EUROPEAN
COMMISSION

Brussels, 19.12.2017
SWD(2017) 466 final

PART 2/4

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

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) 467 final} - {SWD(2017) 468 final} -
{SWD(2017) 469 final} - {SWD(2017) 470 final}

Contents

Glossary

Non-food or industrial product	A substance, preparation or good produced through a manufacturing process other than food, feed, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction.
Union harmonisation legislation	Any Union legislation harmonising the conditions for the marketing of products
Manufacturer	Any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark
Authorised representative	Any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under the relevant Union legislation.
Importer	Any natural or legal person established within the Union who places a product from a third country on the Union market.
Distributor	Any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.
Economic operators	The manufacturer, the authorised representative, the importer and the distributor
Market surveillance	The activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection.
Market surveillance authority	An authority of a Member State responsible for carrying out market surveillance on its territory.
Recall	Any measure aimed at achieving the return of a product that has already been made available to the end user
Withdrawal	Any measure aimed at preventing a product in the supply chain from being made available on the market
Making available on the market	Any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.
Placing on the market	The first making available of a product on the Union market.
Sanction	Action by one or more market surveillance authority toward an undertaking in order to force it to comply with legal obligations. It includes all measures to prohibit or restrict the product's being made available on the national market, to withdraw the product from that market or to recall it, and administrative penalties.
Penalty	A punishment for breaking the law of either administrative or criminal nature.
RAPEX	Rapid alert system for the transmission among all competent market surveillance authorities in the EU of information on measures taken against products presenting a serious risk – ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm
ICSMS	Internet-supported information and communication system for market surveillance authorities in the EU - https://webgate.ec.europa.eu/icsms/

ANNEX 1: PROCEDURAL INFORMATION

1. IDENTIFICATION

- Lead DG: DG Internal Market, Industry, Entrepreneurship and SMEs (GROWTH)
- Agenda planning/Work programme references: 2017/GROW/007

2. ORGANISATION AND TIMING

Work started in January 2016. An Inter-Service Steering Group (ISSG) chaired by DG Internal Market, Industry, Entrepreneurship and SMEs (GROWTH) was established to this purpose. Its members included representatives of:

- Secretariat-General
- DG Climate Action (CLIMA)
- DG Economic and Financial Affairs (ECFIN)
- DG Employment, Social Affairs and Inclusion (EMPL)
- DG Energy (ENER)
- DG Environment (ENV)
- DG Justice and Consumers (JUST)
- DG For Mobility and Transport (MOVE)
- DG Health and Food Safety (SANTE)
- DG Taxation and Customs Union (TAXUD)
- DG Trade (TRADE)

The ISSG met in total nine times (29/01/2016, 07/03/2016, 21/04/2016, 29/09/2016, 28/11/2016, 27/01/2017, 10/02/2017, 27/02/2017 and 06/03/2017).

3. CONSULTATION OF THE REGULATORY SCRUTINY BOARD

The Regulatory Scrutiny Board (RSB) of the European Commission assessed a draft version of the present impact assessment and issued a negative opinion on 07/04/2017. The Board made several recommendations. Those were addressed in the revised IA report as follows:

RSB opinion	Follow-up
(B) Overall assessment and main issues The Board acknowledges the effort to collect evidence on product non-compliance with EU harmonised rules. However, the Board gives a negative opinion, because the report contains important shortcomings that need to	

be addressed with respect to the following key aspects:	
1) The report does not relate this proposal to other legislative initiatives under negotiation. It does not explain why an EU-level response is necessary and proportional to observed problems of product non-compliance.	A new section 'Regulatory context' has been added (1.2.1). It explains the existing framework, how it relates to legislative initiative under negotiation. The problem description (1.3) and proposed options (4) have been expanded to show clearly what/how EU level action is considered to address the problems.
2) The policy options are vague about what actual measures would be taken. As currently organised in the report, they do not provide policy-makers with a transparent choice. Moreover the options do not fully address the issues that the evaluation identifies (e.g. e-Commerce and third countries imports).	The objectives and options have been reorganised and a detailed description of the measures in the options is given (section 4). Reference to how these measures address e-commerce and imports have been added.
3)The report does not do enough to exploit the evidence to quantify costs, and does not identify the potential for simplification or burden reduction as required by REFIT.	The assessment of the options (5) has been expanded adding where possible quantification of costs. In each option assessment (5.2, 5.3, 5.4) a dedicated part is included on simplification potential. Costs of the preferred option are finally also provided (section 7).
(C) Adjustment requirements and other recommendations for improvement	
(1) Context and scope:	
The report explains the existing legislative framework. It should also explain the link with the 2013 Market Surveillance and Product Package. Against this background, it should further clarify the envisaged (broad) scope of this initiative.	The description of the regulatory context is expanded (1.2.1). References to the 2013 package and the rationale for the new initiate have been included. The broad scope of the existing framework and the new initiative is highlighted in this context.
(2) Problem definition and use of the evaluation:	
The report should better highlight the reasons for a more prominent EU dimension to deal with non-compliance. Doing so would usefully underpin the EU solutions that the report presents, e.g. option 5. In addition, the report should establish a stronger link	The problem description and the options have been revisited taking the conclusions of the evaluation into account. The relevant conclusions of the evaluations have been also included in the report (1.7). Besides the evaluation on the market surveillance

between the results of the related evaluation and its identification of problem drivers.	provisions of Regulation (EC) N° 765/2008, the evaluation of the Union harmonisation legislation (2014) is also included in the text.
(3) Baseline and options	
The baseline needs to take into account the implications of the pending 2013 Market Surveillance and Product Package. The report needs to properly explain and justify the various (sub-) options, including all related measures (reliance on PCP, introduction of the representative). It needs to explain the measures to deal with the non-compliance of imported goods from third countries. To do this it will need to consider both the market surveillance and the customs dimensions. The report needs to be clear on how the initiative will address the challenges related to the increasing role of e-commerce. It needs to elaborate on the EU dimension and commitments in terms of resources and enforcement competences of option 5. The report should reorganise the options to provide policy-makers with more transparent choices across the various policy dimensions.	The objectives and options (4) have been completely reorganised to respond to the comments of the Board. The options are presented by increasing ambition and EU dimension/coordination. The report also clearly spells out that none of the options fundamentally changes the balance of enforcement competences, which remain at MS level. The measures in each option are described in more detail. Where relevant specific references have been included to how these measures build on the existing framework or 2013 proposal, or how they address e-commerce or imports and customs controls. The resources implications of each option have been elaborated in the assessments (5.2, 5.3, 5.4).
(4) Impacts	
More detail on measures contained in the options would improve the analysis of the impacts. The report should draw more from the rich (anecdotal) empirical evidence in the annexes. This would help to improve its quantification dimension and provide information on the potential for simplification and burden reduction. The report should also show the cost of the preferred option, including for instance implications in terms of funding and resources at the EU level.	More reference to examples have been incorporated and where possible estimations or indicative impacts and costs added. The costs of the preferred option are set out also in section 7, separating out costs for the EU, member states and businesses.
(5) Presentation	
The report needs to be a self-standing document. It should improve the presentation of a number of sections: scope, the existing legislative framework, the baseline, the policy options and the comparison of the policy options. In this regard, the report should draw policy relevant information from the very	The regulatory context, baseline/problem description sections have been reviewed and significantly expanded to explain the existing framework. The sections 3 to 6 on the objectives, options and comparison of the options have been entirely reworked, adding more information into the report and adding

extensive annexes.	further references and elements to make the report as self-standing as possible.

On 08/06/2017 the RSB issued a 2nd positive opinion on the revised impact assessment report. The Board made several recommendations, which were addressed as follows:

RSB Opinion	**Follow-up**
(B) Main considerations The Board notes that the report addresses several concerns that the Board raised in its first opinion. However, the report still contains important shortcomings that need to be addressed. As a result, the Board expresses reservations and gives a positive opinion only on the understanding that the report shall be adjusted to integrate the Board's recommendations with respect to the following key aspects:	
• The links with the results of the related evaluation are not sufficiently spelled out.	• More explicit links to the evaluation findings have been integrated in the report (in the problem definition as well as in the options and measures).
• The report does not substantiate the feasibility of an externalised EU Product Compliance Network under option 3b and leaves many issues unanswered (resources, governance, and expected impacts). While making the case for the network, the report does not provide an adequate basis for deciding on its implementation modalities.	• The description in the report is expanded to include more information on the intended governance structure of the Network, details on resources, including inputs and results which can be expected in the different scenarios. The report also analyses more in detail the implications of hosting of the Network in an regulatory agency (EU-IPO) versus hosting in the Commission. Full detailed information on the EU Product Compliance Network is added in Annex 12.
• The report does not provide sufficient evidence that the obligation to appoint a responsible person in the EU for third country business is effective and proportionate.	• Details on the responsible person measure are added in Annex 13 (2).
• The REFIT dimension of the report is not clear enough**.**	More explicit links to the evaluation and the REFIT dimension are inserted in the report. The sections on administrative simplifications

	and the costs of the preferred option have been expanded.
(C) Further considerations and adjustment requirements	
(1) Problem definition	
The problem definition should draw more strongly on the REFIT evaluation of the application of the market surveillance provisions of regulation (EC) no 765 (2008). The report should better reflect the evaluation's conclusions and should address the problems that the evaluation identified.	More explicit links to the evaluation findings have been integrated in the report (in the problem definition as well as in the options and measures). In section 1.6 (Conclusions of the evaluation), the findings on the refit-potential have been added with cross-references to the problem definition and measures that address the findings.
(2) Options	
An important measure of the preferred option is the establishment of a **Product Compliance Network.** For this option to be rigorously assessed, an informed analysis of the pros and cons of the different alternative governance forms of the Network (e.g. network within the Commission, integration in existing agency, new agency, regulatory versus executive agency…) is required. As it presently stands, the report does not substantiate the feasibility or the adequacy of the current sub-option of hosting the network in the Agency EU-IPO. This proposal does not appear to have been tested in the consultation and Member States have voiced opposition to an intergovernmental body. In the absence of further analysis and consultations, the evidence-base for considering this option is insufficient.	The description of the measure 3(b) has been expanded, summarising the various governance and hosting variants. The impacts and feasibility of the main hosting options Commission or EU-IPO are compared. Full details on the outputs and costs in different scenarios and the pro's and con's of various hosting option have been included in Annex 12. While the impact assessment is completed with all the elements requested, the report does not express a preferred option for the hosting variant Commission or EU-IPO, as this is essentially a political choice. The Network, including hosting sub-options in the Commission or an existing EU agency, was tested with Member States in March 2017, and received broad support. On the occasion it was clarified that the Network would not entail a transfer of competencies from MS to EU level over which concerns were voiced in initial stages of the impact assessment and scoping of options (written submissions of Member States in response to the public consultation, member state expert group meeting 21 October 2016). The corresponding text in the report ("stakeholder views" on option 3(b)) has been elaborated.
The **sub-option 3(d) requiring a "person responsible"** for goods which are not imported through an importer needs further	Details on the responsible person measure are added in Annex 13 (2).

explanation and substantiation:

• To whom will the obligation apply? Specifically, will it cover passive sales? Fulfilment centres? Online markets?	Sections 2.1 and 2.2.1 of Annex 13(2)
• What is the added value of this measure, as compared to the mandatory digital publication of compliance information (sub-option 3g), also included in the preferred option?	Section 2.4.3 of Annex 13(2)
• How reliable is the EUR 200 estimated cost of having a responsible person?	Section 2.4.3 of Annex 13(2)
• How will market surveillance authorities enforce such an obligation? What are the related enforcement costs?	Section 2.4.3 of Annex 13(2)
• Would the measure discourage third country online compliant retailers to sell in the EU, and therefore run against the Digital Single Market Strategy objective of promoting eCommerce?	Sections 2.1 and 2.4.3 of Annex 13(2)
• What are the liabilities which the responsible person will be submitted to? Are they the same as the liabilities in other existing frameworks? How does this liability affect the estimated costs?	Section 2.4.3 of Annex 13(2)
• Has the concept of responsible person in the legal framework for cosmetics and medical devices demonstrated its effectiveness to address the market surveillance issue of imports of small consignments from third countries?	Section 2.4.3 of Annex 13(2)
• How big is the market segment affected by the obligation? Calculations point to a small proportion (5.6%) of eCommerce and very small segments of the EU harmonised market (EUR 465 million against EUR 2500 billion).	Section 2.2 of Annex 13(2)

(3) Impact and REFIT

The report should present more quantitative data on the REF**I**T dimension. It could draw on the related evaluation for this. Besides information on what the preferred option	Additional quantitative estimates have been added in the report, including on possible administrative simplifications (e.g. costs of reporting). In section 7.1 in addition to costs

would cost, the report should comprehensively present the potential for simplification and burden reduction. Finally, it should try to present some estimates of the costs of strengthening the enforcement tools in Member States, since they might vary heavily between Member States which currently have investigative powers and Member States which do not.

of the preferred option, simplifications and cost reduction potential has been included. The report has been adapted to indicate more clearly which Member States currently have the least investigative and enforcement powers and could as a consequence face more adaptation costs than others (option 2(d), and 3 (e)/(f)). A detailed breakdown by power and by Member State has been put into annex 13, based on the information obtained in the REFIT evaluation.

4. EVIDENCE USED FOR THE IMPACT ASSESSMENT

Besides the evidence that results from the consultations of stakeholders and from the REFIT evaluation, section 5 below and annexes 7, 8 and 9 contain the main elements on which the problem description is based. Annexes 11 to 15 contain the remaining evidence used for assessing the options

5. SOURCES USED FOR THE IMPACT ASSESSMENT

5.1 Other reports, Commission documents and impact assessments

- COM(2016) 1958 final, Commission Notice. The "Blue Guide" on the implementation of EU product rules.

- Centre for Strategy and Evaluation Services (2010), "Interim Evaluation of the Measuring Instruments Directive", Final report.

- Department for Business, Innovation & Skills, Better Regulation Delivery Office (2013), Interim Evaluation of Primary Authority.

- European Commission (2007), Commission Staff Working Document Accompanying the document Proposal for a Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and a decision of the European Parliament and of the Council on a common framework for the marketing of products – Impact Assessment – SEC(2007) 173.

- European Commission (2007) Commission Staff Working Document Accompanying the document Proposal for a Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and a decision of the European Parliament and of the Council on a common framework for the marketing of products - Executive summary of the impact assessment – SEC(2007) 174.

- European Commission (2008) Commission Staff Working Document Accompanying document to the Proposal for a Directive of the European Parliament and of the Council amending Directive 88/378/EEC on the safety of toys – Impact Assessment. SEC(2008) 38.

- European Commission (2011) Commission Staff Working paper. Impact Assessment Accompanying the document Directive of the European Parliament and of the Council amending Directive 94/25/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft, as amended by Directive 2003/44/EC.

- European Commission (2011) Commission Staff Working Paper. Impact Assessment Accompanying document to the 10 Proposals to align product harmonisation directives to Decision No 768/2008/EC.

- European Commission (2011) Commission Staff Working Document. Bringing e-commerce benefits to consumers. SEC(2011) 1640 final.

- European Commission (2012) Commission Staff Working Document Impact Assessment (Disclaimer: This report commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission) Accompanying the document 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 – SWD(2012) 329 final.

- European Commission (2012) Commission Staff Working Document Executive Summary Of The Impact Assessment Accompanying the document revision of Council Directive 96/98/EC of 20 December 1996 on marine equipment - SWD(2012) 437 final.

- European Commission (2013) Commission Staff Working Document – Impact Assessment Accompanying the document "Product Safety and Market Surveillance Package: A proposal for a Regulation of the European Parliament and the Council on consumer product safety and a proposal for a Regulation of the European Parliament and of the Council on market surveillance for products" and Annexes – SWD(2013) 33 final.

- European Commission (2013) Commission Staff Working Document – Executive Summary of the Impact Assessment Accompanying the document "Product Safety and Market Surveillance Package: A proposal for a Regulation of the European Parliament and the Council on consumer product safety and a proposal for a Regulation of the European Parliament and of the Council on market surveillance for products" – SWD(2013) 34 final.

- European Commission (2014) Commission Staff Working Document Part 1: : Evaluation of the Internal Market Legislation for Industrial Product Accompanying the document the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee A vision for the internal market for products – SWD (2014) 23 final.

- European Commission (2014) Commission Staff Working Document Part 2: Results of the case studies Accompanying the document the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee A vision for the internal market for products – SWD (2014) 23 final.

- European Commission (2014) Commission Staff Working Document Impact Assessment Accompanying the document Commission legislative proposal for a

revision of Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to cableway installations designed to carry persons – SWD(2014) 116 final.

- European Commission (2014) Commission Staff Working Document Impact Assessment Accompanying the document Proposal for a Regulation Of The European Parliament And Of The Council on personal protective equipment – SWD(2014) 118 final.

- European Commission (2014) Commission Staff Working Document Impact Assessment Accompanying the document Proposal For A Regulation Of The European Parliament And Of The Council on appliances burning gaseous fuels.

- European Commission (2015) Commission Staff Working Document. A Single Market Strategy for Europe – Analysis and Evidence. Accompanying the document Upgrading the Single Market: more opportunities for people and business. SWD(2015) 202 final.

- European Commission (2015) Commission Staff Working Document Executive Summary of the Impact Assessment Accompanying the document Proposal for a Regulation of the European Parliament and of the Council setting a framework for energy efficiency labelling and repealing Directive 2010/30/EU – SWD(2015) 140 final.

- European Commission (2016) Commission Staff Working Document Impact Assessment Accompanying the Proposal for a Regulation of the European Parliament and the Council on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles – SWD(2016) 9 final.

- European Commission (2016) Commission Staff Working Document SWD(2016)172 on Online Platforms and accompanying the Commission Communication on Online Platforms and the Digital Single Market.

- European Commission (2017) Commission Staff Working Document Impact Assessment Accompanying the Proposal for a Directive of the European Parliament and the Council to empower the competition authorities of the Member States to be more effective enforcers of the rules on competition laid down in Articles 101 and 102 TFEU and to remove obstacles to the proper functioning of the internal market – SWD(2017)…

- European Commission (2017) Commission Staff Working Document Impact Assessment Accompanying the Proposal for a [Single Digital Gateway] – SWD(2017)…

- European Commission, GROW B1 (2016), Summary of Member States' assessment and review of the functioning of market surveillance activities according to Article 18(6) of Regulation (EC) No 765/2008. Available at: http://ec.europa.eu/DocsRoom/documents/15241/attachments/1/translations/en/renditions/native

- European Commission. Proposal for a Directive of the European Parliament and of the Council on the placing on the market of pyrotechnic articles – Impact Assessment.

- Risks and Policy Analysts Limited (RPA). Details relevant for impact assessment of 13 sectors. Available at: http://ec.europa.eu/DocsRoom/documents/6587/attachments/1/translations/en/renditions/native

- European Commission. Press release "Europe's windows on the world: ports and product safety", Brussels, 23 April 2007. Available at: http://europa.eu/rapid/press-release_IP-07-537_en.htm

- European Commission (2008) "Report from the Commission to the European Parliament and to the Council on the implementation of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety" – COM(2008) 905 final.

- European Commission (2010) Commission Staff Working Document – "Results of the Public Consultation on the Revision of the General Product Safety Directive".

- European Commission (2010) "Free movement of goods. Guide to the application of Treaty provisions governing the free movement of goods", Luxembourg: Publications Office of the European Union.

- European Commission (2013) Commission Staff Working Document Accompanying the report from the Commission to the European Parliament, the Council and the European economic and social Committee on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 Organisation of market surveillance in the Member States – SWD(2013) 36 final.

- European Commission (2013) Report From The Commission To The European Parliament, The Council And The European Economic And Social Committee on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/9 – COM(2013) 77 final.

- European Commission (2016) "Cross-border cooperation".

- European Commission (2016). EU general risk assessment methodology (Action 5 of Multi-Annual Action Plan for the surveillance of products in the EU (COM(2013)76).

- European Commission (2016) Commission Notice of 5.4.2016 – The "Blue Guide" on the implementation of EU product rules – COM(2016) 1958 final.

- BSI and Development Solutions (2011) "The future of market surveillance in the area of non-food consumer product safety under the General Product Safety Directive" Final Report, European Commission Health and Consumers Directorate-General.

- BSI and Development Solutions (2011) "The future of market surveillance in the area of non-food consumer product safety under the General Product Safety Directive" A review of the EU market surveillance, European Commission Health and Consumers Directorate-General.

- BSI and Development Solutions (2011) "The future of market surveillance in the area of non-food consumer product safety under the General Product Safety Directive" Task 2.2 Report, European Commission Health and Consumers Directorate-General.

- CEPS (2013). Assessing the costs and benefits of regulation. Final Report. Available at: http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf

- Conclusions Customs 2013 Seminar "Preventing Imports of Dangerous Products", 8 – 10 April 2008, Saalfelden, Austria. Available at: http://ec.europa.eu/taxation_Customs/resources/documents/Customs/policy_issues/Customs_security/product_safety_en.pdf

- European Commission (2010), "CERTIF 2010–02, Sanctions foreseen in the national legislation of Member States against infringements of the provisions of Regulation 765/2008/EC

- European Parliament (2009), Effectiveness of Market Surveillance in the Member States. Directorate A: Economic and Scientific Policies. IPOL/A/IMCO/ST/2009-04

- Panteia and Centre for Strategy and Evaluation Services (CESS) (2014), "Good Practice in Market Surveillance Activities related to Non-Food Consumer Products sold Online" Report and annexe of good practice cases.

5.2 References

- Aalders M. & Wilthagen, T. (1997), "Moving beyond command-and-control: Reflexivity in the regulation of occupational health and safety and the environment" 19 Law & Policy, pp. 415-443.

- Alemani E., Klein C., Koske I., Vitale C. and Wanner I., 'New Indicators of Competition Law and Policy in 2013 for OECD and non-OECD Countries", OECD Economics Department Working Papers No 104, ECO/WKP(2013)96, http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ECO/WKP(2013)96&docLanguage=En

- Andersen, O. (1996), "The Norwegian internal control system: A tool in corporate environmental management?" 3 Eco-Management and Auditing, pp. 26-29.

- Arlen, J. & Kraakman, R. (1997), "Controlling corporate misconduct: An analysis of corporate liability regimes" 72(4) New York University Law Review, pp. 687-779.

- Ashby, S. & Diacon, S. (1996), "Motives for occupational risk management in large UK companies" 22 Safety Science, pp. 229-243.

- Ayres, I. & Braithwaite, J. (1992), Responsive Regulation: Transcending the Deregulation Debate, Oxford University Press, New York.

- Baldini G. et al. (2016); *Enforcers and brand owners' empowerment in the fight against* counterfeiting (updated version of Baldini G. and Cano Pons E., Enforcers and brand owners' empowerment in the fight against counterfeiting, EUR 28400 EN, doi:10.2760/135671)

- Baldwin, R. (1997), "Regulation after 'command and control'" in Hawkins, K. (ed) Human Face of Law, Clarendon Press, Oxford, pp. 65-84.

- Bardach, E. & Kagan, R. (1982), Going by the Book: The Problem of Regulatory Unreasonableness, Temple University Press, Philadelphia.

- Becker, G. (1968), "Crime and punishment: An economic approach", 76 Journal of Political Economy, p. 169.

- Beder, S. (1997), Global Spin: The Corporate Assault on Environmentalism, Scribe Books, Melbourne.

- Blanc F. (2016), "Harmonizing enforcement in product markets and establishments safety at the European level – approaches, outcomes, lessons learned", in "Cross-border cooperation between national inspectorates - Conference paper to be presented at the International Conference on Enforcement in a Europe without Borders, February 23rd 2016, Amsterdam, The Netherlands, http://inspectionconference.nl/wp-content/uploads/2016/02/essay.pdf

- Boggiano, A., Barrett, M., Weiher, A., McLelland, G. & Lusk, C., "Use of the maximal-operant principle to motivate children's intrinsic interest" 53 Journal of Personality and Social Psychology, pp. 866-879.

- Boyd, J. (1998), Searching for the Profit in Pollution Prevention: Case Studies in the Corporate Evaluation of Environmental Opportunities, Discussion Paper 98-30, Resources for the Future, Washington DC.

- Braithwaite, J. (1984), Corporate Crime in the Pharmaceutical Industry, Routledge & Kegan Paul.

- Braithwaite, J. (1985), To Punish or Persuade: Enforcement of Coal Mine Safety, State University of New York Press, Albany.

- Braithwaite, J. (1989), Crime, Shame and Reintegration, Cambridge University Press, Cambridge.

- Braithwaite, J. (1999), "Restorative justice: Assessing optimistic and pessimistic accounts" Crime and Justice: A Review of Research, Tonry M. (ed), pp. 241-364.

- Braithwaite, J. & Makkai, T. (1991), "Testing an expected utility model of corporate deterrence" 25 Law & Society Review, 7–40.

- Braithwaite, J. & Makkai, T. (1994), "Trust and compliance" 4 Policing & Society, pp. 1–12.

- Braithwaite, V. (1993), "The Australian government's affirmative action legislation: Achieving social change through human resource management", 15(4) Law & Policy, 327–354.

- Braithwaite, V. (1995), "Games of engagement: Postures within the regulatory community", 17(3) Law & Policy, pp. 225-255.

- Brehm, S. & Brehm, J. (1981), Psychological Reactance: A Theory of Freedom and Control, Academic Press, New York.

- Brown, R. (1994), "Theory and practice of regulatory enforcement: Occupational health and safety regulation in British Colombia", 16 Law & Policy 63-91.

- Burby, R. and Paterson, R. (1993), "Improving compliance with state environmental regulations" 12 Journal of Policy Analysis and Management, 753-772.

- Calkins, S. (1997), "Corporate compliance and the anti-trust agencies' bi-modal penalties" 60(3) Law & Contemporary Problems, pp. 127-167.

- Chayes, A. (1960), "The modern corporation and the rule of law" in Mason, E. (ed) The Corporation in Modern Society, Harvard University Press, Cambridge, Massachusetts, pp. 25-45.

- Cheit, Ross (1990), Setting Safety Standards: Regulation in the Public and Private Sectors, University of California Press, Berkeley.

- Coffee, J. (1981), "No soul to damn: no body to kick: An unscandalised inquiry into the problem of corporate punishment", 79 Michigan Law Review, pp. 386-459.

- Cooter, R. & Ulen, T. (1988), Law and Economics, Scott, Foresmen & Coy, Glenview, Illinois.

- Davidson, W., Worrell, D., & Cheng, L. (1995), "Are OSHA penalties effective?", 92 Business & Society Review, pp. 25-28.

- DeMott, D. (1997), "Organizational incentives to care about the law" 60(4) Law & Contemporary Problems, pp. 39-66.

- Dimaggio, P. & Powell, W. (1991), "The iron cage revisited: Institutional isomorphism and collective rationality in organizational fields" in Powell, W. & DiMaggio, P. (eds) The New Institutionalism in Organizational Analysis, University of Chicago Press, Chicago.

- DiMento, J. (1989), "Can social science explain organizational non-compliance with environmental law?" 45 Journal of Social Issues, pp. 109-132.

- Dobbin, F., Edelman, L., Meyer, J. Scott, W. R. & Swidler, A. (1988), "The expansion of due process in organizations" in Zucker, L. (ed) Institutional Patterns and Organizations: Culture and Environment, Ballinger Publishing Coy, Cambridge, Massachusetts, pp. 71-98.

- Earnhart D.H. and Glicksman R.L. (2015), "Coercive vs. cooperative enforcement: Effect of enforcement approach on environmental management", International Review of Law and Economics, Volume 42, June 2015, Pages 135–146.

- Edelman, L. (1990), "Legal environments and organisational governance: The expansion of due process in the American workplace", 95 American Journal of Sociology, pp. 1401-1440.

- Edelman, L., Erlanger, H. & Lande, J. (1993), "Internal dispute resolution: The transformation of civil rights in the workplace" 27(3) Law & Society Review, pp. 497–534.

- Ekland-Olson, S., Lieb, J. & Zurcher, L. (1984), "The paradoxical impact of criminal sanctions: Some microstructural findings" 18 Law & Society Review, p. 159.

- Fisse, B. & Braithwaite, J. (1983), The Impact of Publicity on Corporate Offenders, State University of New York Press, Albany.

- Fisse, B. & Braithwaite, J. (1993), Corporations, Crime and Accountability, Cambridge University Press, Cambridge.

- Friedrichs, D. (1996), Trusted Criminals: White Collar Crime in Contemporary Society, Wadsworth Publishing, Belmont, California.

- Fukuyama, F. (1995), Trust: The Social Virtues and the Creation of Prosperity, Free Press, New York.

- Garland, D. (1997), "'Governmentality' and the problem of crime: Foucault, criminology, sociology" 1 Theoretical Criminology, pp. 173-214.

- Geltman, Elizabeth & Skroback, Andrew (1998), "Reinventing the EPA to conform with the new American environmentality" 23 Colombia Journal of Environmental Law, pp. 1-56.

- Genn, H. (1993), "Business responses to the regulation of health and safety in England" 15 Law & Policy, pp. 219-233.

- Gilboy, J. (1998), "Compelled third-party participation in the regulatory process: Legal duties, culture and noncompliance", 20(2) Law & Policy, pp. 135-155.

