (i.e. toys, other consumer products falling under the GPSD, low voltage electrical appliances, electromagnetic compatibility, radio and telecommunication equipment eco-design and energy labelling) and for equipment for use in potentially explosive atmospheres. On the other hand, the "Inspection du Travail et Mines", ITM, has, between 2010 and 2013, been the market surveillance authority responsible for personal protective equipment, civil explosives, pyrotechnic articles, cableways, machinery, lifts, pressure equipment, aerosols, gas appliances and construction equipment.<sup>34</sup> The responsibilities of ILNAS and ITM cover about two-thirds of the sectors mentioned in the reference list.

<sup>33</sup> ILNAS, Métrologie légale, Commissariat aux Affaires Maritimes, Direction du marché intérieur et de la consommation, Direction de la Santé, ITM, Administration de l'Environnement, Département des transports

<sup>34</sup> On 1 August 2014 the responsibility for market surveillance authority in these areas were transferred to ILNAS

ILNAS coordinates market surveillance at national level with the help of a national committee.

<u>Overall resources:</u> Luxembourg reports that the complexity of the budgets of the different administrations involved does not allow an estimation of the total amount of resources dedicated to market surveillance. During the 2010-2013 period ILNAS' annual budget for market surveillance (excluding the technical laboratory) ranged between 50 000 and 75 000 EUR. The budget declined over time. Total staff amounted to 6-7 full equivalent units (FTE). The figure on ITM's market surveillance budget is not available. ITM's total staff amounted to 0.65-1.15 FTEs.

<u>Own assessment:</u> the Luxembourg report focuses on ILNAS achievements in the areas of cooperation with customs (notably the agreement signed in 1998 and updated in 2012), the exchange of data via a common Intranet (EC.SDM) and regular training on product safety and legal requirements.

#### Market surveillance in specific sectors

<u>Coverage:</u> The Luxembourg report covers about two-thirds (19) of the sectors in the reference list (29), as well as non-harmonised consumer products.

<u>Distribution of resources</u>: no information is available in addition to the data mentioned above for ILNAS and ITM.

<u>Own assessment:</u> Luxembourg provides quite detailed information on ILNAS' market surveillance activities and more succinct information on ITM's market surveillance activities; however it does not contain a specific assessment of those activities. Resources available to ILNAS are said to be insufficient to ensure effective market surveillance. The number of inspectors went up by 8 units in 2014, together with a substantial increase in the responsibilities of ILNAS.

# 2.17 Hungary

## General market surveillance activities

<u>General organisation</u>: The report does not supply information on the general organisation of market surveillance at national level but focuses on the activities of each of the authorities separately. Surveillance is dispersed across various bodies, and responsibility for Community harmonisation legislation is allocated according to jurisdiction. There are 14 market surveillance authorities.

<u>Overall resources:</u> The overall resources are stipulated for 8 authorities running in the 2010-2013 period to an annual global amount of 1.8 to 6.6 million EUR. This strong increase is mostly due to a lack of information on the amount of resources in 2010. A similar calculation gave 902 full-time equivalent units (FTE) in 2010 to 1496 FTEs in 2013 in total as the number of staff available to market surveillance authorities. Between 274 and 568 FTEs were available for inspectors.

<u>Own assessment:</u> No specific assessment of the general organisation (e.g. cooperation and coordination) is provided.

#### Market surveillance in specific sectors

<u>Coverage:</u> Hungary's report covers the sectors from the reference list (including non-harmonised consumer products falling under the GPSD).

Distribution of resources: The report covers the distribution of resources per authority, subdivided over most sectors (no calculation method is given). Budget allocated to most sectors range between 1000 and 30 000 EUR per year covering a three-year time span and a staff and inspector availability of between 1 and 4 FTEs. Next to toys (see section below) the biggest sectors mentioned in terms of resource availability are the sector of electrical and electronic goods subject to the low voltage directive with figures ranging from around 633 000 EUR to 672 000 EUR for the years 2010 to 2013, with a staff availability between 36 and 39 FTEs of which 30 and 32 FTEs for inspectors respectively. For the machinery sector a budget of between 74 000 EUR and 169 000 EUR was available with a staff availability of 7 FTEs in 2010 and 9 in 2013. The number of inspectors in the period has been fairly consistent, between 4 and 6 FTEs. For construction products the budget ranged between 64 000 EUR and 92 000 EUR, with 6 to 7 FTEs staff availability of which 4 FTEs for inspectors. Further for personal protective equipment a budget between 38 000 EUR and 55 000 EUR is reported with staff availability between 3 and 4 FTEs of which a consistent inspector availability of 2 FTEs.

<u>Own assessment:</u> The report provides information on enforcement activities carried out by the various market surveillance authorities. It does not provide for an assessment of the effectiveness or efficiency of sector-specific activities.

## 2.18 Malta

## General market surveillance activities

<u>General organisation:</u> Market surveillance tasks in Malta are carried out by the Market Surveillance Directorate within the Technical Regulations Division of the Malta Competition and Consumers Affairs Authority (MCCAA). The report does not provide additional information on the organisation of market surveillance at national level.

<u>Overall resources:</u> in the 2010-2013 period the annual global resources for market surveillance ranged between 0.15 and 0.18 million EUR. The staff dedicated to market surveillance amounted to 5 full time equivalent units (FTE).

<u>Own assessment:</u> Malta does not provide a specific assessment of the general organisation of market surveillance, although it notes that enforcement measures have been hindered by inadequate testing facilities. The difficulty should be mitigated in future as the MCCAA is asking for basic Market Surveillance screening equipment for toys, child care articles as well as to a lesser extent other directives. Other challenges encountered concern:

- the lack of traceability of products brought to Malta via EU intermediate economic operators who import them from third countries. This also gives rise to the problem of lack of documentation such as the Declarations of Conformity, owing to a breakdown in communication between the operator in Malta and the manufacturer.
- the lack of clarity of certain standards which give presumption of conformity to the applicable EU Directives. This leaves room for different interpretations which are not easily enforceable.

#### Market surveillance in specific sectors

Coverage: The report covers all sectors in the reference list.

Distribution of resources: Overall resources are allocated according to priorities that depend on the use of the product groups as well as the vulnerability of consumers. Hence, toys, plant protection products and electrical appliances are given the highest priority due to the widespread distribution of all three kinds of products, coupled with the vulnerability of children and/or untrained consumers as well as the fact that plant protection products are consumed in foods. Other product categories falling under the GPSD or the New Approach Directives are given a secondary level of priority with less emphasis on proactive enforcement. Lack of resources is mentioned as the reason for no or limited market surveillance in sectors such as equipment for use in explosive atmospheres, civil explosives, gas appliances, medical devices, transportable pressure equipment and construction products.

<u>Own assessment:</u> Malta provides detailed information on enforcement activities carried out in most sectors; however in general the report does not provide for an assessment of the effectiveness or efficiency of these sector-specific activities.

## 2.19 Netherlands

## General market surveillance activities

<u>General organisation</u>: Market surveillance of products is organised between six national market surveillance authorities<sup>35</sup>, each with their own sector of responsibility. Political responsibility for the authorities lies with the Ministries of Economic Affairs (which also coordinates and monitors the implementation of Regulation (EC) No 765/2008), Social Affairs and Employment, Infrastructure and the Environment, and Health, Welfare and Sport respectively.

Proactive inspections are carried out based on risk assessments (including compliance risk) while reactive inspections are executed on the basis of RAPEX notifications, alerts from other sources and complaints from businesses and consumers. Product examinations are executed by the authorities' own laboratories as much as possible and tend to focus on manufacturers and EU importers, taking into account (past) compliance behaviour of companies. All authorities are also connected to ICSMS, with one national administrator.

Products are checked by the relevant market surveillance authority before they are released for free circulation, and activities are coordinated with customs four to five times a year through a national forum that was set up in 2008 (the Alliance Working Group on Product Market Surveillance and External Border Controls) and which is chaired by the Netherlands Food and Consumer Product Safety Authority (NVWA).

<u>Overall resources:</u> Overall, in the 2010-2013 periods, the total national budget for market surveillance was estimated to be 20 million EUR. The staff dedicated to market surveillance involves 175 full-time equivalent units (FTE) (the report does not provide further details). Further resource information is provided for the Dutch Food and Consumer Product Safety Authority, stating that the agency has a workforce of 110 FTEs in total, divided over 45

<sup>35</sup> Social Affairs and Employment Inspectortae (I-SZW), Human Environment and Transport Inspectorate (ILT), the Netherlands Radiocommunications Agency (AT), Verispect B.V., Health Care Inspectorate (IGZ), Netherlands Food and Consumer Product Safety Authority (NVWA).

inspectors, 45 laboratory workers and 20 development and strategy employees. An annual budget of around 11 million EUR is provided by the Health, Welfare and Sport ministry. The Netherlands Radiocommunications Agency has a yearly budget of 1.6 million EUR per year, with around 10 FTEs involved in market surveillance activities (of which roughly 6 for inspectors). For the Social Affairs and Employment Inspectorate a staff count of 5.5 FTEs in 2010 is reported with an increase to 12 FTEs in 2013. The Inspectorate for Environmental Affairs and Transport mentions 65 FTEs for market surveillance on a number of sectors EU product legislation. Verispect mentions a budget of 0.2 million EUR market surveillance of measuring instruments and a number of FTEs increasing from 0.3 in 2010 to 1.5 in 2013.

<u>Own assessment:</u> The report states that with <u>Regulation (EC) No 765/2008</u> the market surveillance of products has improved with better sharing and improvement of surveillance methods between authorities, and better cooperation between national and international agencies, while challenges still remain such as in E-Commerce where the Regulation is deemed to be unclear on the legal grounds necessary to execute border controls on consumer products for personal use in a third country.

## Market surveillance in specific sectors

<u>Coverage:</u> the report covers the majority of sectors included in the reference list. The sectors excluded are transportable pressure equipment, cableways, noise emissions for outdoor equipment, pyrotechnics, efficiency requirements for hot-water boilers fired with liquid or gaseous fuels, marine equipment, non-road mobile machinery and fertilisers.

Distribution of resources: the report does not provide this information.

<u>Own assessment:</u> The Netherlands provides an overview of the enforcement activities carried out in a number of sectors, although it does not provides the details about inspections requested in the Commission template. Furthermore, the report does not provide for an assessment of the effectiveness or efficiency of the sector-specific activities but it does so for the authority Netherlands Radiocommunications Agency where its market surveillance is assessed as adequate and has improved over time.

Information-led and risk-oriented surveillance has been integrated into the operations and the agency is held publicly to account for the work performed. More information is warranted according to the agency to make further improvements and internet surveillance could be improved and better deployed in market surveillance. Challenges lie with the private imports of non-conforming equipment for personal use by consumers and the execution of the new regulatory framework for both the electromagnetic compatibility directive and the revised radio equipment directive will require the necessary capacity.

# 2.20 Austria

## General market surveillance activities

<u>General organisation</u>: Depending on the legal provisions that apply to a given product, market surveillance is exercised either by federal or by provincial authorities. The responsibilities of the Federal Government are dealt with by default in the form of indirect federal administration<sup>36</sup> (i.e. the executive powers of the Federal Government are exercised in the provinces by the provincial governor and the provincial departments), except if the Federal

<sup>36</sup> This concerns around 100 district administration authorities across the nine federal provinces.

Constitution attributes them explicitly to federal authorities. Therefore depending on the sectors, market surveillance in Austria is carried out by provincial authorities either exercising their own powers or through indirect administration, or by federal authorities.

The Federal Ministry for Science, Research and Economy coordinates the Austrian market surveillance authorities pursuant to Regulation (EC) No. 765/2008. This Decision, however, is without prejudice to the responsibility of the relevant department or province for the content of each part of the programme. A permanent Market Surveillance Coordination Body composed of representatives of federal and provincial market surveillance authorities and customs acts as a communication and coordination forum.

<u>Overall resources:</u> Austria considers that examining the amount of resources used is not a particularly helpful way to assess market surveillance, as it focuses on expenditure rather than results. Furthermore, in the case of indirect federal administration it is impossible to determine the specific budget allocated to market surveillance as the same staff performs a wide range of tasks. Nevertheless in the area of measuring instruments for which the responsible authority is the Federal Ministry of Science, Research and Economy, Austria mentions an annual budget of between 0.8 and 0.9 million EUR and a staff of 15 full-time equivalent units (FTE) during the 2010-2013 period.

<u>Own assessment:</u> Austrian assessment focuses on the effectiveness of sectoral market surveillance (see below). No specific assessment of the general organisation (e.g. cooperation and coordination) is provided.

## Market surveillance in specific sectors

<u>Coverage:</u> the Austrian report covers the large majority (about four-fifths) of sectors included in the reference list. The sectors excluded are transportable pressure equipment, cableways, energy labelling, non-road mobile machinery, equipment for use in potentially explosive atmospheres, electrical and electronic equipment under restriction of hazardous substances, waste from electrical and electronic equipment and batteries directives.

Distribution of resources: the Austrian report does not include this information.

<u>Own assessment:</u> Austria considers that according to Article 19 of Regulation (EC) No. 765/2008, the extent of market surveillance activities must follow the principle of risk assessment, that is it should depend on the potential of a certain type of product to endanger public interests in a case of non-compliance. Since this potential varies considerably from sector to sector, the level of market surveillance activities must also vary.

Against this background the Austrian report considers that market surveillance functions well in the country and resources are being employed effectively. For the directives whose focus is on user safety, the effectiveness of market surveillance would be substantiated by the extremely low number of accidents caused by defective products recorded in the IDB (Injury Database). For the other directives, whose purpose is not the safety of individuals, but for example measurement accuracy, environmental protection, or an effective use of the radio spectrum, this would be proven by the low number of serious complaints. The fact that a relatively high proportion of non-compliant products was nevertheless found during inspections testifies to the expert knowledge and motivation of the inspectors, and is not a direct reflection of the market situation.

## 2.21 Poland

#### General market surveillance activities

<u>General organisation</u>: Poland refers to the information on the general organisation of markets surveillance provided in the national programmes. In Poland, the Office of Competition and Consumer Protection (OCCP) carries out, monitors and coordinates market surveillance activities. It further cooperates with customs and 9 other market surveillance authorities<sup>37</sup>.

The Market Surveillance Steering Committee is in place to develop cooperation between the authorities involved in the national product control system, share experiences and information, and increase the national system's effectiveness through the harmonisation of procedures applied by the authorities. Representatives of all the authorities participate in the yearly Committee meetings, as does the Ministry of Finance (representing customs) and the Ministry of Economy (responsible for legislative matters).

<u>Overall resources:</u> It is estimated that approximately 8.8 million EUR was available to authorities in 2010 to 10.2 million EUR in 2013, which is a somewhat stable 0.0013% of the national budget. The number of staff available to market surveillance authorities counted 2424 full-time equivalent units (FTE) in 2010 to 2477 FTEs in 2013 in total. Between 1549 of which 1389 FTEs were available for inspectors.

<u>Own assessment:</u> The report mentions that with restricted resources (financial and staffing), market surveillance authorities establish control priorities on the basis of risk analysis. Given these constraints however, the current system is approved of and further systematic cooperation of authorities with customs has contributed to an increase in the effectiveness of the general market surveillance organisation as well.

#### Market surveillance in specific sectors

<u>Coverage:</u> The Polish report covers all sectors in the reference list, except efficiency requirements for hot-water boilers, motor vehicles and tyres and non-road mobile machinery.

Distribution of resources: the report does not include this information.

<u>Own assessment:</u> Poland provides extensive information on enforcement and communication activities carried out in most sectors and points to challenges faced. In general the report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

## 2.22 Portugal

#### General market surveillance activities

<u>General organisation</u>: Pursuant to Regulation (EC) No 765/2008, market surveillance is handled by 8 authorities<sup>38</sup> each with their own sector(s) of responsibility. The report further

<sup>37</sup> National Labour Inspectorate (PIP), Office of Electronic Communications (UKE), Inspection for Environmental Protection (IOS), Rail Transport Inspection (UTK), Construction Audit Authority (ONB),State Mining Authority (WUG), Independent Maritime Offices (UM), Road Transport Inspection (ITD), Office for Registration of Medical Products, Medical Devices and Biocidal Products (URPL).

<sup>38</sup> Authority for Food and Economic Safety (ASEA), National Authority for Medicines and Health Products (INFARMED), National Communications Authority (ICP-ANACOM), Mobility and Land Transport Institute I.P. (IMT), Directorate-General for Natural Resources, Safety and Maritime Services (DGRM), National Directorate for the Public Security Police (DNPSP), Regional Inspectorates for Economic Activities – Azores and Madeira respectively (IRAE).

mentions that external border control is assigned to the Tax and Customs Authority which is not considered a market surveillance authority.

<u>Overall resources:</u> This information is not included in the report but the resources for some of the market surveillance authorities are given. On the basis of the information supplied, ASEA is the biggest authority in budgetary terms. Its budget ranged from approximately 25 million EUR in 2010 to almost 21 million EUR in 2013. Staff available to market surveillance authorities ran up to 526 full-time equivalent units (FTE) in 2010 to 500 FTEs in 2013. Between 277 and 249 FTEs were available for inspectors. ICP-ANACOM's budget ranged from 1.3 million EUR in 2010 to 1.6 million EUR in 2013 with 9 to 10 FTEs for staff (6 to 7 FTEs for inspectors). For INFARMED a budget of 1.6 million EUR to 1.1 million EUR is mentioned, with 23.5 to 22 FTEs for staff of which 22.5 to 19.5 FTEs for inspectors.

<u>Own assessment:</u> The report does not provide an assessment of the effectiveness or efficiency of the general market surveillance organisation.

## Market surveillance in specific sectors

<u>Coverage:</u> the report covers the majority of sectors included in the reference list. The sectors excluded are transportable pressure equipment, lifts, cableways, equipment for use in potentially explosive atmospheres, chemicals, eco-design and energy labelling, efficiency requirements for hot-<u>water</u> boilers and motor vehicles and tyres,

Distribution of resources: the Portuguese report does not include this information.

<u>Own assessment:</u> The report provides extensive information on enforcement and communication activities carried out in most sectors and points to challenges faced. In general the report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

# 2.23 Romania

## General market surveillance activities

<u>General organisation</u>: Market surveillance in Romania is handled by 14 different market surveillance authorities. Coordination and exchange of information between the authorities is facilitated by the Ministry of Economy, Trade and Business Environment which has set up a Coordinating Committee consisting of representatives of market surveillance authorities, customs authority and the national standardisation body.

<u>Overall resources:</u> This information is not included in the report but the resources for some of the market surveillance authorities are given. The State Inspectorate for Construction (the market surveillance authority for construction products except for fixed fire-fighting systems – fixed systems for fire alarm/detection, for fire-fighting, for fire and smoke control and for explosion protection) had a budget allocation of approximately 681 000 EUR in 2010 that was more halved to 300 000 EUR in 2013. Personnel availability in 2010 was 50 full-time equivalent units (FTE), decreasing to 18 FTEs in 2013.

The Ministry of Agriculture and Rural Development's budget for market surveillance activities (responsible for surveillance in the area of fertilizers) ranged from 289 000 EUR in 2010 to 327 000 EUR in 2013 with 53 to 48 FTEs for staff (53 to 48 FTEs for inspectors). For the Labour Inspection (responsible for issues relating to occupational health and safety and to

work relations) a budget of approximately 205 000 EUR is reported for 2010 rising to 280 000 EUR in 2013. Staff allocation is at a stable 22 FTEs. Further, for the National Authority for Management and Regulation in Communications (ANCOM), focussing on electromagnetic compatibility and radio equipment and telecommunications terminal equipment, a budget for 2010 and 2013 of 75 000 EUR is reported, with a stable FTE count of 5 for staff, of which 4 for inspectors.

<u>Own assessment:</u> The report does not provide an assessment of the effectiveness or efficiency of the general market surveillance organisation.

## Market surveillance in specific sectors

<u>Coverage:</u> The report covers all sectors in the reference list except for medical devices.

Distribution of resources: Figures are provided for a few sectors. Budget allocated to recreational craft and marine equipment was approximately 128 000 EUR and dropped to 63 000 EUR from 2010 to 2013 with the staff and inspector availability following from 5 to 3 FTEs. For electromagnetic compatibility and radio equipment and telecommunications terminal equipment, the budget remained relatively stable between 2010 and 2013 with 75 000 EUR, with 5 FTEs for staff (of which 4 FTEs for inspectors). Fertilizers had a budget available from approximately 290 000 EUR in 2010 to 327 000 EUR in 2013. Staff availability (including that for inspectors) ranged from 53 FTEs in 2010 to 48 FTEs in 2013. The biggest sector mentioned is that of construction products with a budget available of 680 917 EUR in 2010 and falling to 299 320 EUR in 2013, with staff availability following that trend from 50 in 2010 and 18 FTEs in 2013 (of which 49 and 18 FTEs for inspectors).

<u>Own assessment:</u> The report provides extensive information on enforcement and communication activities carried out in most sectors. In general the report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities. The lack of certified laboratory in certain fields is mentioned as a challenge for market surveillance. In the sector of fertilisers the authorities noted the limits represented by the lack of transport means and resources to pay laboratory tests.

# 2.24 Slovenia

## General market surveillance activities

<u>General organisation</u>: Market surveillance in Slovenia is handled by 9 different market surveillance authorities<sup>39</sup> subordinated to 6 different ministries. Political responsibility for the authorities lies with the Ministries of Health, Labour, Interior, Agriculture Forestry and Food, Infrastructure and Spatial Planning and the Ministry of Economic Development and Technology respectively.

The latter Ministry is responsible for the implementation of Regulation (EC) No 765/2008 and coordinates the work of the inspectorates and oversees the exchange of information within a Working Group that is made up of representatives of all market surveillance authorities and representatives of the Customs Administration. It meets twice a year or as necessary.

<sup>39</sup> Market Inspectorate of the Republic of Slovenia (TIRS), Metrology Inspectorate, Health Inspectorate, Chemicals Office, Public Agency for Medicinal Products and Medical Devices (JAZMP), Labour Inspectorate, Internal Affairs Inspectorate (IRSNZ), Agriculture and Environment Inspectorate, Transport, Energy and Environment Inspectorate.

The report further mentions that the Customs Administration has, on the basis of EU Guidelines for import controls in the field of product safety and conformity, drawn up a catalogue of measures (e.g. on the release of the free circulation of goods) that supports cooperation between customs authorities and the responsible surveillance authorities.

Overall resources: This information is not included in the report.

<u>Own assessment:</u> The Slovenian report mentions that, between 2010 and 2013, improvement has been made in the knowledge of the requirements of Regulation (EC) No 765/2008 and cooperation in accordance with these requirements. The cooperation between the inspection services for surveillance of products in use and the inspection service responsible for surveillance for products on the market has been reinforced. Further, cooperation between the customs authorities and the inspectorates has been strengthened.

The report also mentions that progress has been made on building a stronger knowledge base on RAPEX and ICSMS where TIRS is the contact point for RAPEX, and the ICSMS falls under the responsibility of the\_Ministry of Economic Development and Technology. The relevant supervisory authorities exchange information with authorities from other Member States through various available fora and working groups such as PROSAFE and ADCO groups.

The report mentions that there is a lack of resources for the implementation of surveillance activities, in particular the testing of products, in combination with a lack of human resources, creating a strain on participation in working groups and in general creating an incomplete picture of the state of affairs in surveying products on the market.

## Market surveillance in specific sectors

<u>Coverage:</u> The report covers all sectors in the reference list except for efficiency requirements for hot-water boilers.

<u>Distribution of resources:</u> Figures are provided for some sectors. Budget allocated to most sectors range between approximately 3000 and 60 000 EUR per year in the period 2010-2013 and a staff and inspector availability between 0.5 and 7 full-time equivalent units (FTE).

<u>Own assessment</u>: The report provides information on enforcement and communication activities carried out in most sectors. It does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

# 2.25 Slovakia

## General market surveillance activities

<u>General organisation</u>: Slovakia provides extensive information on the general organisation of market surveillance. Market surveillance activities pursuant to Regulation (EC) No 765/2008 rest with several ministries. The organisation of market surveillance in Slovakia can be split into two large groups: consumer products and products used by businesses. As a result there are often two surveillance authorities responsible for the enforcement of a given piece of harmonisation legislation (e.g.; personal protective equipment, machinery). However certain products such as medical devices and cosmetics fall under the responsibility of a single surveillance authority, regardless of whether they are consumer or professional products.

The Slovak Trade Inspectorate, which acts under the control of the Ministry of Economy<sup>40</sup>, is the market surveillance authority for most non-food consumer products.<sup>41</sup>

The National Labour Inspectorate (under the control of the Ministry of Labour, Social Affairs and Family) is, together with 8 regional labour inspectorates, the market surveillance authority for most professional products.

The State Institute for Drug Control and the Public Health Authority<sup>42</sup> (both under the control of the Ministry of Ministry of Health) are the surveillance authority for medical devices and cosmetics respectively.

The Regulatory Authority for Electronic Communications and Postal Services and other authorities under the control of the Ministry of Transport, Construction and Regional Development are the surveillance authority for radio and telecommunications equipment and electromagnetic compatibility, motor vehicles, cableways, marine equipment and other products.

The Slovak Metrological Inspectorate (under the control of the Slovak Office of Standards, Metrology and Testing) is the surveillance authority for measuring instruments and prepackaging.

The Slovak report describes the way each of these authorities works.

The authorities cooperate in the organisation and performance of inspections and exchange information on the basis of bilateral agreements. Intra-sector vertical coordination is ensured by individual authorities, which provide guidelines and training to inspectors, and direct their activities.

Overall resources: According to the Slovak report it is not possible to distinguish within the budget of each authority the share of resources allocated to market surveillance from other tasks. The same can be said for staff.

In the 2010-013 period the total annual budget and staff of the Trade Inspectorate amounted to 4.6 million EUR and 252 full-time equivalent units (FTE).

The National Inspectorate employed overall between 109 and 150 staff per year, and estimates that among them about 18<sup>43</sup> FTEs carried out market surveillance. As expenditure per employee (including wages, goods and services) was approximately 18 800 EUR, it is understood that resources for market surveillance in the area of professional products could possibly be estimated around 0.3 million EUR<sup>44</sup>.

The Public Health Authority and the regional authorities estimate that, out of an overall annual budget of between 30 and 33 million EUR, about 0.2-0.35 million EUR were dedicated to market surveillance in the cosmetics area; furthermore, they employed more than 2000 staff, about 150 of which provided market surveillance for cosmetics, alongside other

<sup>40</sup> The Ministry's responsibility also encompasses the Main Mining Office, which carries out the state surveillance of the explosives market.

The Trade Inspectorate is the sole surveillance authority only in relation to toys, pyrotechnics, construction products, electrical 41 appliances and equipment under the low voltage directive, gas appliances, and the labelling of products and recreational craft. 42

Together with 36 regional public health authorities.

<sup>16</sup> inspectors from regional labour inspectorates and 2 employees of the National Inspectorate. 43

<sup>44</sup> This figure is not explicitly provided by the Slovak report, but corresponds to the value of the multiplication of estimated fullequivalent units of staff for market surveillance and expenditure per employee.

activities, such as official inspections of foodstuffs.

The State Institute for Drug Control had a total budget between 3.7 and 4.2 million EUR and overall FTE count between 165 and 196 per year.

<u>Own assessment:</u> Slovakia rates positively the functioning of its market surveillance activities. During the reporting period there were no serious threats to the health and safety of the public or other public interests.

The financial resources allocated by ministries to surveillance authorities for their activities were limited and central government budget rules do not permit an increase in financial resources for market surveillance authorities. Lack of funds particularly affects laboratory testing. Therefore, the market surveillance authorities, in cooperation with the relevant ministries, jointly assessed the market situation in Slovakia and adapted their activities to topical issues.

Slovakia makes use of all possibilities of cooperation with other EU Member States. The situation would be eased if EU legislation were simplified and streamlined in the field of market surveillance concerning harmonised legislation.

Cooperation between authorities, including vertical intra-sector cooperation, is considered effective. So far, there has been no acute need to establish a nationwide coordinating body for market surveillance. This option will be considered after the new EU market surveillance regulation has been adopted.

Cooperation between market surveillance authorities and customs authorities has improved considerably at the end of the reporting period. This can be attributed in part to an initiative of the Commission (DG TAXUD), which produced manuals for customs officers and promoted cooperation between customs authorities and market surveillance authorities. Individual surveillance authorities have signed cooperation agreements with customs authorities. They exchange information on dangerous products, work together on inspections and organise joint training for their employees.

## Market surveillance in specific sectors

<u>Coverage:</u> The Slovak report covers half of the sectors in the reference list. Sectors excluded are pressure equipment, aerosols, machinery, lifts, equipment for use in potentially explosive atmospheres, electromagnetic compatibility, radio and telecommunications equipment, electrical equipment under restriction of hazardous substances, waste from electrical and electronic equipment and batteries, efficiency requirement for hot-water boilers, marine equipment, motor vehicles, non-road machinery and non-harmonised consumer goods (optional).

<u>Distribution of resources:</u> As mentioned in the section on overall resources, according to Slovakia the resources available to market surveillance cannot be easily distinguished from those related to other tasks. A comparison of resources allocated to market surveillance in different sectors cannot be done, however estimates of staff carrying out market surveillance (alongside other activities) in different sectors are given. Excluding medical devices and cosmetics for which no specific estimates are provided, the biggest number of employees work in the sectors of toys, personal protective equipment and low voltage products, together with eco-design/energy labelling.

<u>Own assessment:</u> Slovakia considers that in the reporting period, there were no serious deficiencies in the operation and functioning of market surveillance authorities or situations threatening the health and safety of consumers, professional users and other public interests, and therefore rates positively the overall functioning of market surveillance. Apart from a few exceptions, such as for cosmetics products, a more specific assessment of the activities carried out in a given sector is not provided.

The biggest problem in the area of consumer products falling within the scope of Regulation (EC) No 765/2008 concerns the traceability of individual businesses in the distribution chain. As Slovakia has few manufacturers of consumer products, inspections must focus on distributors and retailers. Most consumer products were manufactured in third countries and entered the Slovak market from other Member States. It was virtually impossible to identify the importers and, sometimes, distributors of such products. Slovakia also notes that the application of Article 21(1) and (2) of Regulation (EC) No 765/2008 tends to be abused by economic operators, and this hampers market surveillance.

In some sectors (low voltage electrical products) the insufficient definition of product ranges by Custom Tariff codes has prevented the ability to draw risk profiles to be used for checks by customs.

## 2.26 Finland

## General market surveillance activities

<u>General organisation</u>: Finland refers to information provided in the general national programmes. There are nine market surveillance authorities in Finland (i.e. seven sectoral authorities, the National Police Board and Customs). Over the 2010-2013 period it appears that some of the tasks previously conducted by other authorities were transferred to the Finnish Safety and Chemical Agency (Tukes).

The Ministry of Employment and Economy carries out coordinative tasks related to market surveillance and is responsible for the coordination of the national implementation of Regulation (EC) 765/2008. The Ministry is supported by the Advisory Board of Conformity Assessment Affairs that brings together the different authorities as well as stakeholders.

Market surveillance is mostly conducted at central authority level, although there are exceptions to this (e.g. market surveillance of certain professional products is conducted by the Department for Occupational Safety and Health at the Ministry of Social Affairs and Health, as well as Regional State Administrative Agencies' occupational health and safety).

<u>Overall resources:</u> Between 2010 and 2013, Finland devoted between 7.2 and 7.7 million EUR per year to market surveillance. Overall staff available to market surveillance can be estimated at around 90-93 full-time equivalent units (FTE), including customs officials. Despite some fluctuations the annual budget for the market surveillance authorities remained fairly constant over the 2010-2013 period. Staff figures diminished very slightly.

<u>Own assessment:</u> Finland considers that cooperation between different market surveillance authorities through the different discussion forums was efficient. Also cooperation with customs worked well.

Finnish authorities used the RAPEX and ICSMS systems actively (for instance 222 RAPEX notifications were made in 2013).

The report mentions the challenge provided by on-line sales by economic operators located outside the EU. It also mentions that in some sectors formal requirements such as technical documentation and CE marking are disregarded by businesses, possibly due to a lack of knowledge or understanding of those requirements.

## Market surveillance in specific sectors

<u>Coverage:</u> The Finnish report covers all sectors indicated in the reference list (including non-harmonised consumer product), with the sole exception of non-road mobile machinery.

<u>Distribution of resources:</u> The sector to which the greatest part by far of resources was allocated is low voltage electrical appliances and equipment (between 1.1-1.4 million EUR per year and 7-8 FTEs). This was followed by toys (0.78 million EUR and 13 FTEs) and other consumer products falling under the General Product Safety Directive (0.7 million EUR and 11.5 FTEs), construction products (0.6-0.7 million EUR and 5.5 FTEs), eco-design and energy labelling<sup>45</sup> (0.3-0.5 million EUR and 3 FTEs), radio and telecommunications equipment (0.5-0.17 million EUR and 4-1.5 FTEs), recreational craft (0.3-0.4 million EUR and 4 FTEs) and pressure equipment (0.3 million EUR and 2.2-3.2 FTEs).

Own assessment: Finland provides extensive information on enforcement and communication activities carried out in most sectors. It reports that market surveillance activities have been carried out according to market surveillance programmes. Depending on the sectors, market surveillance is either carried out proactively or exclusively in response to complaints. In different sectors it is also noted that the level of market surveillance is regarded as sufficient, although the report does not detail the specific criteria used for the assessment (e.g. market sizes, estimate of potential non-compliance). Efficient surveillance was carried out in some areas such as toys (38 recalls and 20 withdrawals in 2010-2013), personal protective equipment (26 recalls and 32 withdrawals), non-harmonised consumer products (70 recalls and 40 withdrawals), machinery (22 recalls and 23 withdrawals), despite the relatively limited amount of resources. Very efficient surveillance was also carried out regarding electrical appliances and equipment under LVD (224 recalls and 437 withdrawals). Due to lack of resources in some sectors markets surveillance was very selective in comparison to market size (medical devices, motor vehicles, eco-design and energy labelling restriction of hazardous substances, waste from electrical and electronic equipment and batteries). The absence of an administrative cooperation group (ADCO) complicates the possibility of crossborder cooperation in the sectors of marine equipment and motor vehicles.

# 2.27 Sweden

# General market surveillance activities

<u>General organisation</u>: Sweden refers to the information on the general organisation of market surveillance provided in the national programmes. Market surveillance is carried out by 16 public authorities and 290 municipalities. The Swedish Board for Accreditation and Conformity Assessment (Swedac) is responsible for coordination, including presiding over the Market Surveillance Council that consists of the 16 authorities as well as the Swedish Customs and the Swedish National Board of Trade. It also functions as the national administrator for ICSMS, whereas the Swedish Consumer Agency is the contact point for RAPEX.

<sup>45</sup> Including checks for hot-water boilers efficiency requirements.

<u>Overall resources:</u> Between 2010 and 2013, Sweden allocated between 10.4 and 14.3 million EUR per year to market surveillance. Overall staff available to market surveillance almost doubled and is estimated at approximately 43.5 in to 2010 to 91.5 full-time equivalent units (FTE) in 2013. There is no distinction made for inspectors since at most Swedish market surveillance authorities no particular distribution of occupational categories exists.

<u>Own assessment:</u> The report mentions that, even though there is room for improvement, cooperation between market surveillance authorities works well. Given that various authorities are responsible for various aspects of the same product, close cooperation is deemed important by Sweden to achieve effective market surveillance.

Many authorities are actively engaged in disseminating information to economic actors, and their cooperation is functioning well and voluntary corrective actions are common. Further, cooperation between authorities and the Swedish Customs has shown a steady improvement over the years.

Cooperation on a European level works well but the administration that is involved in joint projects is seen as burdensome making, it difficult for authorities to prioritise this cooperation in their activities.

Drawing definitive conclusions on how market surveillance is functioning is challenging but a conclusion that may be drawn is that formal non-compliance is common in most sectors while deficiencies in compliance with basic product requirement vary from one sector to another.

A challenge that is mentioned is that authorities find it cumbersome to report via different information exchange systems and a single integrated system would be welcomed. Also the report mentions on-line sales by economic operators located outside the EU is a challenge.

## Market surveillance in specific sectors

<u>Coverage:</u> The Swedish report covers all sectors indicated in the reference list (including non-harmonised consumer products).

<u>Distribution of resources:</u> The biggest sector of resource allocation that is mentioned in the report is medical devices with a budget ranging from 3 million EUR in 2010 to 4 million EUR in 2014 and a staff allocation of approximately 25 FTEs. The cosmetic products sector is mentioned with around 1.1 million for the years 2012 and 2013 with a staff allocation of 8.75 FTEs and 7.5 FTEs, of which for inspectors 5.75 and 4.5 FTEs in 2012 and 2013 respectively. The construction products sector shows a drop in budget from 1.7 million EU in 2010 to 715 000 EUR in 2013 but an increase in staff from 2 to 4.5 FTEs. Other sectors mentioned are radio and telecommunications (approx. 0.7 million EUR and 1.5 FTEs), low-voltage equipment (approx. 0.6 million EUR – 0.7 million EUR and 5.7 FTEs), electrical equipment (approx. 0.1 million EUR and 1.1 FTEs), measuring instruments (approx. 0.4 million EUR – 0.95 million EUR and 4-6.5 FTEs) and other consumer products falling under the General Product Safety Directive (approx. 0.25 million EUR per year and 1.5 FTEs).

<u>Own assessment:</u> The report provides information on enforcement and communication activities carried out in most sectors. It qualifies the market surveillance activities in some other sectors as working well or satisfactorily. The report does not detail the specific criteria used for the assessment. However, for the medical devices sector for example it is stated that market checks and penalties have contributed positively to compliance with regulations.

## 2.28 United Kingdom

#### General market surveillance activities

<u>General organisation</u>: Information on the general organisation of market surveillance in the UK can be found in the national programme. Exercised within a framework of local autonomy, market surveillance generally has been divided between the Health and Safety Executive (HSE) which is responsible for products in the workplace (functions as the national administrator for ICSMS as well) and the UK's Local Authorities' Trading Standards Departments, responsible for consumer product safety. The Medical Devices Regulations and related legislation are enforced by the Department for Health's (DH) specialist Medicines and Healthcare products Regulatory Agency (MHRA). Automotive-related products are the responsibility of the Department for Transport's Vehicle and Operator Services Agency (VOSA). Non-safety legislation is enforced through a number of sector-specialist bodies.

The UK's National Market Surveillance Coordination Committee is responsible for coordination and has set up an MSCC Stakeholders Group to create dialogue between the members of the MSCC, business and other interested parties. The UK Customs authorities work closely with the MSA to identify products that are likely to present a risk, through a targeted border controls approach.

<u>Overall resources:</u> The report states that because all of the UK MSAs are autonomous enforcement bodies and the market surveillance network is diverse, it is not feasible to provide data about the overall resources.

<u>Own assessment:</u> The report does not provide an assessment of the effectiveness or efficiency of the general market surveillance organisation.

#### Market surveillance in specific sectors

<u>Coverage:</u> The report contains statistics on enforcement activities carried out by the UK Trading Standards local authorities in the areas of toys, electrical appliances, cosmetics and childcare articles for 2011 (approximately 60% of Trading Standards responded) and 2012 (approximately 93% of Trading Standards responded).

Distribution of resources: The report does not include this information.

<u>Own assessment</u>: The report provides information on enforcement and communication activities carried out in some sectors. The report does not provide an assessment of the effectiveness or efficiency of these sector-specific activities.

## 3. MAIN FINDINGS

All **Member States fulfilled the obligation** to submit reports in accordance with Article 18(6) of Regulation (EC) 765/2008 and most **Member States were able to provide a significant amount of information**, despite the understandable difficulties of the exercise (notably, the relatively short time available to discuss the common indicators and to collect information).

The information provided is valuable as it provides better and useful insights into the practical enforcement of product legislation in the EU for the first time.

The examination of the reports submitted in this first round of national reviews and assessments shows that the **level of detail of information provided varies from Member State to Member State**. Critical factors in this respect have proven to be the sector-specific focus and the range of sectors covered. The reports, which followed the sector-focused approach proposed by the Commission cover a wider range of sectors and contain in general more accurate and complete information on the enforcement activities carried out.

The following main findings are based on the results of the exercise and the efforts needed to pursue the correct implementation of the Regulation. They are not recommendations or conclusions. Rather this section is to be seen as a synthetic overview of all the information gathered and possible follow up that can be derived thereof.

## 3.1 Main findings on sector coverage

As the scope of Regulation (EC) 765/2008 extends to all EU harmonisation legislation, Member States were requested to include all product areas or sectors falling within this scope. To this end the template prepared by the Commission provided a reference list of 29 sectors which Member States were free to expand, and also covering market surveillance activities carried out in relation to non-harmonised consumer products falling within the scope of the General Product Safety Directive. On the other hand, the Commission indicated that the inclusion of market surveillance activities in relation to chemical products within the scope of Reach and Classification and Labelling Regulations was not considered necessary because of the detailed reporting and assessment already carried out and made public according to the specific provisions of this legislation.

Against this background most Member States have provided detailed information on enforcement activities carried out in the majority of sectors. Even though the actual coverage of national reports varies between Member States, the following snapshot can be made for the ones that followed the common template established by the Commission:

- All or almost all sectors were covered by Latvia, Finland, Sweden, Slovenia, Denmark, France, Malta, Bulgaria, Poland, Czech Republic, Romania, and Hungary.
- More than two thirds of sectors were covered by Austria, Greece, Estonia, Belgium, Ireland, Portugal and Cyprus.
- **About half of the sectors** were covered by Slovakia, Italy and Luxembourg.
- Less than half of the sectors were covered by Spain. The report however includes only aggregate information on activities carried out for two macro areas encompassing respectively products for consumers and professional users.

The products/legislation areas most often left out of national reports are:

- **Non-road mobile machinery** (Directive 97/68/EC) and the efficiency requirements for hot-water boilers fired with liquid or gaseous fuels pursuant to Directive 1992/42/EEC, which are covered only by 7-8 Member States.
- Transportable pressure equipment (Directive 2010/35/EU), Noise emissions for outdoor equipment (Directive 2000/14/EC), Equipment and Protective Systems

**Intended for use in Potentially Explosive Atmospheres** (Directive 1994/9/EC), which are covered only by 15-16 Member States.

A complete overview of the sectors covered by each national report is given in section 7.