- Gordon, C. (1991), "Governmental rationality: An introduction" in Burchell, G., Gordon, C. & Miller, P. (eds), The Foucault Effect: Studies in Governmentality, University of Chicago Press, Chicago, pp. 1-52.

- Grabosky, P. (1994), "Green markets: Environmental regulation by the private sector" 16 Law & Policy, pp. 419-448.

- Grabosky, P. (1995), "Using non-governmental resources to foster regulatory compliance", 8 Governance: An International Journal of Policy and Administration, pp. 527-550.

- Grabosky, P. and Braithwaite, J. (1986), Of Manners Gentle: Enforcement Strategies of Australian Business Regulatory Agencies, Oxford University Press, Melbourne.
- Gunningham, N. (1994), "Beyond compliance: Management of environmental risk" in Boer, B., Fowler, R. & Gunningham, N. (eds) Environmental Outlook: Law and Policy, Federation Press, Sydney, pp. 254-281.
- Gunningham, N. & Grabosky, P. (1998), Smart Regulation: Designing Environmental Policy, Clarendon Press, Oxford.
- Gunningham, Neil & Darren Sinclair (1999), "Environment management systems, regulation and the pulp and paper industry: ISO 14001 in practice", 16 Environmental and Planning Law Journal, pp. 5-24.
- Haines, F. (1997), Corporate Regulation: Beyond "Punish or Persuade", Clarendon Press, Oxford.
- Hancher, L. & Moran, M. (1989), "Organising regulatory space" in Hancher, L. & Moran, M. (eds) Capitalism,Culture and Economic Regulation, Clarendon Press, Oxford, pp. 271-299.
- Hawkins, K. (1984), Environment and Enforcement: Regulation and the Social Definition of Pollution, Clarendon Press, Oxford.
- Hawkins, K. (1990), "Compliance strategy, prosecution policy, and Aunt Sally", 30(4) British Journal of Criminology, pp. 444-466.
- Heimer, C. (1996), "Explaining variation in the impact of law: Organizations, institutions and professions", 15 Studies in Law, Politics & Society, pp. 29-59.
- Hodges C.J.S. (2015), Law and Corporate Behaviour: Integrating Theories of Regulation, Enforcement, Compliance and Ethics, Bloomsbury Publishing, London.
- Hoffman, A. (1997), From Heresy to Dogma: An Institutional History of Corporate Environmentalism, The New Lexington Press, San Francisco.
- Honneland, G. (1998), "Compliance in the fishery protection zone around Svalbard", 29 Ocean Development and International Law, pp. 339-360.
- Hopkins, A. (1994), "Compliance with what? The fundamental regulatory question", 34 British Journal of Criminology, pp. 431-443.
- Hopkins, A. 1995, Making Safety Work, Allen & Unwin, St Leonards, NSW.
- Hutter, B. (1997), Compliance: Regulation and Environment, Clarendon Press, Oxford.
- Jenkins, A. (1994), "The role of managerial self-efficacy in corporate compliance" 18(1) Law & Human Behaviour, pp. 71-88.

- Kagan, R. & Scholz J. (1984), "The 'criminology of the corporation' and regulatory enforcement strategies" in Hawkins, K. & Thomas, J. (eds) Enforcing Regulation, Kluwer Nijhoff Publishing, Boston, pp. 67–95.

- Kohn, A. (1993), Punished by Rewards: The Trouble with Gold Stars, Incentive Plans, A's, Praise and Other Bribes, Houghton Mifflin Coy, Boston.

- Krut, R. & Gleckman, H. (1998), ISO 14001: A Missed Opportunity for Global Industrial Development, Earthscan Publications, London.

- Levi, M. (1988), Of Rule and Revenue, University of California Press, Berkeley.

- McCaffrey, D. and Hart, D. (1998), Wall Street Polices Itself: How Securities Firms Manage the Legal Hazards of Competitive Pressures, Oxford University Press, New York.

- McCaffrey, D. and Faerman S. (1994), "Shared regulation in the United States securities industry" 26(2) Administration & Society, pp. 204-235.

- McInerney, F. & White, S. (1995), The Total Quality Corporation: How 10 Major Companies Added to Profits and Cleaned up the Environment in the 1990s, Truman Telley Books/Plume, New York.

- Makkai, T. & Braithwaite, J. (1993), "Praise, pride and corporate compliance", 21 International Journal of the Sociology of Law, pp. 73–91.

- Makkai, T. & Braithwaite, J. (1994a), "Reintegrative shaming and regulatory compliance", 32 Criminology, pp. 361–385.

- Makkai, T. & Braithwaite, J. (1994b), "The dialectics of corporate deterrence", 31 Journal of Research in Crime & Delinquency, pp. 347–373.

- Manning, P. (1987), "Ironies of compliance" in Shearing, C. & Stenning, P. (eds) Private Policing, Sage Publications, Newbury Park, California.

- March, J. & Simon, H. (1958), Organizations, Wiley, New York.

- Nesterczuk, George (1996), "Reviewing the national performance review", 3 Regulation, pp. 31-39.

- Oded S. (2013), Corporate Compliance: New Approaches to Regulatory Enforcement, Edward Elgar Publishing, Cheltenham.

- Ogus, A. (1994), Regulation: Legal Form and Economic Theory, Clarendon Press, Oxford.

- Osborne, D. & Gaebler, T. (1992), Reinventing Government: How the Entrepreneurial Spirit is Transforming the Public Sector, Addison-Wesley, Reading, Massachusetts.

- Parker, C. (1997), "Converting the lawyers: The dynamics of competition and accountability reform", 33 The Australian and New Zealand Journal of Sociology, pp. 39-55.

- Parker, C. (1999a), "Compliance professionalism and regulatory community: The Australian trade practices regime", 26(2) Journal of Law & Society, pp. 215-239.

- Parker, C. (1999b), "How to win hearts and minds: Corporate compliance policies for sexual harassment", 21(1) Law & Policy, pp. 21-48.

- Parker, C. (1999), Just Lawyers: Regulation and Access to Justice, Oxford Socio-Legal Studies Series, Oxford University Press, Oxford.

- Paternoster, R., Brame, R., Bachman, R. & Sherman, L. (1997), "Do fair procedures matter? The effect of procedural justice on spouse assault" 31 Law & Society Review, pp. 163-204.

- Paternoster, R. & Simpson, S. (1996), "Sanction threats and appeals to morality: Testing a rational choice model of corporate crime" 30 Law & Society Review, pp. 549-583.

- Pearce, F. & Tombs, S. (1990), "Ideology, hegemony, and empiricism: Compliance theories of regulation", 30 British Journal of Criminology, pp. 423-443.

- Pearce, F. & Tombs, S. (1997), "Hazards, law and class: Contextualising the regulation of corporate crime", 6 Social & Legal Studies, 79-107.

- Pearce, F. & Tombs, S. (1998), Toxic Capitalism: Corporate Crime and the Chemical Industry, Ashgate, Dartmouth, Aldershot, England.

- Porter, M. & van der Linde, C. (1995), "Green and competitive: Ending the stalemate", Harvard Business Review, September–October, pp. 120–134.

- Putnam, R. (1993), Making Democracy Work: Civic Traditions in Modern Italy, Princeton University Press, Princeton.

- Rees, J. (1988), Reforming the Workplace: A Study of Self-Regulation in Occupational Safety, University of Pennsylvania Press, Philadelphia.

- Rees, J. (1994), Hostages of Each Other: The Transformation of Nuclear Safety Since Three Mile Island, University of Chicago Press, Chicago and London.

- Rees, J. (1997), "Development of communitarian regulation in the chemical industry", 19(4) Law & Policy, pp. 477-528.

- Reichman, N. (1992), "Moving backstage: Uncovering the role of compliance practices in shaping regulatory policy" in Schlegel, K. & Weisburd, C. (eds) White Collar Crime Reconsidered, Northeastern University Press, Boston, pp. 245-267.

- Schmidheiny, S. (1992), Changing Course: A Global Business Perspective on Development and the Environment, MIT Press, Cambridge, Massachusetts.

- Schmitt, R. (1994), "The Amoco/EPA Yorktown Experience and Regulating the Right Thing", 9(1) Natural Resources and Environment, pp. 11-13, 51.
- Scholz, J. (1997), "Enforcement policy and corporate misconduct: The changing perspective of deterrence theory", 60(3) Law & Contemporary Problems, pp. 253-268.
- Scholz, J. & Gray, W. (1990), "OSHA enforcement and workplace injuries: A behavioural approach to risk assessment", 3 Journal of Risk and Uncertainty, p. 283.
- Scholz, J. & Lubell, M. (1998), "Trust and taxpaying: Testing the heuristic approach to collective action", 42 American Journal of Political Science, p. 398.
- Scholz, J. & Lubell, M. (1999), "Adaptive political attitudes: Duty, trust and fear as monitors of tax policy", 42 American Journal of Political Science.
- Schwartz, M. (1998), "Compliance and business ethics are coming of age in Canada", 12(1) Ethikos & Corporate Conduct Quarterly, pp. 7-9, 12.
- Schwartz, R. & Orleans, S. (1967), "On legal sanctions" 34 University of Chicago Law Review, 274-300.
- Scott, C. (1998), "Analysing regulatory space: Implications for institutional design and reform", Law & Society Association Annual Conference, Aspen, Colorado, June.
- Scott, W. R. (1995), Institutions and Organizations, Sage Publications, Thousand Oaks, California.
- Selznick, P. (1992), The Moral Commonwealth, University of California Press, Berkeley.
- Shearing, C. (1993), "A constitutive conception of regulation" in Grabosky, P. & Braithwaite, J. (eds) *Business Regulation and Australia's Future*, Australian Institute of Criminology, Canberra, pp. 67-79.
- Sherman, L. (1993), "Defiance, deterrence, and irrelevance: A theory of the criminal sanction", 30(4) Journal of Research in Crime & Delinquency, pp. 445–473.
- Sigler, J. & Murphy, J. (1988), Interactive Corporate Compliance: An Alternative to Regulatory Compulsion, Quorum Books, New York.
- Sinclair, D. (1997), "Self-regulation versus command and control? Beyond false dichotomies", 19(4) Law & Policy, pp. 529-559.
- Sparrow, M. (1994), *Imposing Duties: Government's Changing Approach to* Compliance, Praeger Publishers, Westport, Connecticut.
- Stigler, G. (1970), "The optimum enforcement of laws", 78 Journal of Political Economy, p. 526.

- Still, L. (1997), Glass Floors and Sticky Ceilings: Barriers to the Careers of Women in the Australian Finance Industry, Human Rights and Equal Opportunity Commission, Sydney.

- Stone, C. (1975), Where the Law Ends: The Social Control of Corporate Behaviour, Harper & Row, New York.

- Suchman, M. & Edelman, L. (1997), "Legal rational myths: The new institutionalism and the law and society tradition", 21 Law & Social Inquiry, pp. 903-941.

- Tietenberg, T. (1985), Emissions Trading: An Exercise in Reforming Pollution Policy, Resources for the Future Inc, Washington DC.

- Tittle, C. (1980), Sanctions and Social Deviance, Praeger, New York.

- Vaughan, D. (1996), The Challenger Launch Decision: Risky Technology, Culture and Deviance at NASA, The University of Chicago Press, Chicago.

- Ward, A. (1997), "Compliance surveys: Companies say better safe than sorry" 62(7) Corporate Legal Times, pp. 1-3.

- Weait, M. (1994), "The role of the compliance officer in firms carrying on investment business" September Butterworths Journal of International Banking and Financial Law, pp. 381-384.

- Weil, D. (1996), "If OSHA is so bad, why is compliance so good?", 27 RAND Journal of Economics, pp. 618- 640.

- Weinberger, A. (1990), "Preventing insider trading violations: A survey of corporate compliance programs", 18 Securities Law Regulation Journal, 180-193.

6. EXTERNAL EXPERTISE USED FOR THE IMPACT ASSESSMENT

- Technopolis group, Ex-post evaluation of the application of the market surveillance provisions of Regulation (EC) N° 765 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) N° 339/93, 2017.

- BSI - British Standards Institution in partnership with WIFO - Österreichisches Institut für Wirtschaftsforschung**,** Study on the good practices in the area of compliance assistance and compliance schemes, revised final report February 2017.

- VVA Consulting, Evaluation of impact of the "Internal Market for Goods – Digital Compliance", (on-going, not yet published).

ANNEX 2: STAKEHOLDER CONSULTATION

1. OBJECTIVES OF THE CONSULTATION

The Commission wanted to make an evidence-based assessment of the extent to which the provisions on market surveillance of Regulation (EC) No 765/2008 have been effective, efficient, relevant, coherent and achieved EU added-value. The results of the evaluation will support taking actions to enhance efforts to fight non-compliant products made available in the Single Market.

1.1 Consultation methods and tools

The **market surveillance authorities** have been consulted during the meetings of the Expert Group on the Internal Market for Products in 2016 .

A **stakeholder conference -** open to all interested participants - **was** organised by the Commission on **17 June 2016**.

A **public consultation in all EU official languages**, published on a website hosted on Europa, run from 1 July to 31 October 2016. Participation of SMEs in the consultation was promoted and supported through the European Enterprise Network.

2. RESULTS OF THE CONSULTATION ACTIVITIES

2.1 Meetings of the Expert Group on the Internal Market for Products – Market Surveillance Group

The Expert Group on the Internal Market for Products – Market Surveillance Group held its last meetings on 1st February 2016, 21st October 2016 and 31st March 2017.

During the first meeting, the Commission recalled the challenges reported by market surveillance authorities in the national reviews and assessment of activities carried out between 2010 and 2013. The detailed IMP document is annexed to the Impact Assessment (Annex 2).

During the meeting held on 21 October 2016, the Commission informed the participants of the state of play of the enforcement and compliance initiative and explained that the purpose was to receive feedback on the suitability of the ideas under examination. The detailed minutes can be found at: http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=28611.

The meeting held on 31 March 2017 focused on the legislative proposal and especially on how to enhance cooperation between the member states, create a uniform and sufficient level of market surveillance and have stronger border controls of imported products to the European market.

2.2 Meetings of the Customs Expert Group

The Customs Expert Group that met on 22 April was informed about the launch of the Enforcement and Compliance initiative. Customs authorities were invited to participate in the consultations and provide their views on possible challenges and actions needed.

The Expert Group PARCS met to discuss product safety and compliance controls on 1 December 2016. At the meeting the Commission presented the state of play on the revision of Regulation (EC) No 765/2008.

2.3 Stakeholder conference of 17 June 2016

A stakeholders' event was organised on 17 June 2016, to identify the main issues related to the compliance and better enforcement in the Single Market and to identify possible ways forward. 144 participants attended the event, representing businesses (62), national authorities (60) and others (22). The detailed minutes of this conference can be found at: http://ec.europa.eu/DocsRoom/documents/17963.

2.4 Public Consultation

239 replies were received via the online form foreseen during the public consultation. The numbers and percentages used to describe the distribution of the responses to the public consultation derive from the answers under the EU-Survey tool. Other submissions of stakeholders to the public consultation have been taken into account, but without being considered for the statistical representation.

The consultation was divided into five parts. Since only part B1 was obligatory, the other sections were partly answered. Therefore, the average ratio of replies was **80%** for section B2, **66%** for section B3, **80%** for section B4 and **84%** for section B5.

All statistics included in this summary are based on the data gathered from the replies for each section. Detailed statistics for each category can be found in Annex 2 of the Impact Assessment.

Businesses were strongly represented (**127**), followed by public authorities (**80**), and citizens (**32**). More specifically for businesses, **49%** of them represent product manufacturers, **21%** product importer / distributors, **8%** product users, **5%** conformity assessment bodies, **1%** online intermediaries and **16%** other.

Concerning the geographical distribution of responses, all countries were represented except for Latvia, Luxembourg, Malta, and Liechtenstein. The majority of respondents (**116**) exert their activities only in their country of establishment.

2.4.1 Product compliance in the Single Market and deterrence of existing enforcement mechanisms

The majority of respondents (**89%**) consider that their products are affected by non-compliance with product requirements laid down in EU harmonisation legislation.

However, **45%** of the respondents are unable to estimate the approximate proportion of non-compliant products for their sector. This percentage is approximately equal for all type of respondents.

80% of businesses participating in the consultation confirm non-compliance has a negative effect on sales and/or market shares of businesses complying with legal obligations. Many businesses (**42%**), however, are unable to estimate their approximate loss in sales due to non-compliance.

As to the most important reason for product compliance in the Single Market, **33.47%** of the respondents consider that it is about a deliberate choice to exploit market opportunities at the lowest cost, followed by a lack of knowledge (**26.78%**), a technical or other type of inability to comply with the rules (**10.88%**), ambiguity in the rules (**10.46%**) and carelessness (**9.62%**).

All types of respondents have experience / knowledge of instances where market surveillance authorities lacked sufficient financial and human resources as well as the technical means to carry out specific tasks. Nevertheless, **67.36%** of the respondents could not estimate the approximate financial resource gap of the national authority.

Regarding the increase of resources for market surveillance activities, although two of the three solutions receive a unanimous acceptance by the respondents, for the third one, namely that market surveillance authorities should levy administrative fees on operators in their sector to finance controls, the results are contradictory. **55.91%** of the businesses and **40.63%** of the consumers and others strongly disagree with this option, while **50.00%** of the public authorities agree with it (15% strongly agree and 35% agree).

Stakeholders have similar views as regards the effective use of resources for market surveillance activities.

Many respondents (**46%**) agree that market surveillance does not provide sufficient deterrence in their sector or that it provides deterrence to a moderate extent (**34%**) and that the options proposed by the Commission would improve the deterrence of market surveillance action.

2.4.2 Compliance assistance in Member States and at EU level

This section of the questionnaire was optional, so the average ratio of replies came up to **80%** (approximately **190** replies per question).

There is a consensus on the fact that **sometimes** it is difficult to find but also understand the correct information on the technical rules that products need to meet before they can be placed on the domestic and on other EU markets.

The approach taken by respondents to look for support and information on technical rules that products need to meet **slightly** differs according to the type of respondent. The majority of respondents prefer to refer to the information available on Commission websites. Regarding the approaches that should be followed by national authorities to reduce the level of non-compliant products on the market, the respondents consider that the best approach is the **combination of information, support and enforcement by the public authorities**.

2.4.3 Business' demonstration of product compliance

This section of the questionnaire was optional, so the average ratio of replies came up to **66%** (approximately **158** replies per question).

Businesses were asked to provide answers on how they supply information about product compliance. Approximately **30%** of the respondents consider that the proposed options **are not applicable to them**.

A large majority of respondents strongly agrees or agrees that a broader use of electronic means to demonstrate compliance would help to reduce the administrative burden for businesses (**70.62%**), reduce administrative costs of enforcement for authorities (**65.14%**), provide/allow information to be obtained faster (**82.29%**), and provide more and up-to-date information to consumers/end users (**68.00%**).

2.4.4 Cross-border market surveillance within the EU

This section of the questionnaire was optional, so the average ratio of replies came up to **80%** (approximately **190** replies per question).

Most of the respondents (**91**) were unable to estimate the approximate proportion of products placed on the market by manufacturers or EU importers located in another EU Member State.

Public authorities believe that businesses contacted do not reply to requests for information/documentation or for corrective actions, while for **businesses** the main difficulty is that authorities find it more costly to contact businesses located in another EU Member State.

Concerning, the exchange of communication between national authorities in the EU Member States, the majority of respondents stated lack of opinion / experience (**33%**) while **25%** of the respondents consider that national authorities rarely restrict the marketing of a product following exchange of information about measures adopted by another authority in the EU against the same product.

Additionally, as to the adequate mechanisms to increase the effectiveness of the market surveillance in the Single Market, the results showed an extremely large support **for more exchange of information and discussion among authorities**, but also for **close coordination between Member States and simultaneous applicability of decisions against non-compliant products.**

2.4.5 Market surveillance of products imported from non-EU countries

This section of the questionnaire was optional, so the average ratio of replies came up to **84%** (approximately **201** replies per question).

Many respondents (**39%**) were unable to estimate the approximate proportion of products imported from non-EU countries in their sector. However, **21%** of them indicated that the proportion of products imported from non-EU countries is **more than 50%.** At the same time, **88%** of the respondents believe that the products in their sector imported from non-EU countries are affected by non-compliance.

As to the country of origin of often non-compliant imported products, China lead with **137** replies, followed by India (**30**), Turkey and United States (**18**) and Hong Kong (**17**). Finally, the most preferred options in taking actions against non-compliant products traded by businesses located in a non-EU country were the need for more coordination of controls of products entering the EU between customs and market surveillance authorities (**88.27%**).

2.5 Targeted Consultation conducted by the Contractor

In general, **all stakeholders consulted** through the targeted surveys and interviews **uniformly recognise the effectiveness of the Regulation needs to be improved**.[1] Around half respondents declare that the **dimension of product non-compliance** has not changed after the entry into force of the Regulation. While this is true for public authorities, respondents from the private sector perceive that product non-compliance has increased. Most economic operators, industry associations and civil society representatives state to experience discrepancies across Member States in terms of market surveillance. Such discrepancies have more negative impacts in terms of hindering the **free circulation of goods**, influencing **market behaviour, reducing the safety of products** and **raising costs** for public authorities and economic operators to comply with the Regulation. Among all respondents, only customs have a positive opinion on the **adequacy of current border controls**. In general, **industry representatives want to be more involved** in market surveillance activities. According to respondents, the **efficiency** of the Regulation could be improved by solving the existing discrepancies in its implementation.

The majority of respondents **confirm the Regulation's relevance**, this being confirmed by all economic operators and a large part of customs and coordinating authorities. However, the Regulation's relevance can be challenged by its low capacity to **address emerging issues.** All stakeholders agree that the Regulation is not able to tackle issues deriving from **online sales**. **No stakeholder category reported major issues in term of coherence** of the Regulation, both within its provisions and with other legislations relevant for market surveillance.

All stakeholders recognise the EU added value of the Regulation, which enhanced the **free movement** of goods and **legislative transparency**. The **harmonisation of rules** and **cooperation between Member States** are also reported as benefits by all. Different categories also argued that the Regulation can establish **a level playing field across businesses in the EU**.

2.6 Informal consultation of SMEs at the Small Business Act follow-up meeting with stakeholders in December 2016

The Commission presented the reflections on the possible options to address the problem of non-compliance and asked for feedback. Businesses representatives confirmed that SMEs are also hit by non-compliance like bigger companies.

3. FEEDBACK TO STAKEHOLDERS

The consultation processes provided a wide range of views regarding the functioning of market surveillance in terms of what has worked well and what has not worked so well, seen through the eyes of these stakeholders. The meetings with the stakeholders provided an early opportunity to promote the engagement of the national authorities, thus enhancing the chances of a good response rate.

The general objective of this initiative is to reduce the number of non-compliant products in the Single Market by improving at the same time incentives to comply and effectiveness of market surveillance..

[1] All questions of the Public Consultation were basically related to evaluating the effectiveness of the Regulation.

The considered options covered in order of increasing ambition and EU coordination and action: (1) Baseline, (2) Improvement of existing tools and cooperation mechanisms; (3) in addition increased deterrence effect to enforcement tools and stepped up EU coordination and (4) further added-on centralised EU level enforcement in certain cases.

The preferred option (3) includes:

- the extension of Product Contact Points advice role to businesses and ad-hoc public-private partnerships;
- digital systems through which manufacturers or importers would make compliance information available to both consumers and market surveillance authorities and common European portal for voluntary measures;
- regime of publicity for decisions to restrict the marketing of products, fine-tuning authorities powers notably in relation to on-line sales imports from third countries, recovery of costs of controls for products found to be non-compliant;
- stricter obligations for mutual assistance and legal presumption that products found to be noncompliant in Member State A are also non-compliant in Member State B;
- Member States' enforcement strategies setting out national control activities and capacity building needs and an EU Product Compliance Network providing an administrative support structure to peer review Member States' performance coordinate and help implementing joint enforcement activities of Member States.

The measures underlying the preferred option were rated highly favourable across the different categories of respondents in the public consultation. Stakeholders concur on the need for much stronger coordination, more resources and efficient use of resources for market surveillance and more effective tools to improve the enforcement framework for controls within the Single Market and on imports into the EU. A more pro-active approach to prevent non-compliance by providing information and assistance to economic operators is also supported by stakeholders. On a more detailed level some variations occur between the views of authorities and businesses on the most appropriate form of the digital compliance system or the specific powers and sanctions; these concerns have been integrated in the assessment.

More information on the different options, on those retained and on the views of the stakeholders can be found in Sections 6 and 7 of the Impact Assessment.

4. FEEDBACK FROM THE EXPERT GROUP ON THE INTERNAL MARKET FOR PRODUCTS – MARKET SURVEILLANCE AND CONFORMITY ASSESSMENT POLICY (IMP-MSG) – 1 FEBRUARY 2016

4.1 Difficulties and challenges for market surveillance for non-food products in the Single Market

4.1.1 Contributions sent to the Commission in accordance with Article 18(6) of Regulation (EC) No 765/2008

Article 18(6) of Regulation (EC) No 765/2008 requires Member States to periodically review and assess the functioning of their market surveillance activities. Such reviews are to be carried out at least every four years and the results are to be communicated to the other Member States and the Commission and made available to the public.

Many of the national reports reviewing market surveillance activities carried out between 2010 and 2013 comment on major difficulties identified. Common challenges mentioned appear to be the following:

1. Lack of sufficient resources for market surveillance.

2. Current control procedures are not suitable for handling products sold online. 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.

3. There is a need to reinforce customs controls. 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. For some Member States there exists a 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).

4. There is insufficient cross-border cooperation in some sectors (i.e. equipment for use in potentially explosive atmospheres, pyrotechnic articles, civil explosives and gas appliances), which is difficult to tackle when relevant economic operators are located abroad. Complications due to the lack of ADCOs for marine equipment and motor vehicles are also mentioned.

5. There is a lack of traceability of information especially when products are imported into the EU by intermediaries located in other Member States

6. There is the difficulty of dealing with products from third countries sold via informal channels (marketplaces), and the ineffectiveness of market surveillance techniques in this case.

7. 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;

8. The non-existence of test laboratories makes conformity assessment difficult and costly.

9. There is a lack of knowledge amongst economic operators about applicable product rules. In some sectors formal requirements such as technical documentation and CE marking are disregarded by businesses, possibly due to lack of knowledge or misunderstanding of those requirements.

10. There is a lack of cooperation by certain economic operators and some abuses by businesses of the legal principles concerning the notification of restrictive measures contained in Article 21 (1) and (2) of Regulation (EC) 765/2008.

11. There is 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). Furthermore, there is a demand for a single integrated system since reporting in different information exchange systems is deemed cumbersome and not always suitable.

4.1.2 Future new actions to improve market surveillance – initial suggestions by Member States

At the joint IMP-MSG and CSN meeting on 30 January 2015 the Commission asked Member States representatives to come up with informal suggestions about possible future new actions to improve market surveillance. A Member State suggested that a possible way to increase the availability of resources for market surveillance would be to ensure EU-wide agreements (financed by EU funds), with laboratories having recognised competence in a given domain to which national authorities could send on a pro-rata basis products to be tested.

The question about possible new actions to improve market surveillance was also asked at the meeting of ADCO Chairs that took place on 12 March 2015. Some of the suggested new actions informally proposed during that meeting were the following:

1. Workshops with other ADCO Groups

2. Cooperation between inspectors checking products during use and market surveillance

3. Cooperation with producer countries, especially China

4. Supervision of notified bodies and collaboration with market surveillance authorities

5. More documents to be shared through CIRCA BC

6. Joint actions between directives

7. Feedback on safeguard notifications from the Commission

8. Shorter dates between publication of legislation and guidance

9. Exchange between inspectors across Member States

10. Easier contacts with economic operators abroad

11. Team building, networking, exchange of experience

12. More information on what is happening in other fields

13. Review of notified bodies' certificates

14. Exchange of ADCO members

15. Convergence of ICSMS and RAPEX platforms

16. E-commerce: administrative requirements for information to be displayed on websites, legal powers for authorities to carry out test purchases, campaign aimed at consumers

17. More responsibilities for importers

18. More resources

19. Applicability across the EU of sale bans issued by national authorities.

4.2 Questions to the Members of the IMP-MSG Group and overview of replies

On 2 December 2015, the members of the IMP-MSG group were invited to provide input on the following questions:

(1) Do you share the analysis of the problem of non-compliant products in the internal market made by the Commission in the Single Market Strategy? Is there any other relevant problem to take into account?

(2) What action do you consider necessary to tackle those problems?

(3) What action is necessary to address the difficulties faced by national authorities that have emerged in the context of the national reviews according to Article 18(6) of Regulation (EC) 765/2008?

(4) What should be the main priorities when it comes to improving market surveillance and to generally reducing non-compliance in the internal market?

Thirteen Member States provided answers to the above questions.

As to question (1) most of these Member States share the analysis carried by the Commission. The following additional qualifications are noted:

A Member State also stresses the problems of (i) several pieces of legislation applicable to the same product which makes it more complex and difficult for both economic operators and authorities to maintain the overall picture, (ii) uneven quality and quantity of market surveillance activities in different Member States, which could be addressed by establishing common standards, (iii) limited availability of resources.