As regards to some countries that chose not to use the common template, it is noted that, in general they provided less detailed information on enforcement activities carried out specific sectors. In particular:

- The report from Croatia covers activities concerning 12 of the 29 sectors included in the reference list and provides some basic statistics on inspections and checks carried out.
- The report from Germany in principle covers activities concerning 12 of the 29 sectors included in the reference list (see detailed country overview); however, because those activities are not presented on a sector-by-sector basis it is not possible to know whether the information reported actually refers to all relevant product areas or only some of them.
- The report from the Netherlands in principle covers activities concerning 21 of the 29 sectors included in the reference list. However factual he information on activities carried is provided only for a smaller set of sectors and is mostly of qualitative nature.
- The report from the United Kingdom in general does not provide information on inspections in specific sectors in the 2010-2013 period, except for toys, electrical appliances, cosmetics and childcare articles.
- The report from Lithuania provides an assessment of national legal framework and therefore does not contain information on inspections carried in specific sectors.

Based on these findings it would be useful to understand from Member States the reasons why a certain number of sectors were left out of the national reports. In some cases this may be due to the fact that certain products may not be relevant in all countries (e.g. cableways, marine equipment) or that Member States may not have intuitively considered certain pieces of legislation as product harmonisation (e.g. Directive 1992/42/EEC on efficiency requirements for hot-water boilers fired with liquid or gaseous fuels).

Apart from these special cases however the exclusion of a sector might be due either to a **lack** of structured market surveillance in the sector (i.e. authorities make no interventions or those interventions are sporadic and not recorded) or to coordination problems within a **Member State** (i.e. the central authority responsible for the coordination of market surveillance could not obtain the necessary input from the sector-specific authority).

In addition to the sectors included in the reference list, a number of the national reports also included additional product areas (see detailed country-by-country overviews in section 3). This suggests that it could be useful to **discuss with Member States the opportunity to include additional sectors in the reference list of sectors for future exercises**.

## 3.2 Main findings on the overall resources available to market surveillance

With regard to the template drawn up by the Commission, some of the Member States have

indicated that the information on levels of resources could not be easily obtained. This is because in many cases authorities responsible for market surveillance have at the same time to carry out tasks of another nature, and the budget of those authorities does not earmark funds for market surveillance.

The problem also affects the figures on staff, who are often asked to carry out different types of tasks next to market surveillance in sectors falling within the scope of Regulation (EC) 765/2008.

Against this background, it is noted that:

- The information on resources for market surveillance activities is **available** in Denmark, Finland, the Netherlands, Poland and Sweden. It also available to a large extent in France, albeit in a different format (distinction is made between budget and staff dedicated to testing of products and other market surveillance activities).
- The information is **partially available** for Italy (budget available only for the Minister of Economic Development, staff available also for some additional Ministries), the Czech Republic (budget available only for CTIA; staff available also for other authorities although difficult to distinguish between market surveillance and other tasks), Luxembourg (budget available only for ILNAS, staff available also for ITM ), Estonia, Ireland, Latvia, Malta and Slovakia (an estimation of total budget and staff for some but difficulty to distinguish between market surveillance and other tasks), Bulgaria (budget and staff available for DAMTN and KZP), Cyprus (details on resources available for about 10 sectors), Spain (estimation of the combined budget of the consumer affairs authorities) and Portugal, Romania and Hungary (budgets available for 4, 5 and 8 authorities respectively),
- The information is **not available** for Austria and Belgium (impossible to determine the budget allocated to market surveillance tasks carried out under indirect federal administration), the United Kingdom (impossible to provide data on the overall resources because all of the UK MSAs are autonomous enforcement bodies and the market surveillance network is diverse), Germany (according to whom information on the level of resources for market surveillance is not relevant to assess its effectiveness and efficiency), Croatia and Slovenia (no specific reason specified).
- In the case of Lithuania, it is not possible to say if resources for market surveillance are known or not, since the report follows a different approach and therefore does not cover this aspect.

This brief overview suggests that in a number of cases the availability of information on resources for market surveillance could be improved by increasing transparency of resources allocation within national authorities' budgets and by working out methods to estimate which share of certain resources (e.g. staff) can be attributed to different activities. The difficulty of estimating resources when market surveillance tasks are delegated to local authorities is less clear and requires more in-depth investigation.

Information provided by Member States on the level of resources **should be interpreted carefully** due to the significant gaps in information in some of the countries. In some, for instance, resources mentioned concern only the central administration but do not take into account local administrations or other police officers involved in inspections. Furthermore, it

is not clear if all budget figures provided include remuneration of staff as suggested in the Commission's template. For these reasons the information provided can only be subject to cross-country comparisons to a very limited extent.

Despite these limitations however, the information available provides interesting insights into the importance attributed to the enforcement of product legislation by a given Member State and represents a solid starting point for further enquiries. It also allows for some insight into whether authorities have in practice the means to accomplish the tasks attributed to them.

Many Member States note that **resources for market surveillance are limited and lacking**. For instance, a lack of resources is claimed by Spain, Poland, Slovenia, Estonia, Denmark, Italy, Czech Republic, Malta, Luxembourg, Slovakia, Bulgaria (budget for testing, expert staff in certain sectors) and Cyprus. It would then appear useful for Member States to try and **estimate the amount of resources necessary** to increase the amount of enforcement to a more satisfactory level and to take **initiatives to fill the resource gap**.

# **3.3** Main findings on the assessment of market surveillance carried out by Member States – discussion of evaluation criteria

According to Article 18(6) of Regulation (EC) 765/2008 the assessment of the functioning of national market surveillance should be carried out by Member States.

The template prepared by the Commission was meant to help Member States to structure the information in a manner that could facilitate its evaluation. The idea behind the template was that reporting information on the general organisation of market surveillance (infrastructures, distribution of competences, resources available) and sector-specific activities (information and communication activities, number, type and outcomes of inspections) could help present all the basic 'facts' to be assessed.

On the other hand the template left **Member States free to determine the relevant criteria for the assessment** of their (general/sectoral) national market surveillance activities.

It is then interesting to observe that a number of Member States have actually interpreted the requirement of Article 18(6) of the Regulation as for the most part a mere reporting obligation, and have used the Commission template more as a questionnaire on possible 'indicators' of activities rather than as an aid for their own analysis and evaluation. As a result of this, in many cases the reports provide sector-by-sector information but do not actually *evaluate* the amount and type of activities carried out.

However, the following few examples of assessments of market surveillance activities by specific Member States are noted:

- Austria considers that the overall level of market surveillance can be regarded as sufficient in the light of the **low number of complaints** lodged with market surveillance authorities and the **low number of accidents** recorded in the Injury Database.
- Slovakia rates the functioning of market surveillance as generally positive since it considers that in the reporting period there were **no serious deficiencies in the operations of market surveillance authorities** or situations threatening the health and safety of consumers, professional users and other public interests.

- The Netherlands, Sweden, Denmark, Poland, Estonia, Slovenia and the Czech Republic consider the market surveillance activities to be effective or satisfactory since the cooperation and coordination between authorities is of such a level (or has improved) that it has a positive impact on the overall success of surveillance activities.
- Germany, Bulgaria and Finland consider market surveillance activities satisfactory as they were carried out **according to market surveillance programmes**.
- Finland also points to the efficiency of market surveillance by comparing the number of product recalls and withdrawals achieved in 2010-2013 with the relatively small level of resources available during the same period.
- Furthermore, specific attention should be devoted to the approach of Lithuania's evaluation study. Interestingly, it had the objective to **assess whether national law has properly implemented the EU requirements** for market surveillance laid down in Regulation (EC) 765/2008 and makes suggestions on how to further improve the national regulatory framework.

In light of the above, it would appear useful to discuss with Member States the advantages and disadvantages of the different approaches to the assessment of market surveillance and to build a common understanding on the relevant **evaluation criteria**.

In this regard, the assessment of the market surveillance carried out in a given sector is also expected to be connected to the **specific market context** in which the market surveillance activities took place. For this reason figures on the number and type of inspections should be analysed against the backdrop of the relevant estimates of the size of the national market for the products concerned, the number of manufacturers/importer/wholesale or retail distributors based in the Member States and, the volume of imports from other Member States or third countries, and so on. This information seems among those necessary to assess the scale and the reach of market surveillance activities.

The Commission also notes that the Lithuanian approach to evaluation introduces an additional and interesting dimension to the discussion on the assessment of the functioning of market surveillance.

## 3.4 Main findings on challenges faced by market surveillance authorities

Many national reports comment on major difficulties identified in the course of market surveillance activities. One of them is certainly the lack of sufficient resources. Additional common challenges appear to be the following:

- Various reports (e.g. Denmark, France, Germany, the Netherlands, Czech Republic, Finland, Bulgaria) note that current control procedures are not apt to handle **products sold on line**. In this connection, for instance, Germany suggests that it is worth considering whether, for internet commerce, there should be further accountable parties beyond the economic operators defined in Regulation (EC) No 765/2008, for example commercial platforms that do not fall within the current definitions of a distributor or importer. Moreover, for effective market surveillance of products sold on the internet and that are offered from outside the EU, collaboration with customs authorities is of crucial importance.
- Some reports stress the need to reinforce **customs controls.** In this respect Germany

notes that product-specific specialist knowledge must be available to a greater extent locally at import control sites: risk profiles based on the findings of market surveillance authorities have proven worthwhile, but an improvement would be possible, for example, by conducting special training for customs officials or by posting market surveillance specialists at customs offices for direct, joint customs clearance. Furthermore, to make it harder for non-European manufacturers, whose non-compliant products have been rejected by a customs authority, to switch to other customs clearance locations, improved cooperation between the customs authorities of the EU Member States also seems necessary). Slovakia and Cyprus point to the existing mismatch between the customs product classification and the nomenclature used by market surveillance authorities, which hamper cooperation in some areas (e.g. electrical low voltage equipment, personal protective equipment, pressure equipment, equipment for use in potentially explosive atmospheres, lifts and machinery).

- France mentions insufficient **cross-border cooperation** in some sectors (i.e. equipment for use in potentially explosive atmospheres, pyrotechnic articles, civil explosives and gas appliances), as a difficulty to tackle when relevant economic operators are located abroad. Finland mentions complications due to the lack of ADCOs for marine equipment and motor vehicles.
- Spain, the Czech Republic, Malta, Slovakia, Bulgaria and Cyprus note the lack of **traceability** information especially, when products are imported into the EU by intermediaries located in other Member States
- The Czech Republic notes the difficulty of dealing with products from third countries sold via **informal channels** (marketplaces), and the ineffectiveness of market surveillance techniques in this case.
- Spain and Ireland note that penalties laid down in national law might not be a sufficient deterrent, in particular in the case of larger companies trying to market non-compliant products;
- Estonia and Ireland note that **the non-existence of test laboratories** makes conformity assessment difficult and costly.
- Many reports mention **economic operators' lack of knowledge** about applicable product rules. Finland for instance mentions that in some sectors formal requirements such as technical documentation and CE marking are disregarded by businesses, possibly due to lack of knowledge or understanding of those requirements. France suggests a simplification of product legislation and the need to provide summaries of legislation applicable to categories of products to be made available to businesses.
- Bulgaria notes the **lack of cooperation by certain economic operators**; Slovakia refers to businesses' abuses of the legal principles on the notification of restrictive measure contained in Article 21 (1) and (2) of Regulation (EC) 765/2008.
- France mentions the need to reduce the **administrative burden** for market surveillance authorities (i.e. simplify current safeguard clause procedures for serious risk products by using the Rapex system). Sweden notes that there is a demand for a single integrated system since reporting in different information exchange systems is deemed cumbersome and not always suitable.

The reflections of the market surveillance authorities should guide current and future policy initiatives in the on-going implementation of Regulation (EC) 765/2008.

# **3.5** Main findings on possible issues with current practice by market surveillance authorities

The analysis of the specific information provided by Member States for the toys sector that is conducted in the following section sheds light on some aspects of market surveillance activities in practice. The Commission suggests a number of possible concrete follow-up actions that could improve national enforcement of legislation in relation to potential gaps identified. These actions could also be easily applied to other product areas. They have been grouped by relevant area and can be summarised as follows:

- Focus of market surveillance activities: authorities to discuss and compare methodologies for selecting proactive inspections and to screen information provided by stakeholders; draw up a set of best practices; enquire into the accessibility and visibility of national stakeholders' complaint procedures.
- **Follow-up to discovery of non-compliance**: enquire into reasons why a significant number of inspections where non-compliance is found appear to be left without follow up; enquire about criteria used by Member States to choose whether to apply sanctions in addition to compulsory corrective action or not.
- **Cooperation with customs**: identify and overcome obstacles to cooperation between customs and market surveillance authorities; discuss possibility to recognise customs as markets surveillance authorities.
- **Cross-border cooperation**: enquire into obstacles to cross-border cooperation; inform sector authorities of the mutual assistance principles of Regulation (EC) 765/2008; make those principles operational by building up a common procedure.

## 4. CASE STUDY OF A SPECIFIC SECTOR: TOYS

This section showcases a more in-depth analysis of the information provided by Member States in relation to market surveillance activities carried out during the 2010-2013 period in the toys sector.

The reason why a single sector has been chosen is to demonstrate that with the correct use of the template that was provided by the Commission, more insight into the difference and commonalities of market surveillance activities by Member States on a sectoral level can be discerned since the results of the analysis offer indications of the size and the type of enforcement activities carried out in each country<sup>46</sup>. The objective is to shed a brighter light on some aspects of market surveillance activities in practice.

# 4.1 On the number of product-related accidents, user and industry complaints

Information on the number of product-related accidents, user and industry complaints is provided by 17 Member States out of the 28 that submitted a report according to Article 18(6) of Regulation (EC) 765/2008. In half of them (Bulgaria, Ireland, France, Hungary, Malta,

<sup>46</sup> Naturally differences between countries can partly be attributed to different levels/styles of enforcement activities and partly to diverging interpretations of the indicators.

Portugal, Finland and Sweden) the average number of product-related accidents and complaints per year is between 14 and 31; in four cases the average number is much higher (215 for Poland, 212 for Italy<sup>47</sup>, 120 for Czech Republic and 90 for Slovakia); in four other cases very few complaints are reported (4 for Denmark, 1 respectively for Greece and Luxembourg, 0 for Romania and Cyprus)

The number and the importance of product-related accidents, user and industry complaints provides indications to market surveillance authorities of the presence of possible non-compliant products available on the market. These figures should be viewed in relation to the population of each country and to the number of products made available in national markets. The fact that a certain number of the Member States do not provide any information on product-related accidents, user and industry complaints may however suggest that accidents and complaints are not systematically recorded. It also raises the question about the accessibility and visibility of national complaint procedures.

## 4.2 On the number of inspections

The average yearly number of inspections<sup>48</sup> reported for the period between 2010 and 2013 changes significantly from Member State to Member State (from 4 in Ireland to more than 2 800 in France). The following outlook is provided for groups of countries of broadly similar number of inhabitants<sup>49</sup>:

- Germany (81 million inhabitants): no information on toy inspections provided.
- France, Italy and the UK (60-66 million inhabitants): France reports an average of 2 834 inspections per year<sup>50</sup>; Italy reports 1 115 inspections including however both toys and other non-harmonised consumer products; the UK reports 1 482 per year.
- Spain and Poland (38-46 million inhabitants): Poland reports 754 inspections per year on average; no information on toys inspections is provided by Spain.
- Romania and the Netherlands (16-20 million inhabitants): Romania reports 1 496 inspections per year; the Netherlands notes that between 2012 and 2013 135 manufacturers and importers of toys were inspected and that some of the companies were trading in different product groups.
- Belgium, Greece, Czech Republic, Portugal, Hungary, Sweden, Austria and Bulgaria (7-11 million inhabitants): Belgium reports 1 270<sup>51</sup> inspections per year on average; Greece reports 28 inspections<sup>52</sup>, however the yearly activity went down over the period from 38 to 8 inspections; the Czech Republic reports 1 631 inspections; Portugal reports 235 inspections with a big increase in 2012 and 2013 (respectively 453 and 405 inspections) by comparison with 2010 and 2011 (50 and 30 inspections each); Hungary

<sup>47</sup> Also includes those concerning non-harmonised consumer goods.

<sup>48</sup> According to the common template prepared by the Commission, inspections are regular or ad hoc visits, controls (including checks on the internet) or other forms of contacts (mail, telephone) undertaken by an inspector, with an enforcement focus (excluding pure information-exchange) and aimed at verification of product safety and compliance. Where several products/models/regulations are checked during the same exercise, this should be counted as one inspection. In order to be considered an inspection, there must be an official report prepared following the action.

<sup>49</sup> The number of inhabitants is taken here as a very simple (although admittedly very rough) estimate of national market sizes.

<sup>50</sup> The figure does not include checks carried out by customs that in France are market surveillance authorities.

<sup>51</sup> For 2010 and 2011 Belgium reports respectively 110 and 639 investigations to which the follow-up to Rapex notifications concerning toys should be added. The inclusion of toys Rapex notifications for years 2012 and 2013 brings the number of inspections respectively up to 2251 and 2078.

<sup>52</sup> The Greek report notes these were carried out "at virtually zero cost".

reports 1 180 inspections; Sweden reports 84 inspections; Austria reports 584 inspections with a big increase in 2012 and 2013 (respectively 117 and 130 inspections) by comparison with 2010 and 2011 (52 and 37 inspections each); Bulgaria reports 1 739 inspections.

- Denmark, Finland, Slovakia, Ireland and Croatia (4-6 million inhabitants): Denmark reports 113 average inspections per year, with a drop in the number of inspections carried out in 2012 and 2013 (90 per year) compared to those carried out in 2010 and 2011 (respectively 138 and 133); Finland reports 1 351 inspections with big drop in 2013 (808 inspection) compared to the previous year (1 739 inspections); Ireland reports 4 inspections<sup>53</sup>; Croatia reports 384 inspections for the last semester of 2013.
- Lithuania, Slovenia and Latvia (2-3 million inhabitants): no information is available for Lithuania; Slovenia reports 1 757 average inspections per year (including those in kindergartens); Latvia reports 116 inspections.
- Estonia (1.3 million inhabitants) reports 402 average inspections per year
- Cyprus, Malta and Luxembourg (less than a million inhabitants): Cyprus reports 960 average inspections per year, with a peak of activity in 2010 (1 257 inspections) compared to the other years; Malta reports 149 inspections; Luxembourg reports 51 inspections including visual inspections of labelling.

The figures reported in this section should be interpreted carefully as it cannot be excluded that the figures collected by different Member States do not entirely correspond. For instance it is likely that certain checks at the border<sup>54</sup> are included by some Member States and excluded by others depending on the way responsibilities are shared.

The overview above reports the figures provided by the Member States. It does not constitute an assessment of the amount of effort made by market surveillance authorities and whether enforcement activities carried out were to an appropriate scale. Assessing the scale of the checks would presuppose among others information about the number and type of economic operators making products available in a given country, as well as the number of products involved in a given inspection (e.g. an inspection addressing the principal or exclusive national importer of a product made available throughout the whole national market is expected to involve a larger number of products than inspections carried out in a single retail outlet).

## 4.3 On the nature of inspections

*Proactive vs reactive inspections*: When looking at the share of proactive (including inspections prompted by customs) versus reactive inspections, it appears that about 60 % of the inspections reported by Member States<sup>55</sup> for the period 2010-2013 were proactive inspections. However the situation changes from country to country (see Table 7-3 below). At the high end of the spectrum are France, Romania, Luxembourg and Latvia whose reported inspections are virtually entirely self-initiated, followed by Poland and Greece (83%),

<sup>53</sup> Not limited to toys.

<sup>54</sup> For instance sample checks, if any, conducted by customs without prior coordination with market surveillance authority and which did not give rise to subsequent in-depth investigations.

<sup>55</sup> This average is based on data provided by 17 Member States. In particular it excludes Germany, Spain, Lithuania and the Netherlands for which no information on investigations in the toys sectors is provided. It also excludes Estonia, Italy, Czech Republic, Cyprus, Austria, Finland and the UK whose data are incomplete or contained inconsistencies so that the share of self-initiated investigations could not be calculated.

Slovenia (77%), Bulgaria, Hungary, Croatia and Sweden (65-60%), Denmark, Malta and Portugal (55-50%) and then Slovakia (38%). At the low end of the spectrum are Belgium  $(12\%)^{56}$  – recorded a high number of reactions to Rapex notifications – and Ireland (0%).

BE	12
BG	65
CZ	n.a.
DK	55
DE	n.a.
EE	n.a.
IE	0
EL	83
ES	n.a.
FR	99
HR	61
IT	n.a.
СҮ	n.a.
LV	98
LT	n.a.
LU	99
HU	62
MT	54
NL	n.a.
AT	n.a.
PL	83
РТ	50
RO	99
SI	77
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Table 7-3: Share of self-initiated inspections out of total inspections (percentages
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<sup>56</sup> As regards Belgium the share is calculated on the figures provided for 2013 only.

SK	38
FI	n.a.
SE	60
UK	n.a.

*Types of checks*: The share of physical and laboratory checks as opposed to merely administrative checks is about 100% for Bulgaria, Denmark, Cyprus, Latvia and Slovakia, close to 90% for Czech Republic, around 75-80% for Luxembourg and Slovenia, and 57-58% for Finland and Sweden. Lower shares are given for Portugal (27%) and Croatia (18%).

Unfortunately the relevant share cannot be calculated for some countries due to different interpretations of the information requested. It appears nevertheless that a very high total number of physical and laboratory tests were carried out by France, the UK, Hungary and Poland.

In most cases the share of laboratory tests cannot be singled out due to the different approaches used in collecting the data.

## 4.4 On the share of inspections prompted by customs

The average share of inspections prompted by customs is about 20% <sup>57</sup>, but varies between a country such as Ireland, where all inspections concerning toys in the 2010-2013 period were initiated by customs, and countries such as Greece, Romania, Slovenia, Portugal, Malta, Hungary and Slovakia where virtually none or only 1% of the inspections were prompted by border control authorities. The share is 7-11% for the UK, Sweden and Denmark, 19-20% for Poland, Latvia and Cyprus, 25-26% for Luxembourg and Bulgaria, 38% for Croatia, 54% for Finland.

BE	n.a.
BG	26
CZ	n.a.
DK	10
DE	n.a.
EE	n.a.
IE	100
EL	0
ES	n.a.

 Table 7-4: Share of inspections prompted by customs (percentages)

<sup>57</sup> This average is based on data provided by 18 Member States. Notably, it excludes Germany, Spain, Lithuania and the Netherlands, for which no information on investigations in the toys sectors is provided. It also excludes Estonia, Italy, Czech Republic, Cyprus and Austria whose data are incomplete or contained inconsistencies so that the share of self-initiated investigations could not be calculated. It excludes France where customs are market surveillance authorities and carry out checks for themselves.

HR	38
IT	n.a.
СҮ	n.a.
LV	19
LT	n.a.
LU	25
HU	1
МТ	0
NL	n.a.
AT	n.a.
PL	19
РТ	0
RO	0.
SI	0
SK	1
FI	54
SE	7
UK	11

The relatively low involvement of customs in some countries appears at odds with the fact that many of the toys on national markets are imported from third countries. This might be explained by possible cooperation issues between customs and market surveillance authorities. It might possibly also be due to the fact that, traditionally being used to a different 'core business', customs may not feel fully committed to the more recent goal of product safety and compliance. As a matter of fact countries like France and Finland, where customs are directly involved in market surveillance, the percentage of inspections prompted by them is remarkably higher.

## 4.5 On the outcomes of inspections: Finding of non-compliance

The share of inspections reported by Member States giving rise to a finding of noncompliance was on average 44% in the EU<sup>58</sup>. Again however there are significant differences between Member States: the share is 83% for Sweden, 81% for Romania, 73% for Malta, 54% for Poland, 45% for Latvia and Greece, 39-40% for Slovakia and Bulgaria, 32-34% for

<sup>58</sup> This is the simple average of national percentages based on data provided by 16 Member States, while the weighted average is 32%. Those averages exclude Germany, Spain, Lithuania and the Netherlands for which no information on investigations in the toys sectors is provided. They also excludes Belgium, Estonia, Italy, Czech Republic, Cyprus, Austria, Finland and the UK whose data are incomplete or contained inconsistencies so that the share of self-initiated investigations could not be calculated.

Hungary and Luxembourg, 26% for Denmark, 12-15% for Portugal, France, Croatia and Slovenia.

The level of non-compliance rates found by toys market surveillance authorities on the one hand represents an indication of the existence of non-compliance in the sector, while on the other hand it says something about the authorities' ability to spot it. For instance, it is assumed that the rate should be lower overall for proactive inspections involving random sample checks (like, apparently, for France, Slovenia and Luxembourg), while it should be higher for targeted proactive inspections and reactive inspections pursuant to concrete indications (e.g. by complainants, Rapex notifications) that point to the non-compliance of certain products. However, the quality, respectively, of the prioritisation work leading to random sample checks and the screening/assessment of the complaints also has an impact on the probability of spotting non-compliance.

## 4.5 On the outcomes of inspections: Measures and penalties

*Follow up to inspections where non-compliance was found*: The comparison of the number of inspections where non-compliance was found, with the sum of (voluntary or compulsory) measures taken by market surveillance authorities and/or the total number of sanctions/penalties applied, provides an indication of the follow-up given by market surveillance authorities. On the basis of the data provided, it appears that on average the EU authorities were able to provide a follow-up in two-thirds of cases at most.<sup>59</sup>

Table 7-5 shows that, among Member States with percentages higher than the EU average, Estonia and Hungary indicate the application of measures and/or sanctions for all inspections reported for the 2010-2013 period; Latvia, Portugal and Luxembourg indicate a follow up respectively for 86%, 75% and 71% of the inspections; Finland and Denmark for 68-69% of inspections. Among Member States indicating percentages lower than the EU average, Malta and Greece report 52%, Cyprus 46%, Czech Republic, Bulgaria and Sweden 36-37%, France 29%, Slovakia 14%.

BE	n.a.
BG	37
CZ	37
DK	68
DE	n.a.
EE	100
IE	100

Table 7-5: Follow up to inspections:	percentage	of cases	of non-compliance where
measures and/or penalties were applied			

<sup>59</sup> This average is based on data provided by 17 Member States. Notably, it excludes Germany, Spain, Lithuania and the Netherlands for which no information on investigations in the toys sectors is provided. It also excludes the UK, Belgium, Poland, Slovenia, Croatia, Italy and Austria whose data are incomplete or contained inconsistencies so that the share of self-initiated investigations could not be calculated. The average probably overestimates the number of inspections with a follow-up, as in some case both corrective action and sanctions were imposed in a given inspection, so the figures worked out by the Commission involve some double counting.

EL	52
ES	n.a.
FR	29
HR	n.a.
IT	n.a.
СҮ	46
LV	86
LT	n.a.
LU	71
HU	98
МТ	52
NL	n.a.
AT	n.a.
PL	n.a.
РТ	75
RO	100
SI	n.a.
SK	14
FI	69
SE	36
UK	n.a.

*Corrective action vs sanctions*: On average corrective action was taken in the EU for 50% of the inspections that found non-compliance, while sanctions were applied for about 20% of those inspections. It appears that countries like Sweden, Finland, Malta, Luxembourg, Cyprus, Estonia and Denmark have given a net preference to corrective measures, others like Czech Republic, Portugal, and Slovakia have mainly applied sanctions/penalties, while the remaining have used an evenly-balanced mix of both.

*Voluntary vs compulsory corrective action*: The respective roles of voluntary and compulsory corrective action can be estimated only for eleven Member States and shows that Estonia, Greece, Cyprus, Latvia, Luxembourg, Croatia, Hungary and Finland resorted to a large extent to compulsory measures while Bulgaria, Sweden and, to a lesser extent, Denmark resorted mostly to voluntary measures.

The fact that corrective action and/or sanctions are reported only for a subset of inspections where non-compliance is found raises the question of what happens for the remaining inspections that have spotted non-compliance: is this due to lack of traceability/identification of the economic operators, or difficulties to reach him/her abroad, or the fact that the product is no longer on the market. One Member State observed that a small proportion of producers are based in the national territory and that the possibility of imposing measures in relation to the responsibilities of distributors is rather limited. On the other hand the fact that many market surveillance authorities focus their inspections on distributors and importers is expected to influence only the type and not the number of follow-ups provided.

It also appears that sanctions do not systematically accompany the imposition of compulsory corrective action.

## 4.6 On cross-border cooperation

Among the twelve Member States providing information on this point, only the Czech Republic and Denmark reported cases of inspections - 18 and 1 respectively - in which other Member States were invited to collaborate during the 2010-2013 period.

The indicator suggests that cross-border cooperation is extremely low. This is particularly problematic in a sector like toys where products are very often imported from third countries and from other EU countries.

#### 4.7 On budget and staff

Only 10 Member States indicated budget<sup>60</sup> and/or staff available for market surveillance activities in the toys area between 2010 and 2013. These were on average as follows:

- Bulgaria: 640 320 €, 75 overall staff dedicated to market surveillance of both toys and the other 'new Approach' products, of which 30 inspectors;
- Denmark: 233 300 €, 2 overall staff of which 1 inspector;
- France: 1 560 000 € excluding budget for testing products, 23 overall staff of which 20 inspectors;
- Hungary: 441 579 €, 33 overall staff of which 21 inspectors;
- Finland: 780 000 €, 13 overall staff of which 12 inspectors;
- Sweden: 178 641 €, 2.5 overall staff of which 0.5 inspectors;
- Greece: 13 overall staff of which 10 inspectors;

While the budget of Bulgaria and Finland remained stable overall between 2010 and 2013, the budgets of Denmark and France were reduced and those of Hungary and Sweden increased.

According to the indication contained in the common template, the budget figure should cover all financial resources which are assigned by public authorities to market surveillance and enforcement activities as well as to projects and measures aimed at ensuring compliance of economic operators with product legislation. These measures range from communication activities (consumer/business information and education) to pure enforcement and market surveillance activities. They include the remuneration of staff, direct costs of inspections, laboratory tests, training and office equipment costs. Enforcement activities at regional/local level should also be reported. Other activities undertaken by these authorities not related to the enforcement of product legislation laws should be excluded from the calculation.

In addition Ireland and Slovenia report the figures of  $5.875.000 \in$  and  $5.633.460 \in$  respectively, which amount to the total budget of the authorities responsible, amongst others, for toys market surveillance. Ireland indicates that 7 authorised officers work in the product safety unit and that additional officers are available to assist if required. Slovenia reports that the total number of the authority's employees is 133, while the total number of inspectors is 110. They are engaged in the official control of all areas of Inspectorates' field of operation. There is no specialisation by area.

It is surprising that only a few Member States could quantify the resources available for market surveillance of toys. Information on the availability of information on resources appears important to identify major resource gaps to be addressed.

In relation to data provided, it is not clear if all the figures consistently include the remuneration of staff and other possible common costs (overheads), in addition to specific market surveillance costs (e.g. sampling and testing costs).

## 4.8 On the assessment provided by Member States

Most Member States completed the information reported in the previous sections with useful additional descriptions of the activities carried out, the type of non-compliances found or the working methods used. Many consider that enforcement and information actions must be continued. Lack of knowledge about legal requirements applicable to toys and economic operators' responsibilities are very often reported.

Only a few Member States (notably Cyprus and Sweden, as well as in a much less detailed manner Bulgaria, Austria, Slovakia) were able to report information on the number and type of economic operators, value of market, value and import flows, which as noted in the section on the number of inspections, appears as an important piece of information to assess the scale of market surveillance checks. Not surprisingly, therefore, no Member State conducted an explicit assessment of market surveillance along those lines. Nevertheless Bulgaria mentions that a consistent and comprehensive monitoring of the market took place. On the other hand, Finland comments on the efficiency of enforcement efforts which lead to a certain number of products recalls and withdrawals despite relatively small resources. Among the challenges faced, toys market surveillance authorities mention 'Asian marketplaces' and fairs selling cheap toys where low rates of non-compliance are found and where products found to be unsafe are often put back on the market, sometimes after rebranding. Also, Denmark mentions the need to clarify the legal position of agents, and the responsibility of distributors when a manufacturer declares bankruptcy.

# 5. AVERAGE EU STATISTICS PER SECTOR DERIVED FROM THE 2010-2013 REVIEW AND ASSESSMENT REPORTS

The statistics in the next pages are calculated on the basis of data made available by Member States. Statistics should be interpreted with due care due to fact that some inconsistencies in the interpretation of the different definitions given by some respondents. It is also noted that not all Member States provided information on all items. For instance the following table shows the number of Member States reported concrete information on inspections carried out in a given sector.

 Table 7-6: Member States reporting data on the number of inspections per sector

Sector	No of MS reporting data
Medical devices	13
Cosmetics	14
Personal protective equipment	17
Construction products	16
Aerosol dispensers	4
Simple pressure vessels and pressure equipment	12
Transportable pressure equipment	10
Machinery	19
Lifts	5
Cableways	7
Noise emissions for outdoor equipment	6
Equipment and protective systems intended for use in potentially explosive atmospheres	8
Pyrotechnics	17
Explosives for civil uses	12
Appliances burning gaseous fuels	14
Measuring instruments, non-automatic weighting instruments and pre-packed products	16
Electrical equipment under EMC	13
Electrical appliances and equipment under LVD	20
Electrical and electronic equipment under ROHS, WEEE and batteries	9
Chemicals	16

Sector	No of MS reporting data
Eco-design & energy efficiency	15
Recreational craft	7
Marine equipment	3
Motor vehicles and tyres	4
Non-road mobile machinery	4
Fertilisers	13
Other consumer products under GPSD (optional)	13
Biocides	2
Textile & footwear labelling	5
Crystal glass	1

Source: National reports

## Table 7-7: Statistics on inspections carried out in the 2010-2013 period by all national authorities having provided data

Information below is only indicative information as data are not always fully comparable.

		devices (in vitro diagno devices a implantab	1 - Medical icluding in ostic medical nd active ile medical ices)	SECTOR 2	- Cosmetics	SECTOF	R 3 - Toys		4 - Personal Equipment		OR 5 - on Products
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants
BE	11.29					1,269.50	112.49				
BG	7.20	121.00	16.80			1,738.75	241.42	610.25	84.73	805.50	111.84
CZ	10.54	167.00	15.85	1215.25	115.32	1,631.25	154.79	395.75	37.55	349.00	33.12
DK	5.66	16.50	2.92	91.00	16.08	113.00	19.97	32.25	5.70	51.67	9.13
DE	81.20										
EE	1.31	111.00	84.52	485.50	369.69	401.50	305.73	360.75	274.70	24.50	18.66
IE	4.63	47.50	10.27	104.25	22.54	4.33	0.94	29.00	6.27		
EL	10.81					28.25	2.61	24.25	2.24	80.75	7.47
ES	46.44										
FR	66.99			1589.50	23.73	2,833.75	42.30	594.00	8.87	923.75	13.79
HR	4.23					768.00	181.76				

		devices (in vitro diagno devices a implantab	1 - Medical acluding in ostic medical nd active ole medical ices)	SECTOR 2	- Cosmetics	SECTO	R 3 - Toys		4 - Personal Equipment		OR 5 - on Products
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants
IT	60.80	125.00	2.06	1385.25	22.79			35.25	0.58		
СҮ	0.85	20.75	24.50			959.50	1132.81	20.75	24.50		
LV	1.99	25.75	12.97	412	207.44	116.00	58.41	78.00	39.27	105.25	52.99
LT	2.92										
LU	0.56					51.00	90.59				
HU	9.85	39.50	4.01	12351.75	1254.11	1,180.25	119.83	181.75	18.45	509	51.68
МТ	0.43	111.00	258.53	83.75	195.07	149.25	347.62	57.50	133.93		
NL	16.90										
AT	8.58	14.25	1.66	1946.75	226.76	583.50	67.97	52.25	6.09	57	6.64
PL	38.01	33.00	0.87	203.75	5.36	754.00	19.84	562.75	14.81	1573.25	41.40
РТ	10.37	2913.75	280.85	1293.5	124.68	234.50	22.60	52.50	5.06	75.5	7.28
RO	19.86					1,495.75	75.31	294.75	14.84	1595.5	80.33

		SECTOR 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)		SECTOR 2 - Cosmetics		SECTOR 3 - Toys			4 - Personal Equipment		OR 5 - on Products
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants
SL	2.06	16.50	8.00	1921.5 <sup>61</sup>	931.47	1,756.5062	851.48	157.00	76.11	322.75	156.46
SK	5.42	2.25	0.42	10472.5	1931.71	1,517.00	279.82	382.75	70.60	579.75	106.94
FI	5.47	13.25	2.42	382.25	69.86	1,351.25	246.95	182.75	33.40	322.5	58.94
SE	9.75	30.25	3.10	125	12.82	84.00	8.62	71.50	7.34	59.75	6.13
UK	64.88			1327.50	20.46	1,482.00	22.84				

Figures include also all beauty care services inspections. Figures include also inspections in kindergartens. 62

			6 - Aerosol Insers	pressure v	7 - Simple vessels and Equipment	Transporta	OR 8 - ble pressure oment	SECTOR 9	- Machinery	SECTOR	10 - Lifts
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants								
BE	11.29							93.25	8.26	6.75	0.60
BG	7.20	236.50	32.84	650.25	90.28	168.25	23.36	951.00	132.04	184.67	25.64
CZ	10.54	1759.00	166.92	118.25	11.22	10.50	1.00	434.00	41.18	31.00	2.94
DK	5.66	0.50	0.09	29.25	5.17	1.50	0.27	152.25	26.90	0.25	0.04
DE	81.20										
EE	1.31			3.75	2.86			75.75	57.68		
IE	4.63			1.00	0.22			52.25	11.30	57.00	12.32
EL	10.81	9.50	0.88	7.00	0.65	2.50	0.23	41.75	3.86	2.00	0.18
ES	46.44										
FR	66.99			3,300.00	49.26	2.00	0.03	1,027.25	15.33		
HR	4.23										
IT	60.80							102.75	1.69		
СҮ	0.85	65.75	77.63	191.50	226.09	17.75	20.96	70.75	83.53	43.75	51.65
LV	1.99			8.00	4.03	66.75	33.61	21.75	10.95	0.25	0.13

			6 - Aerosol ensers	pressure v	7 - Simple vessels and Equipment	Transporta	OR 8 - ble pressure oment	SECTOR 9	- Machinery	SECTOR	10 - Lifts
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants						
LT	2.92										
LU	0.56										
HU	9.85			26.75	2.72	128.25	13.02	569.50	57.82	97.00	9.85
МТ	0.43	97.25	226.51	97.25	226.51			17.00	39.60	104.00	242.23
NL	16.90										
AT	8.58	3.50	0.41	3.50	0.41	3.50	0.41	51.50	6.00	12.50	1.46
PL	38.01	0.75	0.02	125.00	3.29	230.75	6.07	884.00	23.26	2.25	0.06
РТ	10.37	20.50	1.98	74.25	7.16			51.50	4.96		
RO	19.86	60.00	3.02	81.25	4.09	7.25	0.37	558.50	28.12	7.00	0.35
SL	2.06	4.00	1.94	241.25	116.95	98.00	47.51	178.25	86.41	44.75	21.69
SK	5.42										
FI	5.47	1.00	0.18	22.00	4.02			248.25	45.37	0.25	0.05
SE	9.75	1.00	0.10	3.75	0.38	3.00	0.31	1,903.50	195.28	1.00	0.10
UK	64.88										

		SECTOR 11	- Cableways	emissions	12 - Noise for outdoor oment	Equipn Protectiv Intended Potentially	DR 13 - hent and e Systems for use in Z Explosive pheres		OR 14 - echnics	SECTOR 15 for civ	5 - Explosives ⁄il uses
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants
BE	11.29			68.33	6.06						
BG	7.20	1.33	0.19	183.33	25.46	5.00	0.69	742.25	103.06	26.50	3.68
CZ	10.54	6.75	0.64	119.75	11.36	33.50	3.18	235.50	22.35	3.50	0.33
DK	5.66			2.00	0.35	5.00	0.88	71.50	12.63		
DE	81.20										
EE	1.31							33.25	25.32	14.00	10.66
IE	4.63					2.00	0.43	443.50	95.87	443.50	95.87
EL	10.81							7.50	0.69	1.00	0.09
ES	46.44										
FR	66.99	45.50	0.68			22.50	0.34	85.25	1.27	10.00	0.15
HR	4.23							2.00	0.47		
IT	60.80			134.67	2.22			16.25	0.27	13.25	0.22
СҮ	0.85					0.25	0.30	32.75	38.67	55.50	65.52

		SECTOR 11	- Cableways	emissions f	12 - Noise for outdoor oment	Equipm Protectiv Intended Potentially	DR 13 - ient and e Systems for use in Explosive pheres		DR 14 - echnics		5 - Explosives 7il uses
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants
LV	1.99	0.25	0.13	21.75	10.95			380.25	191.46	380.25	191.46
LT	2.92										
LU	0.56										
HU	9.85			49.25	5.00	10.00	1.02			84.75	8.60
МТ	0.43							1.50	3.49		
NL	16.90										
AT	8.58	6,080.00	708.22					1225.50	142.75		
PL	38.01	5.50	0.14	386.75	10.18	39.50	1.04	110.50	2.91	4.00	0.11
РТ	10.37	4.50	0.43	37.25	3.59			3747.75	361.24	5935.50	572.11
RO	19.86	0.25	0.01	307.25	15.47	21.00	1.06	58.00	2.92	15.50	0.78
SL	2.06	117.50	56.96	69.50	33.69			27.00	13.09	1.25	0.61
SK	5.42	16.75	3.09					244.75	45.15	87.25	16.09
FI	5.47			16.25	2.97	82.00	14.99	36.25	6.62	2.00	0.37

		SECTOR 11	- Cableways	emissions	12 - Noise for outdoor oment	Protectiv Intended	ent and e Systems for use in <sup>y</sup> Explosive		DR 14 - echnics	SECTOR 15 for civ	– Explosives il uses
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections inhabitants		Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants
SE	9.75			8.00	0.82	1.50	0.15	3.50	0.36		
UK	64.88										

			- Appliances seous fuels	instrume automatic instruments	- Measuring nts, Non- e weighing (NAWI) and ed products	SECTOR 18 equipment	3 - Electrical under EMC	telecom equi	- Radio and pment under TE		) - Electrical ces and under LVD
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants
BE	11.29	22.00	1.95					578.00	51.22	788.50	69.87
BG	7.20	466.75	64.81	1339.75	186.02	831.33	115.43	242.25	33.64	1774.75	246.42
CZ	10.54	58.50	5.55	491.50	46.64	840.00	79.71	241.00	22.87	1306.50	123.98
DK	5.66	30.75	5.43	115.25	20.36	112.50	19.88	112.50	19.88	456.00	80.57
DE	81.20					6.53	0.08	6.53	0.08		
EE	1.31	21.25	16.18	6.75	5.14	185.50	141.25	1,865.75	1420.69	193.00	146.96
IE	4.63			14149.50	3058.77					4.33	0.94
EL	10.81			12872.50	1190.52	4.50	0.42	136.50	12.62	103.75	9.60
ES	46.44										
FR	66.99	10.00	0.15	897.00	13.39	525.00	7.84	745.50	11.13	2076.50	31.00
HR	4.23			1106.00	261.76			18.00	4.26		
IT	60.80			103.75	1.71			350.75	5.77	104.25	1.71
СҮ	0.85	9.33	11.02			117.75	139.02	16.00	18.89	121.25	143.15

		SECTOR 16 burning ga	- Appliances seous fuels	instrume automatic instruments	- Measuring nts, Non- e weighing (NAWI) and ed products	SECTOR 18 equipment	3 - Electrical under EMC	SECTOR 19 telecom equi RT	pment under	SECTOR 2( applian equipment	
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants
LV	1.99	8.75	4.41	25.25	12.71	141.00	70.99	9.00	4.53	461.00	232.11
LT	2.92										
LU	0.56	51.25	91.04	717.50	1274.52	441.00	783.36	190.50	338.39	275.75	489.82
HU	9.85	23.00	2.34	214.25	21.75	104.75	10.64	170.00	17.26	2065.25	209.69
МТ	0.43	6.00	13.97			24.00	55.90	24.00	55.90	163.25	380.23
NL	16.90			8 NAWI examined	0.47	150	8.88	150	8.88		
AT	8.58			4699.75	547.44	55.50	6.46	276.25	32.18	55.50	6.46
PL	38.01	28.75	0.76	20.75	0.55	560.50	14.75	285.25	7.51	1105.50	29.09
РТ	10.37	26.00	2.51	221.25	21.33	16.00	1.54	321.75	31.01	149.25	14.39
RO	19.86	101.50	5.11	1723.25	86.76	390.75	19.67	765.00	38.52	1092.50	55.01
SL	2.06	41.00	19.88			8.75	4.24	180.25	87.38	312.50	151.49
SK	5.42	34.00	6.27	206.00	38.00					1318.25	243.16
FI	5.47	3.75	0.69			272.25	49.76	164.75	30.11	2031.25	371.22

			- Appliances iseous fuels	instrume automatic instruments	- Measuring nts, Non- e weighing (NAWI) and ed products		3 - Electrical under EMC		- Radio and pment under TE	applian	) - Electrical ces and under LVD
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	ner 100000		Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants
SE	9.75	6.50	0.67	3.67	0.38	54.25	5.57	44.25	4.54	373.75	38.34
UK	64.88										

		and electron under RoHS	l - Electrical ic equipment , WEEE and eries	(Detergen Persisten	- Chemicals ts, Paints, t organic tants)		3 - Ecodesign zy labelling	requireme boilers fired	l - Efficiency nts for hot- l with liquid ous fuels		DR 25 - onal craft
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants
BE	11.29	18.00	1.59			57.25	5.07	3.25	0.29		
BG	7.20	252.75	35.09	589.25	81.82	717.50	99.62			24.00	3.33
CZ	10.54	57.00	5.41	17.25	1.64	146.25	13.88	10.00	0.95	146.00	13.85
DK	5.66	16.50	2.92	50.25	8.88	194.50	34.37			0.25	0.04
DE	81.20										
EE	1.31	193.00	146.96	673.75	513.03						
IE	4.63	38.75	8.38	85.50	18.48			16.25	3.51		
EL	10.81	130.00	12.02	395.00	36.53	103.75	9.60	4.67	0.43	3.50	0.32
ES	46.44										
FR	66.99			711.00	10.61	262.25	3.91			51.50	0.77
HR	4.23										
IT	60.80					26.00	0.43				
СҮ	0.85					215.75	254.72				
LV	1.99	141.00	70.99	402.00	202.41	141.00	70.99			3.25	1.64

		SECTOR 21 and electron under RoHS batt	ic equipment , WEEE and	SECTOR 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)		SECTOR 23 - Ecodesign and Energy labelling		SECTOR 24 - Efficiency requirements for hot- boilers fired with liquid or gaseous fuels			OR 25 - onal craft
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants
LT	2.92										
LU	0.56					19.50	34.64				
HU	9.85	24.00	2.44	3693.50	375.01	45.25	4.59	6.75	0.69		
МТ	0.43	163.25	380.23	95.00	221.27	32.00	74.53			11.75	27.37
NL	16.90										
AT	8.58			64.25	7.48	56.67	6.60			3.25	0.38
PL	38.01	134.00	3.53	128.75	3.39	254.25	6.69			52.50	1.38
РТ	10.37	120.75	11.64								
RO	19.86	473.75	23.85			136.50	6.87	3.75	0.19	22.00	1.11
SL	2.06	276.75	134.16	44.25	21.45	60.75	29.45			22.50	10.91
SK	5.42			103.50	19.09	120.75	22.27			14.00	2.58
FI	5.47	326.50	59.67	7.75	1.42	616.50	112.67			96.25	17.59
SE	9.75	190.25	19.52	23.50	2.41	94.75	9.72			6.00	0.62
UK	64.88										

		SECTOR 2 Equip	26 - Marine oment		27 - Motor and tyres		8 - Non-road nachinery	SECTOR 29 - Fertilisers			30 - Other oducts under SD
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants								
BE	11.29			256.25	22.71						
BG	7.20			566.25	78.62	68.00	9.44	497.75	69.11	7,643.50	1061.27
CZ	10.54							205.25	19.48	146.00	13.85
DK	5.66			1689.25	298.47			250.00	44.17		
DE	81.20										
EE	1.31			66.50	50.64			216.25	164.67	774.75	
IE	4.63							116.50	25.18	2.33	0.50
EL	10.81										
ES	46.44										
FR	66.99			272.00	4.06			74.50	1.11	1,485.00	22.17
HR	4.23							220.00	52.07		
IT	60.80	1.25	0.02							23.25	0.38
СҮ	0.85			22.00	25.97						
LV	1.99			21.50	10.83	63.50	31.97	232.5	117.06	66.50	33.48

		and electron	l - Electrical ic equipment , WEEE and eries	(Detergen	- Chemicals ts, Paints, t organic tants)		9 - Ecodesign y labelling	requireme boilers fired	- Efficiency nts for hot- l with liquid ous fuels	hot- SECTOR 25 - iquid Recreational craft	
Member State	Population (million)	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants	Number of inspections	Inspections per 100000 inhabitants
LT	2.92										
LU	0.56									40.25	71.50
HU	9.85			15.50	1.57	2.50	0.25	210.75	21.40	2,281.25	231.62
МТ	0.43	0.25	0.58	25.00	58.23			0.25	0.58		
NL	16.90							2.50	0.15		
AT	8.58									1,964.00	228.77
PL	38.01	16.00	0.42					103.25	2.72		
РТ	10.37	13.50	1.30	2.25	0.22			41.25	3.98	292.00	28.15
RO	19.86	9.00	0.45	934.00	47.03	140.00	7.05	1752.5	88.24	6.50	0.33
SL	2.06			28.00	13.57	42.00	20.36	335.5	162.64		
SK	5.42			0.50	0.09			139.75	25.78		
FI	5.47			362.75	66.30			283.5	51.81	931.75	170.28
SE	9.75	1.25	0.13	249.50	25.60	6.00	0.62			264.50	27.14
UK	64.88										

## Table 7-8: Statistics on inspections based on tests performed in laboratories carried out in the 2010-2013 period by all national authorities having provided data

		devices (inclu diagnostic mo and active i	1 - Medical Iding in vitro edical devices implantable devices)	SECTOR 2	- Cosmetics	SECTOR	R 3 - Toys	SECTOR 4 Protective	- Personal Equipment	SECTOR 5 - Prod	
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
BE	11.29							32.00	2.84		
BG	7.20					13.50	1.87			2.00	0.28
CZ	10.54			165.75	15.73						
DK	5.66			40.00	7.07	33.00	5.83	0.00	0.00	0.00	0.00
DE	81.20										
EE	1.31										
IE	4.63	0.00	0.00	21.00	4.54						
EL	10.81					63.00	5.83	1.00	0.09	4.00	0.37

Information below is only indicative information as data are not always fully comparable.

			ıding in vitro	SECTOR 2	- Cosmetics	SECTOF	R 3 - Toys	SECTOR 4 Protective	l - Personal Equipment		Construction lucts
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
ES	46.44										
FR	66.99			608.75	9.09	827.00	12.34	92.00	1.37	37.50	0.56
HR	4.23					60.00	14.20				
IT	60.80							4.50	0.07		
СҮ	0.85	0.25	0.30			61.25	72.31			261.00	308.14
LV	1.99			20.50	10.32	29.50	14.85	11.75	5.92	5.75	2.90
LT	2.92										
LU	0.56					7.50	13.32				
HU	9.85	0.25	0.03	191.50	19.44	70.75	7.18	1.75	0.18	4.00	0.41
МТ	0.43										
NL	16.90										

		SECTOR a devices (inclu diagnostic mo and active i medical	iding in vitro edical devices mplantable	SECTOR 2	- Cosmetics	SECTOR	R 3 - Toys	SECTOR 4 Protective	- Personal Equipment	SECTOR 5 - Proc	
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
AT	8.58	0.00						0.50	0.06	24.00	2.80
PL	38.01	10.50	0.28	35.25	0.93	498.25	13.11	9.25	0.24	30.00	0.79
РТ	10.37	96.75	9.33	142.50	13.74	14.75	1.42	1.50	0.14	0.00	0.00
RO	19.86					3.25	0.16	0.00	0.00	1.50	0.08
SL	2.06	0.00	0.00	15.00	7.27	44.25	21.45	10.25	4.97	5.75	2.79
SK	5.42	0.00	0.00			159.25	29.37	22.50	4.15	16.25	3.00
FI	5.47	0.00	0.00	125.75	22.98	731.75	133.73	37.25	6.81	0.50	0.09
SE	9.75			47.50	4.87	3.75	0.38	26.75	2.74		
UK	64.88					633.00	9.76				

		SECTOR dispe	6 - Aerosol nsers	pressure v	7 - Simple vessels and Equipment	Transporta	OR 8 - ble pressure oment	SECTOR 9	- Machinery	SECTOR	10 - Lifts
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
BE	11.29										
BG	7.20	0.00	0.00					2.00	0.28		
CZ	10.54										
DK	5.66	0.00	0.00	0.00	0.00	0.00	0.00	8.00	1.41	0.00	0.00
DE	81.20										
EE	1.31										
IE	4.63							0.00	0.00		
EL	10.81										
ES	46.44										
FR	66.99			8.00	0.12	2.00	0.03	315.75	4.71		
HR	4.23										
IT	60.80										

		SECTOR dispe	6 - Aerosol nsers	pressure v	7 - Simple vessels and Equipment	Transporta	OR 8 - ble pressure oment	SECTOR 9	- Machinery	SECTOR	10 - Lifts
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
СҮ	0.85										
LV	1.99			0.00	0.00			3.25	1.64	0.00	0.00
LT	2.92										
LU	0.56										
HU	9.85			0.75		0.00	0.00	8.00	0.81	0.00	0.00
МТ	0.43										
NL	16.90										
AT	8.58	1.75	0.20	1.75	0.20	1.75	0.20			0.00	0.00
PL	38.01	0.25	0.01	1.25	0.03	0.00	0.00	2.25	0.06	0.00	0.00
РТ	10.37	0.00	0.00	0.00	0.00			0.75	0.07		
RO	19.86							0.00	0.00		
SL	2.06			0.00	0.00	0.00	0.00	13.25	6.42		

			6 - Aerosol nsers	pressure v	7 - Simple ressels and Equipment	Transporta	OR 8 - ble pressure oment	SECTOR 9	- Machinery	SECTOR	10 - Lifts
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
SK	5.42										
FI	5.47	0.00	0.00	1.25	0.23	0.00	0.00	9.25	1.69	0.00	0.00
SE	9.75										
UK	64.88										

		SECTOR 11	- Cableways	emissions f	12 - Noise `or outdoor oment	and Protect Intended Potentially	- Equipment ive Systems for use in Explosive pheres	SECT( Pyrote			5 - Explosives /il uses
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
BE	11.29										
BG	7.20							8.00	1.11		
CZ	10.54									1.00	0.09
DK	5.66	0.00	0.00	0.00	0.00	0.00	0.00	25.50	4.51		
DE	81.20										
EE	1.31										
IE	4.63							0.00	0.00	0.00	0.00
EL	10.81										
ES	46.44										
FR	66.99	0.00	0.00			21.75	0.32	85.25	1.27	10.00	
HR	4.23										

		SECTOR 11	- Cableways	SECTOR emissions f equip		and Protect Intended Potentially	- Equipment ive Systems for use in Explosive pheres	SECT( Pyrote			- Explosives il uses
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
IT	60.80							0.00	0.00	0.00	0.00
СҮ	0.85							0.00	0.00	0.00	0.00
LV	1.99	0.00	0.00	3.25	1.64						
LT	2.92										
LU	0.56										
HU	9.85			0.50	0.05	0.00	0.00	0.00	0.00	0.00	0.00
МТ	0.43	0.00	0.00								
NL	16.90										
AT	8.58	0.00	0.00	0.00	0.00						
PL	38.01	0.00	0.00	0.00	0.00	1.00	0.03	6.00	0.16	0.00	0.00
РТ	10.37	0.00	0.00	0.75	0.07			2.50	0.24	2.50	0.24

		SECTOR 11	- Cableways	SECTOR 12 - Noise emissions for outdoor equipment		SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres		SECTO Pyrote		SECTOR 15 for civ	-
Member State	Population (million)	Number of inspections based on tests performed in laboratories	inspections based on tests performed in laboratories per 100000		Inspections based on tests performed in laboratories per 100000 inhabitants	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants
RO	19.86			0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
SL	2.06	0.00	0.00	0.00	0.00						
SK	5.42										
FI	5.47	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
SE	9.75										
UK	64.88										

		SECTOR 16 burning ga		SECTOR 17 instrume automatic instrument packaged	nts, Non- e weighing ts and Pre-	SECTOR 18 equipment		SECTOR 19 telecom equi RT	pment under		) - Electrical 1d equipment · LVD
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
BE	11.29	16.50	1.46			29.00	2.57	0.00	0.00	137.75	12.21
BG	7.20	8.00	1.11	0.00	0.00	5.00	0.69			15.00	2.08
CZ	10.54										
DK	5.66	18.00	3.18			0.00	0.00	0.00	0.00	59.50	10.51
DE	81.20					1.11	0.01	1.11	0.01		
EE	1.31			0.00	0.00						
IE	4.63	1.25	0.27	0.00	0.00						
EL	10.81			0.00	0.00			6.50	0.60	7.50	0.69
ES	46.44										
FR	66.99	10.00	0.15	78.75	1.18	48.75	0.73	181.50	2.71	316.25	4.72
HR	4.23										

		SECTOR 16 burning ga		SECTOR 17 instrume automatic instrument packaged	nts, Non- weighing ts and Pre-	SECTOR 18 equipment		SECTOR 19 telecom equi RT	oment under appliances and equipn		nd equipment
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
IT	60.80			1.75	0.03			120.50	1.98	28.25	0.46
СҮ	0.85					4.00	4.72	0.00	0.00	32.75	38.67
LV	1.99	0.00	0.00	13.25	6.67	38.00	19.13	0.00	0.00	66.33	33.40
LT	2.92										
LU	0.56	1.25	2.22	716.25	1,272.30	10.50	18.65	5.75	10.21	18.50	32.86
HU	9.85	0.00	0.00	34.75	3.53	80.50	8.17	168.25	17.08	163.50	16.60
МТ	0.43										
NL	16.90			8	0.47	5	0.30	5	0.30		
AT	8.58	0.00	0.00	2,611.50	304.20	0.00	0.00	0.00	0.00	0.25	0.03
PL	38.01	0.00	0.00	0.00	0.00	119.50	3.14	51.75	1.36	35.25	0.93
РТ	10.37	0.00	0.00	1.00	0.10	2.25	0.22	131.25	12.65	1.50	0.14

		SECTOR 16 burning ga		instrume	weighing ts and Pre-		3 - Electrical under EMC	SECTOR 19 telecom equi RT	pment under		) - Electrical ad equipment · LVD
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
RO	19.86			2,551.75	128.48	5.33	0.27	1.33	0.07	0.00	0.00
SL	2.06	5.00	2.42	4.25	2.06	8.75	4.24	8.75	4.24	46.50	22.54
SK	5.42	9.50	1.75	0.00	0.00						
FI	5.47	2.25	0.41	0.00	0.00	66.50	12.15	18.00	3.29	728.50	133.14
SE	9.75	6.00	0.62					43.25	4.44		
UK	64.88										

		SECTOR 21 and electroni under RoHS batte	ic equipment , WEEE and	Persisten	- Chemicals ts, Paints, t organic tants)		9 - Ecodesign y labelling	requireme boilers fired	4 - Efficiency nts for hot- with liquid or 1s fuels		DR 25 - onal craft
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
BE	11.29	8.00	0.71			43.00	3.81	3.25	0.29		
BG	7.20			1.50	0.21	3.00	0.42				
CZ	10.54			1.00	0.09						
DK	5.66	33.00	5.83	12.75	2.25	60.50	10.69			0.00	0.00
DE	81.20										
EE	1.31										
IE	4.63	38.50	8.32	14.75	3.19	0.00	0.00	0.00	0.00		
EL	10.81	6.00	0.55	227.75	21.06	7.50	0.69	4.00	0.37		
ES	46.44										
FR	66.99			60.75	0.91	0.00	0.00			0.00	0.00
HR	4.23										

		SECTOR 21 and electroni under RoHS batte	ic equipment , WEEE and	(Detergen Persisten	- Chemicals ts, Paints, t organic tants)		9 - Ecodesign ay labelling	requireme boilers fired	4 - Efficiency nts for hot- with liquid or 1s fuels		DR 25 - onal craft
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
IT	60.80					2.00	0.03				
CY	0.85					0.00	0.00				
LV	1.99	38.00	19.13	17.25	8.69	38.00	19.13			0.00	0.00
LT	2.92										
LU	0.56					0.00	0.00				
HU	9.85	0.00	0.00	46.25	4.70	0.00	0.00	0.00	0.00		
МТ	0.43										
NL	16.90										
AT	8.58			23.75	2.77	0.00	0.00			0.00	0.00
PL	38.01	66.00	1.74	41.33	1.09	30.75	0.81			0.00	0.00
РТ	10.37	0.00	0.00								

		SECTOR 21 and electroni under RoHS batte	ic equipment , WEEE and	(Detergen Persisten	- Chemicals ts, Paints, t organic tants)	SECTOR 23 and Energ	- Ecodesign y labelling	-	nts for hot- with liquid or	SECT( Recreation	DR 25 - Dnal craft
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
RO	19.86	19.25	0.97			0.00	0.00				
SL	2.06	0.00	0.00	17.50	8.48	7.50	3.64			0.00	
SK	5.42			0.00	0.00	0.00	0.00				
FI	5.47	73.25	13.39	2.00	0.37	9.75	1.78	0.00	0.00	0.00	0.00
SE	9.75	61.50	6.31	8.00	0.82	100.00	10.26				
UK	64.88										

		SECTOR 2 Equip		SECTOR vehicles		SECTOR 28 mobile m		SECTOR 29	) - Fertilisers	SECTOR consumer pr GP	
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
BE	11.29							55.33	4.90	3.25	0.29
BG	7.20			80.50	11.18			176.00	24.44	1,479.50	205.42
CZ	10.54							66.00	6.26		
DK	5.66	0.00	0.00	0.00	0.00			250.00	44.17		
DE	81.20							4,224.25	52.02		
EE	1.31										
IE	4.63							116.50	25.18	1.00	0.22
EL	10.81							329.00	30.43	46.00	4.25
ES	46.44										
FR	66.99	0.00	0.00	5.00	0.07			41.00	0.61	67.75	1.01
HR	4.23							25.00	5.92		
IT	60.80	0.00	0.00							3.25	0.05

		SECTOR 2 Equip		SECTOR : vehicles :		SECTOR 28 mobile m	3 - Non-road aachinery	SECTOR 29	- Fertilisers	SECTOR consumer pr GP	
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
СҮ	0.85										
LV	1.99					1.00	0.50	80.25	40.41	2.75	1.38
LT	2.92										
LU	0.56									6.25	11.10
HU	9.85			0.00	0.00	0.00	0.00	108.75	11.04	94.25	9.57
МТ	0.43										
NL	16.90										
AT	8.58	0.00	0.00	0.00	0.00						
PL	38.01	0.00	0.00					14.25	0.37		
РТ	10.37	0.00	0.00	0.00	0.00			0.00	0.00	3.00	0.29
RO	19.86					0.00	0.00	127.75	6.43	0.00	0.00
SL	2.06					0.00	0.00	16.50	8.00		

			26 - Marine oment		27 - Motor and tyres		8 - Non-road achinery	SECTOR 29	) - Fertilisers	consumer pr	30 - Other oducts under SD
Member State	Population (million)	Number of inspections based on tests performed in laboratories	Inspections based on tests performed in laboratories per 100000 inhabitants								
SK	5.42			0.00	0.00						
FI	5.47	0.00	0.00	0.50	0.09			283.50	51.81	826.50	151.05
SE	9.75			70.00	7.18	2.00	0.21			13.33	1.37
UK	64.88										

## Table 7-9: Statistics on enforcement activities carried out in the 2010-2013 period by national authorities having provided data (averages per Member State and per year)

Information below is only indicative information as data are not always fully comparable.

Information on enforcement activities carried out in the 2010-2013 period	SECTOR 1 - Medical devices	SECTOR 2 - Cosmetics	SECTOR 3 - Toys	SECTOR 4 - Personal Protective Equipment	SECTOR 5 - Construction Products
1. Number of product related accidents / user complaints	542	36	31	8	18
2. Number of substantiated complaints by industry concerning unfair competition	3	10	10	3	35
3. Number of inspections (total number)	267	2082	891	209	465
3.1 number of reactive inspections	196	840	425	42	46
3.2 number of self-initiated inspections	59	869	487	142	397
3.3 number of inspections prompted by the customs	12	72	211	17	28
4. Number of inspections based on:					
4.1 tests performed in laboratories	12	129	191	17	28
4.2 physical checks of products	1497	2378	1709	251	584
5. Number of inspections resulting in:					
5.1 finding of non-compliance	114	784	283	78	218
5.2 corrective actions taken by economic operators ("voluntary measures")	109	36	97	42	88
5.3 restrictive measures taken by market surveillance authorities	4	69	103	12	46
5.4 application of sanctions/penalties	8	21	124	25	33
6. Number of inspections where other Member States were invited to collaborate	6	4	1	1	1

Information on enforcement activities carried out in the 2010-2013 period	SECTOR 6 - Aerosol dispensers	SECTOR 7 - Simple pressure vessels and Pressure Equipment	SECTOR 8 - Transportable pressure equipment	SECTOR 9 - Machinery	SECTOR 10 - Lifts
1. Number of product related accidents / user complaints	1	8	3	23	1
2. Number of substantiated complaints by industry concerning unfair competition	0	0	0	38	0
3. Number of inspections (total number)	161	277	57	374	147
3.1 number of reactive inspections	21	17	4	70	10
3.2 number of self-initiated inspections	139	273	46	303	144
3.3 number of inspections prompted by the customs	0	13	21	36	0
4. Number of inspections based on:					
4.1 tests performed in laboratories	0	1	1	33	0
4.2 physical checks of products	186	76	47	434	74
5. Number of inspections resulting in:					
5.1 finding of non-compliance	59	17	8	105	15
5.2 corrective actions taken by economic operators ("voluntary measures")	5	12	3	169	4
5.3 restrictive measures taken by market surveillance authorities	1	3	1	14	2
5.4 application of sanctions/penalties	49	2	3	12	1
6. Number of inspections where other Member States were invited to collaborate	0	0	0	2	0

Information on enforcement activities carried out in the 2010-2013 period	SECTOR 11 - Cableways	SECTOR 12 - Noise emissions for outdoor equipment	SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	SECTOR 14 - Pyrotechnics	SECTOR 15 - Explosives for civil uses
1. Number of product related accidents / user complaints	0	1	1	22	1
2. Number of substantiated complaints by industry concerning unfair competition	0	0	0	3	0
3. Number of inspections (total number)	483	108	20	375	442
3.1 number of reactive inspections	0	2	2	4	5
3.2 number of self-initiated inspections	14	69	16	343	346
3.3 number of inspections prompted by the customs	0	5	1	66	0
4. Number of inspections based on:					
4.1 tests performed in laboratories	0	1	4	12	1
4.2 physical checks of products	268	100	25	157	19
5. Number of inspections resulting in:					
5.1 finding of non-compliance	1	26	7	224	426
5.2 corrective actions taken by economic operators ("voluntary measures")	0	20	4	25	2
5.3 restrictive measures taken by market surveillance authorities	0	4	1	212	258
5.4 application of sanctions/penalties	1	5	1	8	0
6. Number of inspections where other Member States were invited to collaborate	0	0	0	2	0

Information on enforcement activities carried out in the 2010-2013 period	SECTOR 16 - Appliances burning gaseous fuels	SECTOR 17 - Measuring instruments, Non- automatic weighing instruments and Pre-packaged products	SECTOR 18 - Electrical equipment under EMC	SECTOR 19 - Radio and telecom equipment under RTTE	SECTOR 20 - Electrical appliances and equipment under LVD
1. Number of product related accidents / user complaints	5	6	7	25	54
2. Number of substantiated complaints by industry concerning unfair competition	3	1	7	5	30
3. Number of inspections (total number)	53	1946	247	307	742
3.1 number of reactive inspections	8	175	13	28	113
3.2 number of self-initiated inspections	35	1303	189	224	580
3.3 number of inspections prompted by the customs	9	0	103	116	107
4. Number of inspections based on:					
4.1 tests performed in laboratories	5	354	27	41	104
4.2 physical checks of products	54	1410	213	253	743
5. Number of inspections resulting in:					
5.1 finding of non-compliance	24	110	144	213	255
5.2 corrective actions taken by economic operators ("voluntary measures")	10	16	53	62	74
5.3 restrictive measures taken by market surveillance authorities	6	15	15	78	95
5.4 application of sanctions/penalties	5	29	51	59	89
6. Number of inspections where other Member States were invited to collaborate	1	0	3	7	2

Information on enforcement activities carried out in the 2010-2013 period	SECTOR 21 - Electrical and electronic equipment under RoHS, WEEE and batteries	SECTOR 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)	SECTOR 23 - Ecodesign and Energy labelling	SECTOR 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	SECTOR 25 - Recreational craft
1. Number of product related accidents / user complaints	5	6	5	1	249
2. Number of substantiated complaints by industry concerning unfair competition	1	5	0	1	0
3. Number of inspections (total number)	160	443	174	6	33
3.1 number of reactive inspections	14	11	6	0	16
3.2 number of self-initiated inspections	138	392	125	6	17
3.3 number of inspections prompted by the customs	8	2	5	0	10
4. Number of inspections based on:					
4.1 tests performed in laboratories	29	34	17	1	0
4.2 physical checks of products	107	512	823	7	127
5. Number of inspections resulting in:					
5.1 finding of non-compliance	40	101	49	4	13
5.2 corrective actions taken by economic operators ("voluntary measures")	12	9	30	3	13
5.3 restrictive measures taken by market surveillance authorities	11	30	8	0	2
5.4 application of sanctions/penalties	7	11	14	1	1
6. Number of inspections where other Member States were invited to collaborate	0	0	0	0	0

Information on enforcement activities carried out in the 2010-2013 period	SECTOR 26 - Marine Equipment	SECTOR 27 - Motor vehicles and tyres	SECTOR 28 - Non-road mobile machinery	SECTOR 29 - Fertilisers	SECTOR 30 - Other consumer products under GPSD
1. Number of product related accidents / user complaints	1	25	2	4	38
2. Number of substantiated complaints by industry concerning unfair competition	0	2	1	1	5
3. Number of inspections (total number)	5	282	54	260	382
3.1 number of reactive inspections	1	64	1	3	74
3.2 number of self-initiated inspections	5	242	53	232	248
3.3 number of inspections prompted by the customs	3	5	2	0	29
4. Number of inspections based on:					
4.1 tests performed in laboratories	0	17	1	370	50
4.2 physical checks of products	10	179	210	488	449
5. Number of inspections resulting in:					
5.1 finding of non-compliance	1	73	7	155	123
5.2 corrective actions taken by economic operators ("voluntary measures")	0	46	5	11	33
5.3 restrictive measures taken by market surveillance authorities	1	38	3	42	37
5.4 application of sanctions/penalties	0	59	4	5	22
6. Number of inspections where other Member States were invited to collaborate	0	1	0	0	1

Information on resources (subject to availability)	SECTOR 1 - Medical devices	SECTOR 2 - Cosmetics	SECTOR 3 - Toys	SECTOR 4 - Personal Protective Equipment	SECTOR 5 - Construction Products
7.1 Budget available to market surveillance authorities in nominal terms (€)	€ 1,391,889.47	€ 4,993,717.97	€ 1,917,787.47	€ 270,913.43	€ 425,273.22
7.2 Budget available to market surveillance authorities in relative terms (%age of total national budget)	29.43254%	1.36390%	1.52086%	0.01616%	0.80222%
8. Staff available to market surveillance authorities (full- time equivalent units)	59	256	32	12	18
9. Number of inspectors available to market surveillance authorities (full-time equivalent units)	48	59	24	10	13
Share of inspections resulting in finding of non- compliance out of total inspections	42.54%	37.68%	31.77%	37.56%	46.91%
Share of self-initiated inspections out of total inspections	22.20%	41.76%	54.67%	68.12%	85.48%
Share of corrective actions taken by economic operators out of finding of non-compliance	96.12%	4.55%	34.12%	54.10%	40.22%
Share of restrictive measures out of finding of non- compliance	3.88%	8.86%	36.29%	15.78%	21.29%
Share of application of sanctions / penalties out of finding of non-compliance	6.98%	2.69%	43.75%	32.37%	15.22%
Share of inspectors out of staff available to market surveillance authorities	82.16%	23.05%	73.51%	78.13%	74.96%

Information on resources (subject to availability)	SECTOR 6 - Aerosol dispensers	SECTOR 7 - Simple pressure vessels and Pressure Equipment	SECTOR 8 - Transportable pressure equipment	SECTOR 9 - Machinery	SECTOR 10 - Lifts
7.1 Budget available to market surveillance authorities in nominal terms $(\in)$	€ 9,634.69	€ 355,539.54	€ 274,911.67	€ 564,027.54	€ 425,111.19
7.2 Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.15992%	0.02177%	3.25103%	0.02428%	0.01378%
8. Staff available to market surveillance authorities (full- time equivalent units)	22	23	23	72	23
9. Number of inspectors available to market surveillance authorities (full-time equivalent units)	18	7	6	51	5
Share of inspections resulting in finding of non- compliance out of total inspections	36.48%	6.20%	13.80%	27.98%	10.15%
Share of self-initiated inspections out of total inspections	85.84%	98.48%	81.37%	80.87%	98.24%
Share of corrective actions taken by economic operators out of finding of non-compliance	8.64%	71.27%	34.51%	161.74%	29.53%
Share of restrictive measures out of finding of non- compliance	0.85%	16.86%	12.07%	13.32%	14.60%
Share of application of sanctions / penalties out of finding of non-compliance	83.98%	9.67%	41.75%	11.56%	5.40%
Share of inspectors out of staff available to market surveillance authorities	84.35%	30.26%	26.52%	71.67%	20.52%

Information on resources (subject to availability)	SECTOR 11 - Cableways	SECTOR 12 - Noise emissions for outdoor equipment	SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	SECTOR 14 - Pyrotechnics	SECTOR 15 - Explosives for civil uses
7.1 Budget available to market surveillance authorities in nominal terms ( $\mathfrak{E}$ )	€ 741,722.38	€ 169,646.69	€ 210,451.04	€ 336,074.13	€ 196,517.44
7.2 Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.00001%	0.00394%	0.00336%	0.01025%	0.00333%
8. Staff available to market surveillance authorities (full- time equivalent units)	18	14	12	10	10
9. Number of inspectors available to market surveillance authorities (full-time equivalent units)	3	3	1	5	1
Share of inspections resulting in finding of non- compliance out of total inspections	0.29%	24.07%	34.65%	59.77%	96.21%
Share of self-initiated inspections out of total inspections	2.96%	63.47%	77.49%	91.28%	78.33%
Share of corrective actions taken by economic operators out of finding of non-compliance	25.81%	77.16%	60.37%	11.30%	0.35%
Share of restrictive measures out of finding of non- compliance	1.61%	14.13%	15.31%	94.60%	60.63%
Share of application of sanctions / penalties out of finding of non-compliance	82.26%	19.23%	12.50%	3.54%	0.08%
Share of inspectors out of staff available to market surveillance authorities	16.98%	24.32%	8.68%	50.80%	15.31%

Information on resources (subject to availability)	SECTOR 16 - Appliances burning gaseous fuels	SECTOR 17 - Measuring instruments. Non- automatic weighing instruments and Pre-packaged products	SECTOR 18 - Electrical equipment under EMC	SECTOR 19 - Radio and telecom equipment under RTTE	SECTOR 20 - Electrical appliances and equipment under LVD
7.1 Budget available to market surveillance authorities in nominal terms $(\bigcirc)$	€ 186,410.22	€ 316,776.94	€ 1,213,246.73	€ 1,630,900.55	€ 663,663.40
7.2 Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.01062%	0.07485%	0.01320%	0.02428%	0.12735%
8. Staff available to market surveillance authorities (full- time equivalent units)	10	10	17	18	17
9. Number of inspectors available to market surveillance authorities (full-time equivalent units)	5	9	5	12	13
Share of inspections resulting in finding of non- compliance out of total inspections	45.51%	5.64%	58.30%	69.43%	34.39%
Share of self-initiated inspections out of total inspections	65.60%	66.96%	76.51%	72.99%	78.16%
Share of corrective actions taken by economic operators out of finding of non-compliance	42.15%	14.32%	37.07%	28.94%	29.17%
Share of restrictive measures out of finding of non- compliance	24.54%	13.51%	10.70%	36.62%	37.31%
Share of application of sanctions / penalties out of finding of non-compliance	21.18%	26.58%	35.46%	27.91%	34.75%
Share of inspectors out of staff available to market surveillance authorities	46.37%	90.47%	30.37%	63.11%	75.56%

Information on resources (subject to availability)	SECTOR 21 - Electrical and electronic equipment under RoHS. WEEE and batteries	SECTOR 22 - Chemicals (Detergents. Paints. Persistent organic pollutants)	SECTOR 23 - Ecodesign and Energy labelling	SECTOR 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	SECTOR 25 - Recreational craft
7.1 Budget available to market surveillance authorities in nominal terms (€)	€ 191,120.50	€ 145,000.46	€ 215,344.26	€ 120,923.50	€ 284,263.69
7.2 Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.01399%	69.55812%	0.03023%	0.00000%	0.07500%
8. Staff available to market surveillance authorities (full- time equivalent units)	14	64	15	9	12
9. Number of inspectors available to market surveillance authorities (full-time equivalent units)	5	38	11	9	5
Share of inspections resulting in finding of non- compliance out of total inspections	25.32%	22.86%	28.48%	61.00%	39.77%
Share of self-initiated inspections out of total inspections	86.10%	88.46%	71.90%	98.50%	51.53%
Share of corrective actions taken by economic operators out of finding of non-compliance	30.28%	8.85%	60.65%	82.42%	99.48%
Share of restrictive measures out of finding of non- compliance	26.12%	29.73%	16.85%	5.14%	17.86%
Share of application of sanctions / penalties out of finding of non-compliance	17.03%	10.85%	28.49%	12.84%	6.42%
Share of inspectors out of staff available to market surveillance authorities	35.20%	58.46%	77.42%	97.88%	36.75%

Information on resources (subject to availability)	SECTOR 26 - Marine Equipment	SECTOR 27 - Motor vehicles and tyres	SECTOR 28 - Non-road mobile machinery	SECTOR 29 - Fertilisers	SECTOR 30 - Other consumer products under GPSD
7.1 Budget available to market surveillance authorities in nominal terms $(\mathbf{f})$	€ 75,853.75	€ 456,843.17	€ 14,324.38	€ 135,640.69	€ 618,900.94
7.2 Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.00005%	0.39436%	0.00334%	0.29036%	3.69804%
8. Staff available to market surveillance authorities (full- time equivalent units)	2	17	0	9	28
9. Number of inspectors available to market surveillance authorities (full-time equivalent units)	1	15	0	7	13
Share of inspections resulting in finding of non- compliance out of total inspections	17.63%	25.95%	13.39%	59.40%	32.12%
Share of self-initiated inspections out of total inspections	88.35%	85.96%	99.38%	89.27%	64.93%
Share of corrective actions taken by economic operators out of finding of non-compliance	21.39%	62.66%	68.41%	7.19%	27.05%
Share of restrictive measures out of finding of non- compliance	55.00%	51.29%	47.83%	27.31%	30.25%
Share of application of sanctions / penalties out of finding of non-compliance	15.28%	80.83%	49.57%	3.55%	17.70%
Share of inspectors out of staff available to market surveillance authorities	86.08%	85.32%	100.00%	77.13%	47.55%

# Table 7-10: Application of penalties by market surveillance authorities in the 2010-2013 period

Sectors	Number of Member States providing penalties information	Average number of penalties applied per Member State and per year (simple average)
Sector 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	11	7.93
Sector 2 - Cosmetics	10	21.10
Sector 3 - Toys	19	123.89
Sector 4 - Personal Protective Equipment	15	25.38
Sector 5 - Construction Products	16	33.17
Sector 6 - Aerosol dispensers	12	49.44
Sector 7 - Simple pressure vessels and Pressure Equipment	11	1.66
Sector 8 - Transportable pressure equipment	11	3.28
Sector 9 - Machinery	15	12.10
Sector 10 - Lifts	9	0.81
Sector 11 - Cableways	11	1.16
Sector 12 - Noise emissions for outdoor equipment	10	5.00
Sector 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	8	0.88
Sector 14 - Pyrotechnics	13	7.95
Sector 15 - Explosives for civil uses	10	0.34
Sector 16 - Appliances burning gaseous fuels	15	5.08
Sector 17 - Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	18	29.18
Sector 18 - Electrical equipment under EMC	15	51.04
Sector 19 - Radio and telecom equipment under RTTE	18	59.40
Sector 20 - Electrical appliances and equipment under LVD	15	88.73
Sector 21 - Electrical and electronic equipment under RoHS, WEEE and batteries	9	6.89
Sector 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)	11	10.98

Sectors	Number of Member States providing penalties information	Average number of penalties applied per Member State and per year (simple average)
Sector 23 - Ecodesign and Energy labelling	16	14.10
Sector 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	5	0.50
Sector 25 - Recreational craft	11	0.83
Sector 26 - Marine Equipment	9	0.14
Sector 27 - Motor vehicles and tyres	10	59.13
Sector 28 - Non-road mobile machinery	4	3.56
Sector 29 - Fertilisers	14	5.48
Sector 30 - Other consumer products under GPSD	11	86.13

#### 6. TEMPLATE FOR THE 2010-2013 REVIEW AND ASSESSMENTS

# [Template for the] review and assessment of the functioning of market surveillance activities pursuant to Article 18(6) of Regulation (EC) No 765/2008 - 2010-2013

# [Member State]

#### Explanations for using this template

The template foresees a review and assessment of the functioning of market surveillance at different levels:

 an aggregate level ("Overview of general market surveillance activities) that allows a snapshot of overall organisation and resources of market surveillance in Member States.

- a sector specific level.

For each of these levels the template organises the information in two sections.

Section A is meant to include some basic 'facts' on the infrastructure in place or activities carried out, which can be used as basis for the evaluation of the functioning of market surveillance. This information is expected to complement - avoiding duplication - information already provided in the National Market Surveillance Programmes for the 2010-2013 period. Please take note of a few important remarks:

- The information indicated in section A can and should be <u>accompanied by any additional</u> (<u>quantitative or qualitative</u>) explanations that allows the meaning of the figures provided to be fully appreciated and to prevent their possible misinterpretation
- If the information indicated in the template is not available but can be estimated, <u>Member</u> States are invited to provide estimates (but are asked to specify that this is the case).
- If the information indicated in the template is not available and cannot be estimated, yet Member States collect analogous information in a different format, they are invited to indicate 'n.a.' (=not available) and to add the information they possess, together with the explanations needed for its correct interpretation.
- The information indicated in the template is meant to be a 'common minimum denominator' that can be complemented with additional information that a Member State may wish to include to provide the appropriate picture on the activities carried out, such as qualitative information on how MSAs have carried out their activities, any trends or key issues that are worth highlighting, legislative initiatives undertaken etc.

Section B contains a <u>Member State's exclusive assessment of its own activities</u>. For this reason, the template does not suggest a specific format. However the assessment should be <u>based on the information provided in Section A</u>, as well on information provided in the National Market <u>Surveillance Programmes</u> for the 2010-2013 period.

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# Scope of the report

[Member States' review and assessments pursuant to Article 18(6) should cover market surveillance activities for all products falling under Union harmonisation legislation. For convenience, Member States *may* extend the scope of the report also to market surveillance activities carried out in the area of consumer non harmonised products.

A non-exhaustive list of sectors concerned is annexed to this template. Member States are invited to indicate: 1) whether certain sectors mentioned in list are expressly excluded from the review and assessment, and, 2) whether additional sectors are included. It is suggested they do so by filling in the last column of the annex]

# **Overview of general market surveillance activities**

#### A. Review of general market surveillance activities

Information on the general market surveillance organisation and infrastructures in place for the 2010-2013 period2013

[This section should provide an overview of the relevant market surveillance organisation and horizontal infrastructures in place for the 2010-2013 period according to Regulation 765/2008 (competence of market surveillance authorities, mechanisms of coordination and exchange of information, cooperation with customs, etc.)]. To avoid duplication when the information has already been provided in the National Market Surveillance Programmes, this section could contain a simple reference to the latest update of the programmes and the relevant link to the websites of the relevant national and European website where the programme is available.

[free text]

#### Information on total resources available for market surveillance activities (subject to availability)

[This section should contain information on total resources allocated to market surveillance authorities by a Member State for all necessary activities (enforcement, communications) at either general or sectoral level.]

		2010	2011	2012	2013
1.1	Budget available to market surveillance authorities in nominal terms <sup>1</sup> (€)				
1.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)				
2	Staff available to market surveillance authorities (full-time equivalent units )				
3	Number of inspectors available to market				

<sup>&</sup>lt;sup>1</sup> The budget figure should cover all financial resources which are assigned by public authorities to market surveilance and enforcement activities (including related infrastructures) as well as to projects and measures aimed at ensuring compliance of economic operators with product legislation.