Another one notes that the problem of non-compliance is to be addressed to ensure a level playing field among economic operators, although accidents due to non-compliance are limited in number overall.

Furthermore, there is no solid proof that the number of non-compliant products is increasing, as statistics on market surveillance differ from statistics on non-compliance that could result from market research.

Similarly, two other Member States note that since market surveillance inspectors focus on areas where non-compliance is expected to be high, results of inspections are not representative of the level of non-compliance in general. Denmark stresses that it is not possible to measure the percentage of non-compliant products in the market.

Some questions exclusive focus on the non-compliance of products stating that market surveillance should also play a role to ensure that legitimate products do not face unfair barriers to trade.

Finally, another Member State would have appreciated a deeper analysis of if, when and in what ways the impact of varying degrees of market surveillance (or the lack of it) harm consumers, compliant competitors, and Member States as a whole (loss of manufacturing, reduced competitiveness, etc.). Such an analysis could indeed give valuable input regarding when and where a lack of enforcement has the least impact on the different interests that a product rule is designed to protect, which in turn could be used in subsequent Refit procedures with a view to reducing the administrative burden.

The suggestions made by the Member States who responded to questions (2) to (4) have been grouped as far as possible by topics as follows:

4.2.1 Information to economic operators

The **lack of knowledge of product rules on the part of economic operators** is one of the main problems that should be addressed.

Informing the national economic operators – who are sometimes not aware of their responsibilities - about specific legislation and their obligations, is a main priority.

Economic operators probably disregard the rules mainly because of a lack of knowledge, or because they lack the resources to follow up the complicated rules on their own (SMEs).

There is a need to intensify efforts to provide early information to economic operators, especially small and medium-sized enterprises, on existing and future product legal requirements but also to raise awareness amongst economic operators via better channels of communication.

It is also suggested **developing rules and best practices** concerning products to be disseminated via internet and improving information on European regulations on the **websites of the Commission** to make it more educational and useful for economic operators (input by product type, not directive).

If the problem which has been identified is referring to economic operators “in general” the solution has to be Commission-led. This might be done, for example, by revisiting the guidance and how it is made available to them, making changes where appropriate. However, if this refers to specific economic operators the approach also has to be specific, and it is more likely to fall to individual Market Surveillance Authorities and Member States to determine the action which should be taken.

In addition, the Commission does not have sufficient manpower to handle a **'first port of call'** to address businesses' questions on all areas of product legislation, which would **require a huge amount of work**. An **eLearning system** is proposed for raising awareness and

educating economic operators through graphic interfaces, and access to applicable standards and conformity assessment procedures, and a "10-20 questions card" for importers to ask when they buy goods overseas.

4.2.2 Simplification of product legislation; alignment between legal requirements and verification procedures by MSAs

Legislation should **set out economic operators' obligations more clearly** and it should be possible to make a clear distinction between basic non-compliance and more serious safety issues. Legislation needs to be simplified and updated.

As regards future legislation, there is a suggestion reflecting on how to **include** the necessary **new rules in existing legal acts** rather than developing new (unknown) specifications but also to better take into account the concerns of market surveillance authorities during the legislative process: the **feasibility of checking specific requirements** and the foreseeable costs of those requirements should be assessed in the development stages of legislation.

The **weakness of verification procedures** in some sectoral legislation is also pointed out. Even when a Member State performs verification tests, the results of these tests may turn out to be inconclusive, because of the unreliability of the results when the tests are replicated, and/or because of ambiguities in dealing with those results. A comprehensive “fitness check” on verification procedures based on established best practice would be useful. For example: a wet-grip-in-tyre labelling regulation where the test method seems to be unsuitable to providing sufficient accuracy (actually the 2sigma-interval of reproducibility uncertainty covers 3 grading classes). Technical requirements for verification of **big products** at the manufacturers site, for instance by means of witness-testing during factory acceptance tests, should also be definitively introduced.

4.2.3 Coordination of market surveillance at EU level

The need for closer cooperation and exchange of information is generally acknowledged. Specific proposals are made with respect to the use of current tools or to the need for additional forms of cooperation.

4.2.3.1 ICSMS and RAPEX

The importance of the development of the **ICSMS and RAPEX** systems for communication between all authorities involved in market surveillance (market surveillance authorities of all Member States, COM and, where appropriate, customs authorities) is stressed. ICSMS should be used consistently by Member States in all areas of legislation while interfaces with national systems should be provided. The creation of single system for exchange of information has also been requested but also the idea of fusion between ICSMS and RAPEX platforms to avoid the double encoding of data; however, this should take into account the fact that the RAPEX system has been used for a long time by all stakeholders.

The focus of the Commission’s wording on the Single Market Strategy is on working better together, with better sharing of information. In this regard Member States could make better and more consistent use of ICSMS; they recognise that this is a medium- to long-term issue, and one which might require funding/support from the Commission in order to make it work – in particular for those Member States who do not use the system.

There is a need for closer cooperation between surveillance authorities in Member States and between surveillance and custom authorities, and between surveillance authorities and notified bodies, and suggests it would be good to converge the ICSMS and RAPEX platforms, so that all information can be in one platform.

4.2.3.2 ADCOS and IMP-MSG groups

The role of **ADCOs** should be revisited and clarified (many discuss policy issues rather than focussing on issues related to technical cooperation, for example), and absences from meetings/participation should be marked. The Commission desk officers for the relevant directives should also take a stronger role in encouraging attendance/participation. Furthermore, the European Market Surveillance Forum, which was proposed in the "Regulation on Market Surveillance", would be a positive way of addressing this issue.

Member States welcome the proposal mentioned in section 3.2 above relating to workshops with other ADCOs. Similarly, a Member State suggests a better use of ADCOs to improve coordination, exploit synergies and avoid duplication. Furthermore, it suggests that the **IMP-group** should develop a shared understanding of the horizontal rules and promote more interaction between the market surveillance authorities of the Member States in the different fields of law by means of visits, joint actions, etc.

There is also a proposal devoting an extra IMP-MSG meeting to the exchange of best practice. ADCOs should contribute to the meeting by reporting on experience accumulated during their earlier joint action projects.

4.2.3.3 Cross-border cooperation

The need for consistent implementation of the **guidelines on cross-border–cooperation** is stressed, 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. Furthermore, a Member State 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.

There is also a need for **guidance on cross-border cooperation** to improve and optimize the results of authorities' actions. To achieve better results in trans-border cooperation between the Member States, in cases of non–compliant products a **contact points list for each product group** should be prepared which could provide fast and easily accessible communication.

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.

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.

It would be useful for Member States to receive **more feedback on safeguard notifications**. In general, more cooperation and exchange of information is needed at EU and **national level**.

'Language borders' are considered as the main obstacle to day-to-day cooperation among authorities.

4.2.4 Harmonisation of market surveillance practice across Member States

There is a suggestion developing **common European standards on the quality and quantity** of their market surveillance activities.

The development and publication of **guidelines and best practices** on market surveillance in general is welcomed as a means to achieve the consolidation of the procedures of the EU market surveillance authorities in many problematic areas.

Publication of guidance documents would considerably help the harmonization of market surveillance in Europe as they would help inspectors and economic operators to interpret and correctly apply the directives and regulations. Shorter dates for the publication of guidance documents are required.

In addition, it is proposed to encourage via EU funding the **participation of** more **Member States in common projects** in which different products can be tested in order to achieve more representative results, and the dissemination of all information, analysis, results and decisions taken for this specific product group after a project is completed.

According to feedback from domestic surveillance authorities having taken part in international cooperation projects, they have provided a good overview of the practices of other countries and have contributed to carrying out uniform surveillance in different Member States.

The problem of limited human resources and **training opportunities** has been pointed out **and** a suggestion was made to promote the **exchange of inspectors** across Member States and closer cooperation among surveillance authorities to improve knowledge and exchange experiences.

Training programmes and exchange of experience between Member States' inspectors are also proposed.

The exchange of experience and best practices between inspectors across the Members States is very important to improve the harmonization of market surveillance in Europe. Regular exchanges of officials could be a solution.

Similarly, exchange of inspectors, teambuilding and networking are endorsed by other Member States.

Moreover, the **Product Safety & Market Surveillance Package** has to be finalized, since it will enable better coherence of the rules regulating consumer products and will improve

coordination of the way authorities check products and enforce product safety rules across the European Union.

The current delay with revision of the Market Surveillance Regulation is considered to be problematical, and stresses the importance of a **horizontal legislative framework on market surveillance**.

The Commission should provide more information on what **instruments are available to the authorities** and how they are used in practice (frequency, criteria for deciding what tools to use in different cases), so that the barriers for putting non-compliant products on the market might be the same for all Member States.

4.2.5 Better control of products imported from third countries

There is a need to strengthen border controls, where the goods are centralised before being dispatched throughout the EU. This could be achieved either by **reinforcing the role of customs** or by ensuring detailed cooperation with market surveillance authorities.

More effective cooperation between market surveillance and customs authorities should also be achieved via a **clearer definition/better alignment of the tasks performed by the customs authorities** in order to ensure compliance with the European product rules. The need for **improved communication** between the customs and market surveillance authorities is also stressed.

Controls would improve if there was **better communication between authorities**. This might potentially be done through an electronic forum which authorities could use to discuss and agree issues which arise on products, and better guidance on the application of the directives concerned and the procedures which need to be followed.

Both the importance of cooperation between customs and market surveillance authorities and the importance of **cooperation among customs** on market surveillance matters are mentioned.

Customs should be enabled to request **manufacturer and type designation as part of the customs declaration**. Furthermore, combined nomenclature (**CN**) **codes** must be amended to be also useful for market surveillance purposes.

There is a need to improve border control of non–compliant products and to ensure **regular exchange of information** on results of controls and lists of products not released for free circulation.

Another problem is that, while many products come from outside the EU, authorities can do little against those manufacturers. Products are often placed on the EU market through "once only importers" that disappear after one or two years, so even there we can do little. **Strong measures against** these **products** are needed **to target the non EU economic operator**. For example, a strong message could be sent when all products need to be recalled if there is no technical file present.

A Member State supports the **strengthening of responsibilities of importers**, especially when the manufacturer is outside the EU. For the supervisory authorities it is especially helpful to have a partner in the EU, which has full responsibility and all the technical

documentation. According to France this could possibly be done by creating a concept of "first placer on the market", which would need to be an economic operator on the EU territory (manufacturer, agent or importer if the manufacturer outside the EU).

Improving the opportunities for the European market surveillance authorities to impose **penalties on operators in third countries** by means of agreements between the EU and third countries was also pointed out. It was also proposed to have a sustainable **education** strategy on the existing European rules in third countries that export mainly to Europe but also some **guidelines** on how to deal with different types of non-conformity (e.g. should a product be rejected at the border if there are shortcomings in labelling?). Measures must be proportionate and consistent across the EU.

4.2.6 Better control of Internet commerce

E-commerce is a great challenge because it's very difficult to trace products which are imported from non-EU countries, and to get the required information from the economic operators who are responsible for the product. A solution would be to improve **market surveillance organisation and strategies** with respect to internet commerce, as well as **broadening the concept of economic operators**.

There is an agreement on the need to incorporate Fulfilment Houses into new legislation (in particular, this might be achieved by including it in a revised Regulation on Market Surveillance), but also the need for **clarity on market surveillance tools** to be used for products bought online, either through guidance documents or legislative action.

The biggest future challenge in e-commerce is the changeover from imports of big consignments (containers with a number of the same products) sent to a distributer vs. a **high number of small consignments** consisting of only one product sent directly to the end user. In such a scenario, market surveillance authorities can only learn of a case when they are involved by customs.

Stronger border controls are also an important factor in terms of control procedures of products sold online. It is also necessary to improve the way authorities **communicate market surveillance work electronically**.

A Member State stresses the need for **authorities' powers to purchase goods** to be tested and to increase the budget for purchase and test of products found **online**. It also notes that MSAs face similar problems to those presented by Internet sales in cases of sales via catalogues (for example for construction products).

As to the products purchased through e-commerce platforms, the need to **develop a method** covering both border control, testing and cross-border communication between market surveillance and customs authorities is noted.

The Commission should capitalise on the opportunity presented by the **revision of the E-commerce Directive** and submit to the competent service the feedback from ADCOs on the needs of market surveillance over the internet.

4.2.7 More and/or better use of resources; tools to support market surveillance authorities

Lack of resources has prevented some authorities from carrying out sufficient market surveillance in some specific sectors. Often, resources are just enough to cover one part of the total market surveillance activities as initially foreseen, so some specific sectors are neglected.

In the current climate it is unrealistic to expect Member States to attribute more funding to market surveillance and that the emphasis should be on how to **use the existing allocation of resource more effectively**, and to consider better and more effective ways to improve market surveillance. The Primary Authority system is considered as a good example of a model which the Commission and other Member States might wish to adopt more broadly.

The problem of limited resources can only be tackled by **streamlining the whole market surveillance process,** from planning to sanction the use of the latest technologies. The following specific suggestions are put forward:

Carry out studies on the inherent risk of the different product categories under the different directives; as an example, see the preliminary study for the next Ecodesign working plan.

Collect information on the number of product categories on the European market: this is one of the crucial factors in determining the "adequate scale of the checks" stipulated in Art. 19 (1) of Reg. 765.

Consider mandatory registration in a product database, as is done partially under the RED, and is envisaged for energy labelling and adaptation of existing registration obligations (WEEE directive) to make them suitable for market surveillance planning.

Facilitate checks at the border by including information on the manufacturer in customs declarations, and amending CN (Combined Nomenclature) to make it useful for market surveillance purposes.

Facilitate documentary checks via a digital compliance system (see below) and by including compulsory photos in the DoC to enable a positive identification of products, EAN (Bar)-Codes and CN-Codes.

Future standardisation mandates, including affordable preliminary testing: only products exceeding the preliminary limits would deserve full testing.

Simplification of reporting duties by providing an integrated IT solution from planning to documentary checks to product identification and reporting.

Market surveillance should be risk-based and should **focus on the minority of non-compliant products that pose a high risk** to persons, livestock and property, while other non-conformities should be addressed by means of education of businesses (see proposals under section4.1 above).

The **lack of notified bodies and testing laboratories** in many technical areas is stressed, which makes testing of products expensive. This lack of laboratories might be a problem **in some sectors**, however **not in all**.

For market surveillance authorities without their own laboratories, budget and administration of external testing costs are a major issue limiting the effectiveness of their surveillance.

Thus, programs **facilitating sufficient laboratory capacity** would be necessary. **EU-wide agreements with laboratories**, to which market surveillance authorities could send products to be tested on a pro-rata basis, would be a perfect solution.

This option of EU-wide agreements with laboratories is also proposed by another Member State, while another one suggests EU **financial support** from the Commission **for laboratory tests** (rather than for 'joint actions', which imply prohibitive administrative costs for MSAs).

On the other hand, the availability of laboratories is not considered as an issue by other Member States, since they believe they have excellent access to a number of test laboratories (test houses) which are also available for other Member States to use. It is not necessary or proportionate to introduce this at a supranational level.

A Member State also stresses the need for: (i) an on-line database where the national market surveillance authorities would be able to download the **harmonised standards**; (ii) **the c**reation of a **rapid advice forum** at EU level; (iii) **legal assistance** from the Commission.

The simplification of the work of national authorities by means of an **easier administration of joint actions** and an integrated reporting system is suggested.

A very serious reshaping by the Commission of the internal approval procedure for joint actions is needed.

Finally, the need for adequate and **reliable 'facts and figures' on products, volumes and economic operators** is stressed as a necessary basis for developing and improving a risk-based approach. This kind of information is also considered useful in showing the importance of market surveillance.

4.2.8 Stronger measures against economic operators; Penalties

There is a need to take **stricter measures against economic operators** and to apply sanctions against economic operators located in third countries.

The **harmonisation of the levels of penalties** has been considered by one Member State, while keeping the possibility to adapt them on a case by case basis.

However, another Member State considers that penalties must remain the **responsibility of Member States** – it is for the Member State to determine what is effective, proportionate and deterrent. It is therefore also for the **Member State to revise its legislation** if it does not provide a sufficient deterrent.

For SMEs especially, limited financial leeway implies **limited ability to react to more deterrence**.

4.2.9 Digital compliance

There should be a **greater emphasis on e-commerce and e-compliance** as there are many more opportunities to take advantage of new and developing technology and make market surveillance more effective (e.g. using e-labelling whereby relevant information is provided online at the point of purchase).

Studying the impact of a possible e-compliance system, which could be useful for strengthening border controls, is supported: the system could be tried for products manufactured outside the EU, for which the technical documentation is more complicated to obtain.

The need for a database where manufacturers upload their declarations of conformity, technical documentation and instructions for **easy reference by market surveillance authorities** is stressed. This database would facilitate data collection of checked products but also provide an excellent basis for information on new and revised products on the market.

By contrast, other Member States **strongly disagree with the suggestion of** developing **a digital compliance system**. Some of the reasons reported are:

- The main problem for market surveillance authorities is not access to documentation but the fact that the documentation received does not always correspond to the actual product. The problem of falsified certificates etc. will not be solved by a digital system.

- The authorities cannot trust the data in the system, because they are supplied by those they are supposed to check.

- While a voluntary system would provide no added value, a mandatory system would create unjustified administrative burdens for economic operators as well as for market surveillance authorities. Compliant economic operators are already put at a competitive disadvantage vis-à-vis rogue traders, who will either report nothing or report false information to the system. Businesses in third countries would more easily escape the application of a mandatory system.

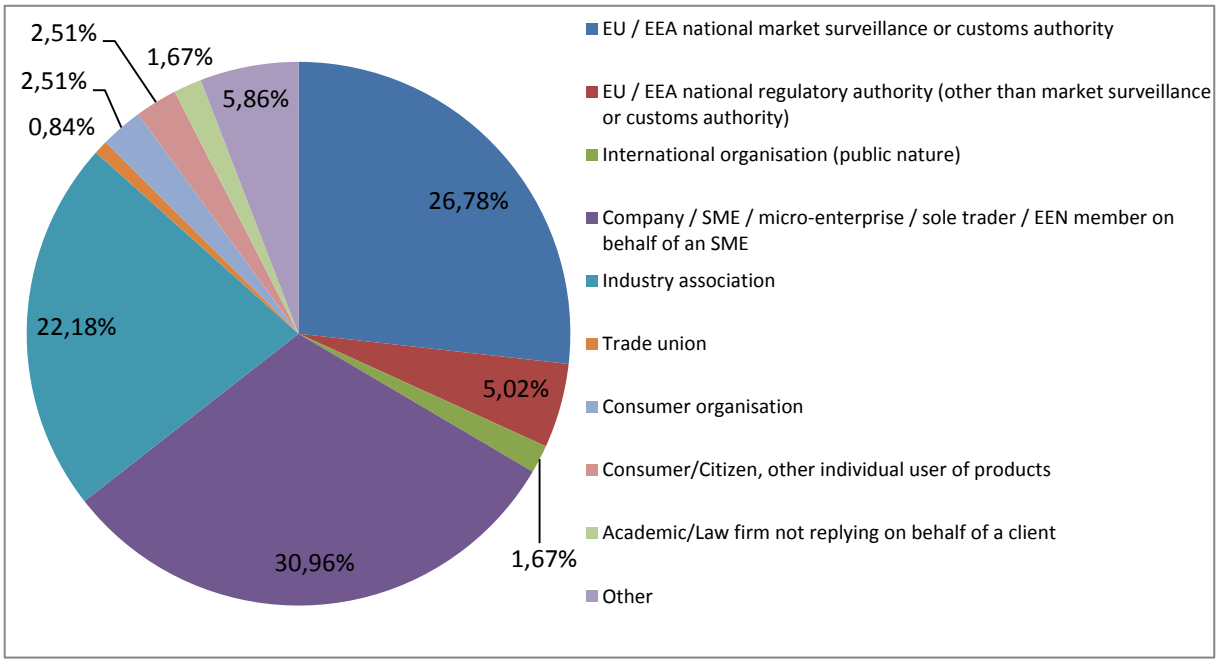
- It could lead to a practice where authorities allow undue time and resources to checking documentation in the database instead of focusing on the actual compliance of products. There is a fear that the emphasis will shift from checking products to checking the data entered in the system, without consideration of the reality of the market.

- There are many questions regarding the confidentiality of data in such a system.

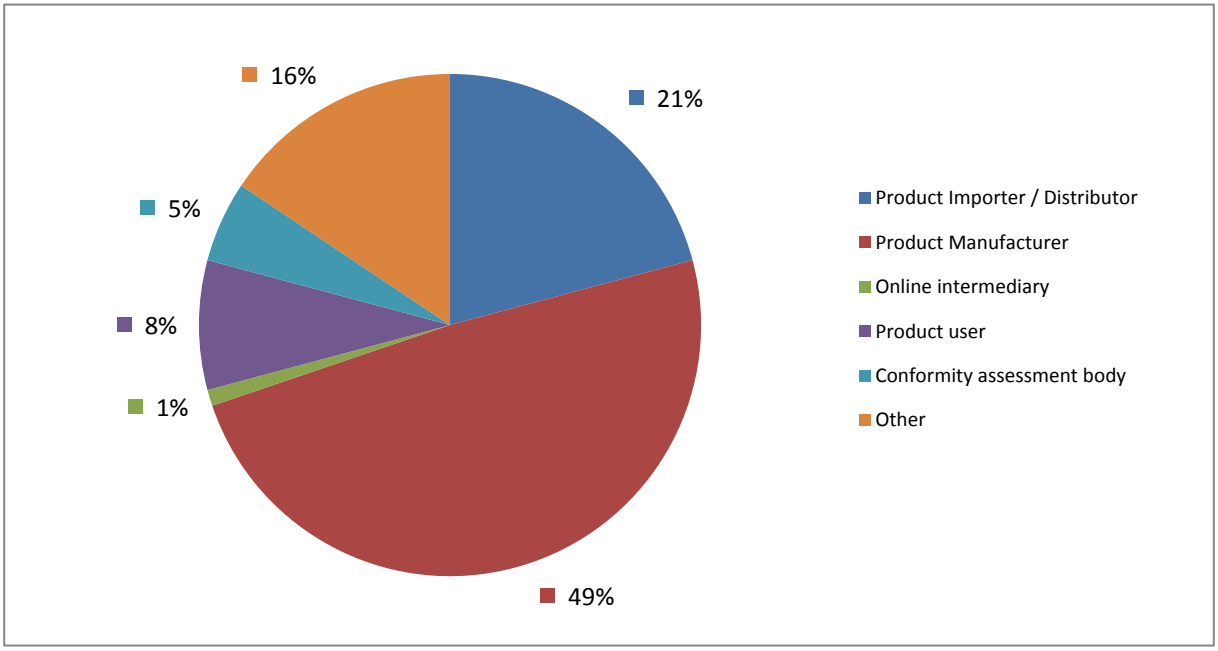
5. DETAILED STATISTICS FROM THE PUBLIC CONSULTATION

A. About you

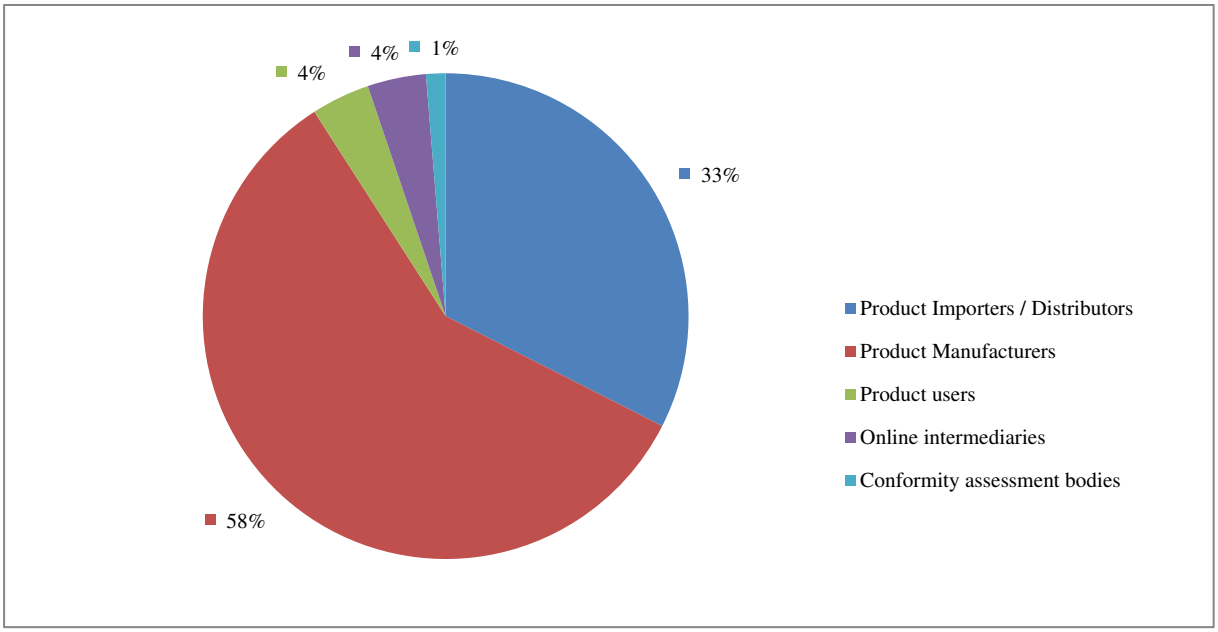
1. Are you replying as:



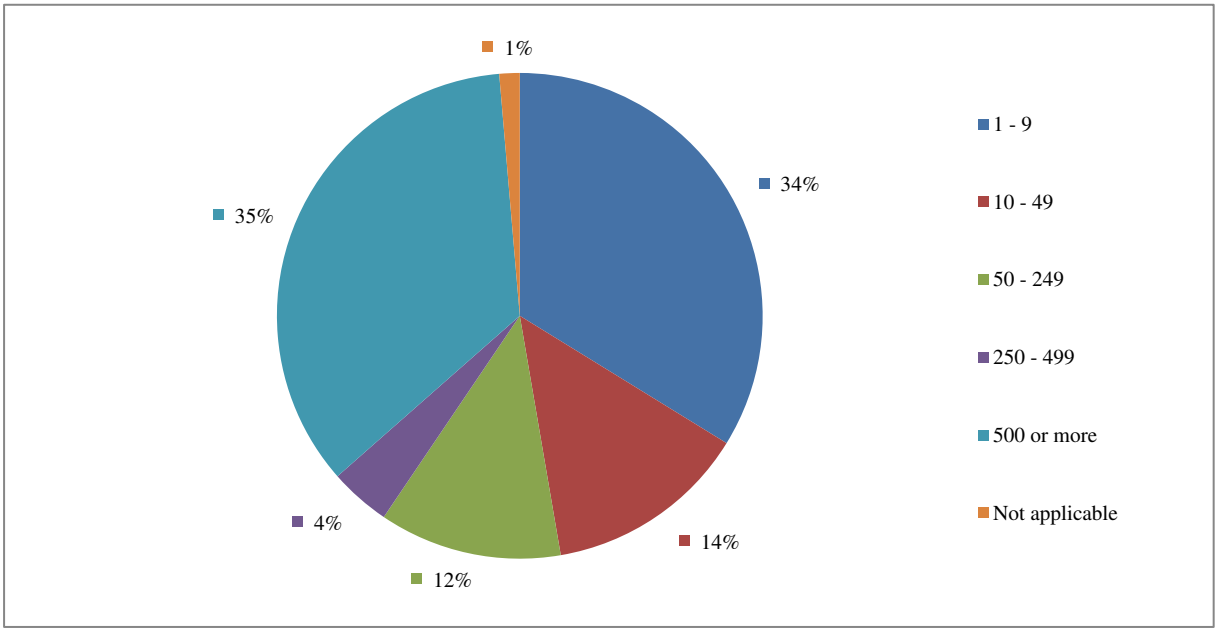
If company/SME/micro-enterprise/sole trader, you are:



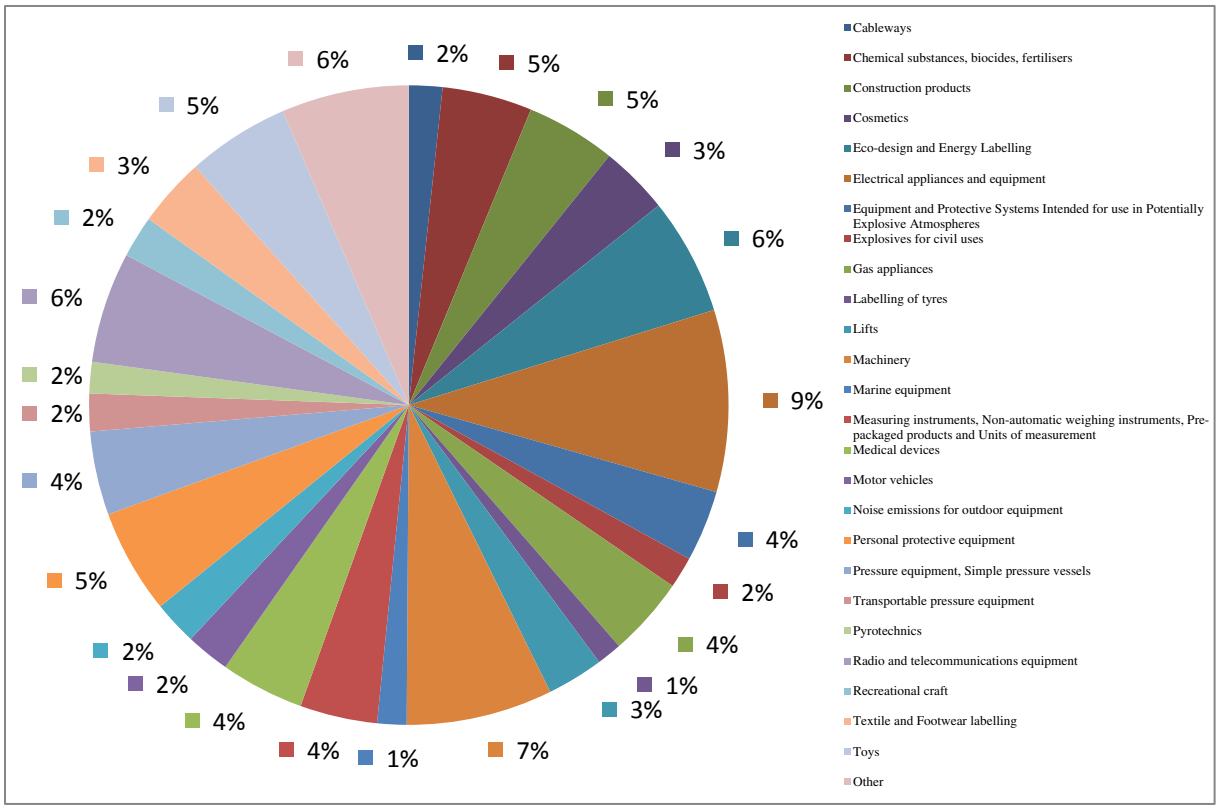
If industry association, you are representing:



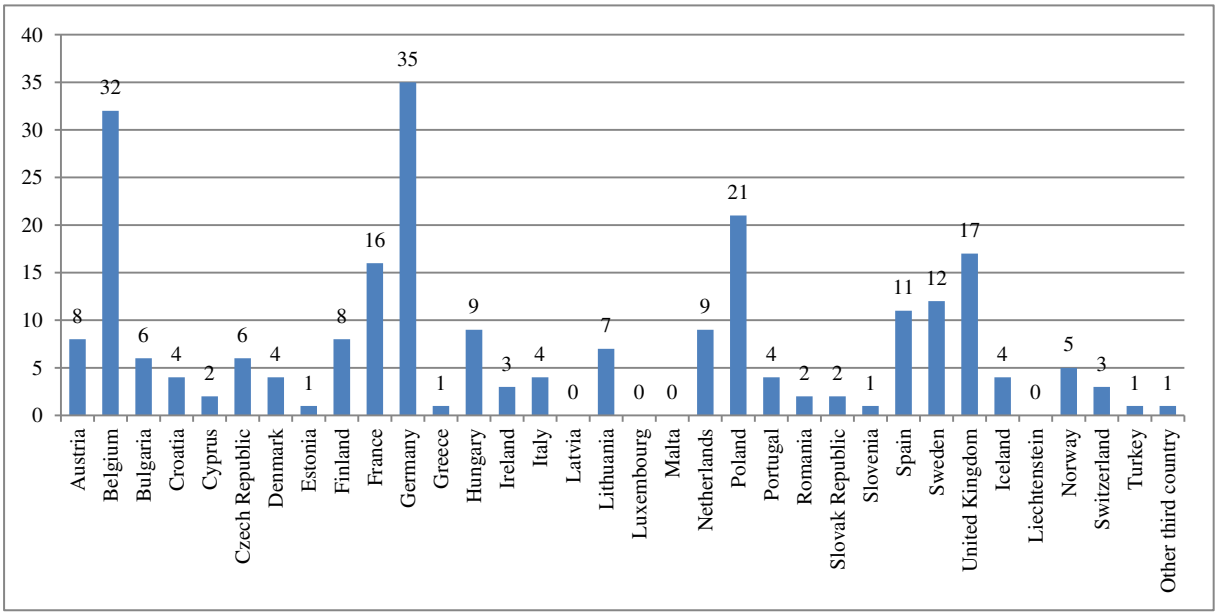
How many employees does your organisation have?