These measures range from communication activities (consumer/business information and education) to pure enforcement and market surveillance activities. They include the remuneration of staff, direct costs of inspections, laboratory tests, training and office equipment cost. Enforcement activities at regional/local level should also be reported. Other activities undertaken by these authorities not related to the enforcement of product legislation should be excluded from the calculation.

surveillance authorities (full-time equivalent			
units )	a	2	

## B. Assessment of the functioning of market surveillance activities

[This section contains a Member State's exclusive assessment of the information provided in Section A. It could point, among others things, to horizontal difficulties, if any, encountered by authorities in carrying out their activities (e.g. lack of traceability information, problems with distribution of competences, lack of resources, insufficient deterrence of penalties, etc.)].

[free text]

# Market surveillance activities in specific sectors

# Sector [Number and Name from Annex, e.g. Sector 1 Medical Devices]

[Market surveillance authorities are requested to provide information for all relevant sectors where they conducted market surveillance in the 2010-2013 period. A list of reference sectors is annexed to this template. National authorities are also of course free to provide information at a more detailed level than the one proposed in the reference list of sectors (e.g. breaking down information on pressure equipment inspections according to the complexity of the equipment dealt with), if this is appropriate in view of the characteristics of a specific sector]

#### 1.A. Review of market surveillance activities in the sector

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints				
2.	Number of substantiated complaints by industry concerning unfair competition				
3.	Number of inspections <sup>2</sup> (total number)				
3.1	number of reactive inspections <sup>3</sup>				
3.2	number of self-initiated inspections <sup>4</sup>				
3.3	number of inspections prompted by the customs <sup>5</sup>				

#### Information on enforcement activities carried out in the 2010-2013 period

<sup>2</sup> Inspections are regular or ad hoc visits, controls (including checks on the internet) or other forms of contacts (mail, telephone) undertaken by an inspector, with an enforcement focus (excluding pure information exchange) and aimed at verification of product safety and compliance. Where several products/models/regulations are checked during the same exercise, this should be counted as one inspection. In order to be considered an inspection, there must be an official report prepared following the action.

<sup>3</sup> Inspections prompted by specific complaints (from consumers/users, notified bodies, competing businesses, trade-unions, etc.), accidents or incidents, information from other Member State authorities (e.g. via RAPEX notifications), etc.

<sup>4</sup> This concerns 'proactive' inspection s explicitly planned to target product categories/economic operator that may be found to be non-compliant on the basis of knowledge built and priorities set by authorities.

<sup>5</sup> These are inspections either initiated following customs' suspension of the release of products for free circulation or carried out directly by market surveillance authorities when they are responsible for the control of products at the border pursuant to Articles 27-29 of Regulation 765/2008.

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4	Number of inspections based on:	
4.1	tests performed in laboratories	
4.2	physical checks of products <sup>6</sup>	
5	Number of inspections resulting in:	
5.1	finding of non-compliance <sup>7</sup>	
5.2	corrective actions taken by economic operators ("voluntary measures") <sup>a</sup>	
5.3	restrictive measures <sup>9</sup> taken by market surveillance authorities .	
5.4	application of sanctions/penalties	
6	Number of inspections where other Member States were invited to collaborate	

#### Information on communication activities carried out in the 2010-2013 period (optional)

[This section should contain information on guidance, training courses and other initiatives carried out by market surveillance authorities for businesses, consumers, users or other stakeholders, namely with the objective of enhancing businesses' understanding of product rules and facilitate compliance, enhancing consumers/users' awareness of product hazards and rules, meaning of markings, prevention of accidents, etc. ]

[free text]

<sup>&</sup>lt;sup>6</sup> This refers to visual examination of the product in order to verify the existence of markings, warnings and information and determining obvious technical shortcomings product according to the requirements of the applicable Union legislation.

<sup>&</sup>lt;sup>7</sup> This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

<sup>&</sup>lt;sup>8</sup> Voluntary measures are defined as corrective action taken manufacturers, importers or distributors either to bring the product into compliance or to limit its availability on the market (e.g. stopping of sales, informing consumers/users, withdrawals from the market, recall from consumers/users) on the business' own initiative, possibly in consultation with the authority but without the measure being imposed by the latter.

<sup>\*</sup> Compulsory measures to prohibit or restrict the product being made available on the national market, to withdraw it or to recall it. These measures are those taken when the economic operators did not follow up on previous request of market surveillance authorities to take corrective action or where authorities have to intervene urgently.

#### Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms <sup>10</sup> (€)				
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)				
8	Staff available to market surveillance authorities (full-time equivalent units )				
9	Number of inspectors available to market surveillance authorities (full-time equivalent units )				

# 1.B. Assessment of the functioning of market surveillance activities in the sector

[This section contains a Member State's exclusive assessment of its own activities. It is expected to be based on information provided in section A, as well on information provided in the sectoral National Market Surveillance Programmes for the 2010-2013 period.

When conducting their evaluation Member States are invited to refer to the specific market context in which surveillance has been carried out (e.g. estimates of size of the national market for the products concerned, number of manufacturers/importer/ wholesale or retail distributors based in the Member state, volume of imports from other Member States or third countries, etc.)]

[free text]

<sup>&</sup>lt;sup>10</sup> The budget figure should cover all financial resources which are assigned by public authorities to market surveillance and enforcement activities as well as to projects and measures aimed at ensuring compliance of economic operators with product legislation. These measures range from communication activities (consumer/business information and education) to pure enforcement and market surveillance activities. They include the remuneration of staff, direct costs of inspections, laboratory tests, training and office equipment cost. Enforcement activities at regional/local level should also be reported. Other activities undertaken by these authorities not related to the enforcement of product legislation laws should be excluded from the calculation.

# Sector [Number and Name from Annex, e.g. Sector 2 Cosmetics]

2.A. Review of market surveillance activities in the sector
[...]

# 2.B. Assessment of the functioning of market surveillance activities in the sector

[...]

# Sector [Number and Name from Annex, e.g. 3 Toys]

Annex 1: Reference list of secto	IS
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	Product sectors	Relevant legislation <sup>11 12</sup>	Included in this report? (Y/N)
1.	Medical devices (including In vitro diagnostic medical devices and Active implantable medical devices)	Directives 93/42/EEC, 98/79/EC and 90/385/EEC	
2.	Cosmetics	Regulation 1223/2009	
3.	Toys	Directive 2009/48/EC	
4.	Personal protective equipment	Directive 89/686/EEC	
5.	Construction products	Regulation 305/2011	
6.	Aerosol dispensers,	Directive 75/324/EEC,	
7.	Simple pressure vessels and Pressure equipment	Directives 2009/105/EC and 97/23/EC	
8.	Transportable pressure equipment	Directive 2010/35/EU	
9.	Machinery	Directive 2006/42/EC	
10.	Lifts	Directive 1995/16/EC	
11.	Cableways	Directive 2000/9/CE	
12.	Noise emissions for outdoor equipment	Directive 2000/14/EC	
13.	Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	Directive 1994/9/EC	
14.	Pyrotechnics	Directive 2007/23/EC	
15.	Explosives for civil uses	Directive 93/15/EEC	
16.	Appliances burning gaseous fuels	Directive 2009/142/EC	
17.	Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	Directives 2004/22/EC, 2009/23/EC and 2007/45/EC	
18.	Electrical equipment under EMC	Directive 2004/108/EC	
19.	Radio and telecom equipment under RTTE	Directive 1999/5/EC	
20.	Electrical appliances and equipment under LVD	Directive 2006/95/EC	
21.	Electrical and electronic equipment under RoHS, WEEE and batteries	Directives 2011/65/EU, 2002/96/EC and 2006/66/EC	
22.	Chemicals (Detergents, Paints, Persistent organic pollutants) <sup>13</sup>	Regulation 648/2004 Directive 2004/42/EC	

<sup>11</sup> For ease of reference this table indicates established EU legislation. New legislation having replaced or amended that listed in the table should be also taken into account for the relevant period in which it is applicable.

<sup>12</sup> For ease of reference in some cases (e. g. eco-design, energy labelling), this table only indicates EU framework legislation, but is intended to cover also product specific EU legislative acts.

<sup>13</sup> This section focuses on chemicals other than those failing under REACH and CLP Regulations. Market surveillance activities conducted under REACH and CLP Regulations fall within the scope of Regulation 765/2008, however, since they are already the subject matter of specific reports available to the public, they may be excluded from the current report. It is nevertheless asked to Member states to include in this section a link to the REACH and CLP reports for the relevant period.

	Regulation 850/2004	
23. Ecodesign and Energy labelling	Directives 2009/125/EC and 2010/30/EU	
<ol> <li>Efficiency requirements for hot-boilers fired with liquid or gaseous fuels</li> </ol>	Directive 1992/42/EEC	
25. Recreational craft	Directive 1994/25/EC	
26. Marine equipment	Directive 96/98/EC	
27. Motor vehicles and tyres	Directives 2002/24/EC and 2007/46/EC, and Regulation (EC) No 1222/2009	
28. Non-road mobile machinery	Directive 97/68/EC	
29. Fertilisers	Regulation 2003/2003	
<ol> <li>Other consumer products under GPSD (optional)</li> </ol>	Directive 2001/95/EC	
31 (Additional sectors - please specify)		

# 7. SECTORS COVERED BY MEMBER STATES REPORTS

	Relevant											I	nclu	ded i	n the	e rep	ort?	(Y/N	)										
Product sectors	legislation	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	МТ	NL	AT	PL	РТ	RO	SI	SK	FI	SE	UK
1. Medical devices (including In vitro diagnostic medical devices and Active implantable medical devices)	Directives 93/42/EEC, 98/79/EC and 90/385/EEC	N	Y	Y	Y	-	Y	Y	N	N	Y	Ν	Y	Y	Y	-	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
2. Cosmetics	Regulation 1223/2009	N	N	Y	Y	-	Y	Y	N	N	Y	Y	Y	N	Y	-	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y
3. Toys	Directive 2009/48/EC	Y	Y	Y	Y	-	Y	Y	Y	N	Y	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
4. Personal protective equipment	Directive 89/686/EEC	Y	Y	Y	Y	-	Y	Y	Y	N	Y	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
5. Construction products	Regulation 305/2011	Y	Y	Y	Y	-	Y	N	Y	N	Y	Y	N	Y	Y	-	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
6. Aerosol dispensers	Directive 75/324/EEC	Y	Y	Y	Y	-	N	N	Y	N	Y	N	N	Y	Y	-	Y	N	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y

	Relevant											]	Inclu	ded i	in the	e rep	ort?	(Y/N	)										
Product sectors	legislation	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	МТ	NL	AT	PL	РТ	RO	SI	SK	FI	SE	UK
7. Simple pressure vessels and Pressure equipment	Directives 2009/105/EC and 97/23/EC	Y	Y	Y	Y	-	Y	Y	Y	N	Y	N	N	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
8. Transportable pressure equipment	Directive 2010/35/EU	N	Y	Y	Y	-	Y	Y	Y	N	Y	N	N	Y	Y	-	N	Y	Y	Y	N	Y	N	Y	Y	N	Y	Y	Y
9. Machinery	Directive 2006/42/EC	Y	Y	Y	Y	-	Y	Y	Y	N	Y	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
10. Lifts	Directive 1995/16/EC	Y	Y	Y	Y	-	Y	Y	Y	N	Y	N	N	Y	Y	-	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	Y
11. Cableways	Directive 2000/9/CE	N	Y	Y	Y	-	Y	N	Y	N	Y	N	N	Y	Y	-	Y	N	Y	N	Y	Y	N	Y	Y	Y	Y	Y	N
12. Noise emissions for outdoor equipment	Directive 2000/14/EC	Y	Y	Y	Y	-	N	N	N	N	Y	N	Y	N	Y	-	N	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y
<ul> <li>13. Equipment and</li> <li>Protective Systems</li> <li>Intended for use in</li> <li>Potentially</li> <li>Explosive</li> <li>Atmospheres</li> </ul>	Directive 1994/9/EC	Y	Y	Y	Y	-	N	Y	N	N	Y	N	N	Y	Y	-	Y	Y	Y	N	N	Y	N	Y	Y	N	Y	Y	Y

	Relevant											]	[nclu	ded i	in the	e rep	ort?	(Y/N	)										
Product sectors	legislation	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	РТ	RO	SI	SK	FI	SE	UK
14. Pyrotechnics	Directive 2007/23/EC	Y	Y	Y	Y	-	Y	Y	Y	N	Y	Y	Y	Y	Y	-	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
15. Explosives for civil uses	Directive 93/15/EEC	N	Y	Y	N	-	Y	Y	Y	N	Y	N	Y	Y	Y	-	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
16. Appliances burning gaseous fuels	Directive 2009/142/EC	Y	Y	Y	Y	-	Y	Y	Y	N	Y	N	N	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
17. Measuring instruments, Non- automatic weighing instruments and Pre-packaged products	Directives 2004/22/EC, 2009/23/EC and 2007/45/EC	N	Y	Y	Y	-	Y	Y	Y	N	Y	Y	Y	N	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
18. Electrical equipment under electromagnetic compatibility	Directive 2004/108/EC	Y	Y	Y	Y	Y	N	N	Y	Y	Y	N	N	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
19. Radio equipment and telecommunication s terminal equipment	Directive 1999/5/EC	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y

	Relevant											]	nclu	ded i	in the	e rep	ort?	(Y/N	)										
Product sectors	legislation	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	РТ	RO	SI	SK	FI	SE	UK
20. Electrical appliances and equipment under the low voltage directive	Directive 2006/95/EC	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
21. Electrical and electronic equipment under restriction of hazardous substances, waste from electrical and electronic equipment and batteries	Directives 2011/65/EU, 2002/96/EC and 2006/66/EC	Y	Y	Y	Y	_	Y	Y	Y	Y	Y	N	N	N	Y	-	N	Y	Y	Y	N	Y	Y	Y	Y	Ν	Y	Y	Y
22. Chemicals (Detergents, Paints, Persistent organic pollutants)	Regulation 648/2004 Directive 2004/42/EC Regulation 850/2004	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	N	N	Y	-	N	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	
23. Ecodesign and Energy labelling	Directives 2009/125/EC and 2010/30/EU	Y	Y	Y	Y	-	N	Y	Y	N	Y	N	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y

	Relevant											]	Inclu	ded i	in the	e rep	ort?	(Y/N	)										
Product sectors	legislation	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	МТ	NL	AT	PL	РТ	RO	SI	SK	FI	SE	UK
24. Efficiency requirements for hot-water boilers fired with liquid or gaseous fuels	Directive 1992/42/EE C	Y	N	Y	Ν	-	N	Y	Y	N	N	N	Ν	Ν	Y	-	N	Y	N	Ν	Ν	N	Ν	Y	Ν	N	Y	Y	N
25. Recreational craft	Directive 1994/25/EC	N	Y	Y	Y	-	Y	N	Y	N	Y	N	N	N	Y	-	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
26. Marine equipment	Directive 96/98/EC	N	N	N	Y	-	Y	N	N	N	Y	N	Y	N	Y	-	N	N	Y	N	Y	Y	Y	Y	Y	N	Y	Y	N
27. Motor vehicles and tyres	Directives 2002/24/EC and 2007/46/EC, and Regulation (EC) No 1222/2009	Y	Y	N	Y	-	Y	Y	N	Y	Y	N	N	Y	Y	-	N	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y
28. Non-road mobile machinery	Directive 97/68/EC	Y	Y	N	Y	-	N	N	N	N	N	N	N	N	Y	-	N	Y	N	N	N	N	N	Y	Y	N	N	Y	Y
29. Fertilisers	Regulation 2003/2003	Y	Y	N	Y	-	Y	Y	Y	N	Y	Y	N	N	Y	-	N	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Y	N

Duodust sostous	Relevant											]	nclu	ded i	in the	e rep	ort?	(Y/N	)										
Product sectors legislat	legislation	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	РТ	RO	SI	SK	FI	SE	UK
30. Other consumer products under GPSD (optional)	Directive 2001/95/EC	Y	Y	Y	N	-	Y	Y	Y	Y	Y	Y	Y	N	Y	-	Y	Y	N	Y	Y	Ν	Y	Y	N	N	Y	Y	N

#### 8. OVERVIEW OF INFORMATION PROVIDED FOR THE TOYS SECTOR

# Belgium

# A. Review of market surveillance activities in the sector

# Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints				
2.	Number of substantiated complaints by industry concerning unfair competition				
3.	Number of inspections (total number)	110 (not including 2660 Rapex inspection not divisible by sector)	639 (not including 4786 Rapex inspection not divisible by sector)	2251	2078
3.1	number of reactive inspections	n.a.	n.a.	2213	1837
3.2	number of self-initiated inspections	n.a.	n.a.	38	241
3.3	number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products				
5	Number of inspections resulting in:				
5.1	finding of non-compliance				
5.2	corrective actions taken by economic operators ("voluntary measures")				
5.3	restrictive measures taken by market surveillance authorities			11	97
5.4	application of sanctions/penalties				
6	Number of inspections where other Member States were invited to collaborate				

#### Information on communication activities carried out in the 2010-2013 period (optional)

#### No information

#### Information on resources (subject to availability)

No information

## B. Assessment of the functioning of market surveillance activities in the sector

No information

# Bulgaria

# A. Review of market surveillance activities in the sector

## Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	20	15	19	13
2.	Number of substantiated complaints by industry concerning unfair competition				
3.	Number of inspections (total number)	1106	1939	2296	1614
3.1	number of reactive inspections	830	820	503	282
3.2	number of self-initiated inspections	276	1119	1793	1332
3.3	number of inspections prompted by the customs	476	393	266	659
4	Number of inspections based on:				
4.1	tests performed in laboratories	17	17	16	4
4.2	physical checks of products	1106	1939	2296	1614
5	Number of inspections resulting in:				
5.1	finding of non-compliance	474	820	1224	282
5.2	corrective actions taken by economic operators ("voluntary measures")	76	105	431	80
5.3	restrictive measures taken by market surveillance authorities	8	3	47	19
5.4	application of sanctions/penalties	60	52	85	60
6	Number of inspections where other Member States were invited to collaborate				

#### Information on communication activities carried out in the 2010-2013 period (optional)

Six seminars with Bulgarian producers and importers of toys were organised in connection to the implementation of Directive 2009/48/EC (from 20 July 2011) - one in 2011 and one in 2012, while four seminars were organised in 2013 in connection with the implementation of the new chemical requirements (from 20 July 2013). Organisers of the seminars were the Bulgarian Institute for Standardisation and the Bulgarian association of producers and importers of toys.

At the initiative and with the support of the European Commission, a seminar was organised in 2012 by the Bulgarian association of producers and importers of toys.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms $(\mathcal{E})$	653072	649252	650465	608490
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)				
8	Staff available to market surveillance authorities (full-time equivalent units)	75	75	75	75
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	30	30	30	30

#### Information on resources (subject to availability)

## B. Assessment of the functioning of market surveillance activities in the sector

The number of toys produced in Bulgaria is small – accounting for no more than 10 % of the market. These are mainly toys made of wood, plastic, soft stuffed toys and sand drawing sets. The bulk of toys placed on the Bulgarian market is imported from third countries and in particular from China.

Given the great variety of products, despite the consistent and comprehensive monitoring of the market, there are still cases of toys marketed with the wrong age restrictions for use by the manufacturer; missing compulsory warnings on the toy as required in Directive 2009/48/EC or imprecise specific warnings; Bulgarian instructions for use which do not match the size and content of the manufacturer's instructions.

## **Czech Republic**

#### A. Review of market surveillance activities in the sector

#### Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	44	71	79	139
2.	Number of substantiated complaints by industry concerning unfair competition	Not recorded	29	23	59
3.	Number of inspections (total number)	1801	1682	1440	1602
3.1	number of reactive inspections	4574	5435	2108	1316
3.2	number of self-initiated inspections	1	4	4	3
3.3	number of inspections prompted by the customs	Not recorded	9	37	68
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products	1634	1550	1286	1314
5	Number of inspections resulting in:				
5.1	finding of non-compliance	1053	925	911	1346
5.2	corrective actions taken by economic operators ("voluntary measures")	1		1	
5.3	restrictive measures taken by market surveillance authorities	1			2
5.4	application of sanctions/penalties	390	49	549	548
6	Number of inspections where other Member States were invited to collaborate			9	27

#### Information on communication activities carried out in the 2010-2013 period (optional)

A market surveillance authority (specifically the Czech Trade Inspection Authority) works with the audit authority to hold public seminars approximately twice a year at toy exhibitions and trade fairs. In addition, the Czech Trade Inspection Authority staff answers all written and telephone enquiries made by the general public. In general, public health authorities under the Ministry of Health organise various training events or participate in those held by various institutions or professional associations. There is regular cooperation, for example, with PROKOS (the association of cosmetics manufacturers) and ČSZV (the Czech Association for Branded Products), whose training events are routinely attended by public health authorities delivering contributions on legislation and the results of surveillance activities. The situation is much the same with associations of packaging material manufacturers, with which there is also intensive communication. In addition, public health authorities regularly organise various seminars and workshops with professionals as a means to exchange experiences. The most extensive series of seminars was held in 2013 with the aim of familiarising the public with new legislation on cosmetics, particularly in relation to the EU's Cosmetic Products Notification Portal (CPNP).

#### Information on resources (subject to availability)

No information

#### B. Assessment of the functioning of market surveillance activities in the sector

The Czech Trade Inspection Authority's activities in this sector have sought to guarantee the same level of consumer protection and consumers' legitimate interests (i.e. life, health, property and the natural environment) within the EU internal market. Consumer product inspections concentrated primarily on third-country products, which were assessed in cooperation with customs authorities before they were released into free circulation in accordance with European TAXUD methodology.

The Czech Trade Inspection Authority is involved in international surveillance actions which are concerned, entirely or marginally, with the Toy Safety Directive and which are financially supported by the European Commission.

Since 2012, it has participated in a joint international surveillance project, co-financed by the European Commission and organised by Prosafe JA China 1 and JA China 2, which has yet to be completed.

The project seeks to establish a platform for cooperation with Chinese customs and surveillance authorities on the one hand and with EU customs and surveillance authorities on the other. The cooperation established should engender confidence in the safety of imported products and facilitate trade between China and the EU. In this context, another pilot project will be launched this year for the mutual assessment and recognition of the conformity of products covered by the Toy Safety Directive.

State health surveillance under the responsibility of the Ministry of Health draws on annual national and regional inspection plans based on methodology and compiled centrally by the Ministry of Health. The preparation of these plans is rooted in the market situation and an analysis of past results of state health surveillance, an analysis of legislative requirements and an assessment of the risk posed by products to consumers. Every year, targeted tasks of the Chief Health Officer are announced, which focus on nationwide problems that have been singled out. Regionally, targeted tasks – aimed at addressing problems typical for the region – are also carried out. In 2013, the focus was on dolls containing soft plastic parts, based on RAPEX notifications and internally conducted market research. This corroborated the presence of high concentrations of such toys, especially in 'Asian marketplaces'. This surveillance was carried out to confirm the high content of phthalates in soft plastic parts to a level that exceeded the limit established by the REACH Regulation and could threaten the health of the youngest members of the population, for whom these toys are intended.

In 2013, there were 408 toy inspections encompassing 1 550 products. A total of 258 product samples were taken for laboratory analysis; 142 of these products were classified as substandard. Customs administration authorities cooperated in the inspections of toys (dolls) with soft plastic parts – this product type was inspected upon entry into the Czech Republic and also directly on the market. In all, 87 products were declared unsafe, and a relatively large number of substandard products were seized by the customs authorities at the border and subsequently destroyed. Market inspections reveal problems with the sale of this type of product at markets, in particular 'Asian marketplaces', as the product origin cannot be traced because, in most cases, only the name of the vendor is known. Documents intended to prove the origin of a product, such as invoices, are false, if they exist at all. In some cases, non-existent barcodes, or companies that do not trade in the given type of product, are reported. Furthermore, it was found that, after a certain period of time had passed, products previously declared unsafe were placed back on sale, sometimes rebranded.

## Denmark

#### A. Review of market surveillance activities in the sector

#### Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints <sup>63</sup>	4	3	5	5
2.	Number of substantiated complaints by industry concerning unfair competition	1	1		
3.	Number of inspections (total number) <sup>64</sup>	138	133	91	90
3.1	number of reactive inspections <sup>65</sup>	66	43	47	46
3.2	number of self-initiated inspections	72	90	44	43
3.3	number of inspections prompted by the customs		11		
4	Number of inspections based on:				
4.1	tests performed in laboratories	25	71	15	21
4.2	physical checks of products <sup>66</sup>	133	81	81	81
5	Number of inspections resulting in:				
5.1	finding of non-compliance	30	20	44	24

<sup>63</sup> Data available from the Environmental Protection Agency only.

<sup>64</sup> The table covers the number of products and not the number of inspections. The number is based on an average.

<sup>65</sup> A significant proportion took place as the result of complaints from consumers, possibly as the result of accidents.

<sup>66</sup> All product inspections within the jurisdiction of the Danish Safety Technology Authority include a physical check. Figures reflect the number of products and not the number of inspections. They cover both the Danish Safety Technology Authority and the Danish Environmental Protection Agency.

		2010	2011	2012	2013
5.2	corrective actions taken by economic operators ("voluntary measures")	8	16	13	11
5.3	restrictive measures taken by market surveillance authorities <sup>67</sup>	10	8	4	4
5.4	application of sanctions/penalties	2	3	0	1
6	Number of inspections where other Member States were invited to collaborate	0	0	1	2

#### Information on communication activities carried out in the 2010-2013 period (optional)

The Environmental Protection Agency holds two dialogue meetings a year with the toy sector. At these meetings, both the Environmental Protection Agency and the sector provide information about what has happened since the last meeting, and they discuss anything that needs to be clarified in relation to both regulation and case handling. In addition to this, the Environmental Protection Agency also published a folder in collaboration with the Danish Safety Technology Authority in 2010, containing ten good tips for the procurement and handling of toys, aimed at buyers in local authorities and day-care institutions: <a href="http://www.sik.dk/Global/Publikationer/Foldere/10-gode-raadtil-haandtering-og-indkoeb-af-legetoej">http://www.sik.dk/Global/Publikationer/Foldere/10-gode-raadtil-haandtering-og-indkoeb-af-legetoej</a>

In order to help toy distributors gain an overview of their obligations, the Danish Safety Technology Authority produced a folder in 2012, for distribution during visits to shops. The folder is also available on the website:

http://www.sik.dk/content/download/23244/300319/version/1/file/Til\_distributoerer\_af\_leget oej\_rev\_+maj\_2014.pdf.

The Danish Safety Technology Authority is happy to make contributions concerning rules, etc. on toys, in order to give the sector the best basis for complying with the rules and only producing and dealing in safe toys. This is primarily done through dialogue meetings every six months, but also for example at the Nordic and Baltic Information Seminar on Toy Safety, which was held in Malmö on 20 September 2012.

The Danish Safety Technology Authority has taken part in the Commission's employee exchange. One colleague involved in toys (as well as one colleague involved in electrical products) was therefore on exchange at the NVWA in the Netherlands in January 2013. In 2013, the Danish Safety Technology Authority undertook a strategic fact-finding initiative on consumer behaviour with a view to producing information materials about the proper use of products. The investigation found that Danish consumers do not perceive toys as risky. They therefore do not read instructions for use or warning labels, and they make up their own rules. Some 16 % of consumers therefore said that they have never refrained from buying a toy purely because it has a warning symbol indicating that it is 'not suitable for children aged 0-3'.

<sup>67</sup> For infringements that do not have any significance for safety, the Danish Safety Technology Authority provides guidance/recommendations to the person responsible. Such infringements are not included in the figures.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ( $\in$ )	381800	213300	168400	169700
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.00056%	0.00031%	0.00024%	0.00024%
8	Staff available to market surveillance authorities (full-time equivalent units)	2.08	1.46	1.62	1.67
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	0.58	1.06	1.23	1.27

## Information on resources (subject to availability)

## B. Assessment of the functioning of market surveillance activities in the sector

#### **Environmental Protection Agency:**

Access to market surveillance in this sector is risk-based. Initiatives in the form of information, guidance and controls are organised and carried out on the basis of risk assessments, based on knowledge from scientific work and news in a broad sense, the age of the rules and the scope of consolidated guidance, the number of reported cases, including via Rapex, and the number of infringements detected during controls. The prioritisation of this product area therefore varies. Information, guidance and controls in collaboration with the Danish Safety Technology Authority have been given a high priority in 2014, particularly information and guidance, as part of a special initiative on the safe use of products for children.

#### Danish Safety Technology Authority:

The Authority's experience is that it is appropriate to keep the sector informed of the focus that the forthcoming proactive initiatives on toys will have. The potential shop types are thus prepared for the possibility of controls, and they can therefore instruct their employees how to react when the authorities pay a visit. A broader, earlier effect is thus achieved in the form of self-discipline. In order to measure the impact that a market surveillance initiative has had, including follow-up activities (usually concluding communication with the sector or consumers), the Authority has repeated some initiatives at intervals of a few years. The Danish Safety Technology Authority has compared the results of the magnetic toy initiative from 2012 with the previous initiative, which ran from 2007 to 2010. There has been an improvement, since 36 % of the toys that were selected posed a danger to consumers, compared to 60 % previously. We published the following article:

http://www.sik.dk/Global/Publikationer/Artikler/OEvrige-artikler/2012/Sikkerhedenvedmagnetlegetoej-kan-stadig-forbedres

Application of the Market Surveillance Regulation to the toy sector poses some challenges, including the following:

- Agents: The legal position for agents must be clarified, i.e. whether an agent may be treated as part of the distribution chain and have the associated responsibilities. The Danish Safety Technology Authority will therefore work to clarify this with the Commission.
- What should be done if the manufacturer responsible has been declared bankrupt or has otherwise ceased to exist? Can the product continue to be sold, and what liability do the other players in the distribution chain have with regard to procuring technical documentation for product safety?
- Manufacturers (and test laboratories) are not particularly aware of the fact that a standard must be harmonised in order for them to assume compliance with the safety requirements contained in the Toy Directive when the standard is complied with.

### Germany

### A. Review of market surveillance activities in the sector

### Information on enforcement activities carried out in the 2010-2013 period

No information

Information on communication activities carried out in the 2010-2013 period (optional)

No information

Information on resources (subject to availability)

No information

### B. Assessment of the functioning of market surveillance activities in the sector

No information

Estonia

#### A. Review of market surveillance activities in the sector

Surveillance activities in numbers	2010	2011	2012	2013
Total number of inspections	427	396	382	401
Number of notices sent by the Tax and Customs Board	12	9	18	11

Total number of products inspected <sup>68</sup>	847	584	442	369
Number of products tested	56	73	58	73

Results of surveillance activities	2010	2011	2012	2013
Number of non-compliant products <sup>69</sup>	49	57	47	15
Number of products presenting a serious risk	10	13	13	17

Measures applied <sup>70</sup>	2010	2011	2012	2013
Number of memos	27	28	39	48
Number of orders	38	34	1	0
Number of penalty payments and total amount	0	0	0	0
Number of substitutive enforcements	0	0	0	0
Number of misdemeanour procedures	0	0	0	0
Fines imposed as part of a misdemeanour procedure	0	0	0	0

Products withdrawn from the market	2010	2011	2012	2013
Total number of products withdrawn from the market <sup>71</sup>	21	10	6	7
Number of products recalled from consumers <sup>72</sup>	2	19	Data not available	Data not available
Number of voluntary measures taken by economic operators <sup>73</sup>	6	8	6	7

<sup>68</sup> The total number of products inspected by only one authority, the Health Board, has been given here. The total number of products inspected by the Consumer Protection Board is not available. With the current information system, it is only possible to return the number of inspection visits. At the same time it is known that the total number of products inspected by the Consumer Protection Board in 2011 was approximately 1 670.

For the Consumer Protection Board, it is only possible to give the number of non-compliant products out of the products tested. The percentage of infringements detected during the inspection visits was as follows: 2010 – 40.1%; 2011 – 34.4%; 2012 - 33%; 2013 – 63.5%.

<sup>70</sup> For the Consumer Protection Board, only the number of memos is available.

<sup>71</sup> The data for 2010–2011 consist of data from both of the authorities; there are no data available about the Consumer Protection Board for 2012–2013. Number of product articles.

The data from 2010–2011 consist of data of the Consumer Protection Board. The Health Board has no data available. Only data from 2010 are available for the Consumer Protection Board. The data from 2011–2013 consist only of the

<sup>73</sup> Only data from 2010 are available for the Consumer Protection Board. The data from 2011–2013 consist only of the data for the Health Board.

As far as toys are concerned, the Health Board has inspected whether the requirements laid down in Directive 2009/48/EC and 2001/95/EC of the European Parliament and of the Council and in the REACH regulation have been implemented. Special attention has been paid to the mechanical and physical properties of toys meant for children below three years of age since such toys may cause choking and injuries to the most vulnerable target group. The Health Board has also studied the phthalate content of rubber toys and childcare products, as phthalates are reproductive toxicants and may cause fertility problems in the long term.

Every year the Health Board carried out the ad hoc study "Inspection of possible phthalate content in childcare products and soft toys". The aim of the ad hoc study was to find out whether the childcare products (toys, childcare articles, etc.) on the Estonian market are in conformity with the requirements of point 51 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH).

During the ad hoc inspection, a total of 60 products per four years were inspected, of which 10 products (16%) were not in conformity with the requirements. In 2010 and in 2011 the Consumer Protection Board along with 14 market surveillance authorities took part in a project on toys financed by the European Commission and managed by the PROSAFE cooperation network. The aim of the project was to ensure that only safe toys were on the EU market; the project was aimed at inspecting magnetic toys, the content of small parts in toys and the content of heavy metals in toys. The project resulted in the preparation of several instructions and reference materials for the organisation of surveillance over toys.

### Information on resources (subject to availability)

No information

### B. Assessment of the functioning of market surveillance activities in the sector

No information

### Ireland

#### A. Review of market surveillance activities in the sector

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	36	36	36	17
2.	Number of substantiated complaints by industry concerning unfair competition				

<sup>74</sup> The Agency is unable to provide detailed statistical information in relation to enforcement activities as detailed in this section as the data relating to complaints, investigations and inspections is not recorded by the Agency in a comparable format and the Agency is not in a position to devote resources to detailed statistical analysis of this data at this time.

		2010	2011	2012	2013	
3.	Number of inspections (total number)		1	3	9	
3.1	number of reactive inspections		0	3 (not limited to toys)	9 (not limited to toys)	
3.2	number of self-initiated inspections		0			
3.3	number of inspections prompted by the customs		1	3 (not limited to toys)	9 (not limited to toys)	
4	Number of inspections based on:					
4.1	tests performed in laboratories					
4.2	physical checks of products	(	)	7	75	
5	Number of inspections resulting in:					
5.1	finding of non-compliance	n.a.	1	3	9	
5.2	corrective actions taken by economic operators ("voluntary measures")	76				
5.3	restrictive measures taken by market surveillance authorities	n.a.	1	3	9	
5.4	application of sanctions/penalties	n.a.	n.a.	n.a.	n.a.	
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0	

The National Consumer Agency hosts and operates 2 websites as follows ;

- Agency corporate-focused website <u>http://corporate.nca.ie/eng/</u>. This website provided information and guidance relating to business and corporate product safety issues including information on the role of the Agency as Ireland's market surveillance authority for safety of products covered by the EU Directives, product safety guidelines and responsibilities for businesses, and related 'Frequently Asked Questions' (FAQs), links to specific sectoral information including toy safety and magnetic toys, RAPEX weekly summary reports, product safety recalls, press releases, business zones guides including a Toy Safety page, Guide to Toy Safety, Toy Safety Tips and links to the relevant Irish legislation containing the transposed legislation.
- 2. General consumer-focused website at <u>http://www.consumerhelp.ie/</u> with information on the role of the Agency as Ireland's market surveillance authority for safety of products

<sup>75</sup> Representative items from customs consignments were visually and physically checked.

<sup>76</sup> The Agency achieved voluntary corrective actions (where necessary) in majority of cases.

covered by the EU Directives, enforcement of product safety legislation, investigation of complaints about unsafe products, alerting consumers about unsafe products by posting product recalls and RAPEX notifications detailing all product recalls that have taken place in the European Union, and general information for consumers on Toys and Play Equipment.

October 2010 - The National Consumer Agency hosted the 'Seminar on new EU Toy Safety Directive' an information seminar on the requirements of the new EU Toy Safety Directive for industry.

2012 – NCA participated in a training event hosted by the Chambers of Commerce and TIE to raise awareness about the new EU Toy Safety Directive and related standards.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms $(\mathbf{f})^{77}$	7200000	6300000	5200000	4800000
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	n.a.	n.a.	n.a.	n.a.
8	Staff available to market surveillance authorities (full-time equivalent units) <sup>78</sup>	7	7	8	8
9	Number of inspectors available to market surveillance authorities (full-time equivalent units) <sup>79</sup>	7	7	8	8

### Information on resources (subject to availability)

### B. Assessment of the functioning of market surveillance activities in the sector

The National Consumer Agency (NCA) is the statutory body established by the Irish Government to enforce consumer law and promote consumer rights with responsibility for market surveillance in respect of the safety of a wide range of non-food consumer products. Our role in relation to product safety includes enforcing product safety legislation, investigating complaints about unsafe products, carrying out surveillance activities, alerting consumers about unsafe products, advising manufacturers, suppliers, retailers and their representative bodies about their responsibilities, and managing Ireland's input to the EU product safety rapid alert system, RAPEX

The National Consumer Agency has also contributed to the National Sector Specific Market Surveillance Programmes 2010 -2011 and 2012 – 2013.

<sup>77</sup> The Budget across is the total NCA budget for all activities (excluding financial awareness and education). It is not possible to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
78 Display the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

<sup>78</sup> Number of authorised officers in Product Safety Unit with additional authorised Officers available to assist on specific projects if required.

<sup>79</sup> Number of authorised officers in Product Safety Unit with additional authorised Officers available to assist on specific projects if required.

### Greece

### A. Review of market surveillance activities in the sector

#### Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	0	0	1	0
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	4	0
3.	Number of inspections (total number)	30	43	32	8
3.1	number of reactive inspections	3	4	4	7
3.2	number of self-initiated inspections	27	38	28	1
3.3	number of inspections prompted by the customs	0	1	0	0
4	Number of inspections based on:				
4.1	tests performed in laboratories	63	68	23	98
4.2	physical checks of products	0	34	9	3
5	Number of inspections resulting in:				
5.1	finding of non-compliance	12	19	6	13
5.2	corrective actions taken by economic operators ("voluntary measures")	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities <sup>80</sup>	10	6	6	4
5.4	application of sanctions/penalties <sup>81</sup>	10	6	6	4
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

### Information on communication activities carried out in the 2010-2013 period (optional)

No information

For the year 2012, the three prohibitions/withdrawals relating to samples with an abnormal phthalate content were issued by the General Chemical State Laboratory (Directorate for the Environment). For the year 2013, the prohibition/withdrawal relating to a sample with an abnormal phthalate content was issued by the General Chemical State Laboratory (Directorate for the Environment).
 Fines as well as mandatory measures (withdrawals) were imposed on economic operators.

### Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms $(\mathbb{C})^{82}$				
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget) <sup>83</sup>				
8	Staff available to market surveillance authorities (full-time equivalent units)	3	3	3	3
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	10	10	10	10

### B. Assessment of the functioning of market surveillance activities in the sector

From 2010-2013, the market surveillance authority for toys carried out 113 inspections, involving the inspection of 261 outlets for toys throughout Greece (importers, distributors and manufacturers) and 900 types of toy were given mainly visual inspections.

All this was carried out at virtually zero financial cost.

Fines totalling EUR 111 611.60 were established and collected.

#### Spain

#### A. Review of market surveillance activities in the sector

#### Information on enforcement activities carried out in the 2010-2013 period

No information

#### Information on communication activities carried out in the 2010-2013 period (optional)

No information

#### Information on resources (subject to availability)

No information

#### B. Assessment of the functioning of market surveillance activities in the sector

No information

<sup>82</sup> The annual budget for resources and training related to the General Secretariat for Industry's entire market surveillance operation (for this purpose rows 7.1 and 7.2 have not been completed, which relate exclusively to toys).

<sup>83</sup> The annual budget for resources and training related to the General Secretariat for Industry's entire market surveillance operation (for this purpose rows 7.1 and 7.2 have not been completed, which relate exclusively to toys).

# France

# A. Review of market surveillance activities in the sector

# Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	22
2.	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	4
3.	Number of inspections (total number)	3773	2694	2224	2644
3.1	number of reactive inspections	15	24	20	15
3.2	number of self-initiated inspections	3758	2674	2204	2639
4	Number of inspections based on:				
4.1	tests performed in laboratories	868	773	877	790
4.2	physical checks of products	18500	15000	19000	17000
5	Number of inspections resulting in:				
5.1	finding of non-compliance	380	341	401	326
5.2	corrective actions taken by economic operators ("voluntary measures")	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures taken by market surveillance authorities	72	54	50	74
5.4	application of sanctions/penalties	52	40	39	42
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

### Information on communication activities carried out in the 2010-2013 period (optional)

No information

# Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms $(\mathbf{f})^{84}$	2000000	1620000	1300000	1320000

<sup>84</sup> Doesn't include the budget for product testing.

		2010	2011	2012	2013
8	Staff available to market surveillance authorities (full-time equivalent units)	26.5	20.5	21.5	21.5
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	24	18	19	19

# B. Assessment of the functioning of market surveillance activities in the sector

No information

# Croatia<sup>85</sup>

# A. Review of market surveillance activities in the sector

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints				
2.	Number of substantiated complaints by industry concerning unfair competition				
3.	Number of inspections (total number)				384
3.1	number of reactive inspections				150
3.2	number of self-initiated inspections				90
3.3	number of inspections prompted by the customs				144
4	Number of inspections based on:				
4.1	tests performed in laboratories				30
4.2	physical checks of products				40
5	Number of inspections resulting in:				
5.1	finding of non-compliance				50
5.2	corrective actions taken by economic operators ("voluntary measures")				2
5.3	restrictive measures taken by market surveillance authorities				60

<sup>85</sup> Data only between 1 July 2013 – 31 December 2013

		2010	2011	2012	2013
5.4	application of sanctions/penalties				40
6	Number of inspections where other Member States were invited to collaborate				

No information

# Information on resources (subject to availability)

No information

### B. Assessment of the functioning of market surveillance activities in the sector

No information

# Italy

### A. Review of market surveillance activities in the sector

# Information on enforcement activities carried out in the 2010-2013 period

No distinguishable information provided: combination of sector 3 and 30

		2010	2011	2012	2013
1.	Number of product related accidents / user	205 (A)	229 (A)	96 (A)	275 (A)
	complaints	13 (C)	13 (C)	11 (C)	7 (C)
2.	Number of substantiated complaints by industry concerning unfair competition				
3.	Number of inspections (total number)	1168	1305	547	1567
3.1	number of reactive inspections	218	450	259	372
3.2	number of self-initiated inspections				
3.3	number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	tests performed in laboratories		415		
4.2	physical checks of products				
5	Number of inspections resulting in:				

		2010	2011	2012	2013
5.1	finding of non-compliance		228		
5.2	corrective actions taken by economic operators ("voluntary measures")				
5.3	restrictive measures taken by market surveillance authorities		185		
5.4	application of sanctions/penalties				
6	Number of inspections where other Member States were invited to collaborate				

No information

### Information on resources (subject to availability)

No distinguishable information	provided: combination of sector 3 and 30
Tto albungaismaole information	provided. combination of sector 5 and 50

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms $(\mathcal{E})$	n.a	n.a.	n.a.	n.a.
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	n.a	n.a.	n.a.	n.a.
8	Staff available to market surveillance authorities (full-time equivalent units)	7	7	11	10
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	100 (NAS)	n.a.	n.a.	n.a.

### B. Assessment of the functioning of market surveillance activities in the sector

Following the RAPEX alerts on microbiological or chemical issues relating to consumer products (toys and other), under the responsibility of the Ministry of Health, NAS (the Health Protection Unit of the Carabinieri) launched a review of the national market. The main issues reported include a lack of detailed information as to the distribution network, imports via unofficial channels and the lack of documentation and invoices showing the origin of the products. The lack of resources significantly restricts the ability to perform control tests.

# Cyprus

### A. Review of market surveillance activities in the sector

### Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	0	0	0	0
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	1257	962	834	785
3.1	number of reactive inspections	9	8	4	3
3.2	number of self-initiated inspections	n.a.	n.a.	21	8
3.3	number of inspections prompted by the customs	0	11	0	5
4	Number of inspections based on:				
4.1	tests performed in laboratories	74	69	59	43
4.2	physical checks of products	1183	893	775	742
5	Number of inspections resulting in:				
5.1	finding of non-compliance	n.a.	27	52	85
5.2	corrective actions taken by economic operators ("voluntary measures")	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities	33	19	17	27
5.4	application of sanctions/penalties	0	2	0	2
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

#### Information on communication activities carried out in the 2010-2013 period (optional)

Information sheets are sent to toy importers, informing them of their obligations and giving them advice and instructions. Furthermore, regular visits are paid to distributors and importers, during which they are given oral information and submitted to inspection. In addition, information material on the implementation of the Toy Safety Directive has been printed (30 000 copies) and will be distributed to importers, distributors and consumer organisations. Moreover, all the communications from the department relating to toys are notified to consumer organisations and associations of economic operators.

A seminary-workshop was held on 22 September 2011 as part of the pan-European campaign for the CE marking. The seminar was intended primarily for economic operators, as well as consumers. The new Toy Safety Directive was presented as part of that seminar. The department also took part in the Christmas pan-European Toy Safety Campaign (December 2011).

# Information on resources (subject to availability)

No information

# B. Assessment of the functioning of market surveillance activities in the sector

Market surveillance activities in relation to toys are being carried out almost on a daily basis, throughout the territory of Cyprus. In particular, inspectors carry out inspections on the basis of the RAPEX weekly report (which includes toys), and at the same time they conduct visual and physical inspections of toys.

In addition, samples of toys are taken and examined twice a year. Usually, the first sampling (2nd quarter of the year) includes 30 toy samples, the physical and mechanical properties (EN71-1) of which are examined, and the second sampling (4th quarter of the year) includes 30 toy samples which are tested for the migration of heavy metals (EN71-3). All laboratory tests are performed by the State General Laboratory. The exact sampling schedule is established in an agreement between the two parties at the beginning of each year. Other laboratory tests may be conducted in the context of our participation in EU programmes, e.g. PROSAFE.

Finally, inspection campaigns are being carried out with respect to specific toy categories (e.g. inflatable toys, skates, projectile toys) or in specific sales premises of toys (e.g. open-air markets).

### **Inspection methodology:**

Conducting visual and physical inspection of toys. These inspections are usually performed on own initiative and/or on the basis of the RAPEX notification. In some cases, these inspections are performed following consumer complaints.

The actions/procedures followed are:

- checking the CE marking;
- checking the warnings that should be affixed on toys;
- assessing the compliance of toys with the basic safety requirements of the applicable national legislation;
- physical inspection of toys for children under the age of 3 for detachable small parts, sharp points, laces, liquids, etc.;
- if there are doubts about any toy, all relevant information and documentation in relation to the product are requested from the economic operator;
- conducting sample checks on products and carrying out laboratory tests on them;

• taking measures when it is found that toys do not comply with the safety requirements of the applicable national legislation.

The specific market framework on which the surveillance scheme is carried out:

- Assumptions as to the size of the national market: n.a.
- Number of manufacturers: 1
- Number of importers: 68
- Number of distributors: 397
- Import volume (third countries): EUR 16 459 997.00

# Latvia

### A. Review of market surveillance activities in the sector

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	n.a.
2.	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3.	Number of inspections (total number)	153	57	145	109
3.1	number of reactive inspections	2	0	5	3
3.2	number of self-initiated inspections	151	51	93	69
3.3	number of inspections prompted by the customs	0	6	47	37
4	Number of inspections based on:				
4.1	tests performed in laboratories	36	12	31	39
4.2	physical checks of products	153	57	145	109
5	Number of inspections resulting in:				
5.1	finding of non-compliance	60	23	61	63
5.2	corrective actions taken by economic operators ("voluntary measures")	59	16	43	41
5.3	restrictive measures taken by market surveillance authorities	1	7	18	22

		2010	2011	2012	2013
5.4	application of sanctions/penalties	15	34	60	22
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

No information

### Information on resources (subject to availability)

No information

### B. Assessment of the functioning of market surveillance activities in the sector

No information

# Lithuania

### A. Review of market surveillance activities in the sector

### Information on enforcement activities carried out in the 2010-2013 period

No information

### Information on communication activities carried out in the 2010-2013 period (optional)

No information

### Information on resources (subject to availability)

No information

### B. Assessment of the functioning of market surveillance activities in the sector

No information

# Luxembourg

### A. Review of market surveillance activities in the sector

### Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	0	0	1	0
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	78	80	22	24
3.1	number of reactive inspections	1	0	2	0
3.2	number of self-initiated inspections	64	49	18	19
3.3	number of inspections prompted by the customs	13	31	2	5
4	Number of inspections based on:				
4.1	tests performed in laboratories	8	2	12	8
4.2	physical checks of products	40	49	14	19
5	Number of inspections resulting in:				
5.1	finding of non-compliance	22	27	13	7
5.2	corrective actions taken by economic operators ("voluntary measures")	1	5	2	1
5.3	restrictive measures taken by market surveillance authorities	10	22	11	6
5.4	application of sanctions/penalties	0	0	0	0
6	Number of inspections where other Member States were invited to collaborate	1	0	0	0

#### Information on communication activities carried out in the 2010-2013 period (optional)

Surveillance was carried out sporadically in retail outlets. These inspections comprised visual inspections of labelling and the documentation provided. Systematic verification was carried out together with officials of the Administration des Douanes et Accises at import.

### Information on resources (subject to availability)

No information

### B. Assessment of the functioning of market surveillance activities in the sector

No information

# Hungary

### A. Review of market surveillance activities in the sector

#### Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	21	25	25	31
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	1153	1510	1015	1043
3.1	number of reactive inspections	465	571	352	393
3.2	number of self-initiated inspections	683	926	656	641
3.3	number of inspections prompted by the customs	5	13	7	9
4	Number of inspections based on:				
4.1	tests performed in laboratories	76	55	62	90
4.2	physical checks of products	1422	2695	2476	2094
5	Number of inspections resulting in:				
5.1	finding of non-compliance	207	305	479	512
5.2	corrective actions taken by economic operators ("voluntary measures")	4	3	2	1
5.3	restrictive measures taken by market surveillance authorities	161	237	223	230
5.4	application of sanctions/penalties	130	197	153	137
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

### Information on communication activities carried out in the 2010-2013 period (optional)

In its communication activities, the NFH gives priority to communicating product safety information to consumers and economic operators. The Authority continuously publishes news, information and changes in legislation relating to market surveillance and individual

product groups, as well as dangerous products prohibited by the Authority, on its website and Facebook account. In addition, news about the market surveillance activities of the Authority is regularly published in various media (national and local television and radio stations, Internet and written press), and information is provided about these in its official journal and newsletter. Furthermore, the Authority tries to draw the attention of the public to products posing a risk with laboratory open days, roadshows and campaigns.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms $(\in)$	317192	522807	465263	461052
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.000637	0.00105	0.000837	0.0008
8	Staff available to market surveillance authorities (full-time equivalent units)	32	35	30	34
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	21	23	19	22

Information on resources (subject to availability)

### B. Assessment of the functioning of market surveillance activities in the sector

The consumer protection authority examined the following types of toys between 2010 and 2013:

- Dolls/doll kits: according to experience, 90 % of the products analysed have a high phthalic ester-type softener content in the heads of dolls. Instead of the heads of dolls, the softener is mostly located in the bodies of dolls and other accessories. 18 % of the labelling is incomplete, 4 % of the products do not have conformity documentation. The complaint ratios were nearly equal in all three years.
- Projectile toys: their most typical defect is the separation of the suction disc and the higher than permitted phthalic ester-type softener content of the suction disc. This product group was also inspected as part of sample testing/individually every year; the Authority increasingly often encountered phthalic-free products in 2013 and this year. Projectiles are already made of different materials, thus they do not contain any softener and the design of projectiles has been changed: they consist of a piece cast in one mould, thus they have no small part that can get separated. In terms of labelling, 25 % of them are inadequate, and 3 % do not have conformity documentation.
- Toys for children under the age of three: Of the baby toys tested in 2012, 112 types or 388 toys (20.9 %) were complained about due to inadequate markings, labels and warnings. During the inspections, samples were taken from 14 toys presumed to be suspicious from a safety point of view. On the basis of the results of laboratory tests, two baby toys proved to be dangerous. One baby chew toy represents a serious risk to small children from the point of view of choking hazard, while a pram rattle poses a

high risk in terms of eye injuries. In 2013, the product group was examined as part of laboratory tests, where dangerous softeners were also found in a small proportion. In the case of this product group, manufacturers pay greater attention to hazards posed by small parts and pull cords. The documentation was correct in the case of 85.7 % of the toys.

- Bubble blowers/replenishers: In the case of this product group, microbiological analyses were carried out on several occasions. In 25 % of the cases, microbiological infections were found, in one case due to a specific defect of the product.
- Tricycles and scooters: The majority of the products did not meet the requirements set for load-bearing capacity, brakes, stability, burr and sticking. With regard to labelling, product-specific warning notices were incomplete or completely missing.
- Textile puppets (2013) and textile doll clothes (2012): The Authority analysed these products for their azo-dye content (in specific analyses); in two analyses, one product did not meet the requirements.
- Expanding toys: A very small group of toys belongs to the group of expanding toys: In 20 % of these products, they expand too much (several fold in size). The Authority checked these products, too, in its own laboratory tests and sampling tests every year.
- Make-up kits: They were not subjected to independent thematic reviews, but about 10 of them were tested (randomly and through consumer complaints) every year. In terms of microbiological and heavy metal content, the products meet the requirements.
- Toy books: During the inspection of children's books, a total of 20 products were sampled, of which deficiencies relating to the conditions of distribution were established in the case of 12 (60 %), and non-conformity affecting product safety, which represents a medium risk, was established in the case of one (5 %). It can be stated from the experience gained that the manufacturers and importers are not aware of the fact that they have to meet not only the requirements set for books, but also those set for children's toys. They do not know the boundary between books and toys. In many cases, therefore, conformity markings were not shown either.
- Toy mobile phones: The Authority inspected these product groups as part of independent thematic reviews in 2011 and 2012. On both occasions, the Authority established that the volume emitted was too high in nearly 82 % of the products, 30 % did not conform to the structural specifications, and 17 % were malfunctioning.

On the basis of experience of the past period, it can be stated that it is a frequent problem in the case of toys that the documentation certifying the conformity of the product is incomplete or inadequate. In the case of EC declarations of conformity, the most frequent errors are the name and ID number of the registered organisation. The inspection of a significant part of the products is carried out by an (unregistered) Chinese subsidiary of a registered organisation. Another error is the ambiguous identifiability (lack/quality of photograph, difference in identification markings). It is an error that occurs less frequently, but so much the more significant, that the product is examined in accordance with inappropriate standards or conformity with the required regulations is not examined, thus not all hazards arising during normal use are taken into account by the manufacturer.

# Malta

# A. Review of market surveillance activities in the sector

# Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	4	3	5	3
2.	Number of substantiated complaints by industry concerning unfair competition	18	13	6	5
3.	Number of inspections (total number)	149	127	159	162
3.1	number of reactive inspections	25	20	75	94
3.2	number of self-initiated inspections	101	91	73	60
3.3	number of inspections prompted by the customs				
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products				
5	Number of inspections resulting in:				
5.1	finding of non-compliance	89	84	108	112
5.2	corrective actions taken by economic operators ("voluntary measures")	33	37	44	43
5.3	restrictive measures taken by market surveillance authorities	27	6	7	7
5.4	application of sanctions/penalties				
6	Number of inspections where other Member States were invited to collaborate				

# Information on communication activities carried out in the 2010-2013 period (optional)

No information

# Information on resources (subject to availability)

No information

### B. Assessment of the functioning of market surveillance activities in the sector

Toys are one of the priority product groups for the Market Surveillance Authority in Malta. Hence, these products feature prominently in the national market surveillance's annual programme. After an initial period of around 3 years in which economic operators were not fully aware of the operations of the market surveillance authority in Malta, and which resulted in a lack of action from the part of the operators to respond to findings by the surveillance authority, an increase in voluntary measures was encountered as awareness increased.

# Netherlands

### A. Review of market surveillance activities in the sector

# Information on enforcement activities carried out in the 2010-2013 period

No information

Information on communication activities carried out in the 2010-2013 period (optional)

No information

### Information on resources (subject to availability)

No information

### B. Assessment of the functioning of market surveillance activities in the sector

In 2012 and 2013, 135 manufacturers and importers of toys were inspected, though it should be noted that some of these companies were trading in many different product groups. Much emphasis was placed on the contents of technical files. Many of the technical files were found to be still missing or incomplete.

From 2011 to 2014, 630 toy samples were examined in terms of their physical and mechanical safety. The focus is on toys for children under 3 years old and especially on combating the risk of choking.

In addition, various groups of toys (wooden and plastic toys, balloons, finger paints, fancy dress costumes, playhouses/tents and cuddly toys) were examined in terms of their chemical safety. Depending on the type of material, they were tested for plasticisers, heavy metals, AZO dyes, preservatives and nitrosamines. Fire safety was also inspected. To this end, tests were conducted to verify compliance with the requirements of Annex XVII to the REACH regulation and those of the GPSD. A general compliance level of 90 % was found. An inspection of the microbiological safety of cuddly toys did not reveal any deviations.

# Austria

### A. Review of market surveillance activities in the sector

### Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	n.a.
2.	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3.	Number of inspections (total number)	592	461	702	579
3.1	number of reactive inspections	n.a.	n.a.	n.a.	n.a.
3.2	number of self-initiated inspections	n.a.	n.a.	n.a.	n.a.
3.3	number of inspections prompted by the customs	n.a.	n.a.	n.a.	n.a.
4	Number of inspections based on:	202	114	229	109
4.1	tests performed in laboratories	n.a.	n.a.	n.a.	n.a.
4.2	physical checks of products	n.a.	n.a.	n.a.	n.a.
5	Number of inspections resulting in:	S	Sampling and r	eviews togethe	r
5.1	finding of non-compliance	n.a.	n.a.	n.a.	n.a.
5.2	corrective actions taken by economic operators ("voluntary measures")	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures taken by market surveillance authorities	n.a.	n.a.	n.a.	n.a.
5.4	application of sanctions/penalties	n.a.	n.a.	n.a.	n.a.
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

### Information on communication activities carried out in the 2010-2013 period (optional)

Information on websites, booklets: Toy booklet produced by the Federal Ministry of Health as of 2009; second booklet produced in association with the Austrian Federal Economic Chamber (WKO) in 2011, both available on the homepage:

http://bmg.gv.at/home/Schwerpunkte/VerbraucherInnengesundheit/Spielzeug/Ratgeber\_zur\_Spielzeugwahl

Educational, informational and training events, particularly during 2010 and 2011 prior to the coming into force of the new Toy Safety Directive 2009/48/EC.

### Information on resources (subject to availability)

No information

### B. Assessment of the functioning of market surveillance activities in the sector

Market surveillance for goods subject to the Austrian Food Safety and Consumer Protection Act (LMSVG) – i.e. food, drinking water, food-contact materials (materials intended to come into contact with food), toys, and cosmetics – follows the indirect federal administration structure. The system of controls is described in the Food Safety Report (LMSB), which is produced annually.

Link:

 $\underline{https://www.verbrauchergesundheit.gv.at/lebensmittel/lebensmittelkontrolle/LMSicherheit.ht}{ml}$ 

The Federal Ministry of Health coordinates the control and surveillance activities by producing an annual Inspection Plan (Sampling and Review Plan), which has to be adhered to by the relevant supervisory authorities in the federal provinces. The extent to which these requirements are met is set out in a comparison of target versus actual performance.

To ensure consistent surveillance and a risk-oriented approach, specially developed procedures are adhered to during the surveillance activities. Internal audits are also held at regular intervals to ensure compliance with the quality assurance system. In addition, in July 2014 a report was submitted to the responsible department of the Directorate-General for Enterprise and Industry, in accordance with Article 48 of the Toy Safety Directive 2009/48/EC.

The sector in Austria features many small and medium-sized businesses, predominantly retail companies. A large percentage of the products come to Austria from other Member States.

The LMSVG stipulates that products on the market must be inspected, as well as the businesses themselves; the number of breaches determined refers to the total of both types of inspections. The most common defect was incorrect labelling. The large degree of fluctuation results from there being a different focus of inspection each year (for example, cheap toys sold at fairs).

### Poland

#### A. Review of market surveillance activities in the sector

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	n.a.	249	188	209

		2010	2011	2012	2013
2.	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.
3.	Number of inspections (total number)	925	727	662	702
3.1	number of reactive inspections	n.a.	132	111	123
3.2	number of self-initiated inspections	n.a.	478	475	493
3.3	number of inspections prompted by the customs <sup>86</sup>	95	113	129	243
4	Number of inspections based on: 87				
4.1	tests performed in laboratories	477	456	544	516
4.2	physical checks of products	925	727	662	702
5	Number of inspections resulting in:				
5.1	finding of non-compliance	512	364	369	383
5.2	corrective actions taken by economic operators ("voluntary measures") <sup>88</sup>	486	1082	1047	1016
5.3	restrictive measures taken by market surveillance authorities <sup>89</sup>	77	80	70	45
5.4	application of sanctions/penalties90	24	34	17	23
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

No information

#### Information on resources (subject to availability)

No information

### B. Assessment of the functioning of market surveillance activities in the sector

Controls of toys were carried out by the Trade Inspectorate continually. In the years 2010 - 2013 controls covered 14670 products, challenging 5003 of them. Controls covered, among other things: soft stuffed toys, dolls, baby toys for watching, catching and/ or squeezing; art and handicraft materials and similar articles, books used in playing, costumes, fancy dress and

<sup>86</sup> The number of opinions issued at the request of the customs authorities is given.

<sup>87</sup> Estimate data. In case of some authorities the number of products is given.

<sup>88</sup> The number of operations is given.

<sup>89</sup> The number of measures applied is given.

<sup>90</sup> The number of administrative decisions is given.

masks, toys for developing skills, toys found in foodstuffs, toys for playing in sand and in water, toys for playing in water, toys - equipment for sports games and balls, toys into which a child can enter, audiovisual equipment, construction toys and puzzles, sets for experimenting, functional toys, game sets, and mechanically and/or electrically propelled vehicles.

For the last few years there has been a noticeable trend on the Polish market of a similar proportion of toys queried in relation to toys which were in compliance with the requirements. Approximately one third of toys checked during a given calendar year are challenged.

Polish operators continue to have problems with correct age classification of toys. As a result, they put incorrect markings on toys, or do not even place any warnings essential for children's carers buying toys.

However, it should be stressed that instructions and warnings are easy to correct and operators have no problems with voluntarily following the recommendations of inspectors.

Another frequent irregularity is an indication of "adult supervision" being necessary. It should be noted that such supervision is necessary only in respect of toys whose use can be dangerous, e.g. functional toys, toys for keeping a child afloat, or chemical toys. Such a warning can mislead a parent making a purchase by suggesting dangers which do not actually arise.

The most frequent danger which has a direct impact on children's safety is the presence of small particles (whether they separate automatically or appear as a result of using a little force). In addition, tests performed every year indicate the presence of other serious risks which have a negative impact on children's health. They include, for example, exceeding the admissible acoustic pressure level in toys emitting sounds (this creates a risk of damage, or even loss, of hearing), the presence of sharp and jagged edges (risk of injury or wounds), or the presence of chemical substances which have a negative impact on reproductive and hormonal systems (phthalates - in 2013, in every third sample tested the acceptable concentration level of these substances was exceeded).

There may be many reasons for these non-compliances. However, the most probable is the absence on the part of operators placing toys on the market, of sufficient knowledge of applicable provisions regarding the assessment of compliance. Regular checks by the Trade Inspectorate regarding correct assessment of compliance of toys with essential requirements raise the awareness of operators, in particular importers, indicating how important it is to check and confirm that goods placed on the market meet the relevant requirements.

# Portugal

### A. Review of market surveillance activities in the sector

### Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	10	60	15	24
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	50	30	453	405
3.1	number of reactive inspections	43	30	133	261
3.2	number of self-initiated inspections	7	0	320	144
3.3	number of inspections prompted by the customs	0	0	0	0
4	Number of inspections based on:	0	0	0	0
4.1	tests performed in laboratories	0	0	59	0
4.2	physical checks of products	14	0	32	144
5	Number of inspections resulting in:	0	0	0	0
5.1	finding of non-compliance	7	0	75	34
5.2	corrective actions taken by economic operators ("voluntary measures")	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures <sup>91</sup> taken by market surveillance authorities	0	0	0	2
5.4	application of sanctions/penalties	0	0	59	26
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

### Information on communication activities carried out in the 2010-2013 period (optional)

**[ASAE]** With the publication of Directive 2009/48/EC, internal training activities were held for its inspectors, in which they were made aware of changes to the legislation on toy safety. Documentary inspection procedures, checklists and sample collection procedures were drawn up, so as to cover various types of toys, with the aim of creating an operating methodology for all cases covered by legislation.

<sup>91</sup> Compulsory measures to prohibit or restrict the product being made available on the national market, to withdraw it or to recall it. These measures are taken when the economic operators did not follow up on a previous request from market-surveillance authorities to take corrective action, or where authorities have to intervene urgently.

The ASAE held an information session for secondary school pupils in February 2011. The session covered toys typical of the carnival season, with specific focus on their labelling and general principles of the CE marking and its meaning.

Following an invitation from Toy Industries of Europe (TIE), the ASAE participated as a speaker in the Seminar on Toy Safety held in Madrid in October 2012. This event, funded by the European Commission, was organised by TIE in collaboration with the Spanish Association of Toy Manufacturers (AEFJ). It was mainly aimed at Portuguese and Spanish economic operators representing various parts of the supply chain (manufacturers, importers and distributors) and testing laboratories.

### Information on resources (subject to availability)

No information

### B. Assessment of the functioning of market surveillance activities in the sector

**[ASAE]** The ASAE participated in a joint action called Joint Action 2010 'Children's Fancy Dress Project' organised by PROSAFE (Product Safety Forum of Europe) and supported by the European Commission. During this action, it collected 59 samples of Halloween and Carnival costumes. The greatest difficulty encountered related directly to the transitional period provided for in the legislation. The main difficulty regarded not impeding the making available on the market of toys which are in accordance with Directive 88/378/EEC and which were placed on the market before 20 July 2011. However, in Portugal, there are virtually no toy manufacturers and the number of importers is not significant, and so inspection actions related to distributors and retailers. The infringements detected related to the lack of labelling in Portuguese, the absence of a CE marking, noncompliance with distributor's duties, violation of the requirements relating to the EC declaration, violation of the rules and conditions on affixing the CE marking and the refusal of economic operators to submit documentation or information requested by the market-surveillance authority.

### Romania

#### A. Review of market surveillance activities in the sector

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	0	0	0	0
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections (total number)	1207	1352	1592	1832
3.1	number of reactive inspections	0	1	5	8
3.2	number of self-initiated inspections	1205	1349	1583	1821

		2010	2011	2012	2013
3.3	number of inspections prompted by the customs	2	2	4	3
4	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	13	0
4.2	physical checks of products	1205	1349	1583	1821
5	Number of inspections resulting in:				
5.1	finding of non-compliance	954	1092	1256	1545
5.2	corrective actions taken by economic operators ("voluntary measures")	0	0	0	0
5.3	restrictive measures taken by market surveillance authorities	670	817	891	898
5.4	application of sanctions/penalties	1058	1286	1433	1647
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

No information

# Information on resources (subject to availability)

No information

# B. Assessment of the functioning of market surveillance activities in the sector

No information

Slovenia

#### A. Review of market surveillance activities in the sector

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	n.a.	n.a.	n.a.	n.a.
2.	Number of substantiated complaints by industry concerning unfair competition	n.a.	n.a.	n.a.	n.a.

		2010	2011	2012	2013
3.	Number of inspections (total number)	1905	1866	1715	1540
3.1	number of reactive inspections	505	468	281	227
3.2	number of self-initiated inspections	1345	1374	1396	1279
3.3	number of inspections prompted by the customs	n.a.	n.a.	n.a.	n.a.
4	Number of inspections based on:				
4.1	tests performed in laboratories	62	76	14	25
4.2	physical checks of products	1345	1374	1396	1279
5	Number of inspections resulting in:				
5.1	finding of non-compliance	303	204	275	231
5.2 5.3 92	corrective actions taken by economic operators ("voluntary measures") restrictive measures taken by market surveillance authorities	278	177	264	260
5.4	application of sanctions/penalties	79	31	99	99
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

To facilitate the understanding and uniform application of the Directive by manufacturers, importers and distributors, at the end of 2010 the Slovenian Chamber of Commerce (TZS), in cooperation with the Ministry of Health, Health Inspectorate and the Institute of Public Health Maribor, organized an all-day conference "Presentation of innovations in the field Toy Safety Directive 2009/48/EC and, consequently, the Slovenian legislation". During the presentation there was also a general discussion with the participants of the conference. In order to facilitate the monitoring of the changes introduced by the Directive, as part of the obligations relating to economic operators that operate toys, such as in the field of security requirements, the Health Inspectorate collected all relevant information on web pages concerning the safety of toys, and prepared summaries of the most important content relating to the requirements of the Directive.

The meetings were organized by the Regional Chamber of Craft; we introduced legislation on the safety of toys.

<sup>92</sup> As the information system does not provide separate information on the number of inspections that result in corrective and restrictive measures based on the number of administrative (listed in pt. 5.2 and 5.3) and violation of measures (5.4) imposed, the number of checks which result in corrective and restrictive measures can only be inferred. On the basis of these it can be concluded that the trader takes the corrective measures identified in the majority of cases of non-compliance before the inspection procedure is completed, and determining whether further restrictive measures are necessary. The number of inspections that result in non-compliance being identified (5.1) does not include the identified inconsistencies in sampling activities. Also included in the number of measures are measures for non-compliant samples.

As a result of the European information seminar on the safety of toys in 2012, the Inspectorate in the field of toys published a translation of frequently asked questions on the website:

http://www.zi.gov.si/si/storitve/gospodarski\_subjekti/varnost\_igrac/pogosto\_zastavljena\_vpra sanja

The website of the Inspectorate includes publicly available information on topical issues (eg. Used toys, toys sold online, puzzle, amber necklaces ...). The Health Inspectorate's website <a href="http://www.zi.gov.si/si/delovna\_podrocja/varnost\_igrac">http://www.zi.gov.si/si/delovna\_podrocja/varnost\_igrac</a> (and links) contains all the information on the safety of toys aimed at economic operators and consumers.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms $(\mathbb{C})^{93}$	6565372	5813788	5171789	4982892
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.066	0.060	0.057	0.051
8	Staff available to market surveillance authorities (full-time equivalent units) <sup>94</sup>	135	133	134	129
9	Number of inspectors available to market surveillance authorities (full-time equivalent units) <sup>95</sup>	112	110	110	109

### Information on resources (subject to availability)

# B. Assessment of the functioning of market surveillance activities in the sector

Inspections on the safety of toys take place in the context of regular and special inspections. Further monitoring is carried out by sampling. The frequency of periodic audits is determined on the basis of a risk assessment that takes into account the nature and scope of activities or facilities that are checked, in relation to the requirements, and changes in regulations and topical issues, taking into account as well the available resources of the inspectorate. A special form of emergency controls are those that are carried out where non-compliance has been identified.

Monitoring also takes place in the context of the various actions which focus on changes each year depending on the results of the checks in previous years, changes to regulations in the field of potential new risks and the latest knowledge of the profession. In addition health inspectors carry out surveillance in kindergartens.

Control of toys that, prior to the enactment of the new Directive were mainly based on the control of the product, has passed to the control of management of the quality assurance system of production of toys, and the monitoring of their safety on the market all the way to the consumer. This approach enables the efficient functioning of market surveillance authorities.

<sup>93</sup> Overall authority budget.

<sup>94</sup> Number of employees instead of full-time equivalent units.

<sup>95</sup> Total number of inspectors instead of full-time equivalent units.

Slovenia has only a small proportion of producers and importers of toys, and therefore the imposition of the measures in relation to the responsibilities of distributors rather limited. In the case of unsafe products information on the RAPEX system is provided, but no feedback on the results of the control of the manufacturers / importers in countries where these companies have their headquarters.

# **Slovak Republic**

### A. Review of market surveillance activities in the sector

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	4	19	18	13
2.	Number of substantiated complaints by industry concerning unfair competition	37	82	107	76
3.	Number of inspections (total number)	1937	1736	1351	1044
3.1	number of reactive inspections	996	1084	923	720
3.2	number of self-initiated inspections	941	652	399	312
3.3	number of inspections prompted by the customs	n.a.	n.a.	29	12
4	Number of inspections based on:				
4.1	tests performed in laboratories	255	113	140	129
4.2	physical checks of products	1682	1623	1211	915
5	Number of inspections resulting in:				
5.1	finding of non-compliance	909	547	846	33
5.2	corrective actions taken by economic operators ("voluntary measures")	n.a.	n.a.	n.a.	n.a.
5.3	restrictive measures taken by market surveillance authorities	n.a.	n.a.	n.a.	n.a.
5.4	application of sanctions/penalties	80	80	80	80
6	Number of inspections where other Member States were invited to collaborate	n.a.	n.a.	n.a.	n.a.

Trade Inspectorate activities in the field of information and other communication activities are described in the report on the evaluation of the application of Directive 2009/48/EC on toy safety, prepared and sent, on request, to the European Commission in July 2014.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms $(\mathbf{f})$	n.a.	n.a.	n.a.	n.a.
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	n.a.	n.a.	n.a.	n.a.
8	Staff available to market surveillance authorities (full-time equivalent units )	n.a.	n.a.	n.a.	n.a.
9	Number of inspectors available to market surveillance authorities (full-time equivalent units )	25	25	25	25

### Information on resources (subject to availability)

### B. Assessment of the functioning of market surveillance activities in the sector

The Trade Inspectorate is Slovakia's only surveillance authority for toys. Inspections are conducted to a high standard. The Trade Inspectorate systematically and annually organises nationwide inspection actions and periodic sampling to verify safety. As there are only a few small toy manufacturers (wooden and fabric toys) in Slovakia, inspections focus mainly on distributors and importers from third countries. Inspections mainly centre on economic operators of Chinese origin established in Slovakia. Particulars concerning inspections (set out in more detail), and related surveillance problems faced by the Trade Inspectorate, are described in the report on the evaluation of the application of Directive 2009/48/EC on toy safety, prepared and sent, on request, to the European Commission.

### Finland

#### A. Review of market surveillance activities in the sector

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	28	14	31	25
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0

		2010	2011	2012	2013
3.	Number of inspections (total number)	1507	1351	1739	808
5.	Number of hispections (total humber)	792 (T)	698 (T)	906 (T)	81 (T)
		715 (C)	653 (C)	833 (C)	727 (C)
3.1	number of reactive inspections	43 (T)	19 (T)	43 (T)	49 (T)
3.2	number of self-initiated inspections	34 (T)	26 (T)	30 (T)	41 (T)
3.3	number of inspections prompted by the customs	0	0	0	0
4	Number of inspections based on:				
4.1	tests performed in laboratories	706	636	777	808
		26 (T)	29 (T)	28 (T)	41 (T)
		680 (C)	607 (C)	749 (C)	672 (C)
4.2	physical checks of products	36	47		60
		1 (T)	1 (T)	84 (C)	5 (T)
		35 (C)	46 (C)		55 (C)
5	Number of inspections resulting in:				
5.1	finding of non-compliance	229	190	203	189
		29 (T)	10 (T)	26 (T)	25 (T)
		200 (C)	180 (C)	177 (C)	164 (C)
5.2	corrective actions taken by economic operators ("voluntary measures")	28 (T)	8 (T)	25 (T)	18 (T)
5.3	restrictive measures taken by market	160	138	73	109
	surveillance authorities	1 (T)	2 (T)	1 (T)	7 (T)
		159 (C)	136 (C)	72 (C)	102 (C)
5.4	application of sanctions/penalties	0	0	0	0
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

Tukes gives press releases and publishes the results of market surveillance activities and other remarks it has made while carrying out market surveillance. During 2010-2013, a total of 9 press releases (1-3 each year) were published based on the Toy Safety Directive.

Tukes also informs consumers, businesses and other stakeholders about changes in legislation or safety requirements. When necessary, training and lectures are provided for associations, schools and other stakeholders.

Tukes also gives guidance to consumers, businesses, and other stakeholders by answering their questions via phone and email. Tukes is also active in the social media and uses its channels to spread information on dangerous products, risks, project results and other issues. Tukes constantly looks for new ways to inform the public and the stakeholders about safety issues.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)	780000 230000 (T) 550000 (C)	780000 230000 (T) 550000 (C)	780000 230000 (T) 550000 (C)	780000 230000 (T) 550000 (C)
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.002	0.002	0.001	0.001
8	Staff available to market surveillance authorities (full-time equivalent units )	13 3 (T) 10 (C)	13 3 (T) 10 (C)	13 3 (T) 10 (C)	13 3 (T) 10 (C)
9	Number of inspectors available to market surveillance authorities (full-time equivalent units )	12 2 (T) 10 (C)	12 2 (T) 10 (C)	12 2 (T) 10 (C)	12 2 (T) 10 (C)

# Information on resources (subject to availability)

### B. Assessment of the functioning of market surveillance activities in the sector

Market surveillance programs have been carried out as planned. Programs include 1-3 current projects (topics vary yearly). Despite the relatively small resources Tukes has been effective, and 38 recalls and 20 withdrawals have been done during 2010-2013.

# Sweden

A. Review of market surveillance activities in the sector

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	32	13	21	35
2.	Number of substantiated complaints by industry concerning unfair competition				
3.	Number of inspections (total number)	52	37	117	130
3.1	number of reactive inspections	39	19	35	43
3.2	number of self-initiated inspections	10	14	77	77
3.3	number of inspections prompted by the customs	3	4	5	10
4	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	15	0
4.2	physical checks of products	18	10	61	88
5	Number of inspections resulting in:				
5.1	finding of non-compliance	19	23	113	124
5.2	corrective actions taken by economic operators ("voluntary measures")	13	13	21	35
5.3	restrictive measures taken by market surveillance authorities	0	2	12	3
5.4	application of sanctions/penalties	0	0	0	1
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

In 2012 and 2013, the three market surveillance authorities in Sweden, the Swedish Consumer Agency, Kemikalieinspektionen [the Swedish Chemicals Agency] and the National Electrical Safety Board cooperated on a joint project. In the joint authority project in 2012-2013, contacts were built up with the Swedish trade associations, Barn och baby [Children and Baby], PUFF (Företagare-Föreningen för grossister och tillverkare inom present-, interiör-och designbranschen) [Company Owners-Association of wholesalers and manufacturers of gift, interior and design products) and Svensk dagligvaruhandel [the Association of Swedish Grocery Retailers]. The Swedish Consumer Agency has an established collaboration with Leksaksbranschen [the Swedish Toy Association]. These industry associations have helped to disseminate information on training courses, market surveillance and other information that the authorities wished to issue. During the joint authority project, there has also been closer cooperation with the Swedish Toy Association, since they have acted as a sounding board for the development of information material.

Through the training courses held within the framework of the joint authority project, an email list was built up with over 100 recipients wishing to have information on toy safety from the authorities. The authorities did not obtain all these recipients via the industry associations. Other interested parties have also taken part in the training sessions for the industry such as SIS [the Swedish Standards Institute], Swerea IVF, the IKEM [Innovation and Chemical Industries in Sweden] industry association (formerly the Swedish Plastics and Chemicals Federation), Leksaksbranschen [the Swedish Toy Association], Naturvårdsverket [the Swedish Environmental Protection Agency] and Läkemedelsverket [the Swedish Medical Products Agency].

The Swedish Consumer Agency has deliberately prioritised work on information for economic operators for the 2011-2014 period, and for that reason no general information campaign aimed at consumers has been conducted. Nevertheless, a training course on the dangers of magnets in toys was carried out for consumer guidance in 2012. This took place in advance of market surveillance of magnets in toys and other products.

The Swedish Consumer Agency and the Swedish Chemicals Agency presented a paper, along with other authorities, at a European Commission information campaign organised by TIE and the Swedish Toy Association in Malmö in 2012.

In 2012 and 2013, the three market surveillance authorities in Sweden cooperated on a joint project.

The joint authority project in the 2012-2013 period included a sub-project on proactive work. In this sub-project, the three authorities reviewed their information on each authority's website. The Swedish Chemicals Agency has developed a new website that deals with legislation relating to toys in various ways. The Swedish Consumer Agency has also produced new pages on its website in order to clarify the information on the new legislation. The National Electrical Safety Board also has a site describing its procedures on toy supervision. These three websites link to one another in the hope that this will make it easier for companies to search for information on toy safety regulations. During the course of the project, the Swedish Consumer Agency's website on toy safety was visited 6887 times (unique page views).

Printed information material aimed at companies has also been produced. This material clarifies companies' responsibilities as regards toy safety according to their role in the supply chain. The material is entitled "Ansvarsroller för leksakers säkerhet" [Roles and responsibilities for toy safety] and consists of a playing card and three leaflets. The card is intended to help determine a company's roles and responsibilities according to the circumstances for each toy. The card contains a question on one side, for example: "What is my role if I buy toys from a company in Sweden or another EU country?" The other side of the card contains the answer: "Distributor". When the company's role for the toy in question has been determined using the guide on the playing card, more information on the responsibilities deriving from that role can be obtained from one of the three leaflets. The three brochures provide information on the responsibilities of manufacturers, importers and distributors and summarise the requirements established for each role. The information material is available in printed format from the three authorities, but can also be downloaded from the Swedish Consumer Agency's website.

During the work on the project, companies requested more information from the authorities, including a checklist of the rules applying to a toy. On the basis of those requests, the

authorities produced joint information material entitled "Är leksaken säker?" [Is the toy safe?] The material is largely based on a "mind-map" and highlights the different regulations with which a toy must comply. The information material is available for download from the Swedish Consumer Agency's website.

During year two of the project, what was, for the authorities, a new way of working with information was used. The three authorities produced a joint information letter about the new rules on toy safety. The letter contained some basic information on requirements for toys and market surveillance, as well as information on market surveillance to be carried out in 2013. The information letter was sent to approximately 300 companies identified as toy dealers using the authorities' own records and import statistics on toys from Swedish Customs. The letter was distributed to members of five industry associations: the Swedish Toy Association, Children and Baby, the Association of Swedish Grocery Retailers, the Swedish Trade Federation and PUFF (Company Owners-Association of wholesalers and manufacturers of gift, interior and design products).

Two training sessions for companies and other operators in the toy industry were organised in the project in collaboration with the industry association the Swedish Toy Association. One occasion in autumn 2012, when the training course had a duration of three days, and one occasion in spring 2013, when the training course had a duration of one and a half days. After the end of the project (May 2014) a further training session of one and a half days was arranged jointly by the authorities and the Swedish Toy Association. Training consisted of presentations on the new rules on toy safety and market surveillance carried out by the three market surveillance authorities for toys. The Swedish Medical Products Agency, the Swedish Environmental Protection Agency, SIS (the Swedish Standards Institute), Swerea IVF, the IKEM [Innovation and Chemical Industries in Sweden] industry association (formerly the Swedish Plastics and Chemicals Federation) also took part. The industry also participated with presenters describing how to work with the requirements in practice. Time at the training sessions was also set aside for questions. The companies were able to give notice of questions in advance. The training materials entitled "Roles and responsibilities for toy safety" and "Is the toy safe?" were distributed to the companies along with additional information material on the EC declaration of conformity and labelling of toys, the requirements regarding chemicals and the Commission's brochure on the Toy Safety Directive. Participation in the training sessions was high, with 80-100 persons per session on the seven training days. The feedback received from the participating companies showed that they considered the training sessions to be good and they requested [...] In order to compile information from the training sessions for the companies taking part and to enable information from the training sessions to be distributed to more companies, special websites were created after the various training sessions where presentations from the training session, as well as questions and answers from the question and answer session, were published.

Links to the training session websites were also posted on the Swedish Consumer Agency website.

The addresses for these websites are:

http://www.eko.kov.se/Leksakerssakerhet/,

http://www.eko.kov.se/Leksakerssakerhet2013/ and

http://www.leksaksbranschen.se/index.php/om-leksaksbranchen/utbildning-i-

leksakerssakerhet-14-15-maj-2014.Since the Swedish law on toy safety also covers public activities in Sweden, a letter on the new rules on toy safety was sent to SKL (Sveriges Kommuner och Landsting – the Swedish Association of Local Authorities and Regions). SKL then produced information for its members, with the support of the Swedish Consumer Agency.

That information was also submitted to the Commission, within the framework of supervision of the Directive, in a separate report on the application of the Toy Safety Directive.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms $(\mathcal{E})$	176800	154300	170365	213100
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	n.a.	n.a.	n.a.	n.a.
8	Staff available to market surveillance authorities (full-time equivalent units )	2.4	2.0	2.2	2.8
9	Number of inspectors available to market surveillance authorities (full-time equivalent units )	0.3	0.3	0.3	0.3

#### Information on resources (subject to availability)

#### B. Assessment of the functioning of market surveillance activities in the sector

There are toys on the Swedish market that do not comply with the applicable safety requirements for toys. Continued market surveillance of toy safety is therefore necessary, both to remove dangerous toys from the market and to disseminate information to companies.