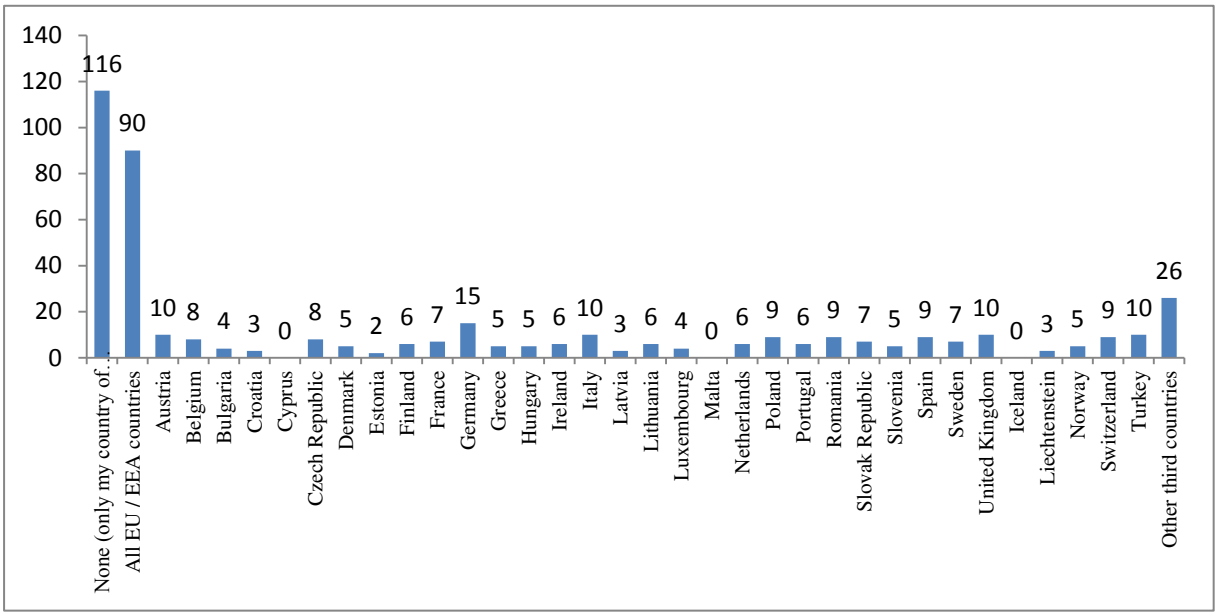
2. Which product sectors do you deal with? (multiple choice possible)



3. Where are you based?

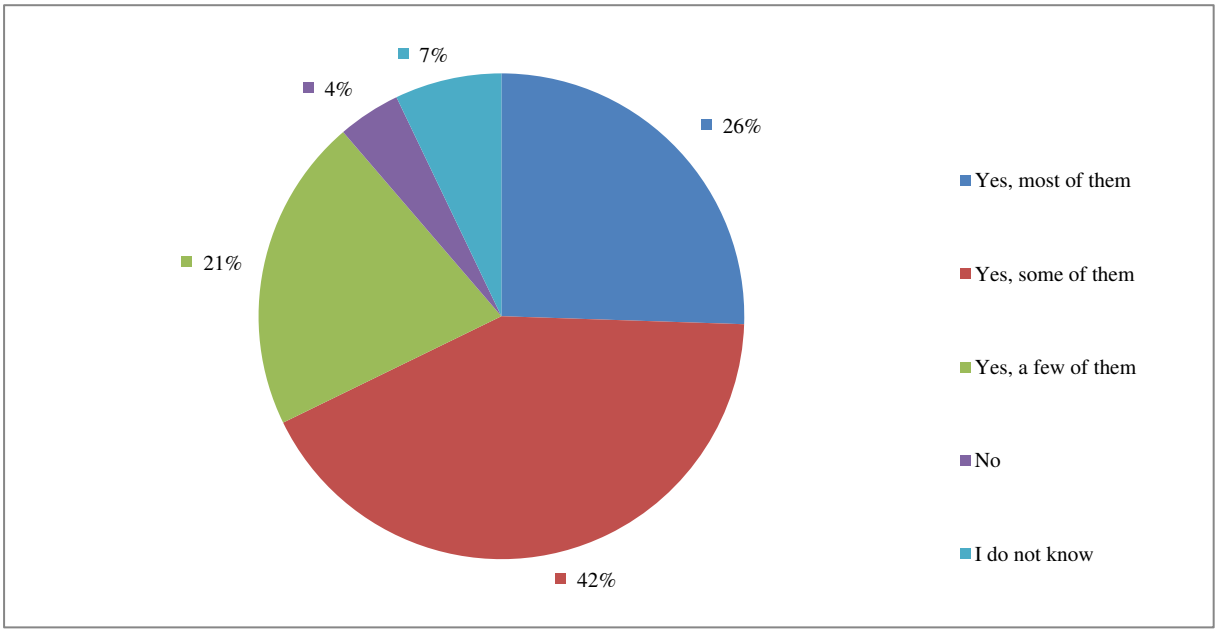


4. In which countries, other than the country of your primary establishment, are you active?

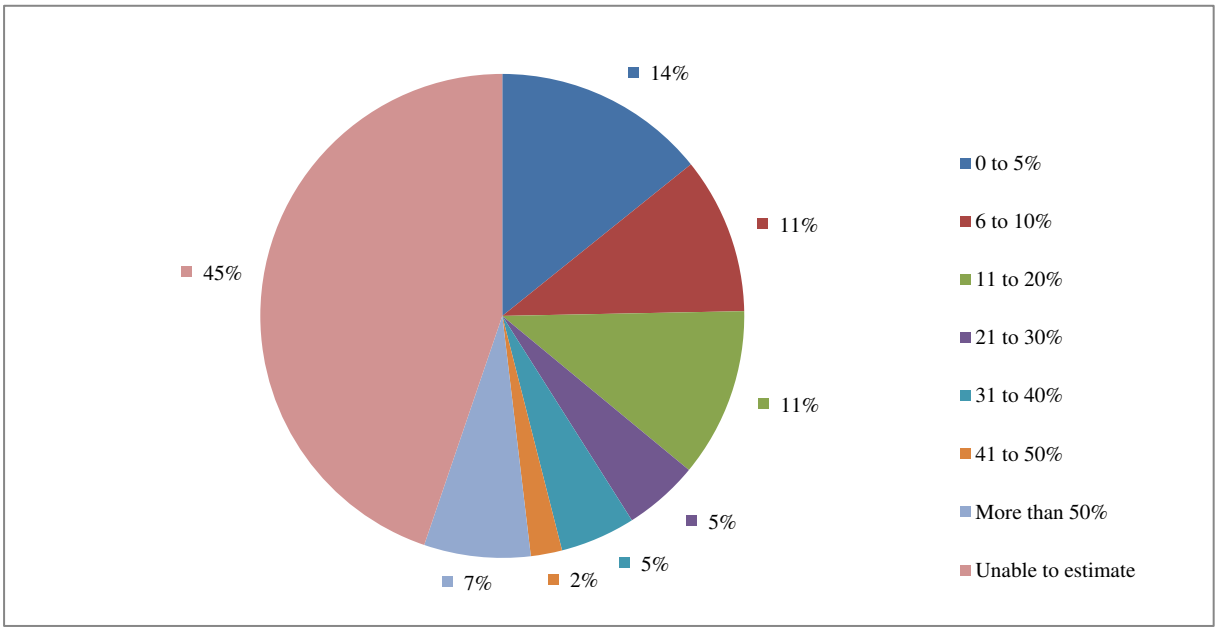


B1. Product compliance in the Single Market and Deterrence of existing enforcement mechanisms

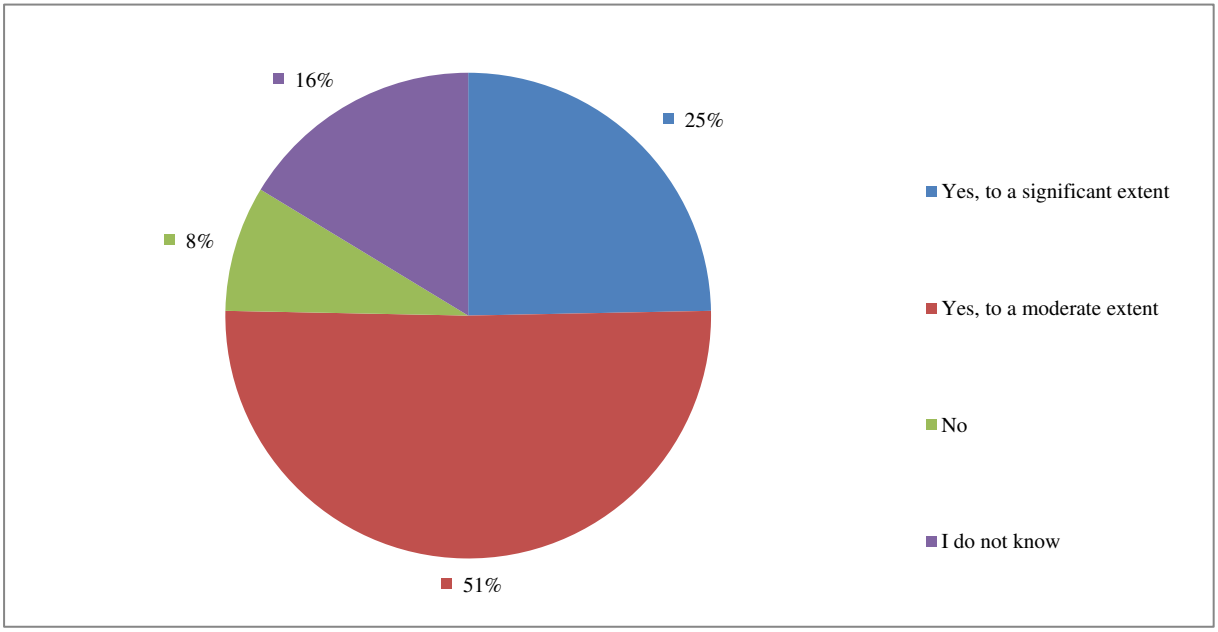
1. Are the products in your sector(s) affected by non-compliance with product requirements laid down in EU harmonisation legislation?



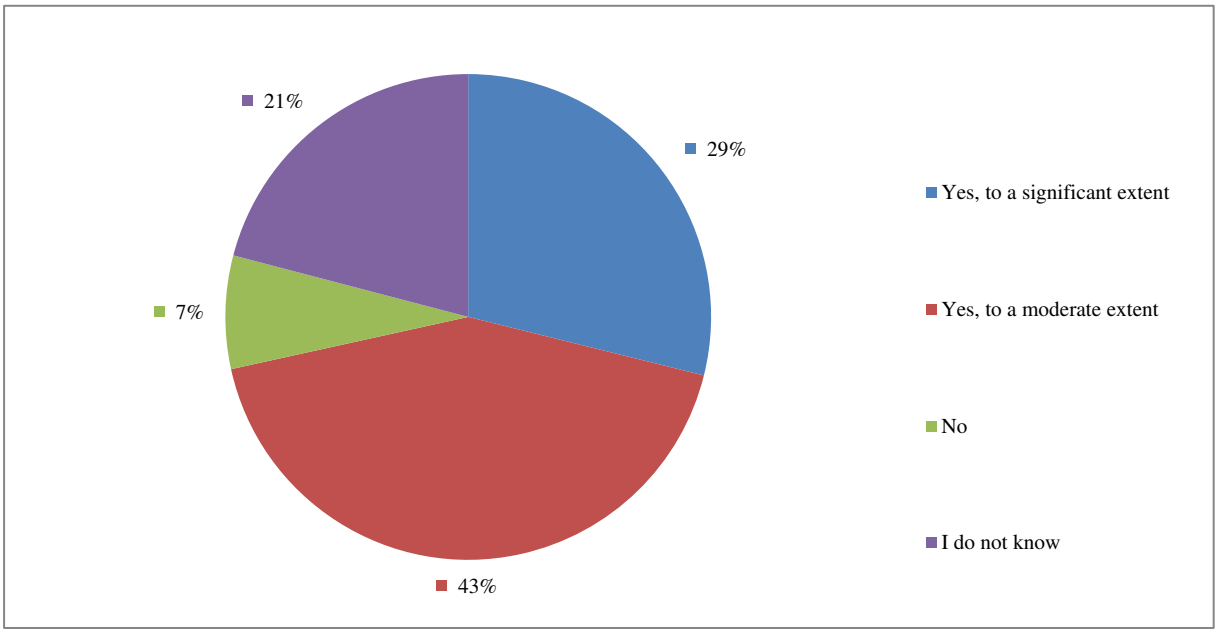
2. What is the approximate proportion of non-compliant products for your sector (product volumes)?



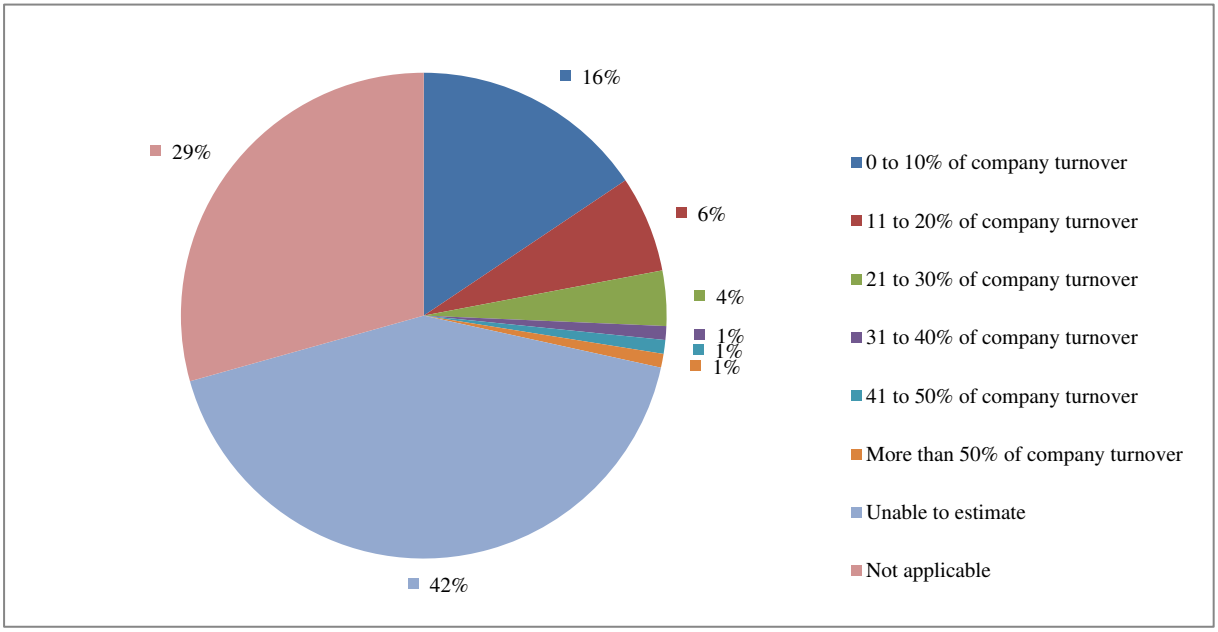
3. Does the problem of non-compliance negatively affect consumers and other end-users in your sector?



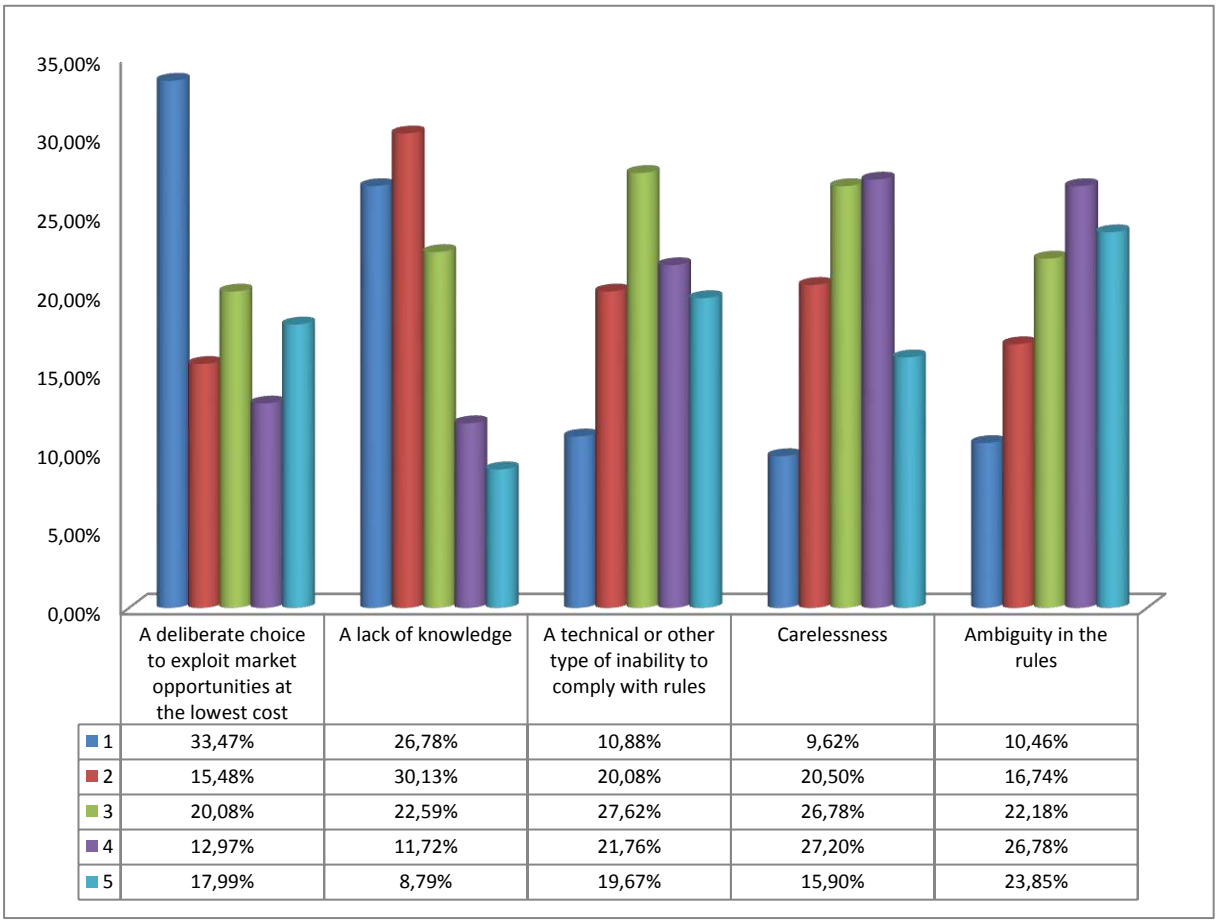
4. Do businesses complying with legal obligations experience negative effects on sales and/or market shares due to the presence of non-compliant products?



5. [Question for businesses only:] What is the approximate loss in sales for your company due to competition from non-compliant products?

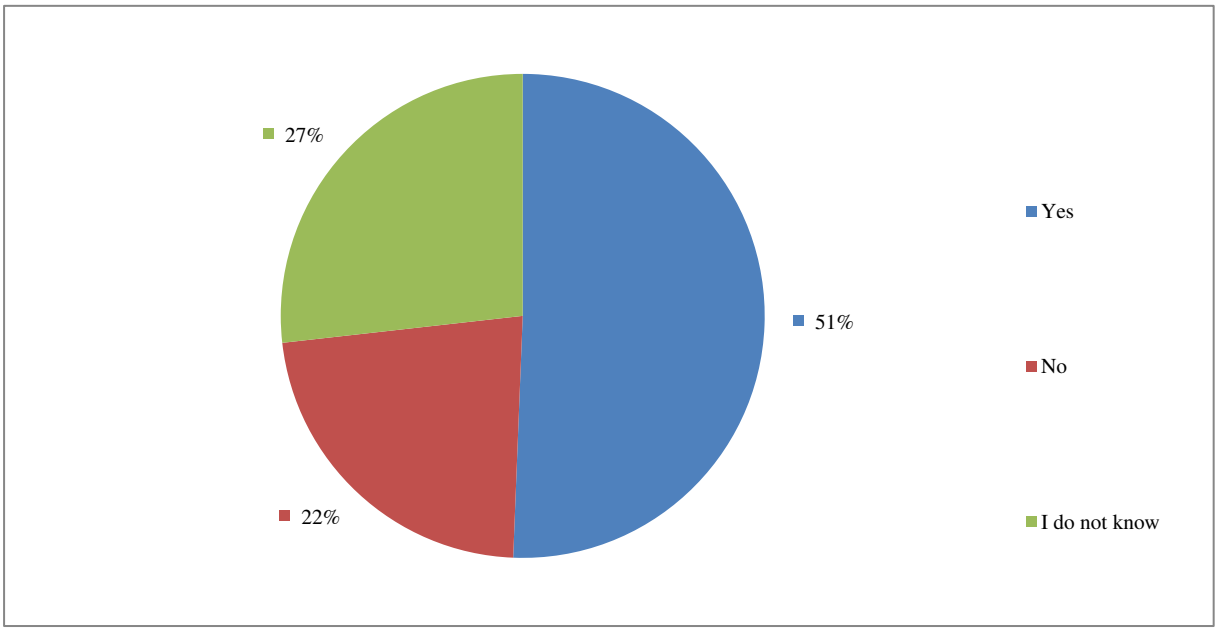


6. What is the main reason for product non-compliance in the Single Market? (Please rank from 1 to 5, 1 being the most important reason):

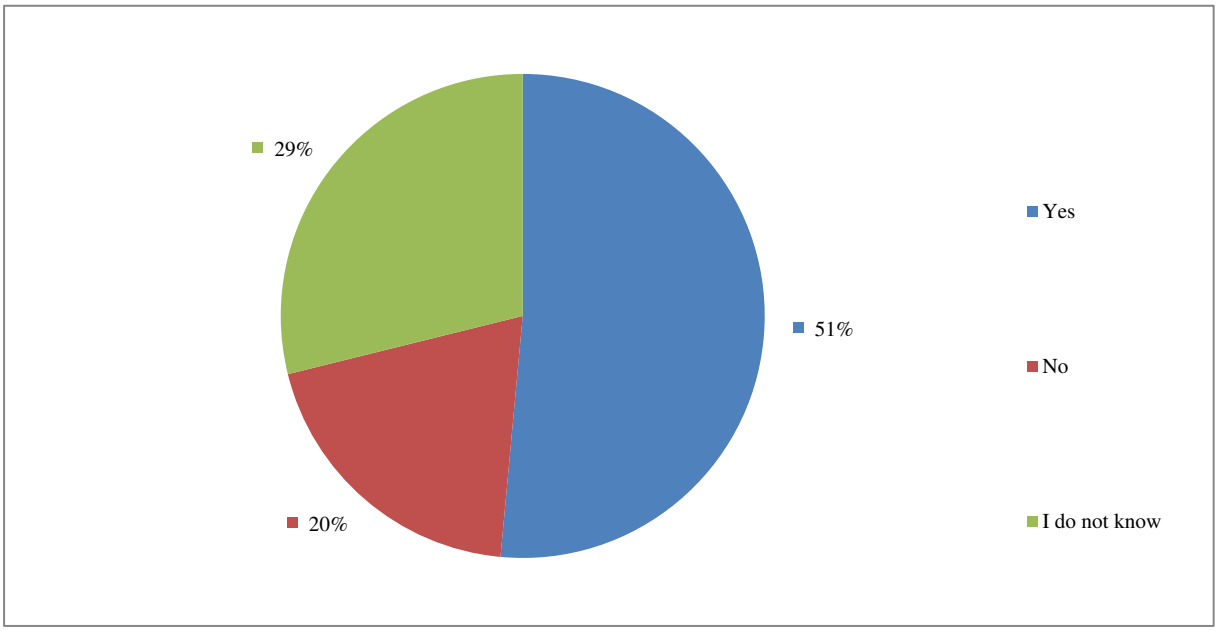


	A deliberate choice to exploit market opportunities at the lowest cost	A lack of knowledge	A technical or other type of inability to comply with rules	Carelessness	Ambiguity in the rules
1	33,47%	26,78%	10,88%	9,62%	10,46%
2	15,48%	30,13%	20,08%	20,50%	16,74%
3	20,08%	22,59%	27,62%	26,78%	22,18%
4	12,97%	11,72%	21,76%	27,20%	26,78%
5	17,99%	8,79%	19,67%	15,90%	23,85%

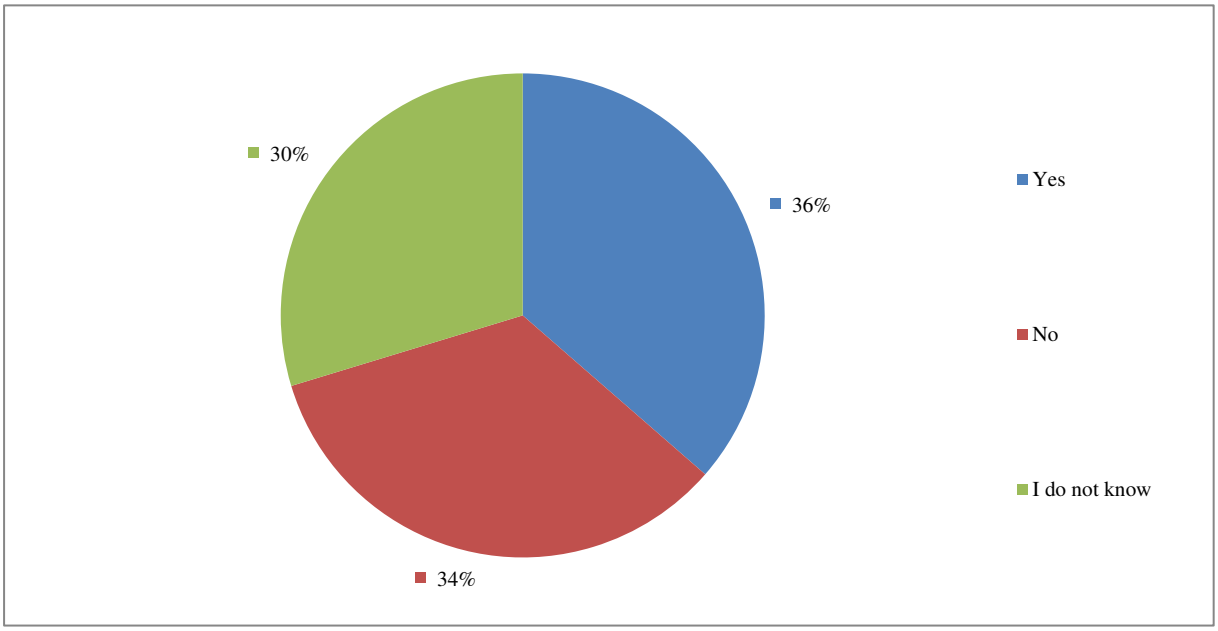
7. Do you have experience/knowledge of instances where a market surveillance authority lacks/lacked sufficient financial resources to carry out specific tasks in your sector?