The total value of toys supplied to the Swedish market each year is around 4 billion Swedish kronor. It is estimated that 300 companies import toys to Sweden. It is estimated that there are 200 manufacturers. The number of operators other than manufacturers can be roughly estimated at over 400. It is difficult to estimate the number of outlets for toys on the market, but there are probably more than 10 000. In addition, there are on-line operators that are not registered in Sweden.

Most toys are manufactured in Asia. During visits to companies it was found that a common way to buy toys is via trading houses or "traders", who in turn have contacts with various factories. Therefore, those purchasing through a trading house or a trader often do not come into direct contact with the manufacturer. This can make the establishment of requirements and communication between the customer and the manufacturer more difficult.

Purchasing via a trading house should not constitute an obstacle to supplying only safe toys. The economic operators have a great responsibility for checking the toys delivered to them and to require that the toys should comply with applicable requirements. It was revealed during visits to companies that several companies have a poor knowledge of the rules on toys, and this naturally makes it more difficult for them to impose requirements on the suppliers.

Nor were many companies aware of their responsibilities according to whether they have manufactured, imported or purchased the toy on the internal market. They were aware that there are differences in terms of responsibility and they considered that the manufacturer should have the greatest responsibility. Having greater knowledge of their own and other operators' responsibility in the supply chain should make it easier for requirements to be imposed between operators.

Toys are heavily regulated products. With the large number of rules applying to toys, there should be a system at each company for imposing requirements on and communicating with suppliers. Many companies lack such a system.

#### **United Kingdom**

#### A. Review of market surveillance activities in the sector

#### Information on enforcement activities carried out in the 2010-2013 period

		2010	2011	2012	2013
1.	Number of inspections		1665	1299	
2.	Number of inspections concerning products sold over the internet		92	62	
3.	Number of products inspected		45517	8806	
4.	Number of products tested in labs		696	570	
5.	Number of non-compliant products found on the market		2195	955	
6.	Number of dangerous products posing a serious risk		353	149	
7.	Number of administrative decisions taken		561	36	
8.	Number of products withdrawn from the market		690	67	
9.	Number of products recalled from the market		8	33	
10.	Number of decisions taken by authorities in charge of external border controls to suspend products at the border			160	
11.	Number of decisions to reject products at the border				
12.	Number of products destroyed		827	451	
13.	Number of voluntary measures taken by companies		347	76	
14.	Number of voluntary withdrawals		135	34	

		2010	2011	2012	2013
15.	Number of voluntary recalls		32	28	
16.	Number of sanctions imposed		18	37	
17.	Number of total pieces of advice offered to all in supply chain			335	

#### Information on communication activities carried out in the 2010-2013 period (optional)

#### No information

#### Information on resources (subject to availability)

No information

#### B. Assessment of the functioning of market surveillance activities in the sector

Trading Standards are part of Local Authorities, of which there are over 200 in the UK. Each local authority acted independently setting its own priorities. The "Home Authority" principle operates among local authorities.

The Home/Lead Authority Partnerships helped councils to work together effectively and avoid duplication of effort when regulating businesses who trade across local council boundaries, and support them by providing contact points for advice and guidance in order to maintain high standards of public protection and develop a consistent approach to enforcement. Further details of Trading Standards market surveillance activities have been described in this document.

In relation to the Toy Safety Directives, the UK provided two reports to the European Commission in 2014 which gave accounts of how they applied the Directives. The two reports were the Questionnaire on the Application of Article 51 of the Directive and on its application.

BIS are encouraging authorities to look at more ambitious strategic projects and projects which involve authorities working in partnership to deliver the outputs. Project proposals should be for products which have been placed on the market i.e. not products intercepted at ports. As before, there is separate funding for testing products at ports via the National Trading Standards Board (NTSB). BIS requires in return a report covering the activities and the analysis of the outcomes. BIS will expect the outputs from successful projects to be made available for all UK Trading Standards Departments via the NTSB Information Hub and other interested bodies.

BIS is also continuously reviewing the UK market surveillance structure with its relevant stakeholders and MSAs. From a workshop organised by BIS earlier in 2014 with these bodies, BIS asked representatives of UK MSAs for their views such as improving enforcement, more effective communication, funding and training. The workshop informed a follow-up exercise where a questionnaire, based on break-out session outcomes, was sent to those who attended. The outputs from these activities have now been summarised by BIS with priority actions identified on how BIS will work together with UK MSAs to improve how the UK's market

surveillance regime operates. In late 2014, BIS commenced an independent review of the UK's consumer product recall system and will expect a report to be with BIS Ministers in autumn 2015.

### ANNEX 8: BACKGROUND INFORMATION ON COOPERATION AMONG MEMBER STATES AND RESOURCES AVAILABLE FOR CONTROLS OF PRODUCTS

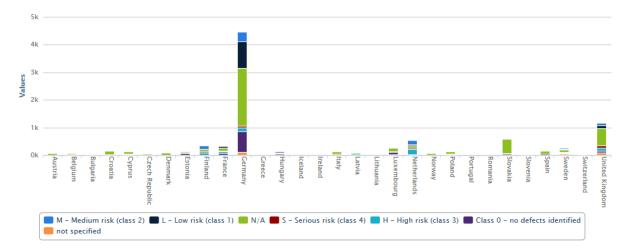
### 1. COORDINATION OF ENFORCEMENT OF PRODUCT LEGISLATION WITHIN THE EU (BASELINE)

The current section provides a short recollection of main legal, technical, administrative and financial tools currently available to optimise **cross-border cooperation and work sharing** among authorities.

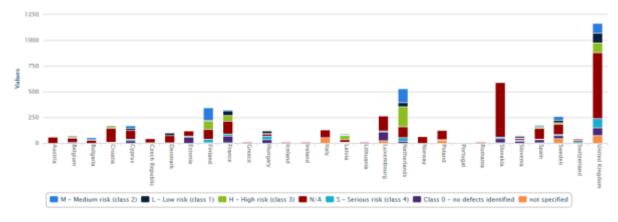
#### 1.1 ICSMS

ICSMS (Information and Communication System for Market Surveillance) is the database for information concerning product compliance (ICSMS) referred to in Article 23 of Regulation (EC) No 765/2008 The Commission carries out continuous activities to facilitate the take up of the ICSMS system among authorities by means of trainings, the development of user guides and discussion in regular experts' groups meetings. More than 7 000 products are encoded in the system every year. In 2015 the database contained information on around 70 000 products and more than 250 000 files stored (i.e.: test lab reports, DoC, pictures, etc.). The Commission also examined the possibility to converge ICSMS and RAPEX (see below) into a single platform.

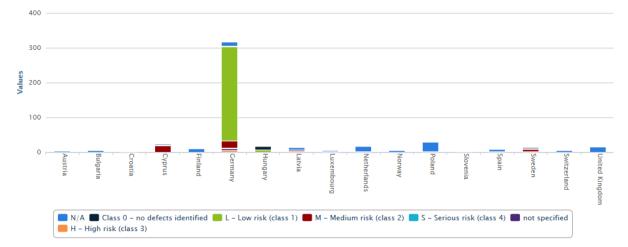
However, Member States use the system to different degrees, as shown in the diagrams below which show the numbers of product information input to the ICSMS system during 2016. Clearly the system is not used very well by many market surveillance authorities and some are not using the system at all. Even within member states, such as the UK and Germany, there is a great variance between different market surveillance authorities on their use of the system.



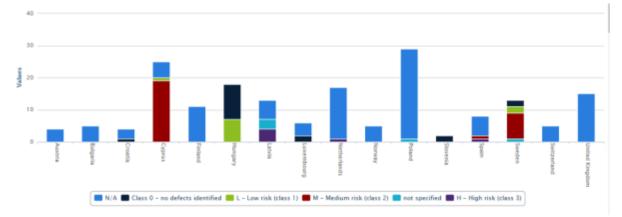
Use of ICSMS by all EU/EEA Member States in 2016 (2 with no entries)



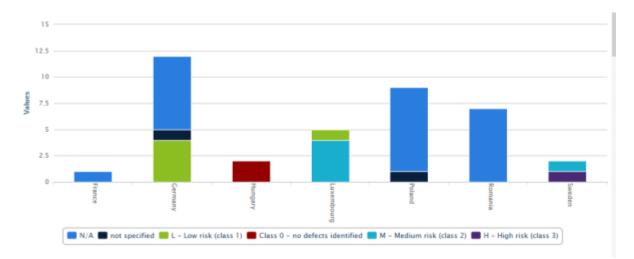
Use of ICSMS by EU/EEA Member States excluding Germany in 2016



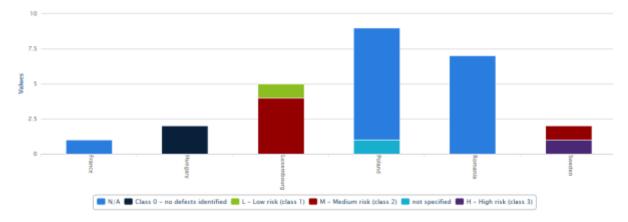
Use of ICSMS for EMC 2004 by all EU/EEA Member States in 2016 (15 with no entries)



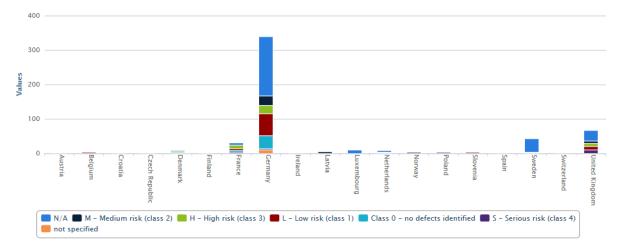
Use of ICSMS for EMC 2004 by EU/EEA Member States excluding Germany in 2016



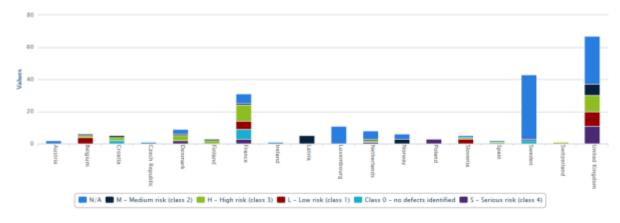
Use of ICSMS for EMC 2014 by all EU/EEA Member States in 2016 (25 with no entries)



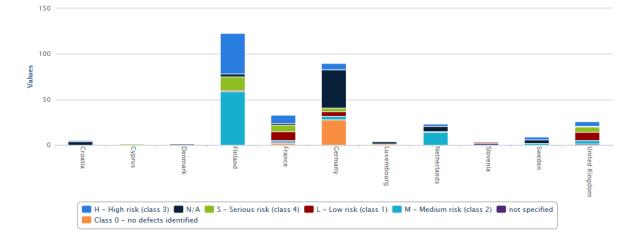
Use of ICSMS for EMC 2014 by EU/EEA Member States excluding Germany in 2016



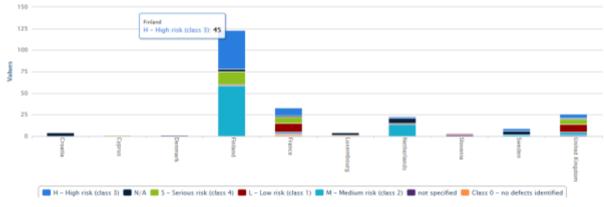
Use of ICSMS for Machinery by all EU/EEA Member States in 2016 (13 with no entries)



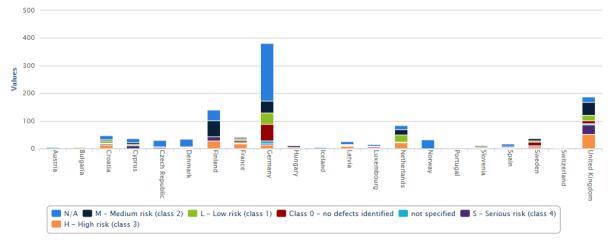
Use of ICSMS for Machinery by EU/EEA Member States excluding Germany in 2016



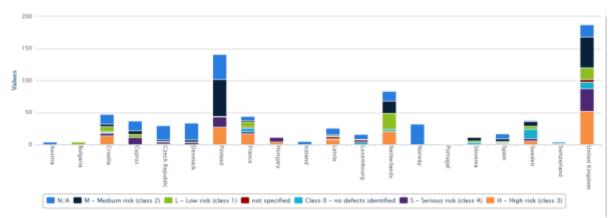
Use of ICSMS for LVD 2014 by all EU/EEA Member States in 2016 (21 with no entries)



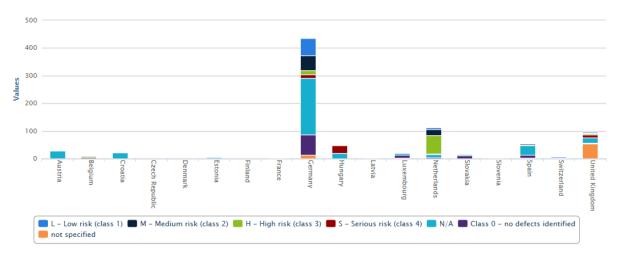
Use of ICSMS for LVD 2014 by EU/EEA Member States excluding Germany in 2016



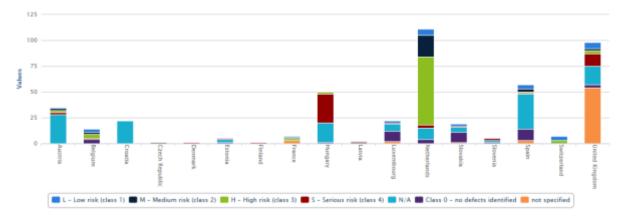
Use of ICSMS for LVD 2006 by all EU/EEA Member States in 2016 (11 with no entries)



Use of ICSMS for LVD 2006 by EU/EEA Member States excluding Germany in 2016



Use of ICSMS for GPSD by all EU/EEA Member States in 2016 (14 with no entries)



Use of ICSMS for GPSD by EU/EEA Member States excluding Germany in 2016

#### **1.2** Official notification of measures to other Member States

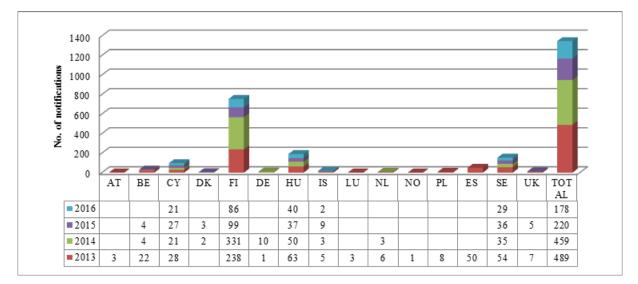
EU product legislation set out an obligation for Member States' competent authorities to communicate to the other Member States restrictive measures taken against non-compliant products. Furthermore, receiving Member States then have an obligation to 'follow up' on those notifications, i.e. adopt in turn appropriate measures in respect of their national territory. In many cases they also have the possibility to object to the measures notified and in this case the Commission will assess whether it was justified<sup>96</sup>. Recent guidance discussed at expert's working group level clarifies principles for cooperation based on the existing legal framework<sup>97</sup>. It also stresses the importance of this transmission mechanism to make sure that in relation to products available in various countries non-compliance found by a single authority could turn into effective corrective action across the whole Single Market.

However, with the exception of few sectors (notably low voltage equipment) only few notifications of restrictive measures are actually officially sent by national market surveillance authorities. Furthermore, even in these 'best case scenarios' sectors many Member States do not actually notify any measures and the number of notifications is decreasing overtime, as illustrated by the following figure.

<sup>96</sup> The possibility of objections is set out in sector-specific legislation aligned to the reference provisions of Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

<sup>97</sup> Guidance on cross-border cooperation among EU market surveillance authorities (http://ec.europa.eu/DocsRoom/documents/17108/attachments/1/translations).

Figure 8-1: State of play of notifications of measures addressing non-compliant products under the Low Voltage Directive



In May 2016 the Commission included in ICSMS an IT tool to allow the simultaneous notification of restrictive measures adopted by a national authority to all Member States, which should facilitate the actual use of the notification mechanism by those Member States. Nevertheless, considering the level of take up of ICSMS and other difficulties faced by authorities, this IT improvement will not be sufficient to address the problem of low notifications.

Finally, there is no official information on the degree of follow-up to the notifications received by authorities. However, this is expected to be rather low.

In case of products presenting a serious risk a notification in the RAPEX Rapid Alert System is also required<sup>98</sup>. Since 2004, more than 20 000 measures taken against dangerous products have been raised in the Rapid Alert System.<sup>99</sup> During the 2010-2015 period Member States' authorities transmitted between 1 800 and 2 500 notifications per year. However the rate of response to each notification remains relatively small as for instance in 2015 each Member State reacted on average to 3% of notifications received.

Country	Notific	cations	Reactions		
Country	Number	Percentage	Number	Percentage	
Austria	17	0.82%	53	1.93%	
Belgium	6	0.29%	29	1.06%	
Bulgaria	151	7.25%	92	3.35%	

<sup>98</sup> Articles 20 and 22 of Regulation (EC) No 765/2008.

<sup>99</sup> Source: RAPEX statistics and reports:

http://ec.europa.eu/consumers/consumers\_safety/safety\_products/rapex/alerts/repository/content/pages/rapex/reports/index\_en.htm The figures reported represent an approximation as they disregards the fact that some of the reactions sent by Member States in 2015 relate to notifications filed in 2014 and vice versa some 2015 notifications received reactions in 2016.

	Notific	ations	Reac	tions
Country	Number	Percentage	Number	Percentage
Croatia	7	0.34%	138	5.03%
Cyprus	117	5.62%	17	0.62%
Czech Republic	109	5.24%	18	0.66%
Denmark	27	1.30%	209	7.61%
Estonia	21	1.01%	32	1.17%
Finland	52	2.50%	179	6.52%
France	135	6.48%	105	3.83%
Germany	208	9.99%	85	3.10%
Greece	14	0.67%	108	3.93%
Hungary	238	11.43%	56	2.04%
Iceland	14	0.67%	26	0.95%
Ireland	5	0.24%	106	3.86%
Italy	56	2.69%	24	0.87%
Latvia	60	2.88%	15	0.55%
Liechtenstein	0	0.00%	0	0.00%
Lithuania	74	3.55%	25	0.91%
Luxembourg	9	0.43%	11	0.40%
Malta	25	1.20%	30	1.09%
Netherlands	62	2.98%	203	7.40%
Norway	15	0.72%	186	6.78%
Poland	19	0.91%	3	0.11%
Portugal	42	2.02%	153	5.57%
Romania	25	1.20%	10	0.36%
Slovakia	74	3.55%	89	3.24%
Slovenia	21	1.01%	132	4.81%

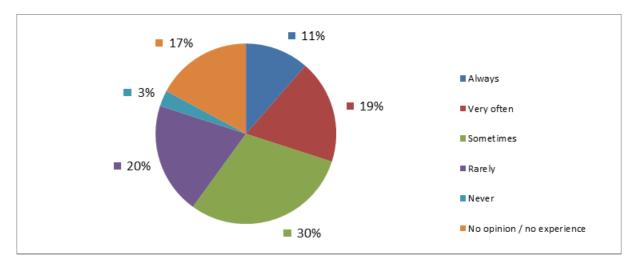
Country	Notific	ations	Reactions			
Country	Number Percentage		Number	Percentage		
Spain	239	11.48%	319	11.62%		
Sweden	78	3.75%	181	6.59%		
United Kingdom	162	7.78%	111	4.04%		
Average	67	3%	89	3%		
Total	2082	100,00%	2745	100,00%		

Source: Rapid Alert System 2015 results

(http://ec.europa.eu/consumers/consumers\_safety/safety\_products/rapex/alerts/repository/content/pages/rapex/reports/index\_en.htm)

While progress was achieved in the legal framework and the actual practice concerning the notification of measures among authorities, there is a feeling that a more systematic follow up of measures notified by other Member States should be achieved. When asked how often authorities measure to restrict the marketing of products are adopted following the exchange of information a good 30% of authorities responding to the consultation still replied this happens 'rarely' or 'never' or declared 'no experience' (see Figure 8-2).

# Figure 8-2: In your experience or knowledge in the relevant product category(-ies) how often do national authorities restrict the marketing of a product following the exchange of information about measures adopted by another authority in the EU against the same product?



#### **1.3** Mutual assistance between Member States' authorities

The current legal framework<sup>101</sup> makes possible mutual assistance among authorities in different Member States to supply each other with information or documentation and to carry out appropriate investigations or any other measure. The relevant provision does not provide

<sup>101</sup> Article 24 of Regulation (EC) No 765/2008.

any detail on the procedure (e.g. the means to be used, the language, the time to reply, etc.) to be followed to request and grant such assistance. Some guidance was recently developed on the applicable principles<sup>97</sup>.

Although no structured information on requests for mutual assistance exists, informal feedback from national authorities experts involved in Administrative Cooperation Groups– see following section – indicate this happens only occasionally. Authorities able to produce figures mentioned in general less than 10 cases per year. An exception seems to be represented by the sector of medical devices where specific procedures have been gradually established and on average several<sup>102</sup> requests of mutual assistance are made annually. In the majority of cases, information on the use of the mutual assistance principle confirms a general tendency among authorities to focus their action exclusively on correcting non-compliance in the national territory.

According to information in their 2010-2013 reports on market surveillance<sup>103</sup>, the practice of collaborating in inspections initiated by a specific Member States is virtually non-existent in most sectors. In the areas of cosmetics, machinery, electrical, electronic and radio equipment it is not completely absent but definitely still at an embryonic stage.

#### **1.4** Administrative Cooperation Groups (AdCos)

In many sectors, cooperation between national administrations takes place in working groups set up under the Union harmonisation legislation. Discussions mainly focus on interpretation issues, but questions related to market surveillance and administrative cooperation are also dealt with.

The Expert Group on Internal Market for Products (IMP-MSG) deals with general policy questions related to the implementation and enforcement of Union harmonisation legislation at 'horizontal' level, i.e. without addressing issues arising in the particular sectors.

Cooperation between national administrations competent for carrying out market surveillance in specific sectors takes place by means of the so-called Administrative Cooperation groups (AdCos)<sup>104</sup>. It concerns a number of sectors.<sup>105</sup> AdCos participants discuss several issues related to the market surveillance, elaborate common guidance documents and sometimes carry out joint enforcement actions. An overview of the most recent concrete outcomes of common discussion can be found on the AdCo webpage hosted by the European Commission.<sup>106</sup>

Since 2013 the Commission provides logistical and financial support to the organisation of the groups' meetings. According to the feedback received from AdCo Chairs this support has proven beneficial to increase and stabilise the rate of participation of national authorities in

<sup>102</sup> The figure of 200 requests was mentioned during a meeting with national authorities.

<sup>103</sup> See figures in Annex 7 Section 5.

<sup>104 &</sup>lt;u>https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups\_en</u>

<sup>105</sup> Measuring instruments and non-automatic weighing instruments (WELMEC), low voltage equipment (LVD ADCO), Eco-Design ADCO Group, electromagnetic compatibility (EMC administrative cooperation), civil explosives (CIVEX), machinery, noise emissions by outdoor equipment (NOISE), medical devices (Vigilance Working Group and COEN – Compliance and Enforcement Group), construction products (CPR), PEMSAC (The Platform of European Market Surveillance Authorities for Cosmetics), Toy-ADCO (The Administrative Cooperation Group of toys), recreational craft (RCD), personal protective equipment (PPE), equipment for use in explosive atmospheres (ATEX), Radio and Telecommunications Terminal Equipment (RED), Cableways (CABLE), Energy Labelling and Eco-design (ENERLAB/ECOD), Gas Appliances (GAD), Lifts (LIFT), Marine Equipment (MED), Pressure equipment sector (PED/SVPD), Pyrotechnics (PYROTEC), Chemicals (REACH), Restriction of the use of certain hazardous substances (ROHS), Transportable Pressure Equipment (TPED), Labelling of tyres.

<sup>106</sup> http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2798

the meetings. However not all Member states participate in administrative cooperation. During the 2014-2016 period for most AdCos (ATEX, CPR, EMC, LVD, MACHINE, PPE, PYROTECH, RCD, TOYS, WELMEC) about two thirds of Member States did take part in meetings (with a peak of 80% participation rate for the radio equipment group); however in others (GAD, LIFT, PED) only about 50% Member States participated in the meetings and in the case of CABLE, NOISE and TPED only about 30-40% of Member States were involved. Details on Member States participation are illustrated in Table 8-2. Furthermore, according to the feedback received by AdCo Chairs many representatives of the Member States participating in the meetings do not get actively involved in common discussions and activities.

As regards the chemical sector a role analogous to that of the AdCos is played by the Forum of the ECHA authority (https://echa.europa.eu/about-us/who-we-are/enforcement-forum). In this case the Forum is a body of ECHA and some ECHA fulfil the role of secretariat for the Forum. The participation of Member States in the meetings of the Forum is very high (90%).

		201	14			20	15		20	16 (1 <sup>st</sup> s	semeste	r)
AdCo	Partici-		present ountrie		Partici-		epreser countri		Partici-		epresent countrie	
	pants -	MSs	Other	Total	pants	MS	6 Other	Total	pants	MSs	Other	Total
ATEX	35	15	3	18	33	17	3	20	33	21	2	23
AIEA	33	17	3	20	33	17	2	19	33	14	2	16
CABLE	23	12	3	15	21	10	2	12	26	12	3	15
CIVEX	n	no data for 2014				20	1	21	Oc	ctober/N	lovembe	er
COEN	no data for 2014				no	no data for 2015			no data for 2016			
CPR	31	20	2	22	43	21	4	25	36	15	4	19
CPR	46	23	3	26	44	25	2	27				
ЕМС	38	20	4	24	37	21	5	26	40	18	4	27
ENIC	36	19	4	23	34	22	4	26				
ENERLAB /		o data f	or 2014	I	32	22	1	23	43	21	1	22
ECOD		o data 1	01 2014	ŀ	34	18	3	21				
CAD	18	14	0	14	15	8	2	10	19	12	2	14
GAD	14	11	0	11	16	11	2	13				
LIFT	25	12	3	15	24	14	3	17	25	17	2	19
LIFT	21	14	2	16								

Table 8-2: Data on participation in AdCos meetings

	31	15	4	19	32	20	4	24	36	17	4	21
LVD	33	19	3	22	34	22	3	25				
	31	18	4	22								
	32	17	3	20	33	20	3	23	38	20	4	24
MACHINE	33	15	3	18	30	19	3	22				
NOISE	22	10	2	12	23	9	2	11	Mee	eting Oc	tober 20	016
DED	22	13	3	16	25	15	4	19	24	15	4	19
PED	25	18	3	21	15	11	1	12				
DDE	44	21	4	25	39	19	4	23	39	20	5	25
PPE	37	19	4	23	40	21	4	25				
DUDOTEC	30	14	0	14	34	17	0	17	32	19	1	20
PYROTEC	30	15	0	15	34	19	0	19				
DCD	35	17	2	19	22	15	2	17	31	19	2	21
RCD	33	16	3	19	30	19	1	20				
	23	12	2	14	41	25	4	28	41	23	2	25
DED	40	24	2	26	41	22	4	26	40	25	2	27
RED	39	19	4	23								
	44	22	3	25								
TOYS		data fo	or 201/	1	37	18	5	23	32	15	4	19
1015	110		л 2012	•	40	25	3	28				
TPED	12	9	0	9	23	12	1	13	21	8	3	11
	13	5	1	6								
WELMEC	no	data fo	$\frac{1}{201}$	1	31	21	1	22	33	19	4	23
VV ELIVIEC	110	uata N	51 2012	T	36	19	4	23				

As regards the development of common market surveillance projects, the following table summarises the joint actions carried out or launched within different AdCos during the 2013-2016 period and number of countries participating in the action

AdCo <sup>105</sup>	2013	2014	2015	2016
ATEX				
CABLE				
CIVEX				
COEN			Information and instructions on reprocessable products (12 MS)	Clinical data (7-8) Harmonising inspections (7-8 MS)
CPR	2012-2013: EPS (10 MS)	Smoke alarms (10 MS)	Windows (7 MS)	
ECOD / ENERLAB / ROHS	ECOD: Lighting and chain lighting (10 MS) ROHS: Toys (8 MS) and Kitchen appliances (10 MS)	ROHS: Cheap products (10 MS)	ROHS: Cables/USB/others (6 MS)	ECOD: Defeat devices (4 MS) ENERLAB: Collecting inspection data methodologies (6 MS)
ЕМС	Switching power supplies (19 MS)	Solar inverters (14 MS)		
GAD				Gas appliances (8 MS)
LIFT				
LVD			LED Floodlights* (13 MS)	
MACHINE <sup>108</sup>	2012-2013: Log Splitters (about 8 MS) 2012-2015: Firewood Processors (about 7-8 MS) 2011-2015: Impact Post Drivers (3-4 MS)	Boom saws (3 MS)		Portable chain- saws and vehicle servicing lifts* (9- 10 MS)

Table 8-3: Joint actions organised within AdCos and number of Member States (MS) participating<sup>107</sup>

<sup>107</sup> 

Most joint actions are indicated under the year during which they were launched, although projects lasted two or more years. Joint actions organised in previous periods were: NOMAD Survey of machinery instructions on noise information and noise declarations (original survey work 2007-2012) about 10 Member States participating; Pinspotters/Pinsetters (machines in 10 pin bowling alleys), mostly between 2008 and 2012, about 5 Member States participating; Skid-steer Loaders, 2010-2012, 2-3 Member States; Scissor Lifts, 2010-2012, 5-6 Member States; Wind Turbine access (provision of lifts in towers), 2010-2012, about 4-5 108 Member States.

NOISE				
PED		Air receivers for compressors (2 MS)		
РРЕ				
PYROTEC				
REACH	1 big action/year ir		tates. Additional pilot a ale	actions on a smaller
RED		Mobile phone repeaters (14 MS)	Drones (18 MS)	
RCD			Small inflatable crafts (6 MS)	
ΤΟΥS				
TPED				
WELMEC WG5		Electric energy meters* (11)	Heat meters* (10)	

\* project co-financed by the European Commission.

#### **1.5** Joint actions co-financed by the European Commission

As mentioned in the point above ADCO sometimes organise joint market surveillance campaigns; in a few cases those actions have been financed by the European Commission on the basis of financing provisions included in the current legal framework<sup>109</sup>. In particular, the following calls for proposals were made since 2013:

- In 2013 the Commission launched the first call for proposals for joint enforcement actions under the multi-annual plan for market surveillance of products in the EU. The grant was awarded to project focussed specifically on active electrical energy meters and heat meters. The grant took the form of a 70% reimbursement by the Commission of the eligible costs of the action (amount approximately allocated 350 000 EUR) and was fully managed by Member States. The action was carried out by a consortium of authorities under the coordination of a Spanish authority.
- In 2014 a new call for proposals for joint enforcement actions was launched and led to funding by the Commission of two proposed actions respectively the field of machinery safety and LED floodlights. The grants that have been awarded are in the form an 80% reimbursement by the Commission of the eligible costs of the actions (total amount allocated is approximately 1000 000 EUR). One of the actions was coordinated by a Finish authority, while the other was coordinated by the private company "Prosafe"<sup>110</sup>.
- In July 2015 a call for proposals was launched with a maximum budget foreseen for EU financing of 500 000 EUR. One proposal was received by the deadline of 1 October

<sup>109</sup> Chapter V of Regulation (EC) No 765/2008.

<sup>110 &</sup>lt;u>http://www.prosafe.org/about-us/contentall-comcontent-views/what-is-prosafe</u>

2015 but did not lead to the award of any grant since the proposal received did not address the objectives as stipulated in the call.

- In March 2016 a call for proposals was launched with a higher maximum budget foreseen for EU financing of 750 000 EUR to maximum 3 projects coupled with a maximum EU financing rate of eligible costs of up to 80% of the action for joint actions involving bodies from 10 or more EU-EEA Member States, and 50% involving bodies from less than 10 EU-EEA Member States. No proposal was received by the deadline of 9 June of this year.
- In July 2016 a further call for proposals was launched. The maximum budget of 540 000 EUR was set with maximum financing rates of 95% and 80% respectively. For this call no proposal was received by the deadline for submission of 30 September 2016.

When discussing with market surveillance authorities the reasons why three calls for proposals went void why authorities do complain about limited resources, authorities stressed they welcomed the principle of joint actions financed through grants, and also their outcomes. However they pointed out the administrative complexity of managing these projects (e.g. heavy administrative requirements, problems in coordinating work by partners in other Member State authorities, and taking financial commitments on their behalf). They pointed out that the Commission should offer an administrative framework for the management of these actions and of the available money - money is not enough if it is not accompanied by some sort of infrastructure to allow for the management of the project.<sup>111</sup>

Furthermore, joint actions are regularly financed by the Commission under the Consumer Programme<sup>112</sup>. The following table summarises those carried out or launched during the 2013-2016 period. The projects financed under the Consumer Programme have always been coordinated by Prosafe.

	Member States + EFTA countries	Authorities		Product categories	Budget (in M€)	Grant (70%) (in M€)	Work- days
JA2010	21	23	5	Food imitation child- appealing products Children's Fancy Dresses (chemicals in textiles) Laser Pointers Ladders Visibility Clothing & Accessories	2.03	1.42	3462
JA2011	19	28	4	Child Care Articles Fireworks Battery chargers Lawnmowers	2.49	1.69	3995
JA2012	24	31	5	Nanotechnology and	2.14	1.48	3169

Table 8-4: Joint actions	financed	under the	Consumer	Programme
			00110411101	

<sup>111 &</sup>lt;u>http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=28611&no=1</u>

<sup>112 &</sup>lt;u>http://ec.europa.eu/consumers/eu\_consumer\_policy/financial-programme/index\_en.htm</u>

				<u>Cosmetics</u> Childcare Articles- <u>Highchairs,</u> <u>Cords and Drawstrings,</u> Ladders, <u>CO and smoke detectors</u> )			
JA2013	21	25	5	<u>Toys</u> <u>Children's Kick Scooters</u> Childcare Articles- <u>Cots</u> , Chemicals risks in <u>Clothing</u> , <u>Smoke Detectors</u>	2.27	1.59	3664
JA2014	27	35	5	Noisy toys Fireworks Power tools CFL and LED Lighting Childcare Articles - Safety Barriers	2.87	1.99	4410
JA2015	26	35	5	Plasticised Toys Power Tools Electrical Appliances (incl. electric irons) Child Care Articles- Soothers and soother- holders; Playgrounds	3.12	2.18	243.35 person / month

The Commission has also financed the following initiatives under the Horizon2020 programme:

- ECOPLIANT<sup>113</sup> joint action in the area of ecodesign legislation (many products covered) running from 2012 to 2015 and involving 10 Member States; cost of the project: approximately € 2.4 mln; grant by the European Commission: € 1.8 mln under the Intelligent Energy Europe program.
- EEPLIANT<sup>114</sup>- joint action in the area of ecodesign and energy labelling (heaters, LED lamps, printers): 2015-2017, 13 authorities from 12 MS- cost of the project: approximately € 2.5 mln entirely funded by the European Commission under the Horizon 2020 programme.
- INTAS (ecodesign, power transformers and large fans): 2016-2019, not a traditional joint action as about half of the 12 participants are not surveillance authorities, but energy agencies, research institutes, consultancies and civil society organisations cost of the project: approximately € 1.9 mln entirely funded by the European Commission under the Horizon 2020 programme.

<sup>113 &</sup>lt;u>http://www.ecopliant.eu/wp-content/uploads/2012/10/Final-Publishable-Report.pdf</u>

<sup>114 &</sup>lt;u>http://www.eepliant.eu</u>

MsTyr15<sup>115</sup> joint action concerning tyre labelling launched in March 2016 (until February 2018) with 13 MS plus Turkey- cost of the project: approximately € 2 mln entirely funded by the European Commission under the Horizon 2020 programme.

The ECOPLIANT was successfully coordinated by a UK authority, however it revealed an important administrative burden for them. For the EEPLIANT and Ms Tyr15 projects the coordination was ensured by Prosafe. INTAS which does not constitute an enforcement activity is coordinated by an organisation with experience in managing projects from EU funds.

#### 1.6 Views of market surveillance experts on cross-border cooperation

In the context of the consultation of market surveillance experts carried out within the IMP-MSG expert group prior to the 1 February 2016 meeting Member States expressed their views on the problems affecting cross-border cooperation and the possible solutions. The following excerpt is taken out of document 2016-IMP-MSG-07rev01 (section 4.3.3) summarising the results of this consultation:

[Member State A] underlines the need for consistent implementation of the guidelines on cross-border-cooperation, complemented if necessary by the set-up of additional legal arrangements. Furthermore, under the safeguard clause procedure all European market surveillance authorities must take, where necessary, measures to enforce requirements under European law. [Member State A] also suggests that where a public authority prohibits the making available on the national market, this should automatically apply in all MS, with the ECJ possibly acting as appeal. Member States should reflect on the possibility of specialising in specific fields. In order to achieve an effective market surveillance system, the adaptation of national legislation to the EU legislation will be necessary in a number of areas (cross-border cooperation, mutual recognition of activities of the market surveillance authorities of other Member States - for example, recognition of test reports, etc.). The organisation of market surveillance at national level should be reconsidered in order to reduce the fragmentation of responsibilities.

[Member State B] stresses the need for guidance on cross-border cooperation to improve and optimize the results of authorities' actions. According to [Member State B], to achieve better results in trans-border cooperation between the Member States, in cases of noncompliant products a contact points list for each product group should be prepared which could provide fast and easily accessible communication.

According to [Member State C], a mandatory harmonized procedure for MSA cooperation will facilitate cases of cross-border cooperation and will further harmonize existing market surveillance approaches. The administrative burden for MSAs of this procedure should nevertheless be as minimal as possible.

[Member State D] stresses that prior to setting additional requirements for mutual change of information, the Commission should ensure that all Member States actively use the present procedures and notes that for example EMC and LVD notifications are made by only a few States.

<sup>115 &</sup>lt;u>http://www.mstyr15.eu/index.php/en /</u>

[Member State E] would find it useful to receive **more feedback on safeguard notifications**. In general, more cooperation and exchange of information is needed at EU and **national** *level*.

[Member State F] notes that **'language borders'** are the main obstacle to day-to-day cooperation among authorities.

#### 2. **PRODUCTS IMPORTED FROM THIRD COUNTRIES (BASELINE)**

Points of entry to the EU are relevant to stop non-compliant and unsafe products coming in from third countries. Being the place where all products from third countries have to pass by, they are the ideal place to stop unsafe and non-compliant products before they are released for free circulation and subsequently circulate freely within the European Union. Thus, customs have an important role in supporting market surveillance authorities in carrying out product safety and compliance controls at the external borders.

The most effective way to avoid making available non-conforming or unsafe goods imported from third countries in the Union market is to carry out adequate checks during the import control process. This requires involvement of customs and cooperation between customs and market surveillance authorities.

The authorities in charge of the control of products entering the Union market, customs or market surveillance authorities depending on the national organisational structure, are very well placed to carry out initial checks, at the first point of entry, on the safety and compliance of the imported products. There are specific guidelines for import controls in the area of product safety and compliance. To ensure such controls, the authorities in charge of controls of products at the external borders need an appropriate technical support in order to carry out the checks on the characteristics of the products on an adequate scale. They can perform documentary, physical or laboratory checks. They also need appropriate human and financial resources.

#### 2.1 The control procedure laid out in Regulation (EC) No 765/2008

Regulation (EC) No 765/2008 on checks for conformity with Union harmonisation legislation in the case of products imported from third countries requires the customs authorities to be closely involved in the market surveillance activities and information systems provided for under EU and national rules. Article 27(2) of Regulation (EC) No 765/2008 foresees the obligation for cooperation between customs officers and market surveillance officers. Obligations for cooperation are also included in Article 13 of the Community Customs Code which establishes that controls performed with customs and other authorities are undertaken in close cooperation between each other. In addition, the principles of cooperation between the Member States and the Commission established in Article 24 of the Regulation are extended to authorities in charge of external controls, when relevant (Article 27(5)).

Cooperation at national level should allow for a common approach taken by customs and market surveillance authorities during the control process. This should not be hampered by the fact that various ministries and authorities may be responsible for the implementation of Regulation (EC) No 765/2008.

Customs authorities have the following responsibilities under Regulation (EC) No 765/2008:

- to suspend the release of products when there is a suspicion that the products present a serious risk to health, safety, environment or other public interest and/or do not fulfil documentation and marking requirements and/or the CE marking has been affixed in a false or misleading manner(Article 27(3)),
- not to authorise the release for free circulation for the reasons mentioned in Article 29,
- to authorise the release for free circulation for any product in compliance with the relevant Union harmonisation legislation and/or nor presenting risks to any public interest,
- where the release for free circulation has been suspended, customs have to immediately notify the competent national market surveillance authority which is given 3 working days to perform a preliminary investigation of the products and to decide:
- if they can be released since they do not present a serious risk to the health and safety or cannot be regarded as being in breach of Union harmonisation legislation,
- if they must be detained since further checks are necessary to ascertain their safety and conformity.

Customs authorities must notify their decisions to suspend release of a product to the market surveillance authorities, which in turn must be in a position to take appropriate action. Four hypotheses must be distinguished as from the moment of the notification.

1. The products in question present a serious risk

If the market surveillance authority ascertains that the products present a serious risk, it must prohibit their placing on the EU market. The market surveillance authorities have to request the customs authorities to mark the commercial invoice accompanying the product, and any other relevant accompanying document, with the words 'Dangerous product — release for free circulation not authorised — Regulation (EC) No 765/2008'. Member State authorities may also decide to destroy the products or otherwise render them inoperable, where they deem it necessary and proportionate. The market surveillance authority must use in those cases the system for rapid exchange of information — RAPEX. As a consequence, market surveillance authorities in all Member States are informed, and they may in turn inform the national customs authorities about products imported from third countries, which display characteristics giving rise to a serious doubt as to the existence of a serious risk. This information is of particular importance for customs authorities where it involves measures banning or withdrawing from the market products imported from third countries.

Feedback from market surveillance authorities on whether goods are considered as unsafe or non-compliant is crucial for customs risk management and control processes. It ensures controls can be concentrated on risky consignments, allowing for the facilitation of legitimate trade.

Furthermore, when non-compliant or unsafe products are found in the internal market, it is often extremely difficult to identify how they entered the EU. Cooperation between customs and market surveillance authorities is encouraged to improve tracing in those cases. 2. The products in question do not comply with Union harmonisation legislation

In this case the market surveillance authorities must take appropriate measures, if necessary prohibiting the placing on the market under the rules in question. In cases where placing on the market is prohibited, they must ask the customs authorities to mark the commercial invoice accompanying the products, and any other relevant accompanying document, with 'Product not in conformity — release for free circulation not authorised — Regulation (EC) No 765/2008'.