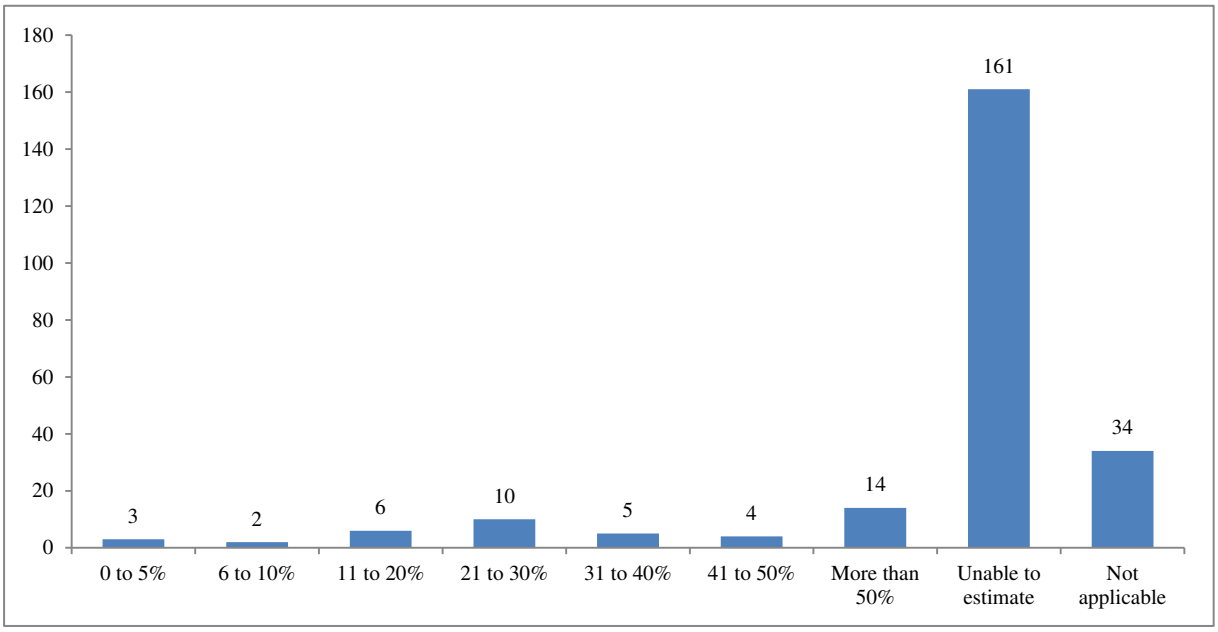
8. Do you have experience/knowledge of instances where a market surveillance authority lacks/lacked sufficient human resources to carry out specific tasks in your sector?



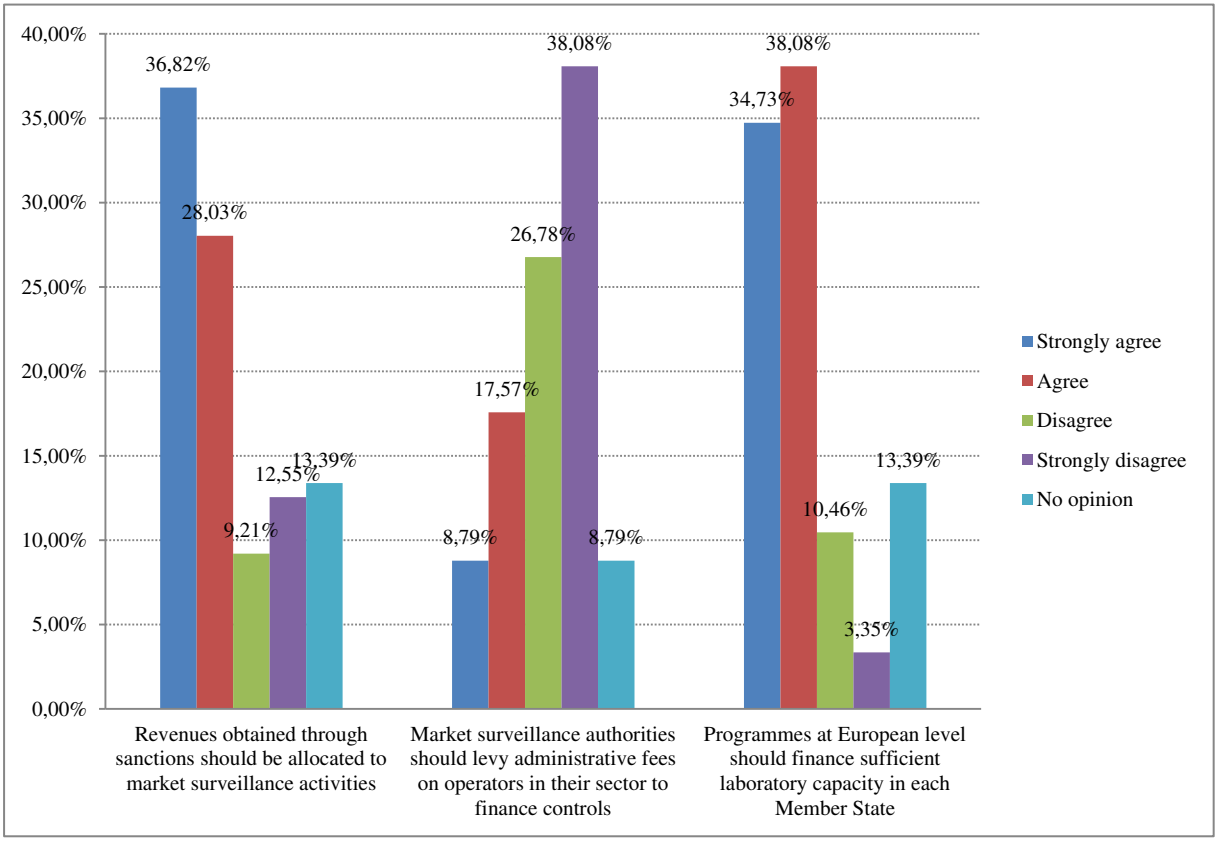
9. Do you have experience/knowledge of instances where a market surveillance authority lacks/lacked the technical means (notably testing facilities) to carry out specific tasks in your sector?



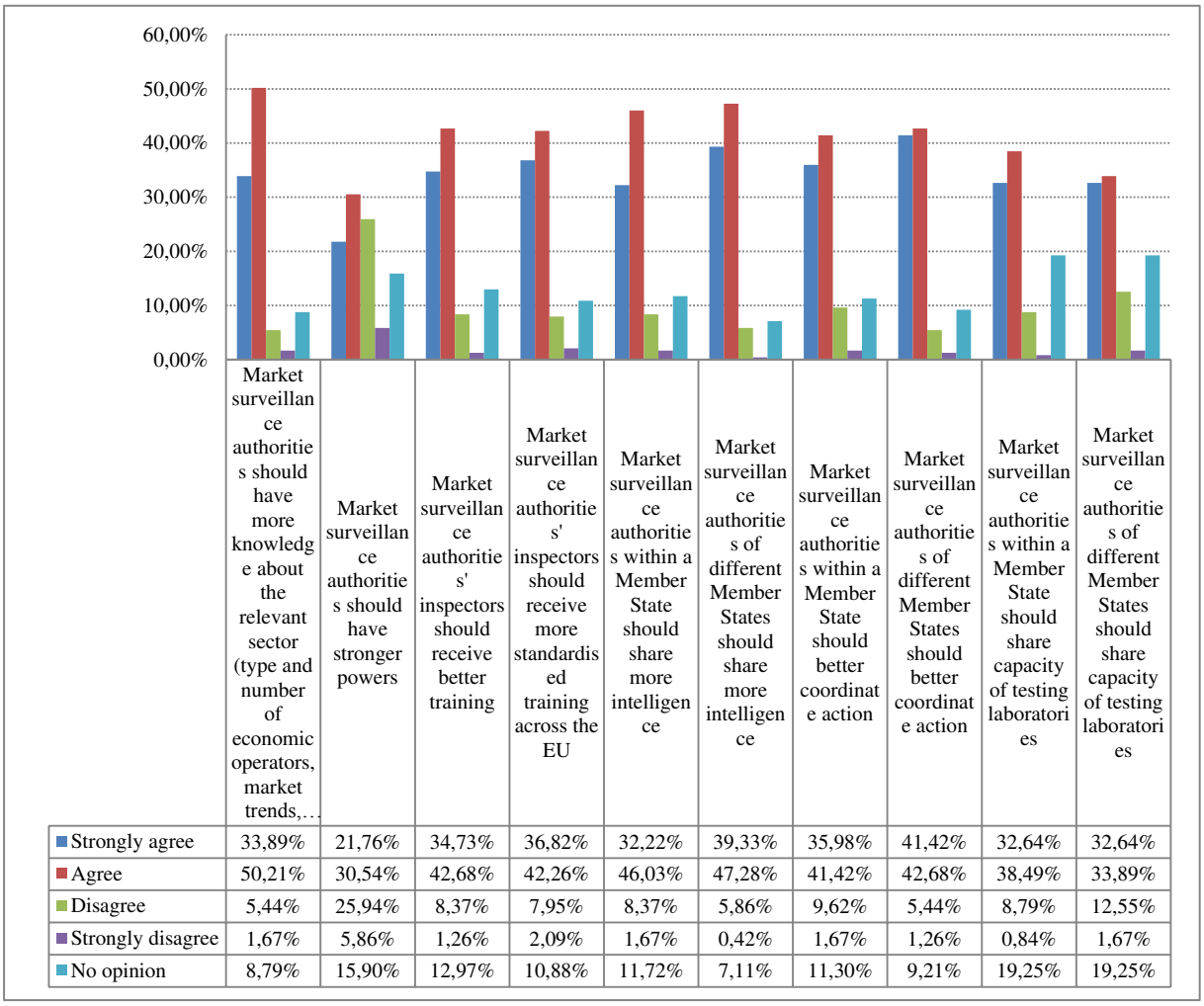
10. What is the approximate financial resource gap of the national authority in your sector?



11. How could the resources for market surveillance activities be increased in your sector?

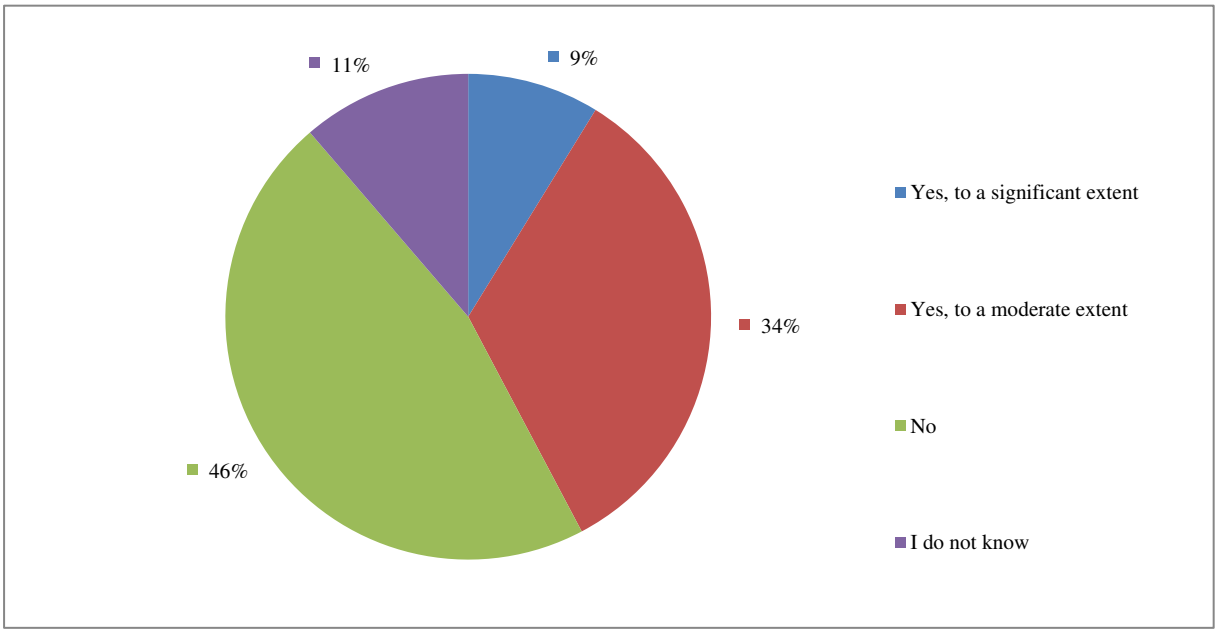


13. How could the resources for market surveillance activities be used more efficiently in your sector?

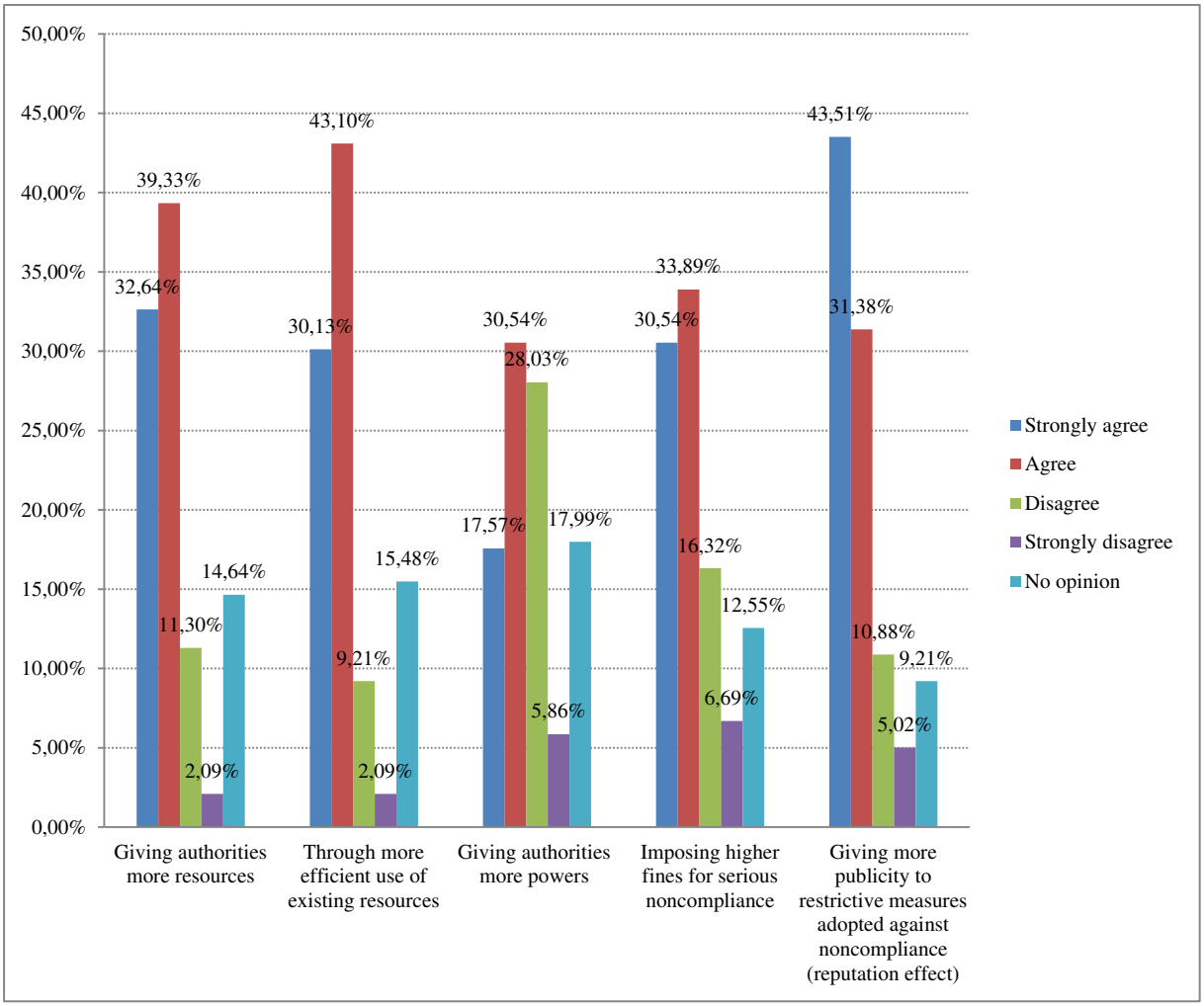


	Market surveillance authorities should have more knowledge about the relevant sector (type and number of economic operators, market trends,…	Market surveillance authorities should have stronger powers	Market surveillance authorities' inspectors should receive better training	Market surveillance authorities' inspectors should receive more standardised training across the EU	Market surveillance authorities within a Member State should share more intelligence	Market surveillance authorities of different Member States should share more intelligence	Market surveillance authorities within a Member State should better coordinate action	Market surveillance authorities of different Member States should better coordinate action	Market surveillance authorities within a Member State should share capacity of testing laboratories	Market surveillance authorities of different Member States should share capacity of testing laboratories
Strongly agree	33,89%	21,76%	34,73%	36,82%	32,22%	39,33%	35,98%	41,42%	32,64%	32,64%
Agree	50,21%	30,54%	42,68%	42,26%	46,03%	47,28%	41,42%	42,68%	38,49%	33,89%
Disagree	5,44%	25,94%	8,37%	7,95%	8,37%	5,86%	9,62%	5,44%	8,79%	12,55%
Strongly disagree	1,67%	5,86%	1,26%	2,09%	1,67%	0,42%	1,67%	1,26%	0,84%	1,67%
No opinion	8,79%	15,90%	12,97%	10,88%	11,72%	7,11%	11,30%	9,21%	19,25%	19,25%

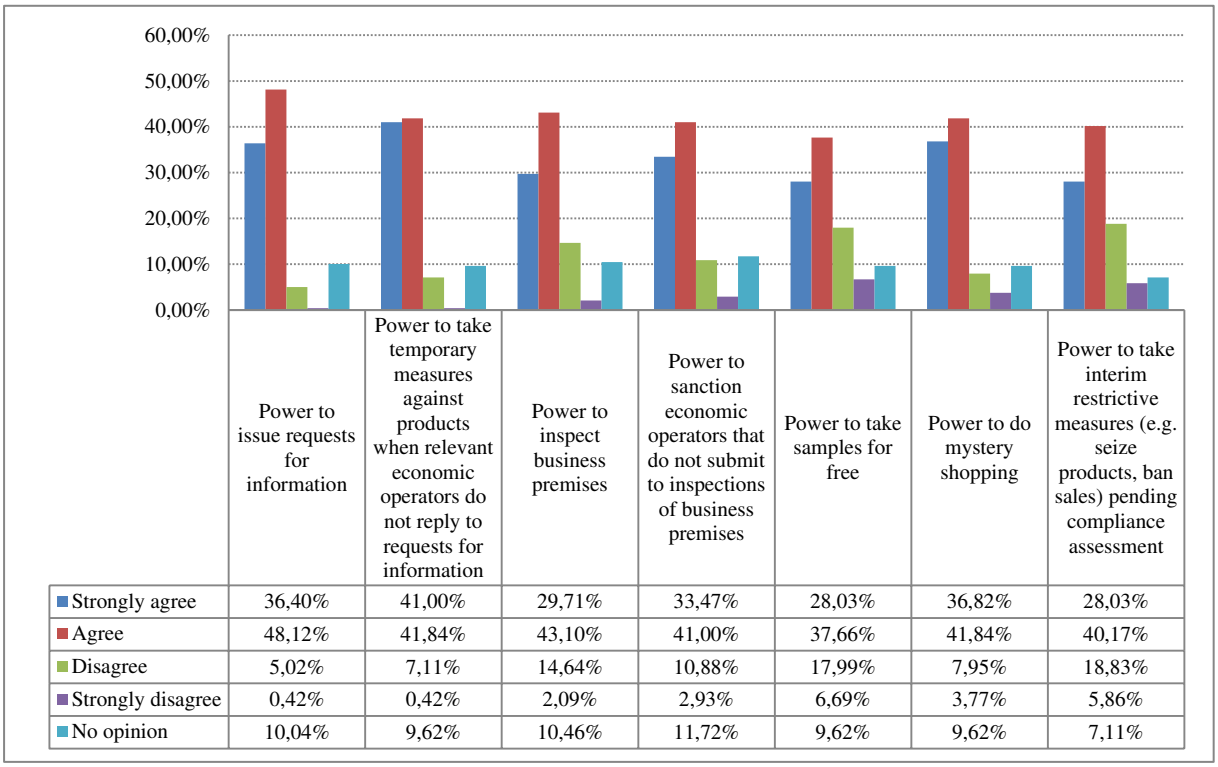
14. Do you think that market surveillance in your sector provides sufficient deterrence?



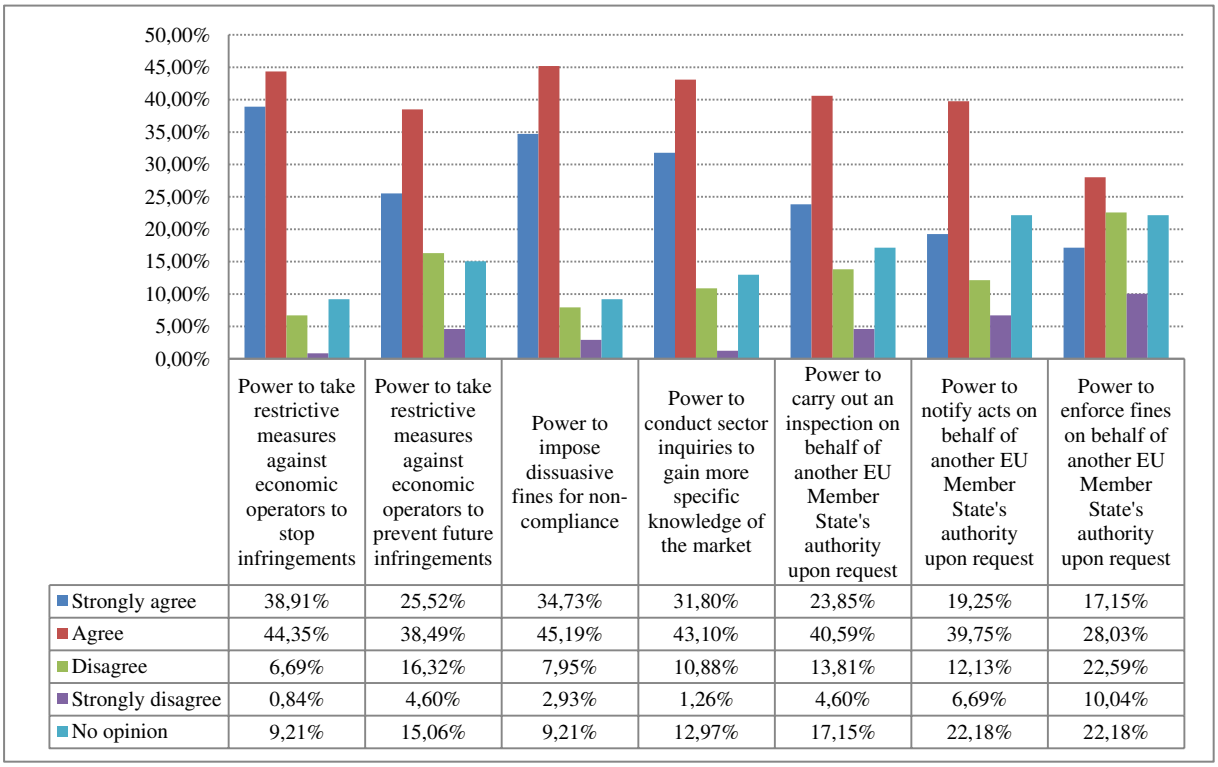
15. How could the deterrence of market surveillance action be improved in your sector?



17. What powers do you think market surveillance authorities need in order to carry out more effective and deterrent action in your sector?