- 3. The products in question do not present a serious risk and cannot be considered as not conforming to the Union harmonisation legislation. In this case the products must be released for free circulation, provided that all the other conditions and formalities regarding release for free circulation are met.
- 4. The customs authorities have not been notified of any action taken by the market surveillance authorities.

If, within 3 working days of the suspension of release for free circulation, the market surveillance authority has not notified customs of any action taken by them, the product has to be released for free circulation provided that all the other requirements and formalities pertaining to such release have been fulfilled.

The entire procedure from the suspension until the release for free circulation or its prohibition by customs should be completed without delay to avoid creating barriers for legitimate trade but does not necessarily have to be completed within 3 working days. The suspension of release can remain valid for the time required by the market surveillance authority to carry out appropriate checks on the products and allow them to take the final decision. Market surveillance authorities must ensure that the free movement of products is not restricted to any extent greater than that which is allowed under Union harmonisation legislation or any other relevant EU legislation. To that end market surveillance authorities perform their activities regarding products originating from third countries — including the interaction with the relevant economic operators — with the same urgency and methodologies as for products originating from within the EU.

In this case, the market surveillance authority notifies customs within these 3 working days that their final decision on the goods is pending. The release for free circulation has to remain suspended until the market surveillance authority has made a final decision. That notification empowers customs to extend the initial suspension period. The products will remain under customs supervision even if they are allowed to be stored at another place approved by customs.

#### 2.2 Cooperation and coordination of action among Customs

#### 2.2.1 Administrative assistance

Customs cooperation based on the UCC enables exchanging information among customs to ensure correct application of the customs legislation and customs rules as well as creating a level playing field for business operators.

In 2015, almost 2 000 requests for administrative assistance were sent within the EU. There is an upward trend linked to cooperation in the form of administrative assistance between individual customs administrations.

#### 2.2.2 The Customs Risk Management Framework (CRMF)

A sophisticated common customs risk management framework (CRMF) had been introduced into the previous customs legislation and is now covered by Article 46 UCC.

The CRMF is based on the recognition of a need to establish an equivalent level of protection in customs controls for goods brought into or out of the EU and to ensure a harmonised application of customs controls by the MS. It aims to support a common approach so that priorities are set effectively and resources are allocated efficiently with the aim of maintaining a proper balance between customs controls and the facilitation of legitimate trade.

The CRMF therefore comprises:

- the identification and control of high-risk goods movements using **common risk criteria** see section 2.2.2.1.;
- the identification of **priority control areas** subject to more intense controls for a specific period; see section 2.2.2.2.;
- systematic and intensive **exchange of risk information** between customs- see section 2.2.2.3.;
- the contribution of **Authorised Economic Operators** (AEO) in a customs-trade partnership to securing and facilitating legitimate trade; and
- pre-arrival/pre-departure security risk analysis based on cargo information submitted electronically by traders prior to arrival or departure of goods in/from the EU specifically to cater primarily for security and safety risks.
- 1. The common risk criteria and standards

The Commission has adopted a set of criteria to be applied in the Member States' risk analysis systems in order to continuously screen electronic advance cargo information for security and safety purposes. The criteria are set out in an implementing act based on the empowerment of <u>Article 50(1) UCC</u>, which is not public for obvious reasons. The CRC are aimed primarily towards identifying high-risk consignments/goods that could have serious implications for the security and safety of the EU and its citizens and providing equivalent protection throughout the external frontier based on common risk analysis.

While in all other types of movements, the customs office where goods and declaration are presented is responsible for the processing of the declaration and for the risk analysis, customs at the first point of EU entry has a legal obligation to carry out the security and safety risk analysis on all the cargo regardless of the country of EU destination. Consignments crossing the EU border are thus screened on the basis of those criteria 365 days a year.

#### 2. Priority Control Areas

Priority Control Areas (PCAs) are the key mechanism in the CRMF allowing the Union to designate specific areas to be treated as a priority for customs control. The identified areas are subjected to reinforced customs controls carried out in a co-ordinated manner based on common risk assessment criteria and real-time exchange of risk information.

Priority areas may relate to any customs procedure, types of goods, traffic routes, modes of transport or economic operators. The chosen areas are to be subject to increased levels of risk analysis and customs controls for a pre-determined limited period with a start and end date and possibility for interim review.

Priority control areas have built-in assessment procedures and flexibility for Member States in order to ensure that the control action to be taken is not disproportionate or unduly disruptive in terms of the effect on trade flows within a Member State or a particular port or frontier point.

3. The exchange of risk information

The Common Customs Risk Management System (CRMS) is designed to provide a fast and easy-to-use mechanism to distribute and exchange customs control and risk-related information directly amongst operational officials and risk analysis centres in the 28 Member States.

It facilitates EU-wide customs intervention for the highest risks at the external frontier and inland and is thus an integral element in the development of a Union risk management framework. It consists of a form (Risk Information Form, called RIF) to be filled in on-line and instantly made available to all customs offices connected.

The RIF is a means of ensuring a consistent level of customs control is applied at the external frontier of the Union in relation to identified risks thereby offering the necessary level of protection to citizens and to the financial interests of the EU and MS while ensuring equivalent treatment of traders throughout the Union.

4. Authorised Economic Operators

The AEO concept is based on the Customs-to-Business partnership introduced by the World Customs Organisation (WCO). Traders who voluntarily meet a wide range of criteria work in close cooperation with customs authorities to assure the common objective of supply chain security and are entitled to enjoy benefits throughout the EU.

The EU established its AEO concept based on the internationally recognised standards, creating a legal basis for it in 2008 through the 'security amendments' to the "Community Customs Code" (CCC) (Regulation (EC) 648/2005) and its implementing provisions.

The programme, which aims to enhance international supply chain security and to facilitate legitimate trade, is open to all supply chain actors. It covers economic operators authorised for customs simplification (AEOC), security and safety (AEOS) or a combination of the two.

On the basis of Article 39 of the Union Customs Code (UCC), the AEO status can be granted to any economic operator meeting the following common criteria:

Conditions and criteria	AEOC	AEOS
Compliance with customs legislation and taxation rules and absence of criminal offences related to the economic activity.	Х	Х
Appropriate record keeping.	Х	Х
Financial solvency.	Х	Х
Proven practical standards of competence or professional qualifications.	Х	
Appropriate security and safety measures.		Х

The AEO status granted by one Member State is recognised by the customs authorities in all Member States (Article 38 (4) UCC). The conditions and criteria to grant the status do not take explicitly into account the economic operators' compliance with EU product harmonisation legislation.

AEO benefits are an integral part of the EU legislation governing the AEO status. The AEO benefits, dependent on the type of the authorisation, are summarised in the table below:

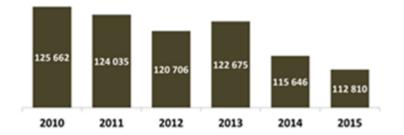
Benefit	AEOC	AEOS
Easier admittance to customs simplifications	Х	
Fewer physical and document-based controls		
• related to security & safety		Х
related to other customs legislation	Х	
Prior notification in case of selection for physical control (related to safety and security)		Х
Prior notification in case of selection for customs control (related to other customs legislation)	Х	
Priority treatment if selected for control	Х	Х
Possibility to request a specific place for customs controls	Х	Х
Indirect benefits (Recognition as a secure and safe business partner, Improved relations with Customs and other government authorities; Reduced theft and losses; Fewer delayed shipments; Improved planning; Improved customer service; Improved customer loyalty; Lower inspection costs of suppliers and increased co- operation etc.)	Х	Х
Mutual Recognition with third countries		Х

#### 5. Customs resources

Customs face a significant challenge to manage increasing volumes of goods and tasks while facing a downward trend in resources<sup>116</sup>. The total number of personnel working in Customs

<sup>116</sup> Developing the EU Customs Union and its governance, COM(2016)813 final, 21.12.2016.

Administrations in EU was 112.8 thousand at the end of 2015, this is a 10% decline since 2010 and a reduction of 2% in comparison to 2014.



\*When interpreting these figures, it should be taken into consideration that not all the MS are able to provide the exact data on the allocation of their staff. This could be due to merged organisations where the customs are mixed together with tax administrations, etc. In such cases, data was only estimated by the MS.

#### **3.** RESOURCES AND EXPERTISE OF AUTHORITIES (BASELINE)

EU rules on market surveillance for products contain an obligation for Member States to entrust market surveillance authorities with the power, resources and knowledge necessary for the proper performance of their tasks. No definition is provided for the concept of 'proper performance' of the tasks of market surveillance authorities. The provision does not set out an obligation to indicate the desirable level of performance or the amount of resources allocated. Common rules simply specify that authorities' should perform 'checks on the characteristics of products on an adequate scale'. In order to increase transparency on available resources the Commission in collaboration with Member States has proposed specific market surveillance indicators concerning budget and staff and developed methodology to estimate them.

#### 3.1 Information on resources based on national reports for the 2010-2013

The analysis<sup>117</sup> of the information on budget and staff provided by the member states for the 2010- 2013 period allowed the identification of the following findings:

- The total **budget available to MSAs** in nominal terms at EU level:<sup>118</sup>
  - Decreased during 2010-2013 (from €133.4 mil. to €123.8 mil.),
  - It was concentrated in a reduced number of countries and large differences could be noticed in terms of budget available to each country during the four year-period;
  - It represented around 0.1-1.33%<sup>119</sup> out of the total national budget;
- A similar evolution was registered by the **human resources**. During the period 2010-2013 a reduction of FTEs available to MSAs can be registered as well as a concentration of FTEs on a reduced number of countries;

<sup>117</sup> Source: Final report of the Ex-post evaluation of the application of market surveillance provisions of regulation (EC) No 765/2008.

<sup>118</sup> Not all EU-28 Member States provided reliable data for this indicator. Therefore, figures do not include Austria, Cyprus, Estonia, Greece, Croatia, Luxembourg, Slovenia, the United Kingdom and Hungary.

<sup>119</sup> The figures refer to 10 countries that provided reliable data, precisely: Denmark, Estonia, Spain, Finland, Italy, Latvia, Malta, Poland, Sweden and Slovakia.

• However, the analysis revealed an increasing trend in the **number of inspectors**, though specific interviews are needed to further investigate differences across countries and to triangulate data.

More details on each of these findings are presented below. Moreover, they should be considered only preliminary findings that will be further investigated and correlated with results from other study activities (market analysis and field research).

#### **3.2** Financial resources available for market surveillance activities

As for the **total budget available to MSAs in nominal terms**, the data indicates reduced annual fluctuations at the EU level, though in a negative direction. The figures refer to 19 out of 28 EU Member States, as Austria, Cyprus, Estonia, Greece, Croatia, Luxembourg, Slovenia and United Kingdom have not included this data in their national reports. Moreover, Hungary has reported values since 2011, therefore it was not considered the lack of data for 2010 would have created a different perspective on the 2010-2013 trends.

### Table 8-5: Budget available to market surveillance authorities in nominal terms (€) for selected sectors in the 2010-2013 period

Sectors	Number of Member States providing budget information	Average amount of resources per Member State and per year (simple average)	Average amount of resources per 1000 inhabitants (population on 1 January 2015) <sup>120</sup>
SECTOR 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	8 <sup>121</sup>	1,391,889€	34.14 €
SECTOR 2 - Cosmetics	8122	4,993,718€	43.21 €
SECTOR 3 - Toys	8123	1,917,787€	17.48€
SECTOR 4 - Personal Protective Equipment	7 <sup>124</sup>	270,913€	2.53 €
SECTOR 5 - Construction Products	8 <sup>125</sup>	425,273 €	3.39€

<sup>120</sup> Population on 1 January 2015 as provided by Eurostat

<sup>121</sup> Denmark, Ireland, Cyprus, Latvia, Portugal, Slovenia, Finland and Sweden.

<sup>122</sup> Denmark, France, Hungary, Portugal, Slovenia, Slovak Republic, Finland and Sweden

<sup>123</sup> Bulgaria, Denmark, Ireland, France, Hungary, Slovenia, Finland and Sweden. For Ireland, the budget across is the total NCA budget for all activities (excluding financial awareness and education), since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities. For France, the number provided doesn't include the budget for product testing. Slovenia has provided the overall authority budget. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

<sup>124</sup> Bulgaria, Denmark, France, Hungary, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

<sup>125</sup> Bulgaria, Denmark, France, Cyprus, Hungary, Romania, Finland and Sweden.

Sectors	Number of Member States providing budget information	Average amount of resources per Member State and per year (simple average)	Average amount of resources per 1000 inhabitants (population on 1 January 2015) <sup>120</sup>
SECTOR 6 - Aerosol dispensers	4 <sup>126</sup>	9,635€	0.50€
SECTOR 7 - Simple pressure vessels and Pressure Equipment	6 <sup>127</sup>	355,540€	3.39€
SECTOR 8 - Transportable pressure equipment	6 <sup>128</sup>	274,912€	2.86€
SECTOR 9 - Machinery	7 <sup>129</sup>	564,028€	5.27€
SECTOR 10 - Lifts	4 <sup>130</sup>	425,111€	15.08 €
SECTOR 11 - Cableways	2 <sup>131</sup>	741,722€	57.67€
SECTOR 12 - Noise emissions for outdoor equipment	4 <sup>132</sup>	169,647€	1.94€
SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	6 <sup>133</sup>	210,451 €	2.04 €
SECTOR 14 - Pyrotechnics	5 <sup>134</sup>	336,074€	3.90 €
SECTOR 15 - Explosives for civil uses	4 <sup>135</sup>	196,517€	2.44 €
SECTOR 16 - Appliances burning gaseous fuels	8 <sup>136</sup>	186,410€	1.70€

<sup>126</sup> Bulgaria, Denmark, Cyprus and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

<sup>127</sup> Bulgaria, Denmark, France, Hungary, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

<sup>128</sup> Bulgaria, Denmark, France, Cyprus, Hungary and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

<sup>129</sup> Bulgaria, Denmark, France, Hungary, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

Bulgaria, Denmark, Hungary and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

Bulgaria and Denmark. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

Bulgaria, Italy, Hungary and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

<sup>133</sup> Bulgaria, Denmark, France, Hungary, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

<sup>134</sup> Bulgaria, Denmark, France, Cyprus and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

Bulgaria, France, Cyprus and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

Sectors	Number of Member States providing budget information	Average amount of resources per Member State and per year (simple average)	Average amount of resources per 1000 inhabitants (population on 1 January 2015) <sup>120</sup>
SECTOR 17 - Measuring instruments, Non- automatic weighing instruments and Pre-packaged products	9 <sup>137</sup>	316,777€	2.74 €
SECTOR 18 - Electrical equipment under EMC	11 <sup>138</sup>	1,213,247€	5.51 €
SECTOR 19 - Radio and telecom equipment under RTTE	11 <sup>139</sup>	1.630.901€	7.37€
SECTOR 20 - Electrical appliances and equipment under LVD	10 <sup>140</sup>	663,663€	5.74 €
SECTOR 21 - Electrical and electronic equipment under RoHS, WEEE and batteries	5 <sup>141</sup>	191,120€	5.83 €
SECTOR 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)	7 <sup>142</sup>	145,000€	1.50 €
SECTOR 23 - Ecodesign and Energy labelling	8 <sup>143</sup>	215,344€	1.99€
SECTOR 24 - Efficiency requirements for hot- boilers fired with liquid or gaseous fuels	4 <sup>144</sup>	120,924 € €	2.65 €
SECTOR 25 - Recreational craft	4 <sup>145</sup>	284,264 €	2.86 €
SECTOR 26 - Marine Equipment	2 <sup>146</sup>	75,854€	2.97 €

136 Belgium, Bulgaria, Denmark, France, Cyprus, Hungary, Slovenia and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

137 Bulgaria, Denmark, France, Hungary, the Netherlands, Austria, Slovenia, Finland and Sweden. Bulgaria calculated the budget by multiplying the number of staff available to market surveillance authorities by the average amount per unit applicable to the year concerned. France included budget only for pre-packaged products.

- 138 Belgium, Bulgaria, Denmark, Germany, France, Cyprus, Hungary, Romania, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 139 Belgium, Bulgaria, Denmark, Germany, Estonia, France, Portugal, Romania, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.
- 140 Belgium, Bulgaria, Denmark, France, Cyprus, Latvia, Hungary, Slovenia, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities. For Slovenia, the number of the budget includes also the costs of laboratory tests and payment for samples taken, with a corresponding claim from the liable party for the reimbursement of costs in the case of a compliant product.
- 141 Bulgaria, Denmark, Ireland, Hungary and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

145 Bulgaria, France, Romania and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

146 Denmark and Romania.

<sup>142</sup> Denmark, Ireland, France, Latvia, Hungary, Slovenia and Finland.

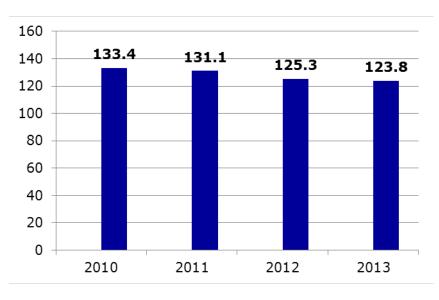
<sup>143</sup> Belgium, Bulgaria, Ireland, France, Cyprus, Hungary, Slovenia and Finland. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

<sup>144</sup> Belgium, Ireland, Hungary and Romania.

Sectors	Number of Member States providing budget information	Average amount of resources per Member State and per year (simple average)	Average amount of resources per 1000 inhabitants (population on 1 January 2015) <sup>120</sup>
SECTOR 27 - Motor vehicles and tyres	6 <sup>147</sup>	456,843€	4.30 €
SECTOR 28 - Non-road mobile machinery	2148	14,324€	0.73 €
SECTOR 29 - Fertilisers	9 <sup>149</sup>	135,641 € €	1.06€
SECTOR 30 - Other consumer products under GPSD	5 <sup>150</sup>	1,514,284€	15.26€

Source: national reports

Figure 8-3: Total budget available to MSAs in nominal terms during 2010-2013,  $\in$  millions <sup>151</sup>



Source: National reports

As emerged from the national reports, the budget reflects all financial resources assigned to market surveillance and enforcement activities, including related infrastructures as well as projects and measures aimed at ensuring compliance of economic operators with product legislation. These measures range from communication activities (consumer/business information and education) to pure enforcement and market surveillance activities. They

<sup>147</sup> Belgium, Bulgaria, Denmark, France, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

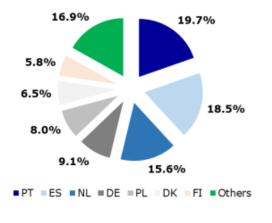
<sup>148</sup> Hungary and Sweden.

<sup>149</sup> Czech Republic, Denmark, France, Latvia, Hungary, Romania, Slovenia, Slovak Republic and Finland. Belgium provided also figures but this has not been taken into account, since the FASFC submitted its total annual budget which covered integrated inspection services covering the whole of the food chain.

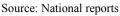
<sup>150</sup> Bulgaria, France, Hungary, Finland and Sweden. Bulgaria provided the budget for all activities since it is not possible for the authority to identify the specific amount of the annual budget which is directly related Product Safety Market Surveillance or related activities.

<sup>151</sup> The data correspond to 19 out of 28 EU Member States (please see the explanation in the paragraph above the figure)

include the remuneration of staff, direct costs of inspections, laboratory tests, training and office equipment cost. Enforcement activities at regional/local level should also be reported. Other activities undertaken by these authorities not related to the enforcement of product legislation should be excluded from the calculation.



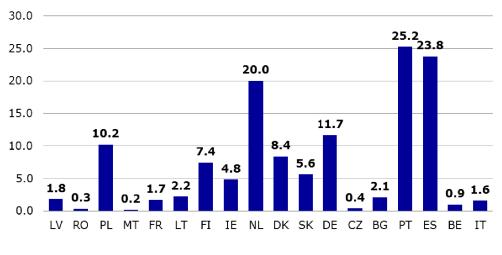
# Figure 8-4: Contribution of each MS to the total budget available in nominal terms to MSA at EU level over 2010-2013<sup>152</sup>



At country level, during 2010-2013, the following findings emerged:

- More than 80% of the total budget available to the 18 MSAs reporting data in nominal terms is concentrated in seven Member States;
- More than half of the Member States providing data had an available annual budget smaller than €10 million;
- Only three countries (Portugal, the Netherlands, and Spain) declared an annual budget allocated to market surveillance activities equal to or greater than €20 million.

## Figure 8-5: Annual budget available to MSA in nominal terms, average 2010-2013, € millions



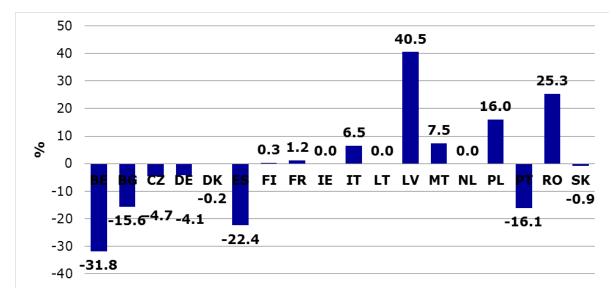
Source: National reports

<sup>152</sup> Please consider that data for the UK are not available. "Others" includes France.

As shown in the figure below, over the period considered the total budget allocated annually to market surveillance activities increased in eight Member States<sup>153</sup> and decreased in seven Member States.<sup>154</sup> In other countries (Ireland, the Netherlands and Lithuania) the budget remained stable over the period 2010-2013. The magnitude of reduction and increase of the total budget available to national MSAs also differs. On a three-dimension scale (0-10% – limited, 10-30% – moderate, 40-50% – high) the variation of total budget (both in positive and negative terms) was:

- High in two Member States (Belgium -32% and Latvia +40.5%);
- Moderate in five Member States (increase in Romania and Poland, reduction in Bulgaria, Spain and Portugal);
- Limited in more than half of the Member States, i.e. in 12 out of 18.

Figure 8-6: Variation (%) of the average annual budget available to MSAs in nominal terms average 2010-2013, € M



Source: National reports

Compared to the total national budget, the total budget allocated per country for market surveillance activities (total budget available to MSAs in relative terms) represents no more than 0.2% in half of Member States reporting data. There are also countries that concentrated a higher percentage of financial resources on the functioning of market surveillance activities, namely: Estonia (an average of 0.52%) and Poland (1.33%). Bulgaria and the Czech Republic also provided data on the total budget available to MSAs in relative terms, though they were not considered in the analysis as their reliability is questionable (the values being significantly higher than the ones reported by the other Member States: the national authorities from Bulgaria declared values that amount to an average of 47.2%, while the Czech authorities values around 92.58% of the total national budget). As mentioned also

<sup>153</sup> FI, FR, IT, LT, LV, MT, PL, RO.

<sup>154</sup> BÉ, BG, CZ, DE, ÉS, PT, SK.

for the first indicators, Hungarian authorities have not reported data for 2010, therefore the country was not included in the analysis.

#### **3.3** Human resources available for market surveillance activities

The **staff available to MSAs (FTE units)** is another indicator relevant for computing the enforcement costs incurrent by national authorities. The uninterrupted negative trend registered by the budget available for MSA expressed in nominal terms can be observed also in this case, potentially as a result of the budget decrease. Consequently, the costs incurred by the national authorities in their endeavours to enforce the implementation of the Regulation related to the staff are lower starting in 2013 compared with 2010. Nineteen countries compliant with the Regulation provision to provide the data for all four years have been considered in the data processing; Hungary, as stated before, did not provide all necessary data.

### Table 8-6: Staff available to market surveillance authorities for selected sectors in the 2010-2013 period

Sectors	Number of Member States providing staff information	Average amount of staff available per Member State and per year(simple average)	Average amount of staff available per 1000000 inhabitants (population on 1 January 2015) <sup>155</sup>
SECTOR 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)	12 <sup>156</sup>	58.60	0.46
SECTOR 2 - Cosmetics	11 <sup>157</sup>	255.55	1.33
Sector 3 - Toys	9158	32.28	0.26
Sector 4 - Personal Protective Equipment	8 <sup>159</sup>	12.38	0.10
SECTOR 5 - Construction Products	11 <sup>160</sup>	17.94	0.11
SECTOR 6 - Aerosol dispensers	6 <sup>161</sup>	21.82	0.53
SECTOR 7 - Simple pressure vessels and Pressure Equipment	8162	23.40	0.18

<sup>155</sup> Population on 1 January 2015 as provided by Eurostat

<sup>156</sup> Czech Republic, Denmark, Ireland, Italy, Cyprus, Latvia, Hungary, Portugal, Slovenia, Slovak Republic, Finland and Sweden.

<sup>157</sup> Czech Republic, Denmark, Ireland, France, Italy, Hungary, Portugal, Slovenia, Slovak Republic, Finland and Sweden.

<sup>158</sup> Bulgaria, Denmark, Ireland, Greece, France, Hungary, Slovenia, Finland and Sweden. For Ireland, the number includes the number of authorised officers in Product Safety Unit with additional authorised officers available to assist on specific projects if required. Slovenia has submitted the total number of employees. Bulgaria has submitted the total number of employees.

<sup>159</sup> Belgium, Bulgaria, Denmark, Greece, France, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

<sup>160</sup> Belgium, Bulgaria, Czech Republic, Denmark, Greece, France, Cyprus, Hungary, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.

<sup>161</sup> Belgium, Bulgaria, Denmark, Greece, Cyprus and Finland. Bulgaria has submitted the total number of employees.

<sup>162</sup> Belgium, Bulgaria, Denmark, Greece, France, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

Sectors	Number of Member States providing staff information	Average amount of staff available per Member State and per year(simple average)	Average amount of staff available per 1000000 inhabitants (population on 1 January 2015) <sup>155</sup>
SECTOR 8 - Transportable pressure equipment	8163	23.27	0.21
Sector 9 - Machinery	8 <sup>164</sup>	71.67	0.41
SECTOR 10 - Lifts	5 <sup>165</sup>	22.51	0.58
SECTOR 11 - Cableways	6 <sup>166</sup>	18.41	0.42
SECTOR 12 - Noise emissions for outdoor equipment	6 <sup>167</sup>	13.54	0.14
SECTOR 13 - Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	7 <sup>168</sup>	12.41	0.12
SECTOR 14 - Pyrotechnics	9 <sup>169</sup>	10.30	0.06
SECTOR 15 - Explosives for civil uses	8 <sup>170</sup>	9.62	0.08
SECTOR 16 - Appliances burning gaseous fuels	9 <sup>171</sup>	9.82	0.08
Sector 17 - Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	10 <sup>172</sup>	9.91	0.07
SECTOR 18 - Electrical equipment under EMC	11 <sup>173</sup>	17.45	0.08

Bulgaria, Denmark, Greece, France, Cyprus, Hungary, Slovenia and Finland. Bulgaria has submitted the total number of employees.
 Bulgaria, Denmark, Greece, France, Italy, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.
 France provided an estimate of the staff available to market surveillance activities. Sweden submitted numbers for both the Swedish Work Environment Authority and the Swedish National Board of Housing, Building and Planning.

<sup>165</sup> Bulgaria, Denmark, Greece, Hungary and Finland. Bulgaria has submitted the total number of employees.

<sup>166</sup> Bulgaria, Denmark, Portugal, Slovak Republic, Finland and Sweden. Bulgaria has submitted the total number of employees.

<sup>167</sup> Bulgaria, Denmark, Italy, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

<sup>168</sup> Bulgaria, Denmark, France, Cyprus, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

<sup>169</sup> Bulgaria, Czech Republic, Denmark, Ireland, Greece, France, Italy, Cyprus and Finland. Bulgaria has submitted the total number of employees.

<sup>170</sup> Bulgaria, Czech Republic, Ireland, Greece, France, Cyprus, Hungary and Finland. Bulgaria has submitted the total number of employees.

<sup>171</sup> Belgium, Bulgaria, Denmark, Greece, France, Cyprus, Luxembourg, Hungary and Finland. Bulgaria has submitted the total number of employees.

<sup>172</sup> Bulgaria, Denmark, France, Hungary, the Netherlands, Austria, Slovenia, Slovak Republic, Finland and Sweden. Bulgaria has submitted the total number of employees.

<sup>173</sup> Belgium, Bulgaria, Denmark, Germany, Greece, France, Cyprus, Hungary, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.

Sectors	Number of Member States providing staff information	Average amount of staff available per Member State and per year(simple average)	Average amount of staff available per 1000000 inhabitants (population on 1 January 2015) <sup>155</sup>
SECTOR 19 - Radio and telecom equipment under RTTE	11 <sup>174</sup>	18.49	0.08
Sector 20 - Electrical appliances and equipment under LVD	10 <sup>175</sup>	16.64	0.13
SECTOR 21 - Electrical and electronic equipment under RoHS, WEEE and batteries	6 <sup>176</sup>	13.54	0.31
SECTOR 22 - Chemicals (Detergents, Paints, Persistent organic pollutants)	9 <sup>177</sup>	64.44	0.55
SECTOR 23 - Ecodesign and Energy labelling	10 <sup>178</sup>	14.53	0.11
SECTOR 24 - Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	6 <sup>179</sup>	9.18	0.15
SECTOR 25 - Recreational craft	7 <sup>180</sup>	12.35	0.12
SECTOR 26 - Marine Equipment	5 <sup>181</sup>	1.58	0.01
SECTOR 27 - Motor vehicles and tyres	10 <sup>182</sup>	17.43	0.12
SECTOR 28 - Non-road mobile machinery	3 <sup>183</sup>	0.43	0.02
SECTOR 29 - Fertilisers	12 <sup>184</sup>	9.19	0.06

<sup>174</sup> Belgium, Bulgaria, Denmark, Germany, Estonia, France, Cyprus, Portugal, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.

<sup>175</sup> Belgium, Bulgaria, Denmark, Greece, France, Cyprus, Latvia, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

<sup>176</sup> Bulgaria, Denmark, Ireland, Greece, Hungary and Finland. Bulgaria has submitted the total number of employees.

<sup>177</sup> Czech Republic, Denmark, Ireland, Greece, France, Latvia, Hungary, Slovenia and Finland.

<sup>178</sup> Belgium, Bulgaria, Czech Republic, Ireland, Greece, France, Cyprus, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

<sup>179</sup> Belgium, Ireland, Greece, Hungary, Romania and Finland.

<sup>180</sup> Bulgaria, Denmark, Greece, France, Romania, Finland and Sweden. Bulgaria has submitted the total number of employees.

<sup>181</sup> Denmark, France, Italy, Romania and Finland.

<sup>182</sup> Belgium, Bulgaria, Denmark, France, Cyprus, Portugal, Romania, Slovenia, Finland and Sweden. Bulgaria has submitted the total number of employees.

<sup>183</sup> Denmark, Hungary and Sweden.

<sup>184</sup> Belgium, Czech Republic, Denmark, Ireland, Greece, France, Latvia, Hungary, Romania, Slovenia, Slovak Republic and Finland.

Sectors	Number of Member States providing staff information	Average amount of staff available per Member State and per year(simple average)	Average amount of staff available per 1000000 inhabitants (population on 1 January 2015) <sup>155</sup>
SECTOR 30 - Other consumer products under GPSD	5 <sup>185</sup>	46.94	0.47

<sup>185</sup> Bulgaria, France, Hungary, Finland and Sweden. Bulgaria has submitted the total number of employees.

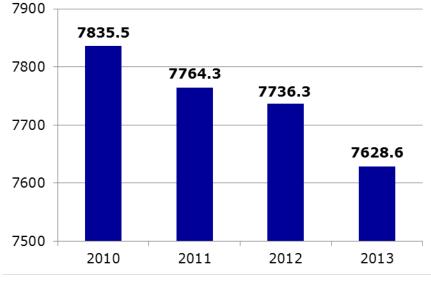


Figure 8-7: Total staffs available to MSAs (FTE units) during 2010-2013 at EU level<sup>186</sup>

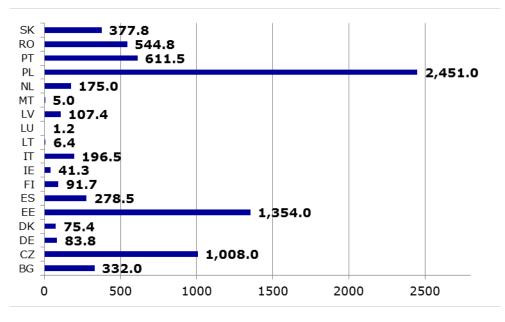
The analysis at country level concerning the total staffs available to MSAs (FTE units) revealed the following:

- On average, 7,741 staff resources (FTEs) were available for the MSAs of 18 EU countries during the period 2010 2013;
- 86.3% of staff resources (6,679) were based in seven Member States (Poland, Estonia, the Czech Republic, Portugal, Romania, Slovakia, and Bulgaria;
- More than 30% of total staff resources were based in one country (Poland;
- There were large differences among countries in terms of total staff resources available over the period 2010-2013. On the one hand, a large number of Member States (15 out of 18) involve less than 1,000 FTEs in market surveillance activities. On the other hand, Poland reported a significantly greater number of FTEs available to the MSAs, more than five times higher than staff resources declared by the majority of the countries.

Source: National reports

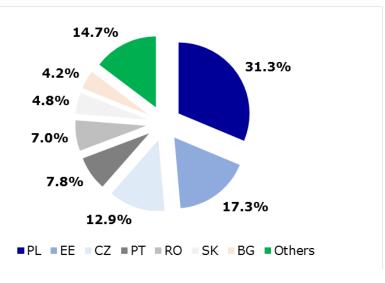
<sup>186</sup> The analysis includes the following countries: Bulgaria, Czech Republic, Deutschland, Denmark, Estonia, Spain, Finland, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Poland, Portugal, Romania, Sweden, Slovakia; the other EU Member States have not provided complete and reliable data in their national reports

Figure 8-8: Total staff available to MSAs at country level (average 2010 - 2013), FTEs



Source: National reports

Figure 8-9: Total staff available to MSAs (FTE units) per country over 2010-2013



Source: National reports

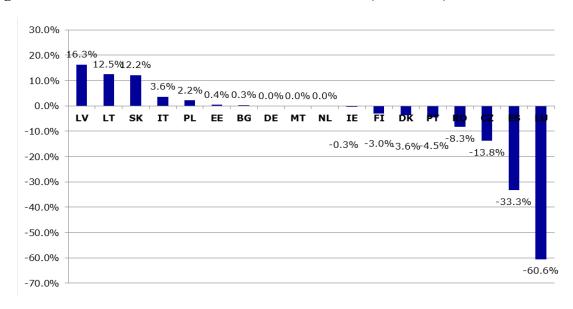


Figure 8-10: Variation of total staffs available to MSAs (FTE units) over 2010-2013

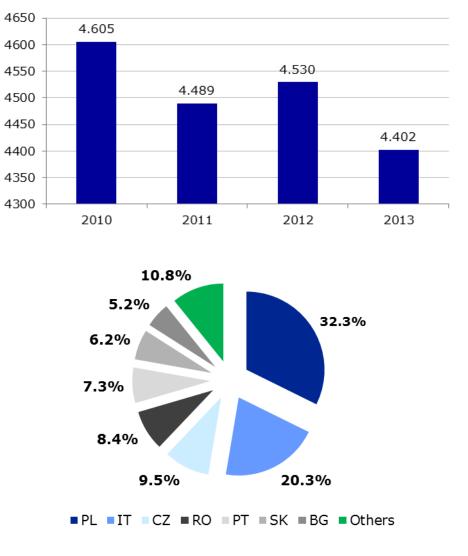


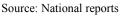
The highlights of the analysis concerning the **variation** of total staff resources available to MSAs (FTE units) over the period 2010-2013 are:

- More than half of the Member States considered (11) displayed a relatively stable trend in the number of staff resources available to MSA (FTE units) with a variation of less than 5% of the value registered in 2010;
- three Member States(Latvia, Lithuania and Belgium) declared an increase between 12.2% and 16.3%;
- The magnitude of total staff reduction was very different: the largest percentage decrease (-60.6% Luxembourg) was almost twice as high as the second largest percentage reduction (33.3% Spain) and 202 times higher than the smallest reduction (0.3% Ireland).

While at the EU level the budget available to market surveillance activities suffered continuous adjustments and the total staff resources available to MSAs (FTE units) registered a negative trend, the **number of inspectors (FTE units)** followed a fluctuating trend (decreasing one year, increasing in the next one, then decreasing again) which could be translated into fluctuating staff costs during this period (Figure 20). In this case, only 16 Member States provided completed data and were included in the analysis.

# Figure 8-11: Total number of inspectors available to MSAs (FTE units) over 2010-2013 at EU level and Total number of inspectors (FTE units) available to MSAs per country over 2010-2013

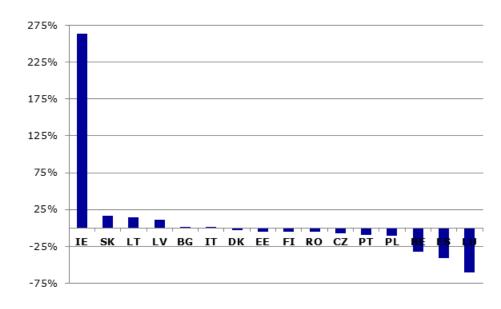


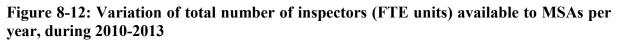


Regarding the total number of inspectors (FTE units) available to MSAs over 2010-2013 at country level, the following emerged:

- On average, 4,506 inspectors were available to the 16 Member States considered for inspection activities;
- The majority (90%) of inspectors (4,019) were based in six Member States Poland, Italy, the Czech Republic, Romania, Portugal, and Slovakia;
- Around half (2,372) of the FTEs dedicated to inspection activities were employed in two Member States (Poland, and Italy);
- The magnitude of the costs derived from the number of inspectors (FTE units) varies across Member States, as for instance in Luxembourg and Lithuania (included in the Others category) only 4.6 and 21.74 FTEs, respectively, have been allocated to market surveillance activities, while Poland involved 5,822 FTEs.

The reasons behind all of the differences presented in this section of the study will be further investigated during the interviews, the details to be required depending on the interviewee's experience and expertise.





#### Source: National reports

At country level, the analysis of the change in the number of inspectors available to MSAs annually reflects the following:

- In the majority of countries (10 out 16) the number of inspectors decreased;
- Six countries (Bulgaria, Italy, Denmark, Estonia, Finland, and Romania) had relatively stable trends, with the increase or decrease in the number of inspectors not being higher than 5% of the number of inspectors available to MSAs in 2010;
- A significant increase (263.8%) was registered in Ireland.
- Except for two countries (Ireland and Poland), the overall trend in the total inspectors available to MSAs during the four years considered tends to be aligned with the one for the total staff available to MSAs..
- On the basis of the figure on budgets and number of inspections provided by Member States the following estimates of costs of enforcement are provided. It is noted they are largely variable due to the limited number of data points and some issues of comparability.

Country	Average	Average	Average	Average	Average
_	number of	Annual	costs per	annual	costs per
	annual	Budget	inspection	number	inspector
	inspections	available		of	
		for		Inspectors	
	(A)	(B)	(B)/(A)	(C)	(B)/(C)
AT	1966	n/a	n/a	n/a	n/a
BE	n/a	946903	n/a	9.375	101003
BG	121	2114559	17475.7	232.25	9104.668
CY	20.75	n/a	n/a	n/a	n/a
CZ	1382.25	384594.1	278.2377	426.25	902.2734
DE	n/a	11675000	n/a	n/a	n/a
DK	107.5	8386750	78016.28	32.5	258053.8
EE	1277.75	n/a	n/a	42.25	n/a
EL	n/a	n/a	n/a	n/a	n/a
ES	n/a	23785801	n/a	183.25	129799.7
FI	395.5	7417861	18755.65	64.85	114384.9
FR	1589.5	1680000	1056.936	n/a	n/a
HR	103.75	n/a	n/a	n/a	n/a
HU	12391.25	n/a	n/a	n/a	n/a
IE	48.25	4825000	100000	70.2025	68729.75
IT	1416.5	1561372	1102.274	917	1702.695
LT	n/a	74875	n/a	5.4375	13770.11
LU	n/a	n/a	n/a	1.15	n/a
LV	437.75	1818645	4154.528	78.125	23278.65
MT	83.75	163592.3	1953.34	n/a	n/a
NL	n/a	20000000	n/a	n/a	n/a
PL	236.75	10229088	43206.29	1455.5	7027.886
PT	3182	25229517	7928.824	330.375	76366.3
RO	n/a	320108.1	n/a	377.25	848.5305
SE	155.25	12370917	79683.85 n/a		n/a
SK	n/a	5634232	n/a	280.75	20068.5
min	20.75	74875	278.2377	1.15	848.5305
max	12391.25	25229517	100000	1455.5	258053.8
average	1465.618	7295727	29467.66	281.6572	58931.49

Source: draft Evaluation study

#### **3.4** Information on resources based on reports for the chemicals area

REACH and Classification and Labelling of Products regulation (CLP), 22 countries provided information on the resources allocated to enforcing authorities for tasks related to the enforcement of REACH. Among them, 12 indicated that it was difficult, and in most cases impossible to provide an estimate of the annual budget and staff dedicated to REACH enforcement, since inspectors carry out tasks related to more than 1 legislation, often in joint inspections, and no separate budget is allocated specifically to REACH. 15 countries provided an estimate of annual staff and/or budget dedicated to REACH enforcement.

Country	Staff dedicated to REACH enforcement	Budget allocated to REACH enforcement
Austria	In average, a resource of 1 man-year is available for enforcement activities related to the whole chemical legislation in the competence of the inspectorates in each of the Lander (9 man-year in total).	
Croatia	4 inspectors on national level 30 inspectors on regional level	
Czech Republic	13 regional inspectors responsible for chemical legislation	
Denmark	The Chemical Inspection Service: 3 man-years enforcing REACH	
	Danish Working Environment Authority special unit on market surveillance: 2 man-year enforcing SDS and ES; 0.1 man-year for general inspection in which REACH is discussed	
	Danish Maritime Authority: 0.1 man-year for general inspection in which REACH is discussed	
France	Ministry of Ecology: 26 environment inspectors enforce REACH	
Greece	55 chemists in NEA perform tasks related to REACH	
Hungary	There are approximately 90 chemical safety inspectors responsible for the whole chemical safety legislation in the competence of the NEA	
Ireland	EPA: ~0.2FTE for work associated with REACH DAFM: 27 staff enforcing REACH related to pesticides	EPA: Approximately €6,200 (not including labour costs) for REACH and Detergents Regulation
	HSA: 12.9 FTEs inspectors for chemical legislation (approximately 3.2 FTE for REACH and CLP)	HSA: 250,000 - 300,000 Euros (including only human resources)
Liechtenstein	1 inspector in NEA	

Table 8-8: Staff and budget allocated to REACH enforcement

Country	Staff dedicated to REACH enforcement	Budget allocated to REACH enforcement
Lithuania	State environmental protection service has 3 inspectors specialised in enforcing chemical legislation	
Norway	There is approximately 8.6 FTE in the NEA working on REACH	
Poland	The Inspection of Environmental Protection has allocated 20 full-time jobs dedicated to enforcement of REACH to regional (Voivodship) inspectorates of Environmental Protection.	
	The State Labour Inspectorate and the District Labour Inspectorates all have a REACH coordinator.	
Portugal	IGAMAOT has 7 inspectors allocated to REACH, CLP, Seveso Directive and other environmental legislation	
Slovenia	4 inspectors in NEA	
United Kingdom	The Compliance Team of HSE has 3 FTEs to work on REACH. There are other Enforcers also working on REACH.	
	HSENI has 0.1 FTE. NIEA has 4 staff (not full time on REACH). Environmental Agency has 5.4 staff (not full time on REACH).	