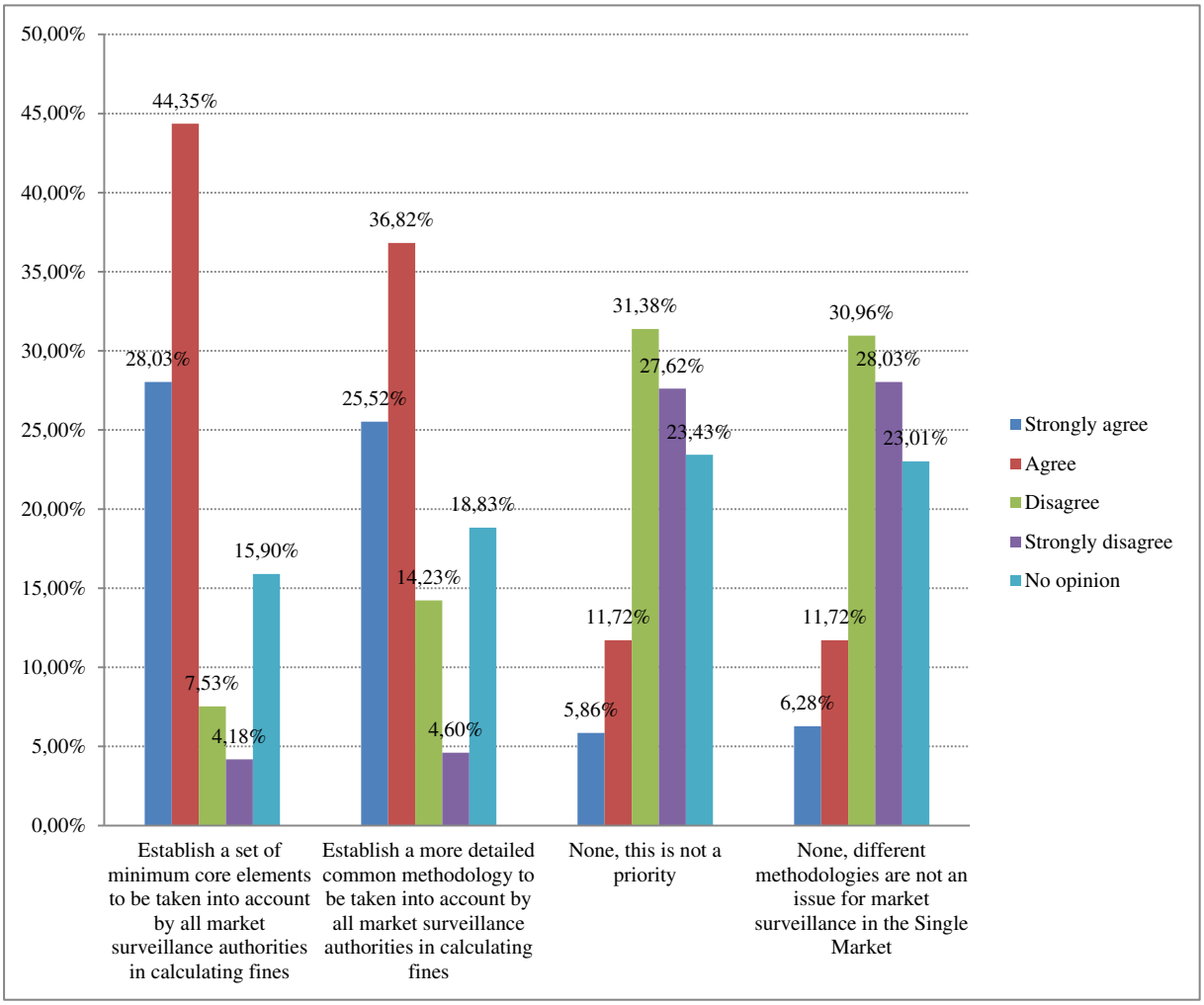


	Power to issue requests for information	Power to take temporary measures against products when relevant economic operators do not reply to requests for information	Power to inspect business premises	Power to sanction economic operators that do not submit to inspections of business premises	Power to take samples for free	Power to do mystery shopping	Power to take interim restrictive measures (e.g. seize products, ban sales) pending compliance assessment
Strongly agree	36,40%	41,00%	29,71%	33,47%	28,03%	36,82%	28,03%
Agree	48,12%	41,84%	43,10%	41,00%	37,66%	41,84%	40,17%
Disagree	5,02%	7,11%	14,64%	10,88%	17,99%	7,95%	18,83%
Strongly disagree	0,42%	0,42%	2,09%	2,93%	6,69%	3,77%	5,86%
No opinion	10,04%	9,62%	10,46%	11,72%	9,62%	9,62%	7,11%



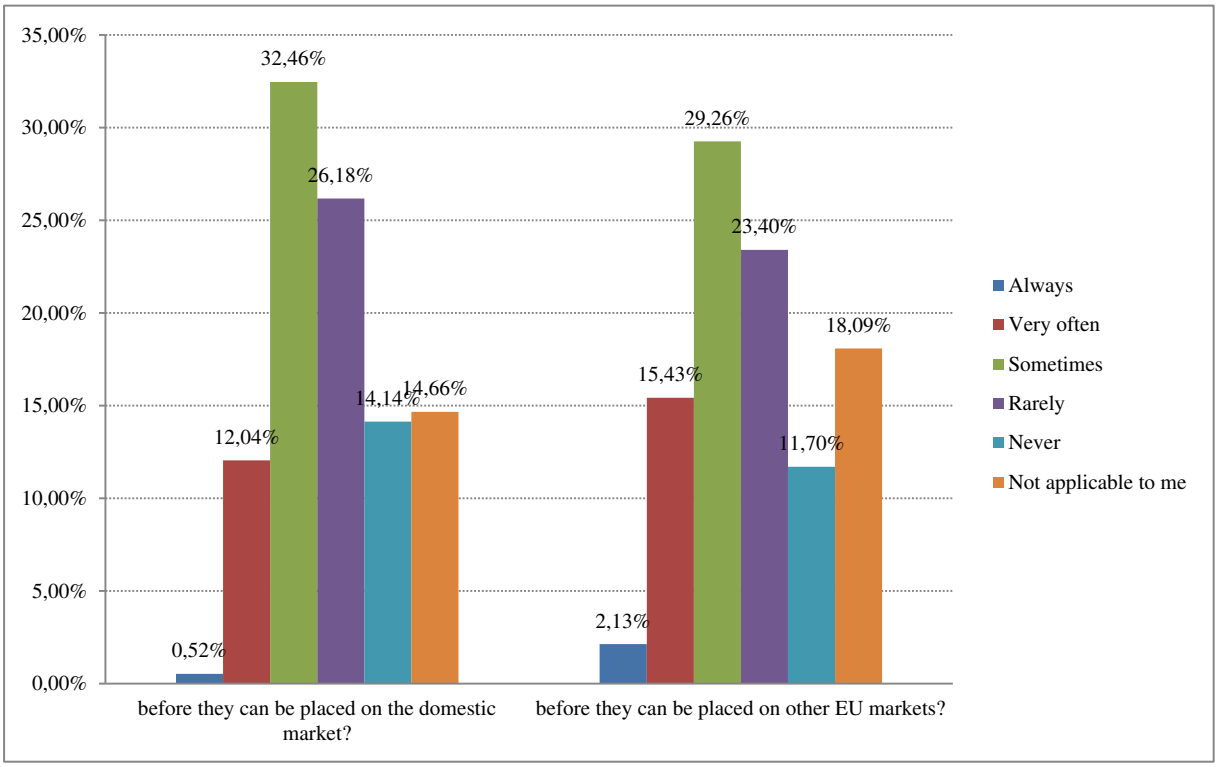
	Power to take restrictive measures against economic operators to stop infringements	Power to take restrictive measures against economic operators to prevent future infringements	Power to impose dissuasive fines for non-compliance	Power to conduct sector inquiries to gain more specific knowledge of the market	Power to carry out an inspection on behalf of another EU Member State's authority upon request	Power to notify acts on behalf of another EU Member State's authority upon request	Power to enforce fines on behalf of another EU Member State's authority upon request
Strongly agree	38,91%	25,52%	34,73%	31,80%	23,85%	19,25%	17,15%
Agree	44,35%	38,49%	45,19%	43,10%	40,59%	39,75%	28,03%
Disagree	6,69%	16,32%	7,95%	10,88%	13,81%	12,13%	22,59%
Strongly disagree	0,84%	4,60%	2,93%	1,26%	4,60%	6,69%	10,04%
No opinion	9,21%	15,06%	9,21%	12,97%	17,15%	22,18%	22,18%

18. Divergences exist in the methodologies applied by market surveillance authorities in different Member States to sanction non-compliant businesses. Which measures do you think should be taken to address this issue?

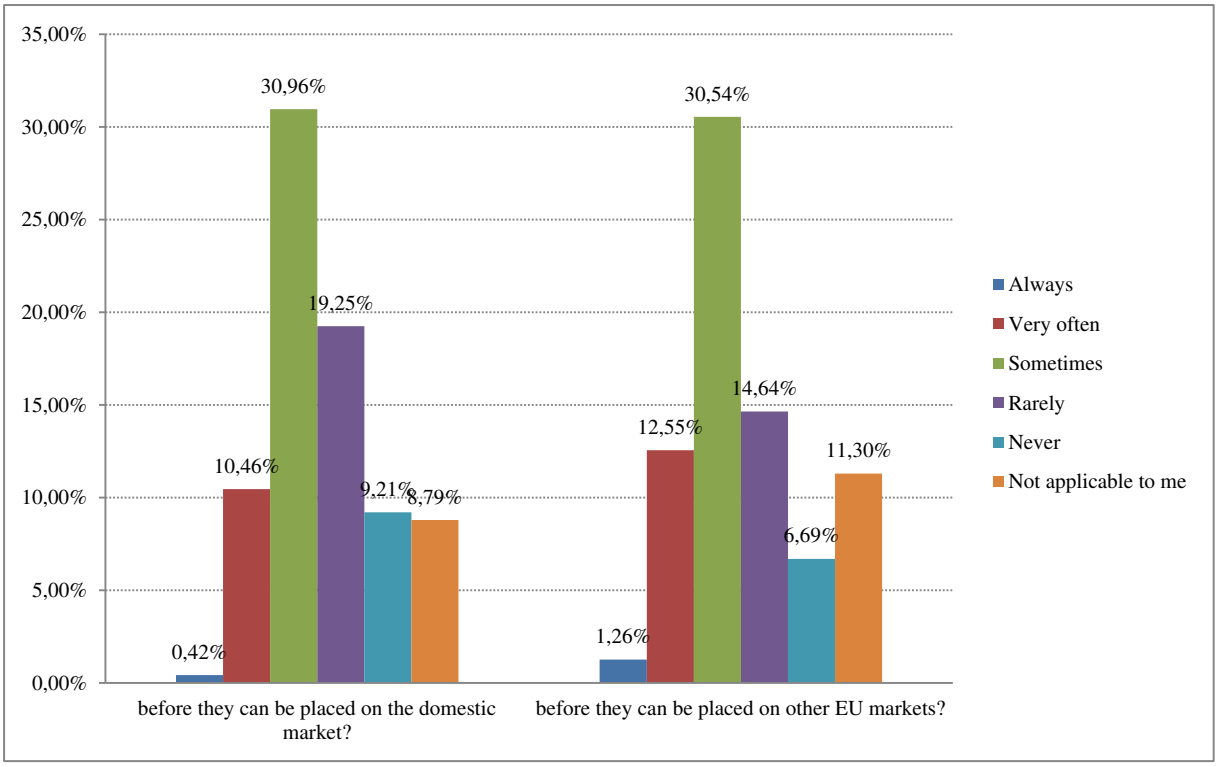


B2. Compliance assistance in Member States and at EU level

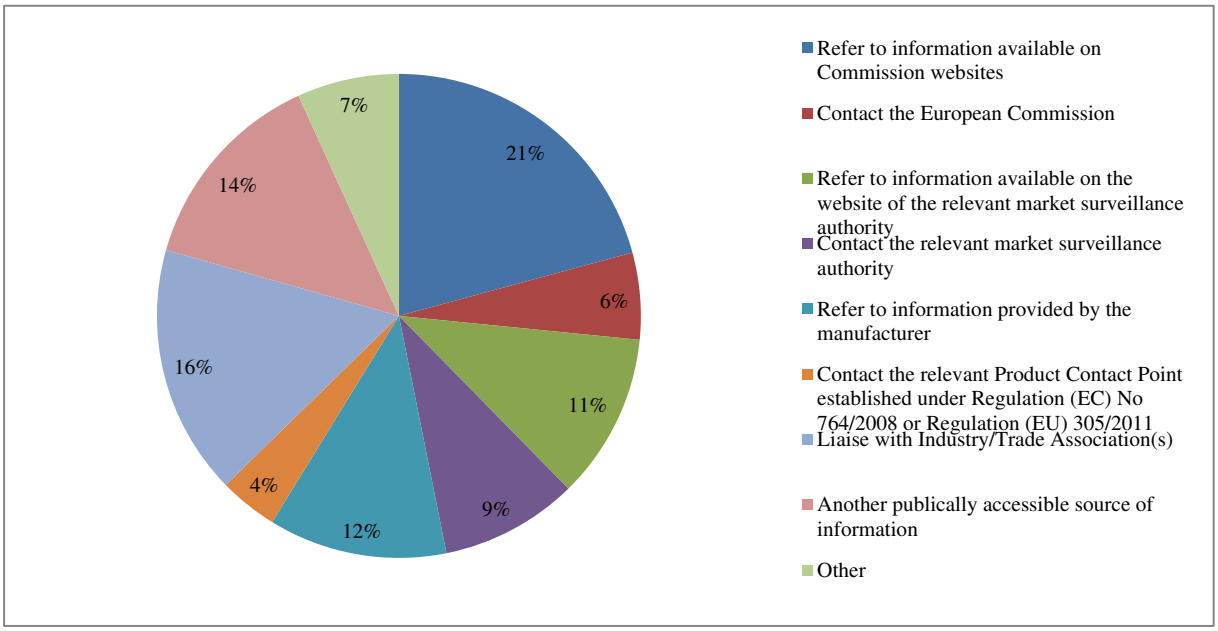
1. Have you had difficulty in finding the correct information on the technical rules that products need to meet?



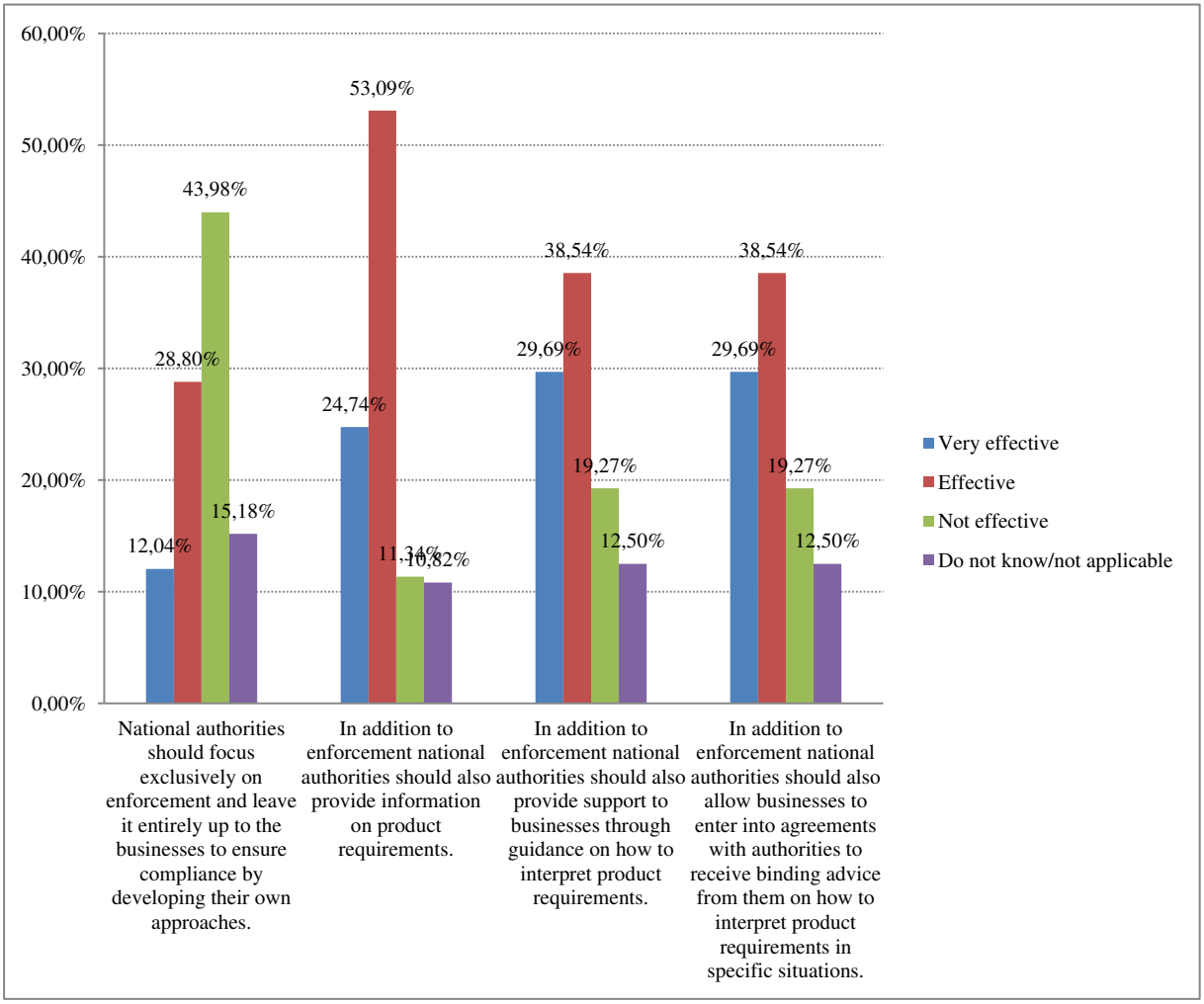
2. Have you had difficulty understanding the correct information on the technical rules that products need to meet



3. What is the approach you most often use to look for support and information on technical rules that products need to meet?

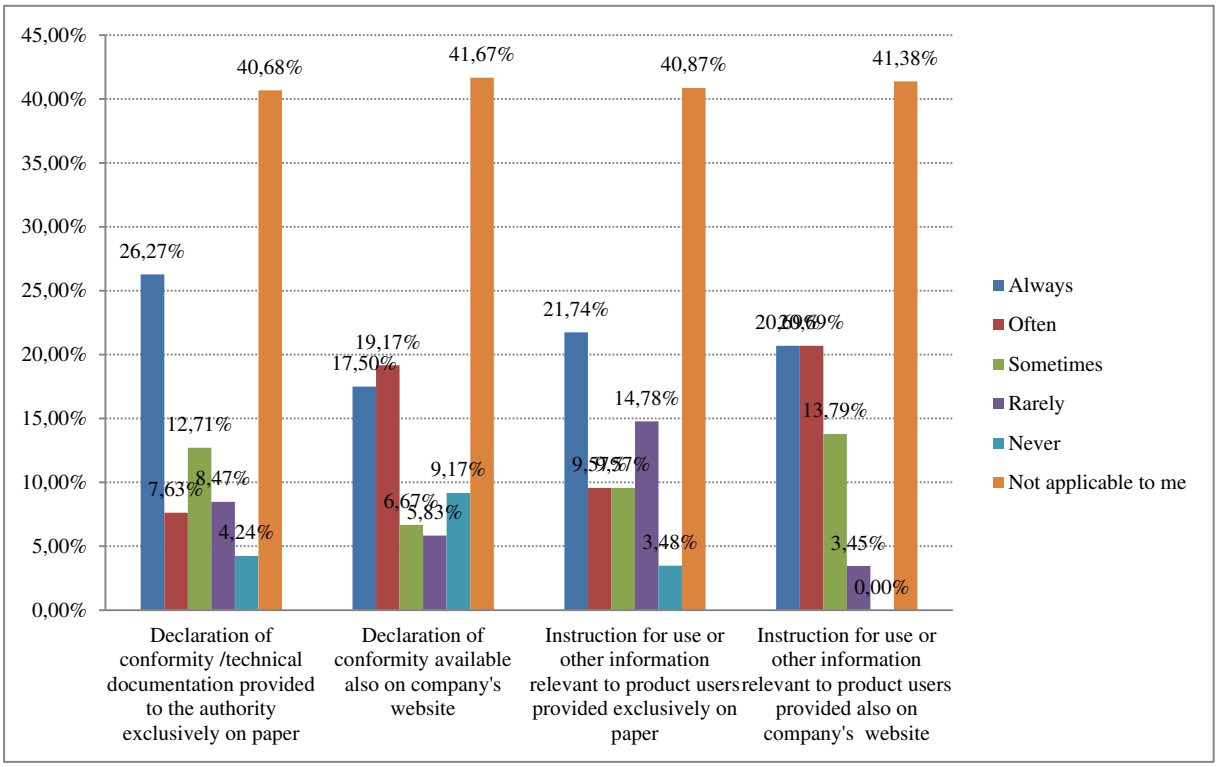


4. What is your opinion on the following approaches by national authorities to reduce the level of non-compliant products on the market?

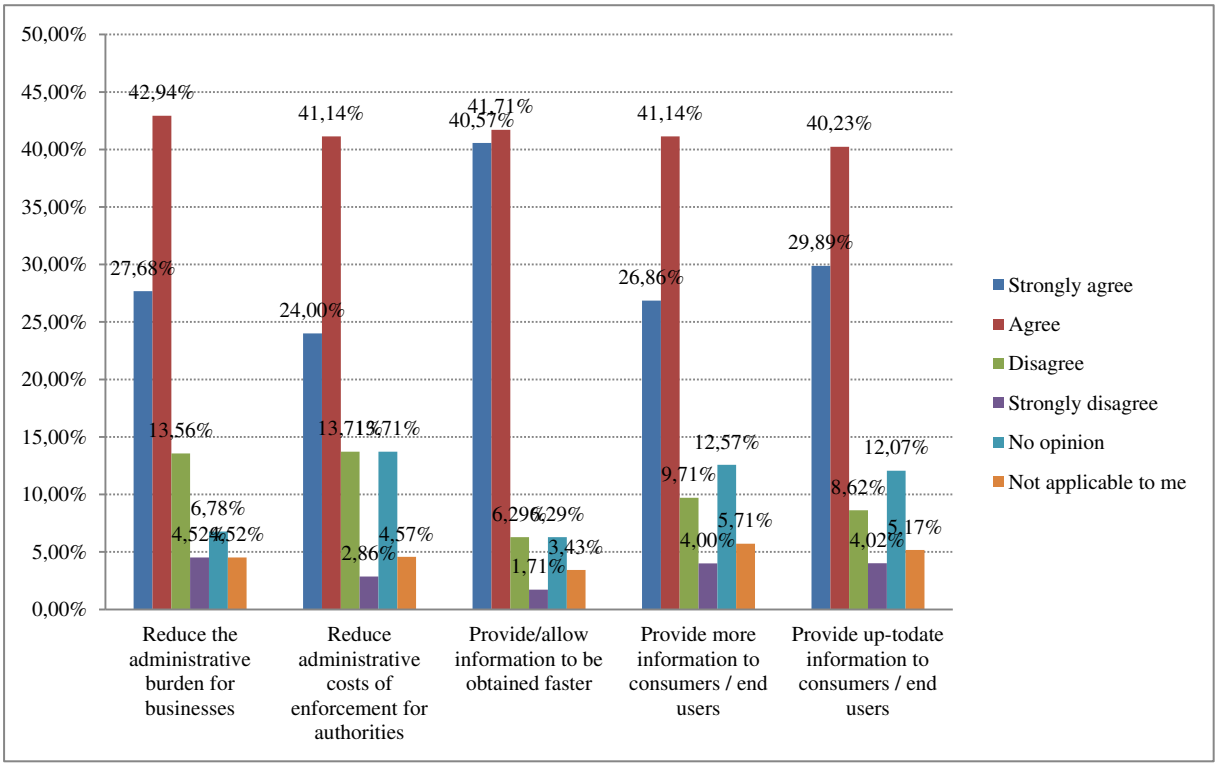


B3. Businesses' demonstration of product compliance

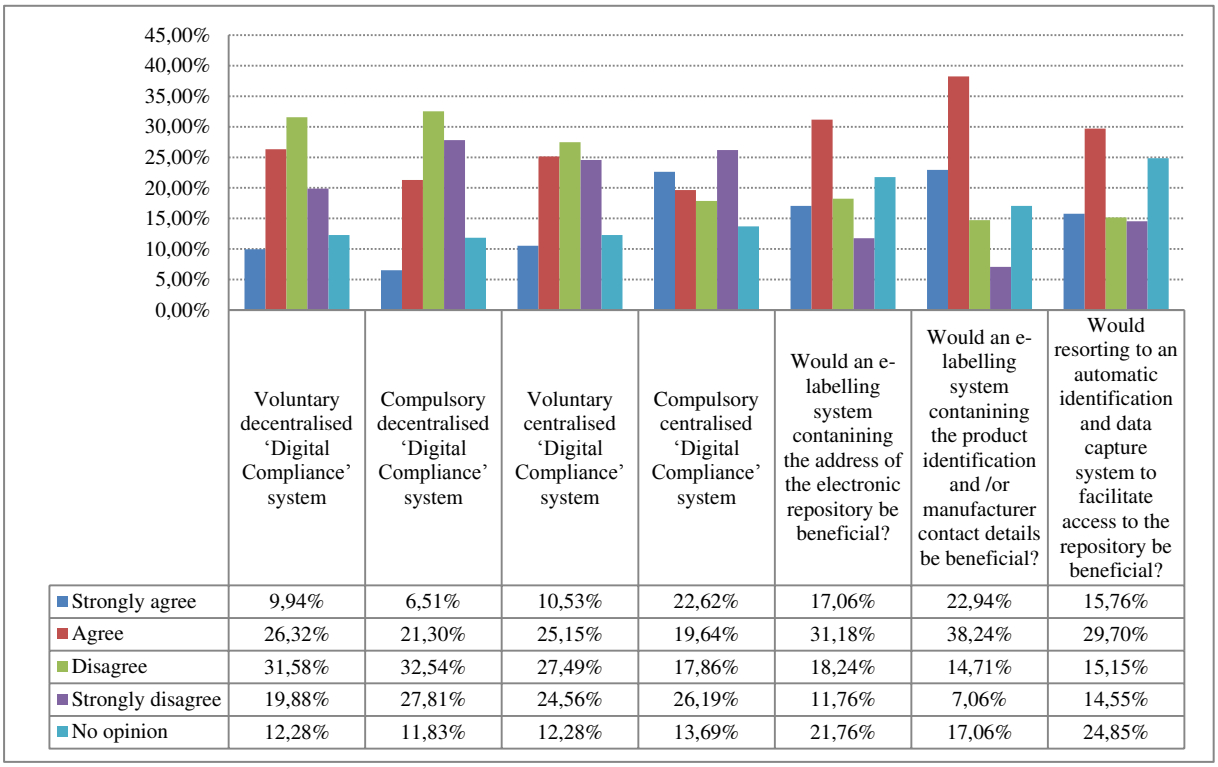
1. [For businesses only] How do you supply information about product compliance?



2. In your experience or understanding would a broader use of electronic means to demonstrate compliance help to:



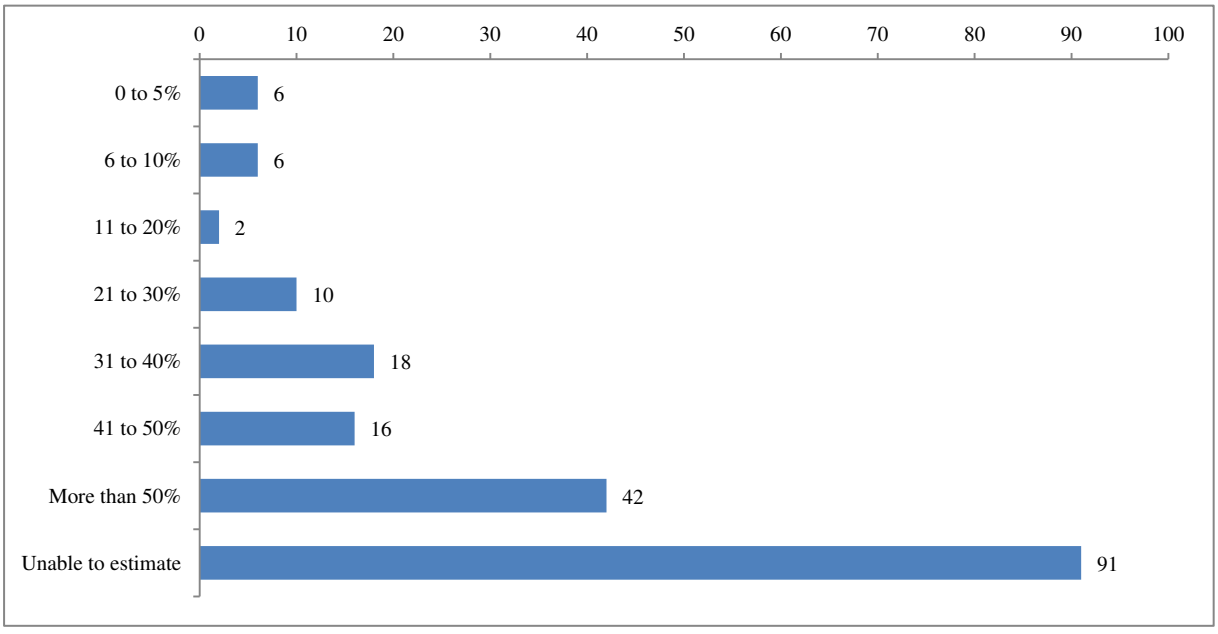
3. What is your view about the following options to better exploit the potential of electronic means for demonstrating compliance?