Cells were left blank when CAs have not reported any information.

Out of the 22 countries which provided information on the level of resources dedicated to the Classification and Labelling of Products regulation (CLP), 13 have reported the same information as for the enforcement of REACH. As previously mentioned, a lot of countries do not have resources specifically allocated to the enforcement of CLP or REACH, which is covered by the CA's budget. 5 countries provided specific data for CLP:

#### Table 8-9: Staff and budget allocated to CLP enforcement

Country	Staff dedicated to CLP enforcement	Budget allocated to CLP enforcement
Belgium	Federal Environmental Inspection: 2011: 7 FTE; 2012: 5 FTE; 2013: 6 FTE; 2014: 7.2 FTE	General budget (including analysis) 2011: $\notin$ 276,000; 2012: $\notin$ 289,000; 2013: $\notin$ 223,000; 2014: $\notin$ 160,350 (total cost for the inspection service (inspectors, technical experts and controllers on the transit of waste).
Croatia	4 inspectors at national level 20 inspectors at regional level	
Denmark	2 man-year	

Country	Staff dedicated to CLP enforcement	Budget allocated to CLP enforcement
Iceland	0.1 FTE in the Environment Agency	
Latvia	Impossible to distinguish resources only dedicated to CLP. However Health Inspectorate has indicated that they have 10 persons involved in CLP control.	Annual budget of Health Inspectorate for enforcement of chemicals and cosmetics legislation is approximately 300,000 EUR.

## ANNEX 9: JRC REPORT ON MARKET SURVEILLANCE OF NON-FOOD PRODUCTS BASED ON A SMALL-SCALE SURVEY CARRIED OUT IN FEBRUARY 2017

#### **1. INTRODUCTION**

This report presents the result of a survey on Market Surveillance (MS) conducted by the Joint research Centre (European Commission), on behalf the Single Market Policy, Mutual Recognition and Surveillance Unit, in DG GROW.

A short questionnaire – in the Annex of this report – was sent via e-mail to a subset of ADCO (Administrative Cooperation Groups) members. These had volunteered to provide their view on the current status of Market Surveillance activity in EU and on future possible developments. Out of the 13 members contacted, 10 replied to the survey (a 77% response rate). However, 2 respondents – based in the same Country – submitted the very same reply, across all questions. We decided to include only one of these two replies as, given the small size of the sample, this would have biased the results.

The questionnaire includes 6 sections: 1) on market surveillance, in general; 2) on cooperation, in general; 3) on internal cooperation; 4) on EU cooperation; 5) on national cooperation and 6) on personal information. We will present the results by following the various sections of the questionnaire.

#### 1.1 On market Surveillance, in general

In question 1 we asked the respondents' view on 13 statements related to Market Surveillance. Respondents could choose between the following options:

- a) Strongly agree;
- b) Agree;
- c) Disagree;
- d) Strongly disagree;
- e) Not to express any view ("don't know (DK)").

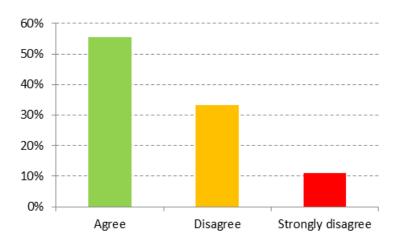


Figure 9-1: "Product harmonisation legislation is overly complex"

We observed divergent views on whether "product harmonisation legislation is overly complex", with roughly half of respondents agreeing this is the case, and the other half of them either disagreeing or strongly disagreeing (see Fig. 9-1). It would be interesting, in the future, to find out the motivations underpinning such different views, for example, whether this is due to specific sectors or to other reasons.

The second statement tackles the reverse side of the coin of complex legislation. Whether or not we agree that product harmonisation legislation is complex, it is relevant to find out whether the resources allocated to effectively perform MS are sufficient. Almost 80% of respondents expressed the view that MS is under-budgeted in their own Country, or in their sector of activity (Fig. 9-2).

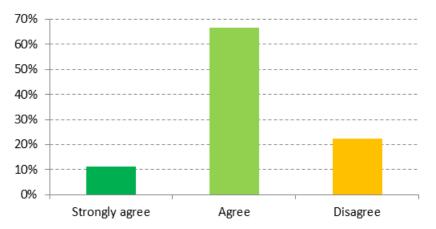


Figure 9-2: "MS is under-budgeted in my own Country, in my sector of activity"

From a behavioural perspective, in order to explore all possible explanations of a specific behaviour, it is often interesting to find out about what others are doing or about our perceptions of what others do. Indeed, we do not live in a social vacuum but we are rather influenced by others. This is particularly the case with respect to an activity with is performed and financed by each EU MSs, but that is functional to the pursuit of a public good. For example, in the iterative Public Good Game - used to study the tension between the individual incentive to free ride in collective activities of this type, and the social benefit generated by the sum of individual investments – the investment of a specific member decreases when (s)he observes free-riding behaviour from others. In the absence of corrective measures, this often leads to a *race to the bottom*. In our case, 2/3 of respondents shared the view that MS is under-budgeted across the EU, in their sector of activity (Fig. 9-3). In the future, it would be worth finding out whether there is any causal relationship between the perceptions described in Fig. 9-3 and each individual EU Country's willingness to invest in MS.

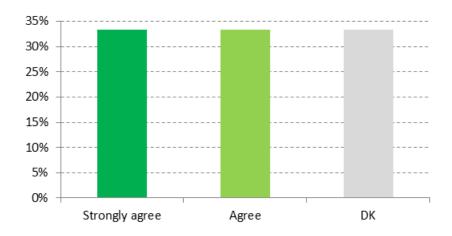


Figure 9-3: "MS is under-budgeted across the EU, in my sector of activity"

Within-Country coordination between the various office of MS Authorities doesn't seem to be too much of an issue, though there seems to be room for improvement in specific Countries. 30% of respondents agreed with the following statement: "There is poor within-Country coordination between the various local offices of MS Authorities" (Fig. 9-4).

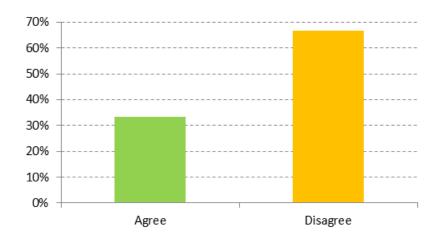


Figure 9-4: "There is poor within-Country coordination between the various local offices of MS Authorities"

The respondents' view of the quality of within-Country coordination with Customs roughly reflects the situation within MS Authorities, with 1/3 of respondents agreeing that there is a margin of improvement (Fig. 9-5).

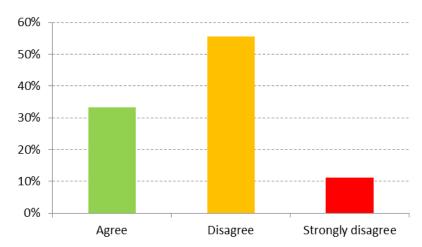


Figure 9-5: "There is poor within-Country coordination with Customs"

Interestingly, respondents seemed to be slightly less happy about the quality of cross-border coordination of national MS Authorities. 40% of them agreed with the following statement: "There is poor cross-border coordination of national MS Authorities" (Fig. 9-6).

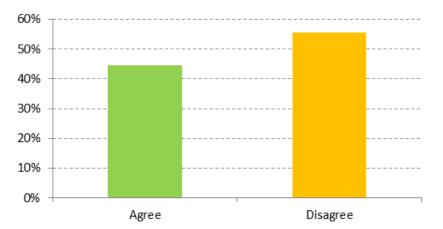


Figure 9-6: "There is poor cross-border coordination of national MS Authorities"

When it comes to solutions or possible remedies, it is fairly clear that MS cannot rely on consumers' awareness. Indeed, there is a common view that consumers are not aware about EU product harmonisation legislation (Fig. 9-7).

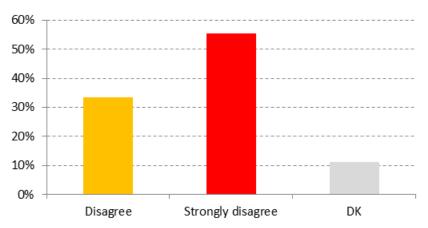


Figure 9-7: "There is great consumers' awareness about EU product harmonisation legislation"

As to firms' awareness of EU product harmonisation legislation, respondents' perception seems to be different, depending on whether this relates to EU or non-EU firms (Figures 9-8 and 9-9, respectively). In particular, while 30% of respondents think that EU firms have great awareness of EU product harmonisation legislation, none of the respondents believe this is the case for non-EU firms.

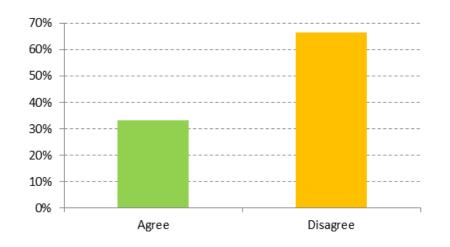


Figure 9-8: "EU firms have great awareness of EU product harmonisation legislation"

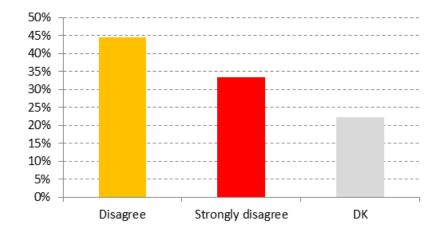


Figure 9-9: "Non-EU firms have great awareness of EU product harmonisation legislation"

Cooperation with the private sector to identify non-compliant products seems to be a relatively under-explored area (Fig. 9-10).

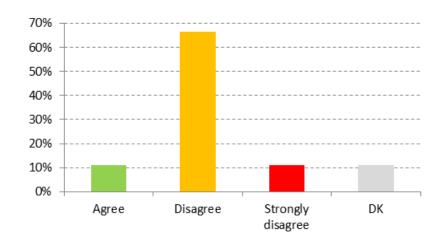


Figure 9-10: "There is great cooperation with the private sector to identify noncompliant products (e.g, with actors in the online supply chain)"

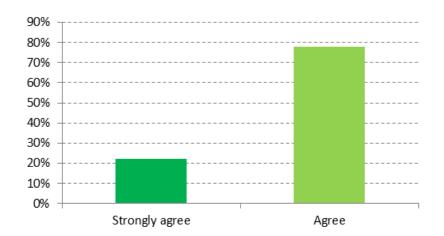


Figure 9-11: "Over the last 10 years, there has been an improvement of MS activity in EU"

We also observed a marked divergence of opinions as to whether product compliance should be encouraged by using the carrot instead of the stick (Fig. 9-12), that is by timely advice and information to operators (only 1/3 of the respondents were of this opinion) instead of by imposing fines and penalties for non-compliance (55% believed that the latter are more effective).

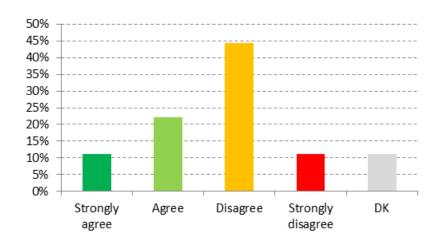
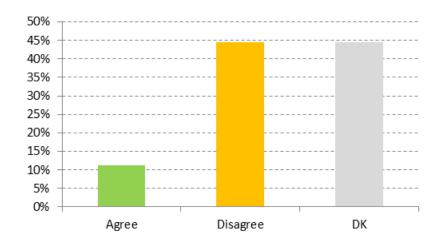


Figure 9-12: "Penalties and fines for non-compliance are less effective than timely advice and information to operators"

We also wondered whether using incentives for consumers contributing to MS Activity could in time become a complementary approach, but only 10% agreed whereas 45% disagreed and the remaining 45% said they "didn't know" (Fig. 9-13).



### Figure 9-13: "Consumers filing an appropriate complaint related to product-related harmonisation should be properly compensated, for having contributed to MS Activity"

Finally, we asked whether the respondents identified any other specific factors that are relevant to pursue an effective MS Activity, and we collected interesting insights:

"On e-Commerce: The import of products directly to the end user and the new concept of involving "fulfilment houses" with (at the moment) no responsibilities is a large problem. The competitive disadvantage for both European manufacturer and importers are obvious. Furthermore the European end-users are receiving and using non-compliant products for which – in most of the cases – no responsible party in the EU exists. A responsible party for each product located within EU (like for Medical devices) or the introduction of a registration system for all products could be a solution. A registration system would make it easier for customs to determine if a product can enter the market or not without involving

national MSA. In a nutshell, there seems to be a lack of effective measures and tools to prevent a flow of dangerous products sold online."

"The availability of specialist resources to carry out testing, or lack of in-house laboratories. This is particularly the case for eco-design and energy labelling, the testing of which is often costly."

"Reinforcement of cooperation via AdCo Groups, despite some AdCO members are not entitled to take decisions."

"Accessibility and cost of standards for the MSA and economic operators, especially if the MSA covers several Directives."

"A better definition of the role of Customs, in order to better address the many imports of non-compliant products."

- "in many cases, the time spent for a MS procedure is longer than the *life cycle of the product. This means that a product is no longer on the market when the sales ban is pronounced;*
- *it is simple for a manufacturer to shorten a sales ban: by changing the identification of the product, the MS authority is obliged to start a new procedure;*
- a sales ban in one country is not automatically valid for all countries;
- *legal procedures too time-consuming and resource-intensive*
- no control if a product banned from the market of an EU country may come back through other channels to another national market;
- even if there is the idea of a common internal market, it seems that market surveillance is still focussed on national market;
- different national prosecution legislation."

The replies to our questions and the comments provided constitute invaluable insights for any discussion as to the approaches and priorities of any future MS Activity.

#### **1.2** Cooperation activity

In the general section on cooperation activity, we asked a series of question that were designed to convey respondents' relative appreciation of the potential benefits coming from various types of cooperation activity.

In question 3 we asked "In your view, what specific type of market surveillance cooperation brings most value for money". Interestingly, no respondent mentioned national cooperation, while almost 80% mentioned EU Cooperation, and the remaining 20% opted for International Cooperation (Fig. 9-14).

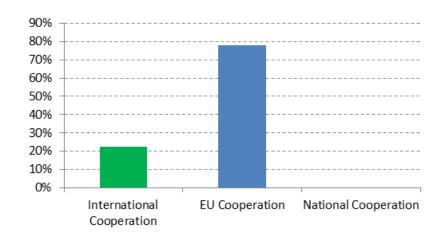


Figure 9-14: "In your view, what specific type of market surveillance cooperation brings most value for money"

A number of reasons were put forward to justify the preference for international and EU cooperation:

"With the globalisation and Internet, there are no border any more for products, this means that in future, there will be a change, people will buy more and more from internet and less from "normal" shops. Most of the products will be delivered from outside EU and the resources needed for their check at the EU border will be disproportionate. Therefore if an international cooperation would be possible to stop the products at the source, it will be more effective and efficient. Furthermore, as soon as a manufacturer has placed a product on a specific market (e.g. outside EU), this product is not anymore under its control. An EU importer may buy a batch of this product and placed it on the EU market even if the intention of the manufacturer was not to place it on the EU market."

"Free movement of goods allows to place products anywhere within the European Economic Area, so the cooperation among EU MSAs is crucial to stop rough traders effectively. Networks created within ADCO groups as well as EU RAPEX or ICSMS systems help to communicate rapidly and to ensure consumers safety. Cooperation with big producers' countries is important as well but education and awareness campaigns addressed to European economic operators and a simplification of EU product harmonisation legislation seem to be more effective."

"It gives most value if the market surveillance authority can take non-complaint product out of the marked in EU and not only out of national markets."

"International cooperation with MSA/Government outside EU might reduce the number of non-compliant products being made available on the EU market."

With questions 5-7, we further explored the same issue. The replies to these questions could be used in the future to strike to most appropriate balance between various types of cooperation activities, avoiding overinvesting or underinvesting in any of them. We asked respondents to provide an estimate of the budget percentage allocated to

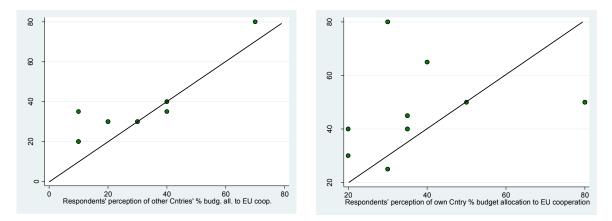
- International cooperation
- EU cooperation and

• national cooperation

both by their own Country and by other Countries. We also asked what budget percentage they would themselves allocate to each cooperation level, were they free to choose.

The results show first of all that respondents understood the objective of the question – which was a follow-up of question 3 (see Fig. 9-14) – and its relevance, as they all provided estimates.

On international cooperation, whereas the average perceived budget allocation by the home Country is 3.3%, the respondents' average ideal budget allocation is 18%, which provides a quantification of the extent to which international cooperation should represent more of a priority.

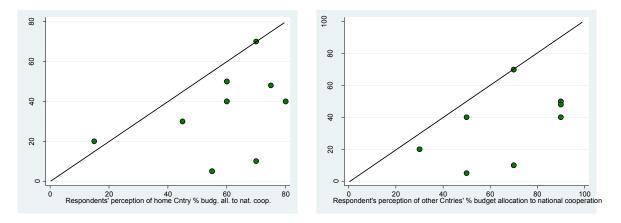


Figures 9-15a and 9-15b: Respondents' perception of and preference for budget allocated to EU cooperation

On EU cooperation, two results are worth noticing:

- respondents tend to perceive their home Country as more engaged (at least from a budgetary point of view) in EU cooperation (Fig. 15a). Indeed, if all respondents perceived other Countries to invest as much as their home Country in EU cooperation, all observations would fall on the 45° line (whereas in our case, all but one fall above the 45° line). From a behavioural point of view, perceiving others as less engaged could discourage one's own engagement. Therefore this could be object of a specific intervention;
- respondents ideal budget allocation on EU cooperation tends to be larger than the perceived budget allocation of one's own Country. When this is not the case, it is to the benefit of international cooperation, rather than to national cooperation (Fig. 15b).

Finally, on national cooperation, the opposite applies. Respondents' ideal budget allocation to national cooperation is below the perceived budget allocation of both their own Country (Fig. 9-16a) and of other Countries (Fig. 9-16b). Again, these results clarify the respondents' view as to what type of cooperation activity should be seen as a priority.



# Figures 9-16a and 9-16b: Respondents' perception of and preference for budget allocated to national cooperation

#### **1.3** International cooperation activity

In question 8 we asked the respondents' view on 7 statements related to International Cooperation Activity. Respondents could choose between the following options:

- a) Strongly agree;
- b) Agree;
- c) Disagree;
- d) Strongly disagree;
- e) Not to express any view ("don't know (DK)").

From a behavioural perspective, an analysis of the target population is a fundamental prerequisite to be able to design effective interventions. Indeed, considering the private sector as a homogeneous population of firms, regardless of their size, their sector, their international exposure or their Country, would prevent any possibility of targeting and tailoring specific interventions.

Respondents see differences between various types of companies, multinationals, EU SMEs and non-EU SMEs. Only 10% of respondents perceived that multinationals tend to be non-compliant, while 20% of them said the same about EU SMEs, and a striking 80% thought that non-EU SMEs tend to be non-compliant (Figures 9-17 to 9-19). This result, coupled with the view that more attention should be paid at international (beyond EU) cooperation, should suggest specific lines of actions which have probably been under-explored so far.

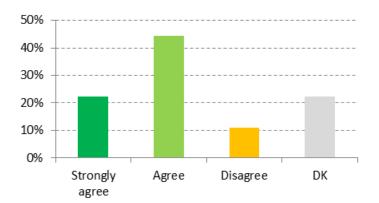


Figure 9-17: "Multinationals tend to be compliant with EU product harmonisation legislation"

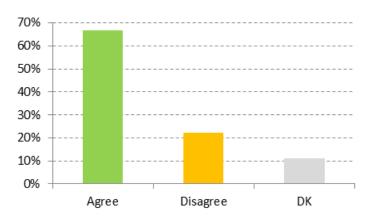


Figure 9-18: "EU SMEs tend to be compliant with EU product harmonisation legislation"

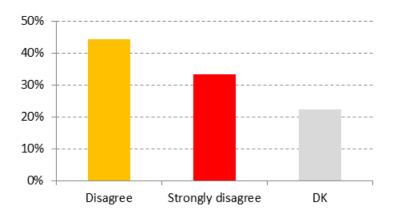


Figure 9-19: "Non-EU SMEs tend to be compliant with EU product harmonisation legislation"

As it happened to the data presented in Figure 9-15, respondents tended to show some level of "overconfidence" projected to their own country. To the question "Do national customs perform thorough controls of incoming goods", they in fact responded differently depending on whether this referred to their own Country (Fig. 9-20) or to other Countries (Fig. 9-21).

While 45% agreed that national Customs of their own Country perform through controls of incoming goods, only 45% disagreed that this also applies to national Customs of foreign EU Countries.

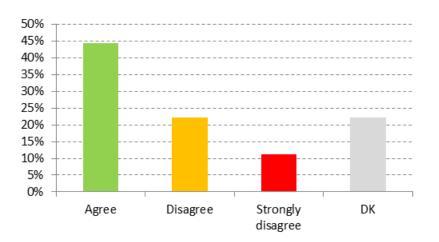


Figure 9-20: "National Customs of my Country perform thorough controls of incoming goods"

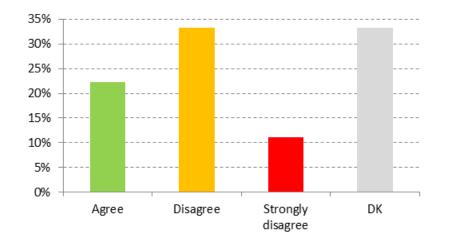


Figure 9-21: "National Customs of other EU Countries perform thorough controls of incoming goods"

The scale of the challenge for MS Authorities should not be undermined, however. Although all respondents agreed that "Over the last 10 years, there has been an improvement of MS activity in EU" (see Fig. 9-11 above), more that half of them believe that "Over the last 10 years, the proportion of non-EU non-compliant products that entered the EU market has decreased" (Fig. 9-22).

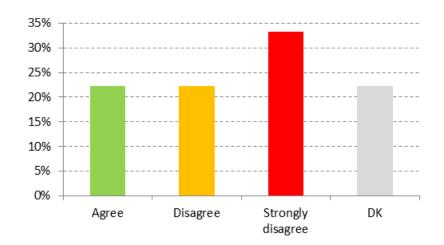


Figure 9-22: "Over the last 10 years, the proportion of non-EU non-compliant products that entered the EU market has decreased"

Interestingly, 2/3 of respondents agree that "Cooperation with sectoral SMEs associations of non-EU Countries could provide up-front advice and information and limit enforcement costs" (Fig. 9-23), a finding that resonates well with the view that international surveillance cooperation brings good value for money (see Fig. 9-14 above).

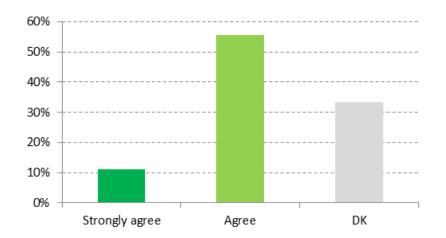


Figure 9-23: "Cooperation with sectoral SMEs associations of non-EU Countries could provide up-front advice and information and limit enforcement costs"

Finally, we asked whether the respondents identified any other specific factors that may improve the effectiveness of International cooperation on Market Surveillance activity for goods or services, we collected interesting insights:

"Improving the communication, control, cooperation, performance and enforcement among Custom authorities in the EU member states, for example early notifications for incoming risky goods."

"European standards should be obligatory to eliminate uncertainty of law and be changed only due to technology progress."

"Stop non-compliant products at the border. Improve cooperation between MSAs and Customs."

"- to give a certain responsibility to the consumer who is buying products from outside EU, looking only at the price (in this case the consumer is responsible to support unfair competition);

- to find an effective way on how to perform market surveillance on products sold via Internet;

- to concentrate the information on non-compliant products on one single homepage (e.g. public part of ICSMS) instead to have this information on many homepages;

- to concentrate the information on the rules on one single point (today the information is located on various homepages between commission an Member States);

- to give consumers the tools to search for and filter out non-compliant products."

"More joint actions funded by the EU, organized and carried out by MSAs in ADCOs"

"A number of products manufactured in a non-EU country do not fulfil the requirements of the applicable European legislation. Importers (if available because of the new "fulfilment houses" challenge) are only partly able to verify if a product complies with the requirements or not, as they are often just salesmen."

Some of these insights identify the underlying causes challenging the effectiveness of MS activity, whereas others rather focus on possible remedies. In this perspective, these indicate possible lines of work that could further pursued by ADCOs.

#### **1.4** Within-EU cooperation activity

With reference to the work and discussions taking place within the Administrative Cooperation Working Group (ADCO), in question 10 we asked "what does prevent or hamper you from implementing the necessary changes within your national context?" Respondents could select up to 3 options and could rank them from 1, the most important, to 3, the thirdmost important.

The three main reasons hampering the implementation of the necessary changes within each respective national context seems to be (see Table 9-1):

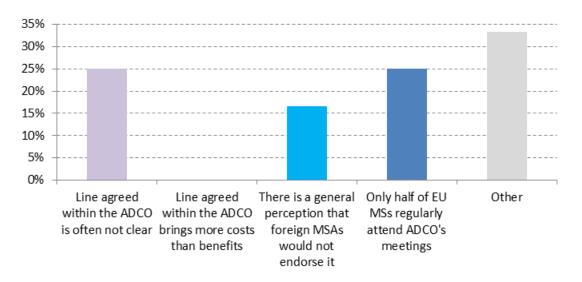
- 1. The complexity of the respondent's administration, and the fact that the common line agreed within the ADCO does not trickle down to all levels;
- 2. The low recognition and value attributed by the respondent's respective administration to his/her role of "connector" between his/her MSA and foreign MSAs;
- 3. The fact that "only half of EU countries regularly attend ADCO's meetings".

Number of replies per rank			3
My management does not show interest for the views expressed by the ADCO		2	
My colleagues do not show interest for the views expressed by the ADCO	1		3
My role of "connector" between my MSA and foreign MSA is not properly recognised and	2	2	

valued by my administration			
Our administration is complex, and the common line agreed within the ADCO does not trickle down to all levels	4	2	
There is a general perception that foreign MSAs don't take any concrete action			3
Only half of EU countries regularly attend ADCO's meetings	2	1	
My management does not show interest for the views expressed by the ADCO		2	

Table 9-1: "What does prevent or hamper you from implementing the necessary changes within your national context? (Up to 3 possible options, ranked from 1 (top one) to 3 (bottom one)"

As to the reasons why each respondent's management and/or colleagues do not easily endorse the common line agreed within the ADCO, on certain matters, all respondents agreed that this is *not* because the line agreed within the ADCO brings more costs than benefits. This is a key result as it is a clear acknowledgement of the benefits of following the line agreed with the ADCO (see Fig 9-24). However <sup>1</sup>/<sub>4</sub> of replies stressed that the line agreed within the ADCO is often not clear, another <sup>1</sup>/<sub>4</sub> complained that only half of EU MSs regularly attend ADCO's meetings, and about 1/6 of replies stated that there is a general perception that foreign MSAs would not endorse the line agreed within the ADCO and that such perception, as a result, discouraged others to endorse it.



#### Figure 9-24: "What could be the reasons why your management and/or colleagues do not easily endorse the common line agreed within the ADCO, on certain matters? (Multiple replies possible)"

One third of respondents opted for "Other" reasons, and suggested that:

"In general there is easy endorsement of a common line agreed, within the ADCO (ECHA FORUM), once the common line is robust and well founded/argumented, in relation to the relevant EU aquis. Also clear positions by COM or EU Agencies (like ECHA) are helpful for having good national endorsement."

"- The decisions taken by ADCO are not legally binding

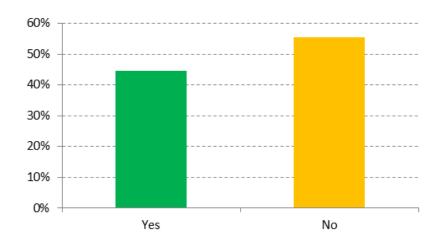
- National prosecution legislation is instead binding though it differs by Country.

- Less than half of MSA attending ADCO are concretely active, the rest attends on a rather listening mode."

"Sometimes implementing the common line agreed within the ADCO requires us to commit significant resource outside our core function."

"In some cases, my administration cannot implement ADCO agreements as these are not compatible with the national transposition of the relevant Directive."

From the previous result it does not come as a surprise that most respondents state that they do not find it easy to involve their own MSA in joint actions proposed in ADCO meetings (Fig. 9-25). Indeed, some argue that this is due to the specific governance structure of their own Country, to their involvement in other type of joint actions or simply to funding issues. On the other hand, some of those replying that it is easy, point out that "the number of participants to joint actions is very important for the acceptance of the results of those actions."



## Figure 9-25: "Do you find easy to involve your MSA in joint actions proposed in ADCO meetings?"

#### **1.5** National cooperation activity

In question 13 we asked the respondents' view on 8 statements related to national cooperation activity. Respondents could choose between the following options:

- a) Strongly agree;
- b) Agree;
- c) Disagree;
- d) Strongly disagree;
- e) Not to express any view ("don't know (DK)").

The landscape of Market Surveillance seems to be less complex and problematic. 2/3 of respondents say that their respective Country has a single Authority responsible on their specific sector, <sup>3</sup>/<sub>4</sub> of respondents declare that cooperation within the local offices of their respective Authority is effective and only 10% thinks that "within my Authority, there are overlapping responsibilities that generate confusion and waste of resources" (Figures 9-26 to 9-28).

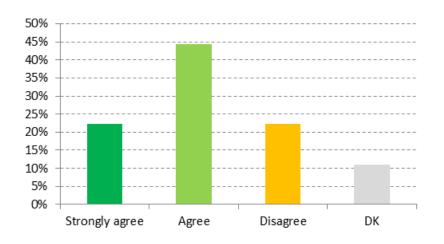


Figure 9-26: "We have a single Authority responsible on my sector"

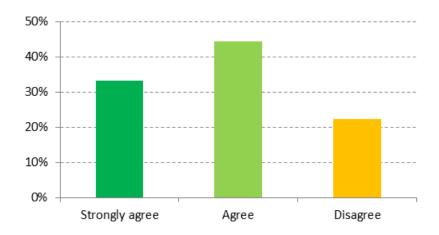


Figure 9-27: "Cooperation within the local offices of our Authority is effective"

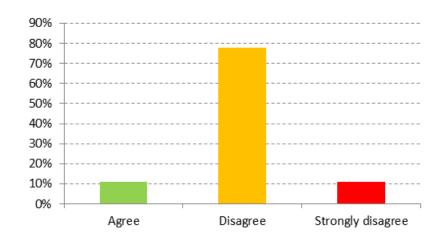


Figure 9-28: "Within my Authority, there are overlapping responsibilities that generate confusion and waste of resources"

Notwithstanding, <sup>3</sup>/<sub>4</sub> of respondents believe that collaboration with national Customs could be further developed and deepened, perhaps in view of avoiding overlapping responsibilities, witnessed by 30% of respondents (respectively Fig. 29 and Fig. 30).

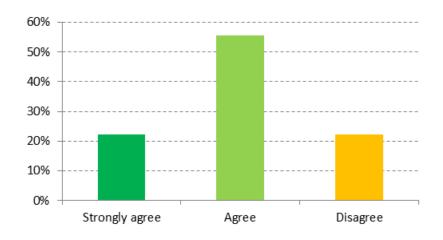


Figure 9-29: "Collaboration with Customs could be further developed and deepened"

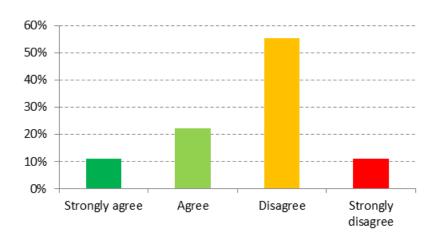


Figure 9-30: "Between national relevant bodies, there are overlapping responsibilities that generate confusion and waste of resources"

On the possible remedies to improve national cooperation activity, almost half of the respondents believe that "Incentives for effective MS Activity could be better designed (e.g., the overall national budget for MS Activity should better reflect the results obtained by each office)" (Fig. 9-31).

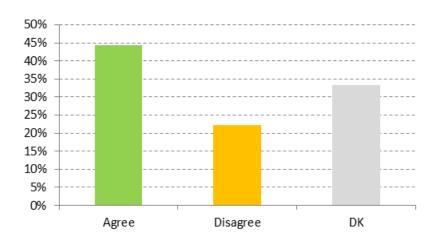


Figure 9-31: "Incentives for effective MS Activity could be better designed (e.g., the overall national budget for MS Activity should better reflect the results obtained by each office)"

In this section we also enquired about the potential usefulness of consumer awareness campaigns. Surprisingly, as respondents had previously stated that consumers are not aware about EU product harmonisation legislation (Fig. 9-7), in this case respondents argue that consumer awareness campaigns bring concrete results (Fig. 9-32). In the future, it would be necessary to clarify whether they think that future awareness campaigns are necessary because of consumers' currently low level of awareness of EU product harmonisation legislation.

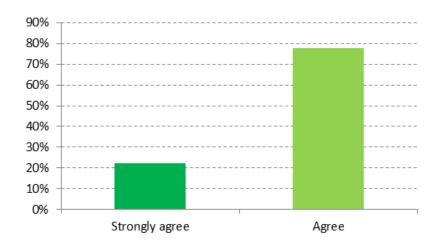


Figure 9-32: "Consumer awareness campaigns are good value for money (i.e., they bring concrete results)"

Finally, in line with a more preventive approach observed in other sections of the survey, 2/3 of respondents agreed that "more collaboration with business sectoral associations should be developed" (Fig. 9-33).

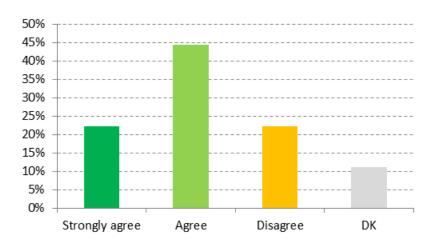


Figure 9-33: "More collaboration with business sectoral associations should be developed"

Finally, we asked whether the respondents identified any other specific factors that may improve the effectiveness of national cooperation on Market Surveillance activity, and we collected insightful comments:

"Clear joint actions planning of the inspections."

"More frequent and perhaps real-time communication and consultation on tough cases."

"It might be useful (necessary) to agree on a common working language (e.g. English) and colleagues enforcing EU-harmonisation legislation should be familiar with that language. Capacity-building actions could be considered as we should make sure that officers should be competent in the relevant sector."

"- Common national prosecution rules;

- No "safeguard clause" anymore: the decision taken by a national market surveillance authority is automatically valid for the whole EU internal market (economic operators have the possibility to appeal from a decision at national level);

- Better coordination and exchange of information between MSA to avoid double checks;

- Benchmarking between MSA on how to assess the requirements."

*"- Better cooperation between colleagues participating in meetings with the European Commission and the people who do the market surveillance.* 

- Better cooperation between the people who do the national market surveillance in the harmonized area."

"- Most of the products entering the EU market are not only covered by one European Directive. Customs sometimes do not know which national MSA to involve. This should be improved.

- More clear rules for products imported from non EU would make it easier for customs to determine if a product can enter the EU market (e.g., mandatory DoC accompanying the product; the identification of one responsible party for placing a product on the EU market and at least one contact party within the EU; the obligation of a user manual in the language of the customs country)."

#### 2. ANNEX: QUESTIONNAIRE

#### SECTION 1 / 6: ON MARKET SURVEILLANCE, IN GENERAL

#### Question 1

Please express your view on the following statements related to Market Surveillance (MS):

	Strongly agree	Agree	Disagree	Strongly disagree	I don't know
1. Product harmonisation legislation is overly complex					
2. MS is under-budgeted in my own Country, in my sector of activity					
3. MS is under-budgeted across the EU, in my sector of activity					
4. There is poor within-Country coordination between the various local offices of MS Authorities					
5. There is poor within-Country coordination with customs					
6. There is poor cross-border coordination of national MS Authorities					
7. There is great consumers' awareness about EU product harmonisation legislation					
8. EU firms have great awareness of EU product harmonisation legislation					
9. Non-EU firms have great awareness of EU product harmonisation legislation					
10. There is great cooperation with the private sector to identify non-compliant products (e.g, with actors in the online supply chain)					
11. Over the last 10 years, there has been an improvement of MS activity in EU					

12. Penalties and fines for non compliance are less effective than timely advice and information to operators			
13. Consumers filing an appropriate complaint related to product-related harmonisation should be properly compensated, for having contributed to MS Activity			

#### Question 2

Please indicate and comment on other specific factors that, in your view, may hinder an effective Market Surveillance activity:

#### **SECTION 2 / 6: COOPERATION ACTIVITY**

#### Question 3

In your view, what specific type of market surveillance cooperation brings most value for money?

- □ International cooperation (outside EU)
- □ EU cooperation
- □ National cooperation

#### **Question 4**

Please briefly explain why:

#### Question 5

Speaking of cooperation, <u>how do you believe</u> your Market Surveillance Authority <u>roughly</u> allocate the available budget across the following cooperation activities, on average, in percentage terms? (Please make sure the total adds up to 100)

Description of the Activity	Percentage
International cooperation (outside EU)	
EU cooperation	
National cooperation	
	100

#### Question 6

How do you <u>believe</u> foreign Market Surveillance Authorities <u>roughly</u> allocate their available budget across the following cooperation activities, on average, in percentage terms? (Please make sure the total adds up to 100)

Description of the Activity	Percentage
International cooperation (outside EU)	
EU cooperation	
National cooperation	
	100

#### **Question 7**

<u>Imagine</u> you could freely decide how to allocate your Authority's budget across the following cooperation activities. How would you allocate it in percentage terms? (Please make sure the total adds up to 100)

Description of the Activity	Percentage
International cooperation (outside EU)	
EU cooperation	
National cooperation	
	100

### SECTION 3 / 6: INTERNATIONAL COOPERATION ACTIVITY

#### **Question 8**

Please express your view on the following statements related to international cooperation related to Market Surveillance (MS) activity:

	Strongly agree	Agree	Disagree	Strongly disagree	I don't know
1. Multinationals tend to be compliant with EU product harmonisation legislation					
2. EU SMEs tend to be compliant with EU product harmonisation legislation					
3. Non-EU SMEs tend to be compliant with EU product harmonisation legislation					
4. National customs of my Country perform thorough controls of incoming goods					
5. National customs of other EU Countries perform thorough controls of incoming goods					
6. Over the last 10 years, the proportion of non-EU non-compliant products that entered the EU market has decreased					
7. Cooperation with sectoral SMEs associations of non-EU Countries could provide up-front advice and information and limit enforcement costs					

### **Question 9**

Please indicate and comment on other specific factors that, in your view, may improve the effectiveness of cooperation on Market Surveillance activity for non-EU goods or services:

#### SECTION 4 / 6: WITHIN-EU COOPERATION ACTIVITY

#### **Question 10**

With reference to the work and discussions taking place within the Administrative Cooperation Working Group (ADCO), what does prevent or hamper you from implementing the necessary changes within your national context? (Up to 3 options can be selected please order them from 1, the most important, to 3, the third-most important)

- □ My management does not show interest for the views expressed by the ADCO
- □ My colleagues do not show interest for the views expressed by the ADCO
- □ My role of "connector" between my MSA and foreign MSA is not properly recognised and valued by my administration
- Our administration is complex, and the common line agreed within the ADCO does not trickle down at all levels
- There is a general perception that foreign MSAs don't take any concrete action
- Only half of EU countries regularly attend ADCO's meetings

#### **Question 11**

What could be the reasons why your management and/or colleagues do not easily endorse the common line agreed within the ADCO, on certain matters? (multiple replies are possible)

- □ The common line agreed within the ADCO is often not clear
- □ The common line agreed within the ADCO brings more costs than benefits
- □ There is a general perception that foreign MSAs would not endorse it
- □ Only half of EU countries regularly attend ADCO's meetings
- □ Other

If "other", please briefly explain why:

### **Question 12**

Do you find it easy to involve your MSA in joint actions proposed in ADCO meetings?

□ Yes

□ No

Please briefly explain why:

#### SECTION 5 / 6: NATIONAL COOPERATION ACTIVITY

#### Question 13

Please express your view on the following statements related to the cooperation activity carried out with other offices of your Authority, or with other relevant national bodies of your Country:

	Strongly agree	Agree	Disagree	Strongly disagree	I don't know
1. We have a single Authority responsible on my sector					
2. Cooperation within the local offices of our Authority is effective					
3. Within my Authority, there are overlapping responsibilities that generate confusion and waste of resources					
4. Collaboration with Customs could be further developed and deepened					
5. Between national relevant bodies, there are overlapping responsibilities that generate confusion and waste of resources					
6. Incentives for effective MS Activity could be better designed (e.g., the overall national budget for MS Activity should better reflect the results obtained by each office)					
7. Consumer awareness campaigns are good value for money (i.e., they bring concrete results)					

#### Question 14

Please indicate and comment on other specific factors that, in your view, may improve the effectiveness of national cooperation on Market Surveillance activity:

#### **SECTION 6 / 6: Contact details**

Please include your contact details here below, and tick the appropriate box should you agree to be contacted by telephone, in the week of 27<sup>th</sup> February, to follow up on your replies to this survey:

#### **Country:**

**Organisation Name:** 

Type of organisation:

- MSA with national vs. local competences (delete accordingly)
- Product specialised vs. cross-sectoral portfolio (delete accordingly)

Sectoral activity, if any (e.g., chemicals, transport):

**Contact Person**:

**Position**:

E-mail address:

#### **Telephone number:**

Yes, I accept to be contacted by telephone for a follow-up interview

No, I am not available to be contacted by telephone for a follow-up interview