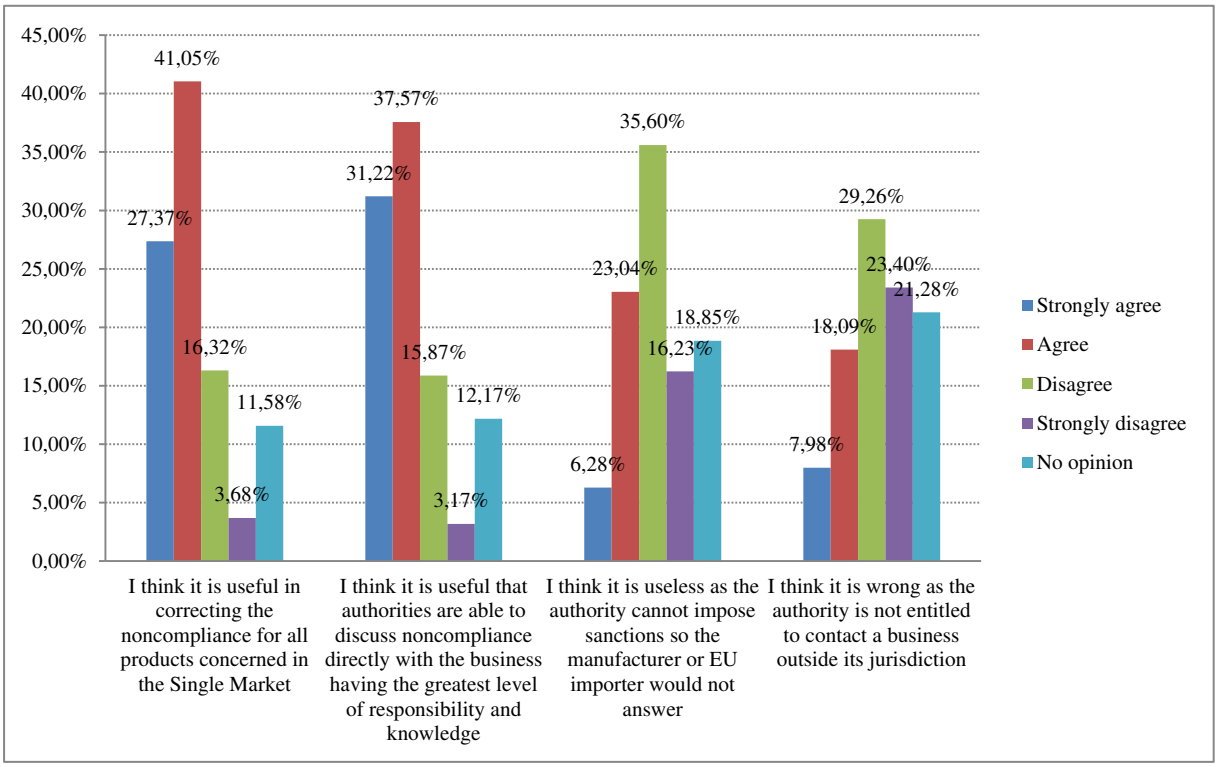
	Voluntary decentralised 'Digital Compliance' system	Compulsory decentralised 'Digital Compliance' system	Voluntary centralised 'Digital Compliance' system	Compulsory centralised 'Digital Compliance' system	Would an e-labelling system containing the address of the electronic repository be beneficial?	Would an e-labelling system containing the product identification and /or manufacturer contact details be beneficial?	Would resorting to an automatic identification and data capture system to facilitate access to the repository be beneficial?
Strongly agree	9,94%	6,51%	10,53%	22,62%	17,06%	22,94%	15,76%
Agree	26,32%	21,30%	25,15%	19,64%	31,18%	38,24%	29,70%
Disagree	31,58%	32,54%	27,49%	17,86%	18,24%	14,71%	15,15%
Strongly disagree	19,88%	27,81%	24,56%	26,19%	11,76%	7,06%	14,55%
No opinion	12,28%	11,83%	12,28%	13,69%	21,76%	17,06%	24,85%

B4. Cross-border market surveillance within the EU

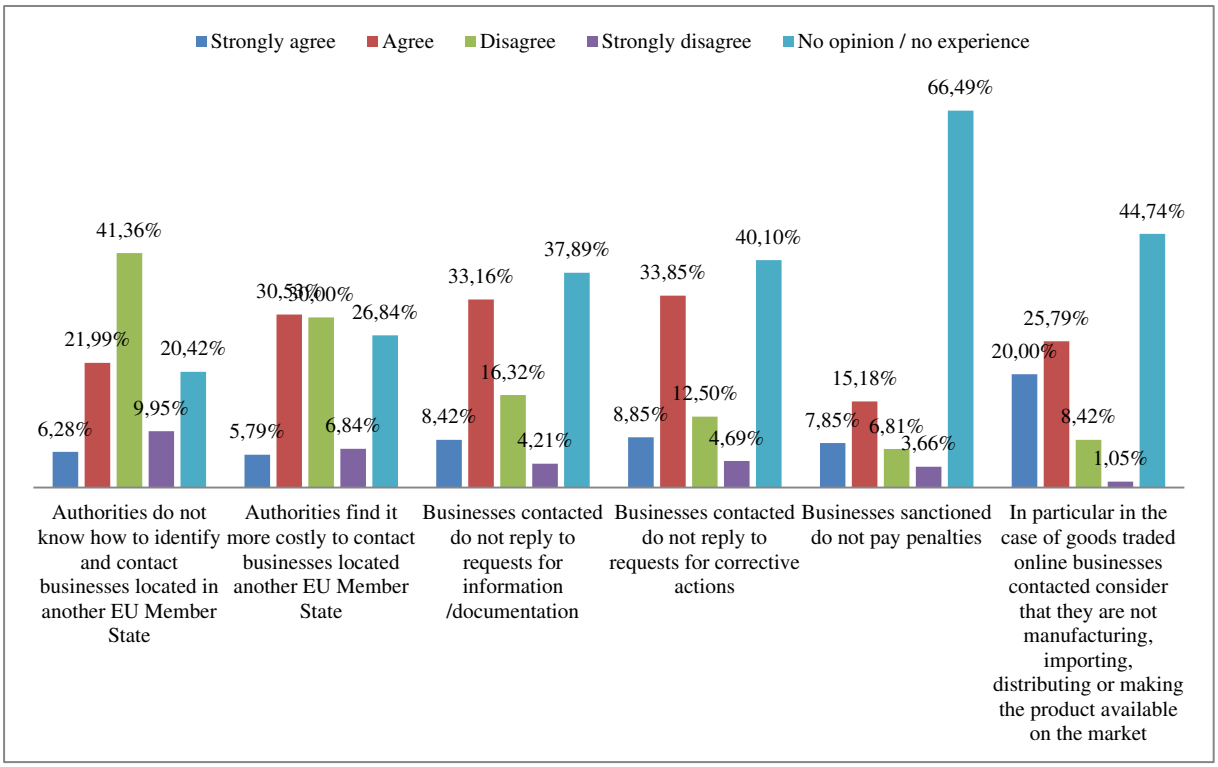
1. What is the approximate proportion of products placed on the market by manufacturers or EU importers located in another EU Member State in your sector (based on product volumes)?



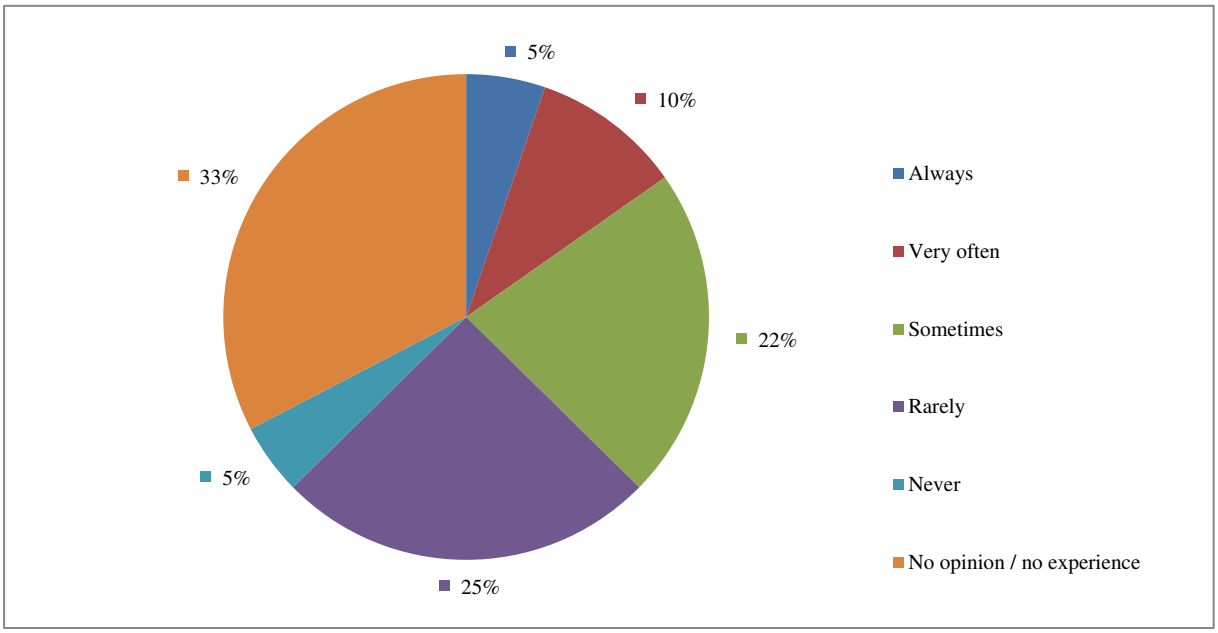
2. Based on your experience what is your view on manufacturers or EU importers being contacted by a market surveillance authority of another EU Member State?



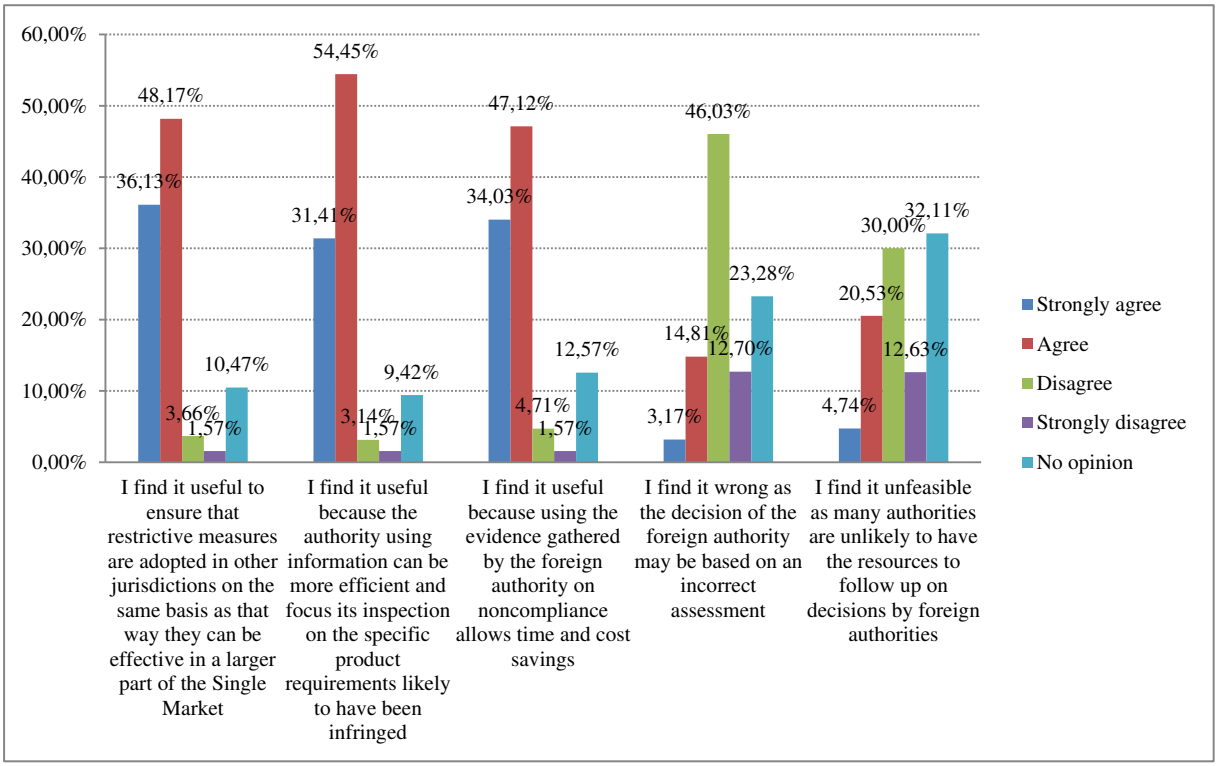
3. In your experience what makes it difficult for a surveillance authority to take action against non-compliant products traded by businesses located in another EU Member State?

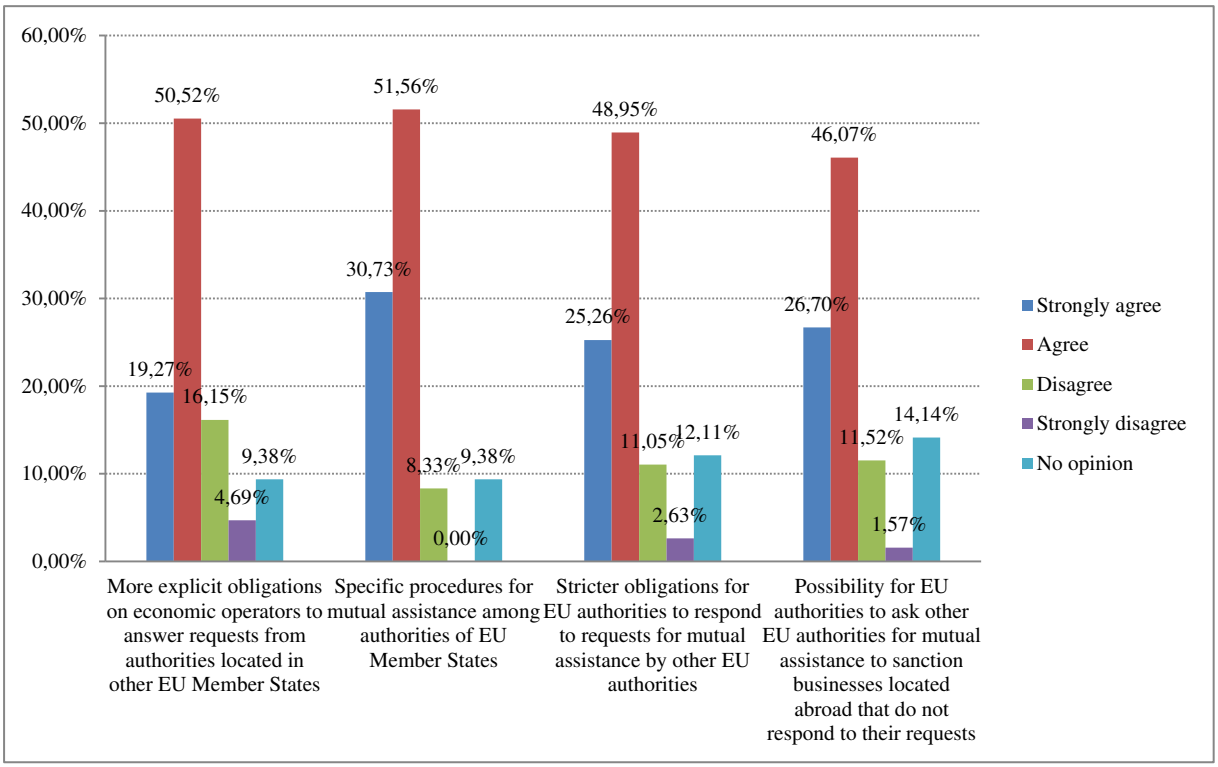


4. National authorities in the EU Member States can currently exchange information on measures adopted to restrict the marketing of non-compliant products via several means (Rapid Alert System, notification procedures, common databases (ICSMS), expert groups, administrative cooperation groups). In your 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?

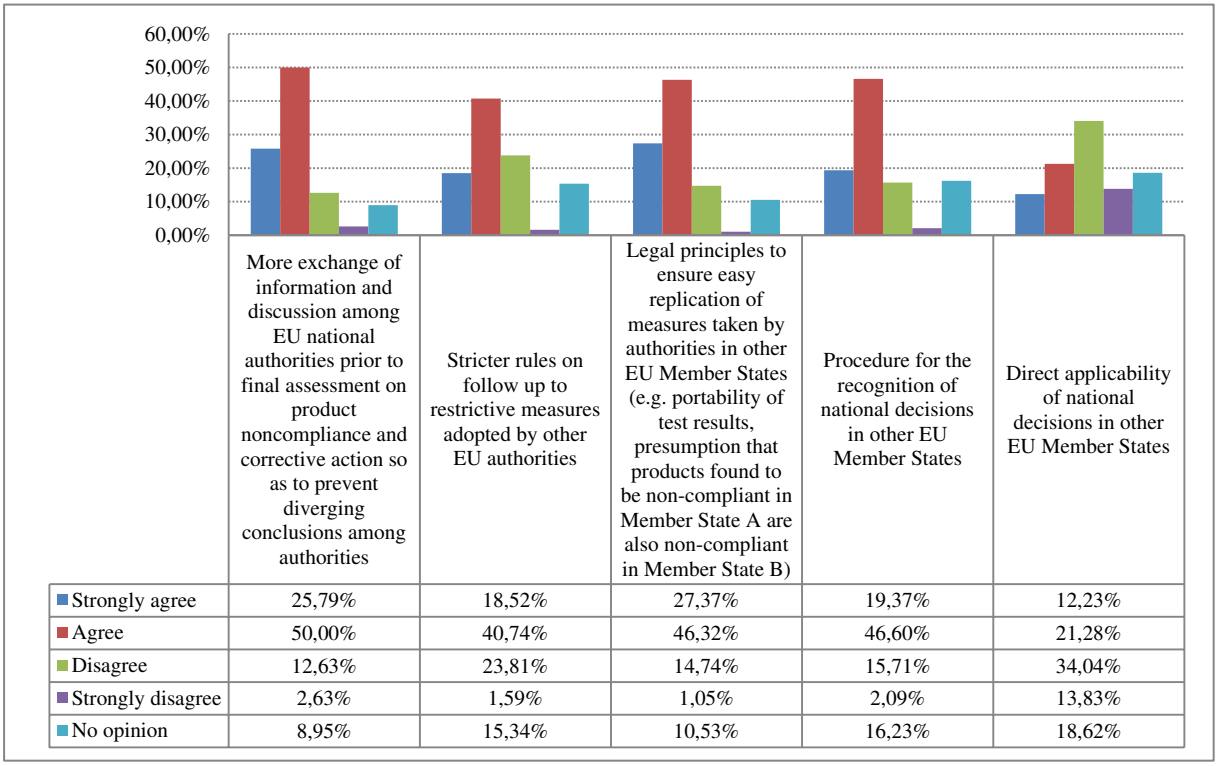


5. What is your view about the possibility that a national authority uses information on measures adopted to restrict the marketing of non-compliant products by another EU authority to adopt restrictive measures against the same products supplied within its own jurisdiction?

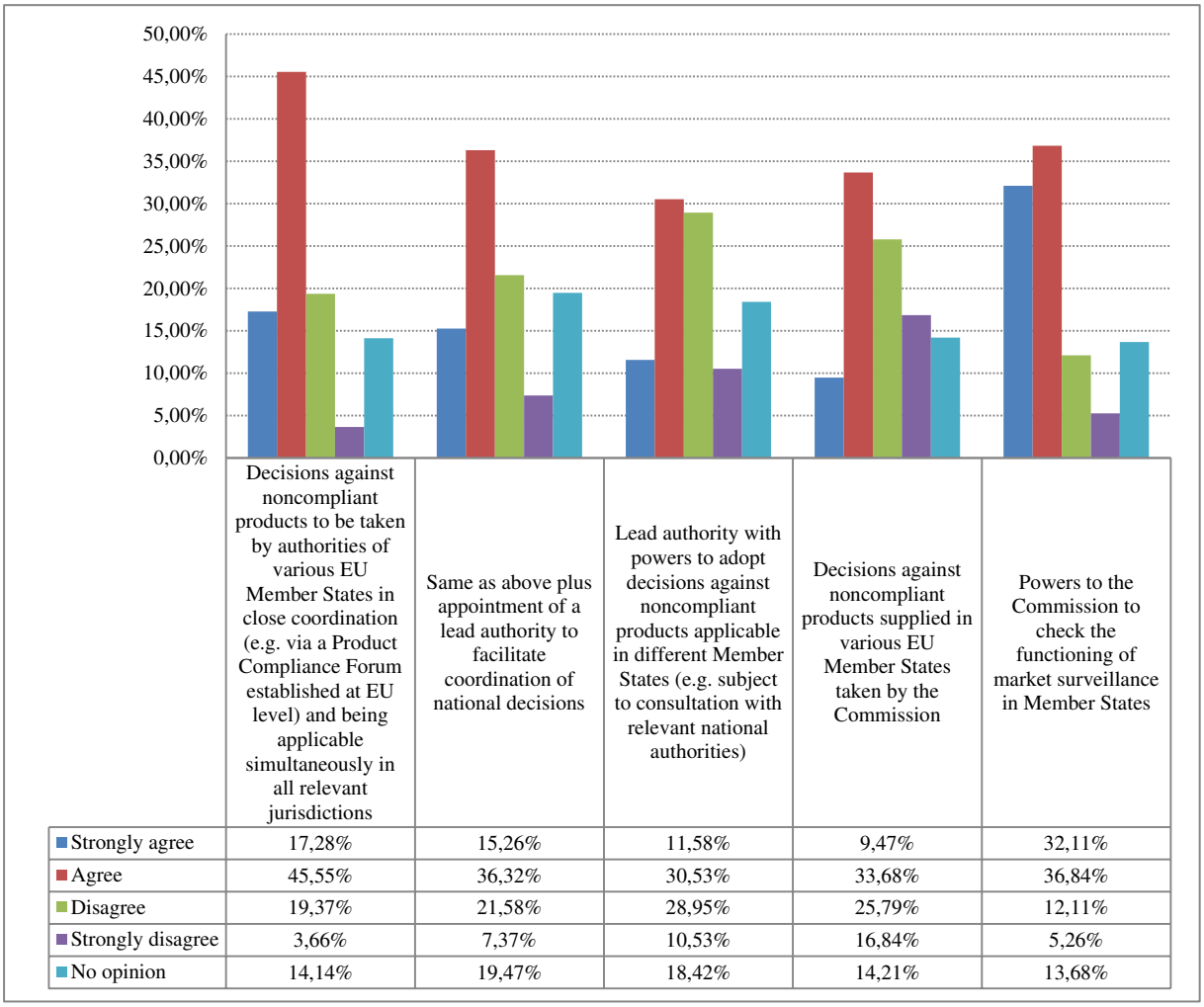




8. Do you agree that the following mechanisms would increase the effectiveness of market surveillance in the Single Market?

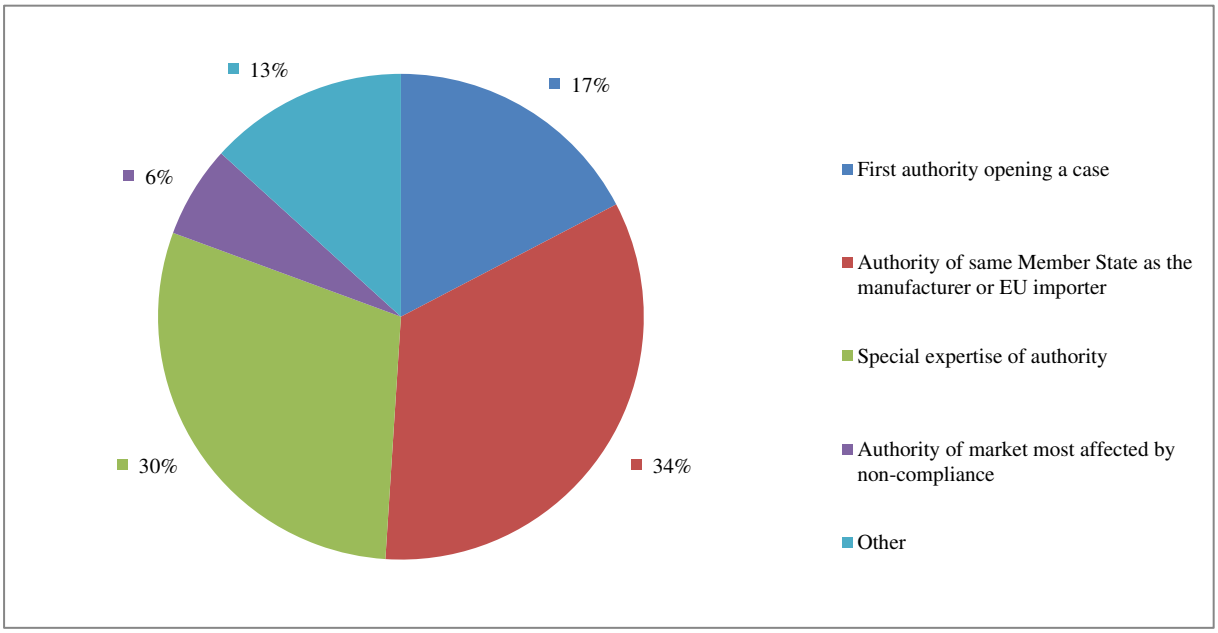


	More exchange of information and discussion among EU national authorities prior to final assessment on product noncompliance and corrective action so as to prevent diverging conclusions among authorities	Stricter rules on follow up to restrictive measures adopted by other EU authorities	Legal principles to ensure easy replication of measures taken by authorities in other EU Member States (e.g. portability of test results, presumption that products found to be non-compliant in Member State A are also non-compliant in Member State B)	Procedure for the recognition of national decisions in other EU Member States	Direct applicability of national decisions in other EU Member States
Strongly agree	25,79%	18,52%	27,37%	19,37%	12,23%
Agree	50,00%	40,74%	46,32%	46,60%	21,28%
Disagree	12,63%	23,81%	14,74%	15,71%	34,04%
Strongly disagree	2,63%	1,59%	1,05%	2,09%	13,83%
No opinion	8,95%	15,34%	10,53%	16,23%	18,62%

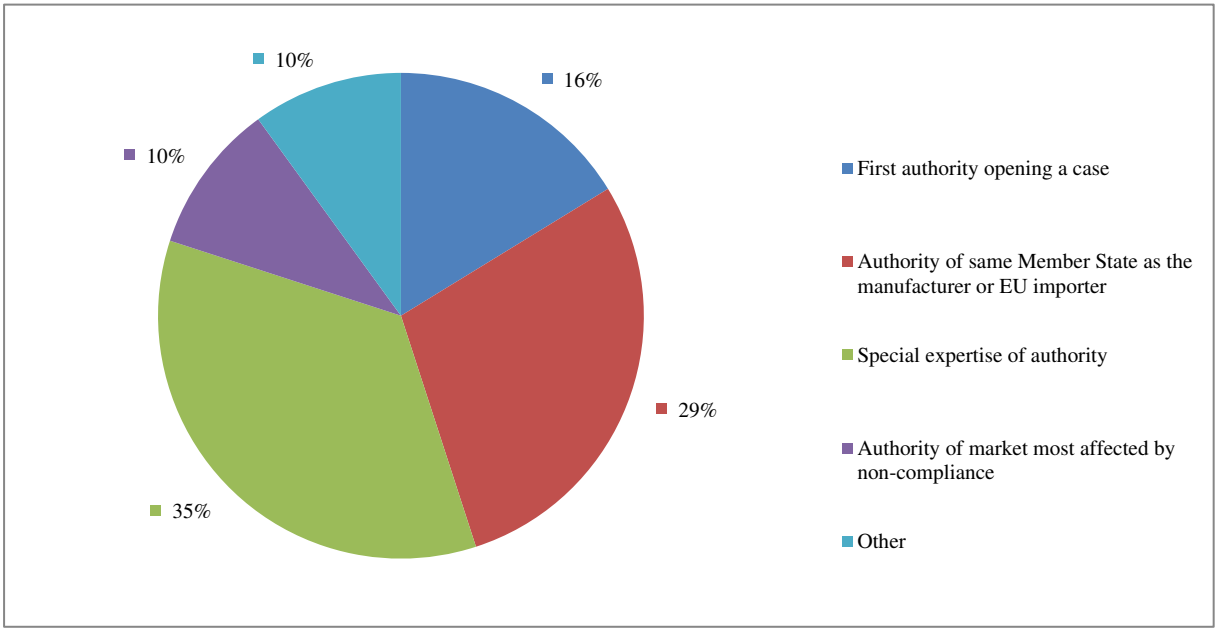


	Decisions against noncompliant products to be taken by authorities of various EU Member States in close coordination (e.g. via a Product Compliance Forum established at EU level) and being applicable simultaneously in all relevant jurisdictions	Same as above plus appointment of a lead authority to facilitate coordination of national decisions	Lead authority with powers to adopt decisions against noncompliant products applicable in different Member States (e.g. subject to consultation with relevant national authorities)	Decisions against noncompliant products supplied in various EU Member States taken by the Commission	Powers to the Commission to check the functioning of market surveillance in Member States
Strongly agree	17,28%	15,26%	11,58%	9,47%	32,11%
Agree	45,55%	36,32%	30,53%	33,68%	36,84%
Disagree	19,37%	21,58%	28,95%	25,79%	12,11%
Strongly disagree	3,66%	7,37%	10,53%	16,84%	5,26%
No opinion	14,14%	19,47%	18,42%	14,21%	13,68%

If you agree with the concept of a lead authority coordinating decisions to be taken simultaneously by authorities in different Member States, which criterion should be used to select the lead authority?

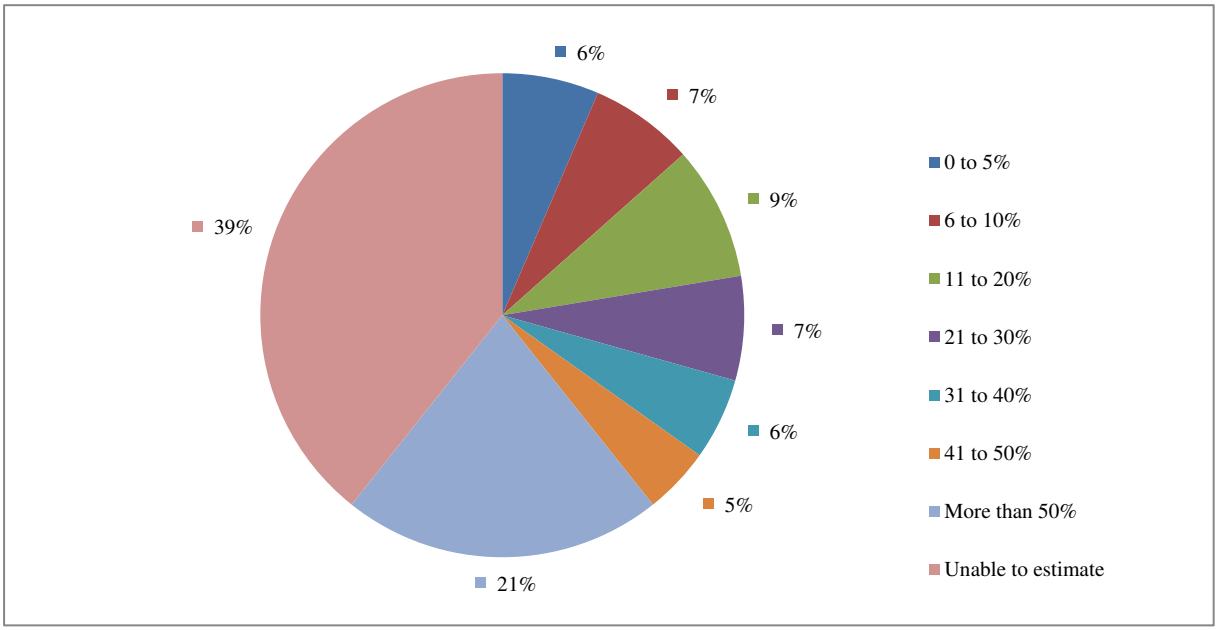


If you agree with the concept of a lead authority with powers to adopt measures applicable in different Member States (e.g. subject to consultation with relevant national authorities), which criterion should be used to select the lead authority?

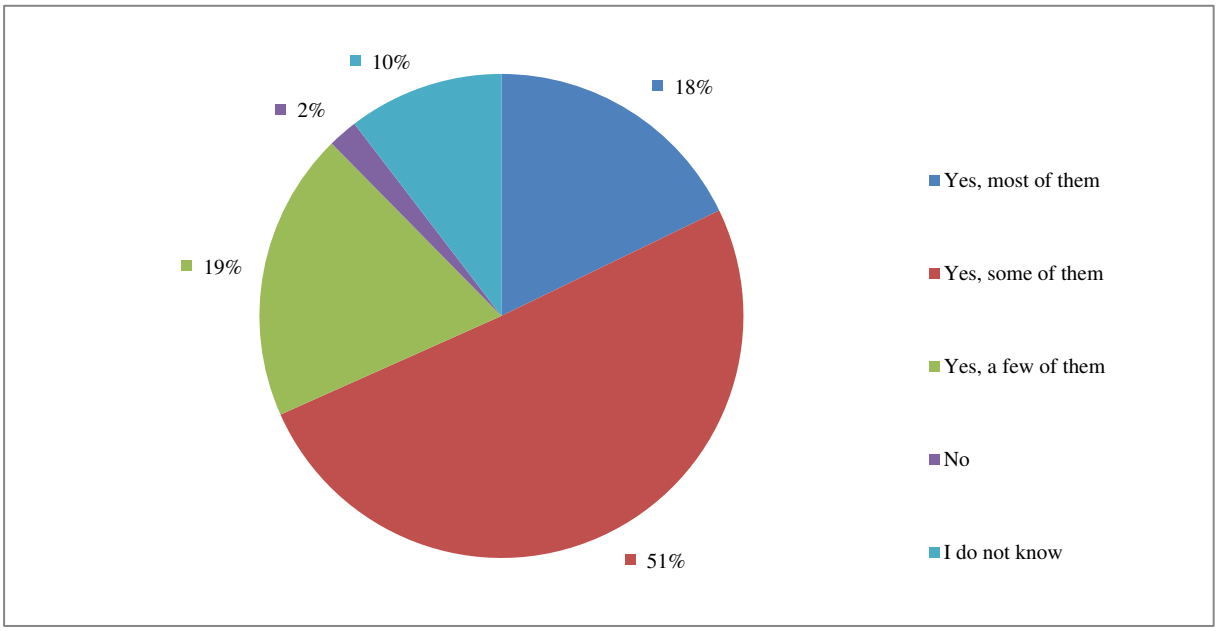


B5. Market surveillance of products imported from non-EU countries

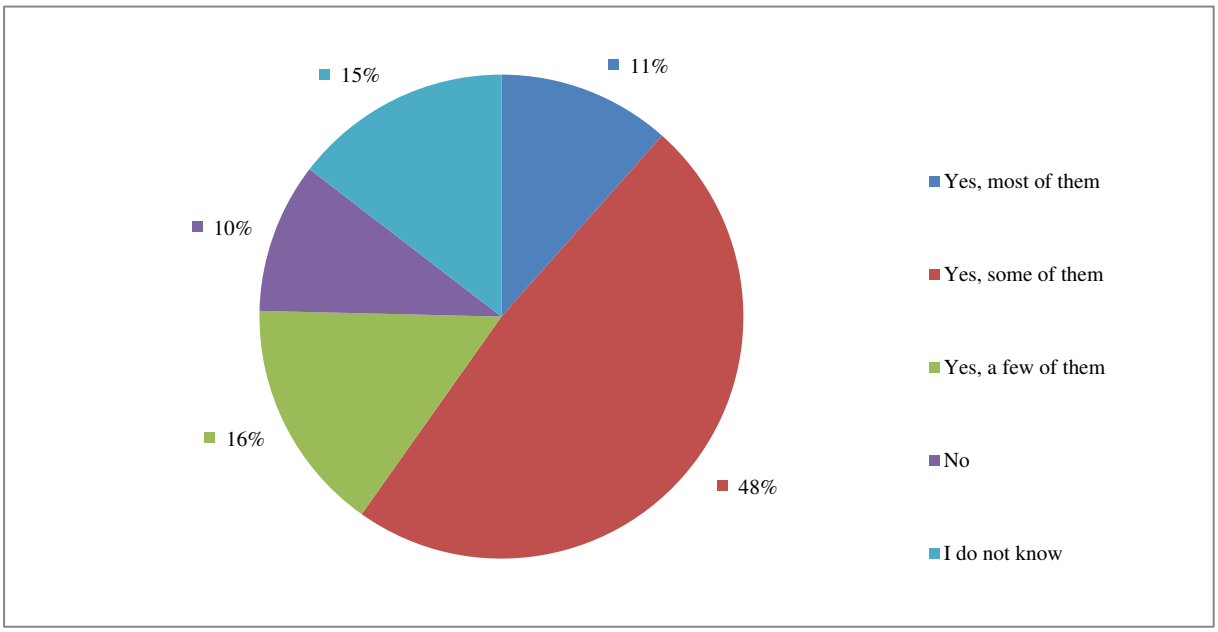
1. What is the approximate proportion of products imported from non-EU countries in your sector (based on product volumes)?



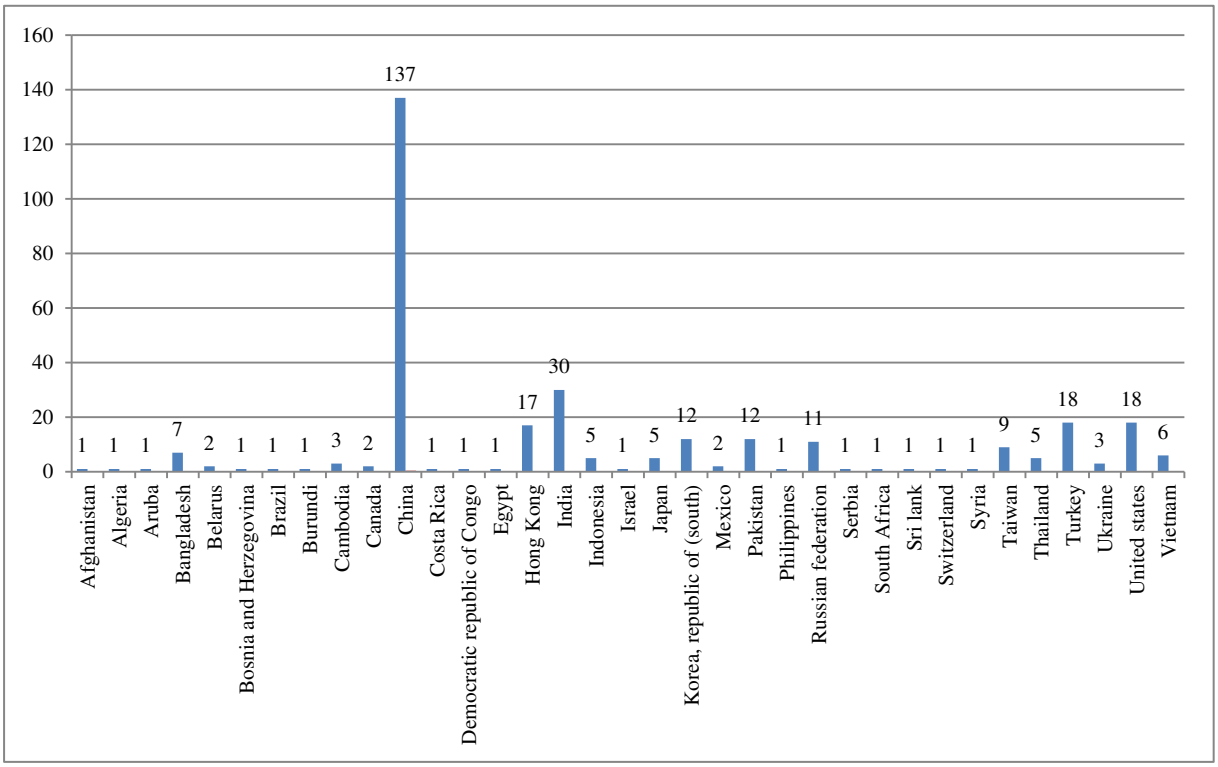
2. Are products in your sector imported from non-EU countries affected by non-compliance?



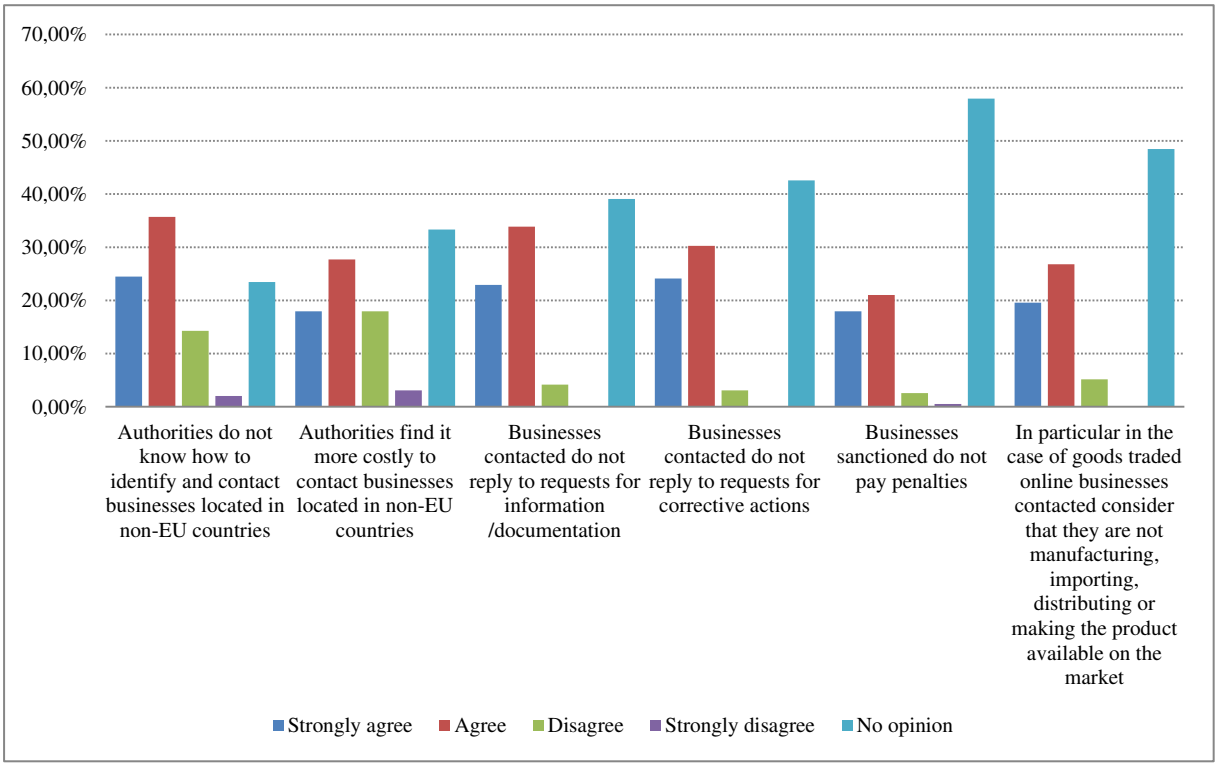
3. Are the non-compliant products in your sector imported from non-EU countries supplied 'online'? (as opposed to through 'brick and mortar' shops)



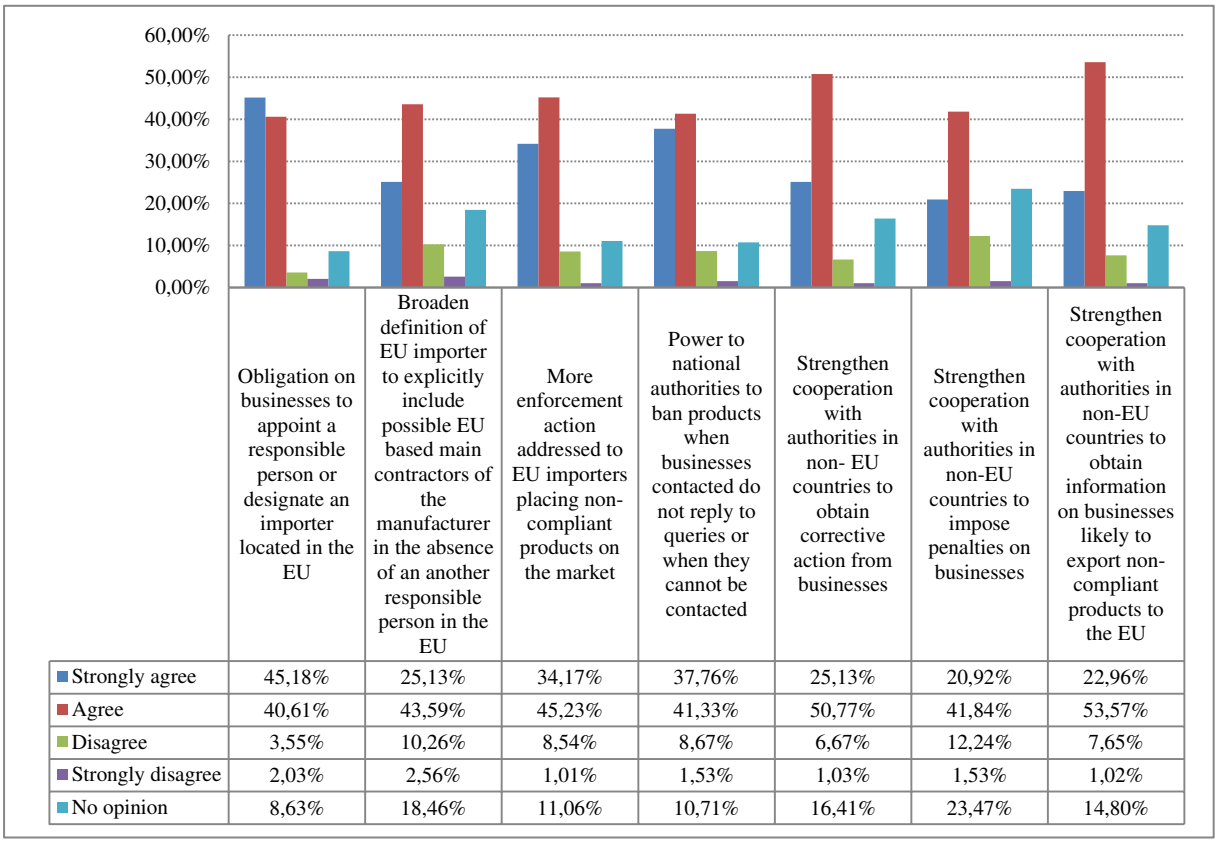
4. What is the country of origin of imported products you often found to be non-compliant (if any)



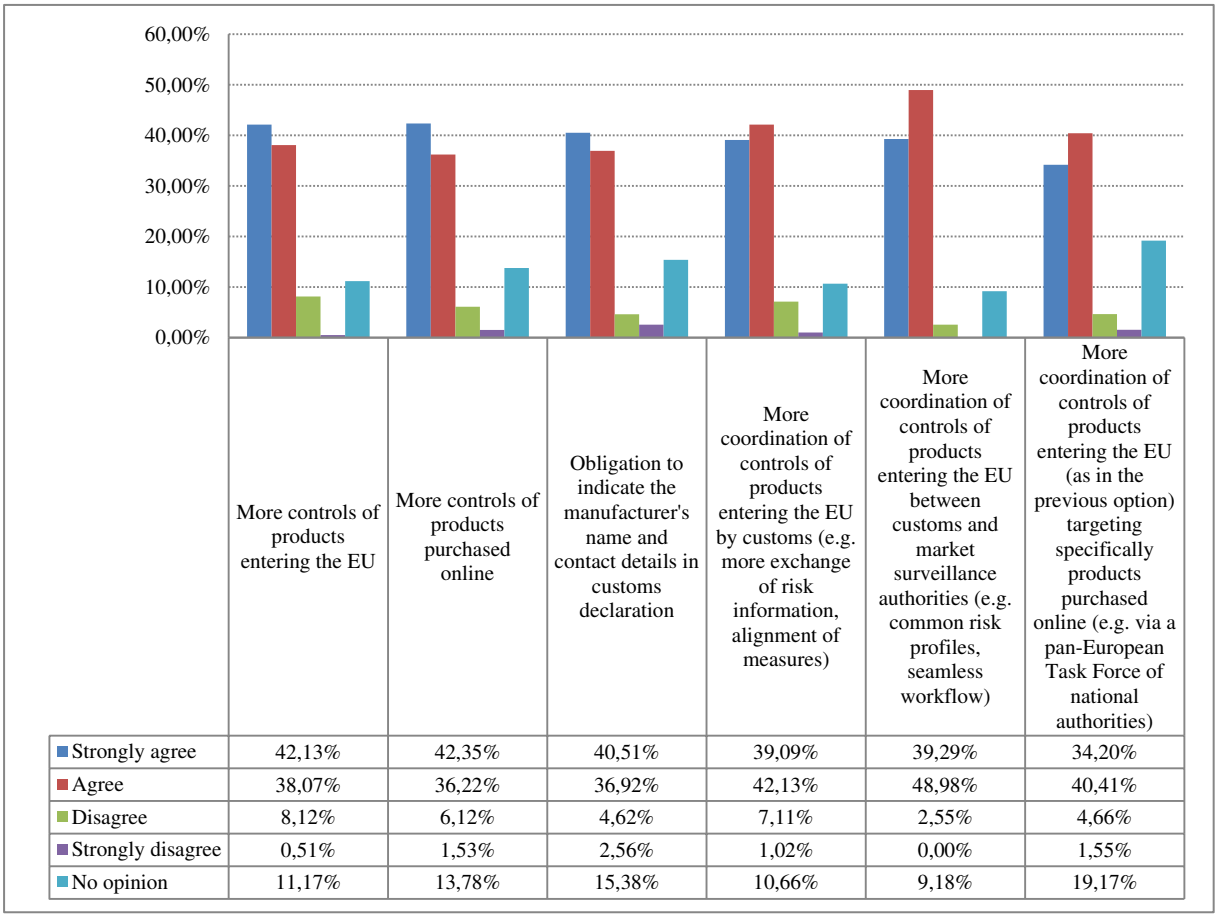
5. In your experience what makes it difficult to take action against non-compliant products traded by businesses located in a non-EU country?



6. In your experience or understanding would the following options help in taking action against non-compliant products traded by businesses located in a non-EU country?



	Obligation on businesses to appoint a responsible person or designate an importer located in the EU	Broaden definition of EU importer to explicitly include possible EU based main contractors of the manufacturer in the absence of an another responsible person in the EU	More enforcement action addressed to EU importers placing non-compliant products on the market	Power to national authorities to ban products when businesses contacted do not reply to queries or when they cannot be contacted	Strengthen cooperation with authorities in non- EU countries to obtain corrective action from businesses	Strengthen cooperation with authorities in non-EU countries to impose penalties on businesses	Strengthen cooperation with authorities in non-EU countries to obtain information on businesses likely to export non-compliant products to the EU
Strongly agree	45,18%	25,13%	34,17%	37,76%	25,13%	20,92%	22,96%
Agree	40,61%	43,59%	45,23%	41,33%	50,77%	41,84%	53,57%
Disagree	3,55%	10,26%	8,54%	8,67%	6,67%	12,24%	7,65%
Strongly disagree	2,03%	2,56%	1,01%	1,53%	1,03%	1,53%	1,02%
No opinion	8,63%	18,46%	11,06%	10,71%	16,41%	23,47%	14,80%



	More controls of products entering the EU	More controls of products purchased online	Obligation to indicate the manufacturer's name and contact details in customs declaration	More coordination of controls of products entering the EU by customs (e.g. more exchange of risk information, alignment of measures)	More coordination of controls of products entering the EU between customs and market surveillance authorities (e.g. common risk profiles, seamless workflow)	More coordination of controls of products entering the EU (as in the previous option) targeting specifically products purchased online (e.g. via a pan-European Task Force of national authorities)
Strongly agree	42,13%	42,35%	40,51%	39,09%	39,29%	34,20%
Agree	38,07%	36,22%	36,92%	42,13%	48,98%	40,41%
Disagree	8,12%	6,12%	4,62%	7,11%	2,55%	4,66%
Strongly disagree	0,51%	1,53%	2,56%	1,02%	0,00%	1,55%
No opinion	11,17%	13,78%	15,38%	10,66%	9,18%	19,17%

ANNEX 3: WHO IS AFFECTED BY THE INITIATIVE AND HOW

1. SME TEST

(1) Consultation with SMEs representatives	Consultation with SMEs took place throughout the following process: • A stakeholder conference held on 17 June 2016, open to all interested participants (industry, consumers, authorities, SMEs etc.) • Public consultation which ended on 31 October 2016. Participation of SMEs in the consultation was promoted and supported through the European Enterprise Network. Regarding the number of employees, 33.78% of the business representatives declare that their organisation has 1 – 9 employees, 13.51% 10 – 49 employees, and 12.16% 50 – 249 employees. • Informal consultation of SMEs at the Small Business Act follow-up meeting with stakeholders in December 2016. **Feedback from SMEs:** The Commission presented the reflections on the possible options to address the problem of non-compliance and asked for feedback. Businesses representatives confirmed that SMEs are also hit by non-compliance like bigger companies. When SMEs are themselves non-compliant this is most likely due to the lack of adequate knowledge about applicable requirements and therefore compliance assistance would be welcome. Deterrence could be improved if authorities could take into account feedback from businesses (notably following peer reviews among businesses).
(2) Preliminary assessment of businesses likely to be affected	The value of EU harmonised products amounted on average to more than 2 400 billion euro per year during the period 2008-2014, and corresponds to about 69% of the overall value of manufacturing products in the EU. About 900,000 businesses are involved in the manufacturing of industrial products (53% of all businesses active in the EU manufacturing sector) employing more than 20 million people (68% of all persons employed in the manufacturing sector. Furthermore, the value added of wholesale and retail traders whose sales are likely to include harmonised products during the 2008-2015 period is estimated around 850 billion euro per year. The number of enterprises active in the distribution of products in these sectors is estimated around 4 million and the number of their employees over 22.5 million people. 99% of manufacturing enterprises are SMEs (78% micro-enterprises, 16.4% SMEs employing up to 49 persons and 4.4% SMEs employing between 50 and 249 persons). Almost 100% of retail enterprises are SMEs (93.6% microenterprises, 5.4%, employing up to 49 persons and 0.7% SMEs employing between 50 and 249 persons).

	The public consultation revealed that finding and understanding the correct information on the technical rules that products need to meet before they can be placed on the domestic and on other EU markets is a problem but probably not a major problem. Yet, considering that few compliance practices are specifically aimed at SMEs, the need for **assistance** is probably more pressing for SMEs in the supply chain. National and multi-national economic operators already have the resources to determine product compliance and current schemes do not benefit SMEs sufficiently. 50% of the SMEs' respondents to the public consultation declared that they had difficulty in finding the correct information on the technical rules that products need to meet before they can be placed on the domestic market and 47.7% before they can be placed on other EU markets. Additionally, 50% of the same respondents agreed that a broader use of electronic means to demonstrate compliance would help to allow information to be obtained faster. Furthermore, an increased level of **transparency** of compliance, via various means such as the publication of compliance related information on company websites and the publication of enforcement decisions addressing non-compliant products should help SMEs to determine product compliance. The reduction of the risk of 'free-trading' by unscrupulous operators and improvement of the level playing field among businesses trading harmonised products in the Single Market will have a positive impact on the competitiveness of responsible businesses which are affected by the unfair competition of non-compliant products. Among others, improving **fairness** on the Single Market will affect SMEs. 61.36% of the SMEs representatives replied to the public consultation that the products in their sectors are affected by non-compliance with product requirements laid down in EU harmonisation legislation. 50% of them agreed that the problem of non-compliance negatively affects consumers and other end-users, while 61.37% stated that businesses complying with legal obligations experience negative effects on sales and/or market shares due to the presence of non-compliant products. SMEs like other businesses will be able to benefit of more information at lower or no costs. SMEs will also be able to return non-compliant products purchased for their use or to have them replaced at no cost]. On the other hand, SMEs found to be trading non-compliant products will be asked, like other business, to pay the costs of controls borne by authorities.
(3) Measurement of the impact on SMEs	The proposals under the selected option would imply benefits for businesses helping them to comply, increasing transparency and reduce the negative effects of unfair competition. Concerning the compliance assistance to businesses via information, the assumption is that mainly information would be

	given, free of charge. Therefore, this option would not entail any costs for businesses. There would be indirect positive impacts on the efficiency and availability of resources for market surveillance. The digital compliance system would create, for many companies, a one-off setup cost to create an in-house database with electronic versions of the documents to be uploaded into the centralised database as well as a new process for demonstrating compliance. In particular, this database would impose potentially significant costs related to security. The significance of these costs would depend to a large extent on the system that would be implemented and how compatible it is with each company's current procedures For the common for voluntary measures, no costs for businesses were identified. The possibility to inform consumers through this portal would not create a new obligation for economic operators, thus it would not constitute an additional administrative burden. It would help them to comply with their obligations to take the necessary measures to inform consumers free of charge, thus not entailing additional expenses for economic operators. In general, no other costs or significant impacts were identified, which would lead to additional requirements or need for extra compliance efforts by businesses. However, there is no specific analysis of the distribution of the potential costs and benefits of the policy options over the businesses' size.
(4) Assess alternative options and mitigating measures	At the end of the impact assessment, the selected option shows that the initiative might have a very positive economic impact on the stakeholders in general, including SMEs. Consequently, there is no element showing the need for SME specific measures in order to ensure compliance with the proportionality principle.

2. STAKEHOLDERS AFFECTED BY THE PREFERRED POLICY OPTION

The following stakeholders would be affected by the initiative as set out in the preferred policy option (section 7 of the impact assessment report):

National market surveillance authorities

National market surveillance authorities will benefit from a **more effective tool box** to trace, intercept and punish trader of non-compliant products. They would **save costs** by making use of evidence and enforcement decisions prepared by other authorities. Also costs recovery of control costs from operators supplying non-compliant products would be extended to more member states. Respondents in the public consultation rated these measures **highly favourably**.

They would benefit from direct support of the EU Product Compliance Network which would allow them to **coordinate and participate in cross-border joint action in a more efficient manner** than is currently the case. On the other hand Member States would have

adjustments costs to more intensive use or new mutual assistance or coordination procedures and the EU Product Compliance Network.

Commission

Cost for the Commission/EU budget would be associated with the establishment of an EU Product Compliance Network. In the baseline scenario, the Commission manages various tasks (support contract, IT tools) in a fragmented, ad-hoc manner. These tasks would pass onto the Network which could upscale and provide a more substantial and coherent support structure. Regardless of a possible hosting of the Network within the Commission or within an existing agency, the Commission would continue to participate in the Networks activities and focus on legislative and regulatory matters. This role of the Commission would be proportionate and carefully balanced viz. subsidiarity concerns. Respondents in the public consultation were more favourable to enforcement decisions taken in close coordination via a product compliance forum (63% strongly agree/agree) than enforcement decisions taken by the Commission (42% strongly agree/agree).

The improved coordination and strengthened enforcement strategies by Member states would allow the Commission to **gain better insight** in the gaps and needs of market surveillance authorities and the overall performance of market surveillance in the Single Market. This will help the Commission to exercise oversight.

Businesses

In the public consultation 71% of respondents indicated that in their sector businesses would be negatively affected by problems of non-compliance (of which nearly 30% even to a significant extent). The impacts specifically on SME are detailed above in section 3,1 of this annex.

The measures in the preferred option should help to reduce the magnitude the problems:

The initiative would have positive effects on the business environment of law-abiding companies at little to no additional costs or new obligations. By reducing the risk of 'free-trading' by unscrupulous operators and improving the l**evel playing field among businesses trading harmonised products in the Single Market** the measures in the preferred option will have a positive impact on the competitiveness of responsible businesses which are affected by the **unfair competition** of non-compliant products. On the contrary, the more and more effective enforcement by market surveillance authorities in domestic markets and viz. imports should lead to **more detection of non-compliant and sanctioning of rogue traders**.

To increase transparency and facilitate compliance throughout the supply chain, manufacturers and importers would be asked to provide in a digital form (e.g. website) relevant compliance information which they are already require to hold and maintain.

To ensure the implementation of this principle, businesses that place products on the EU market (i.e. including directly from 3rd countries without an importer such as in the case of on-line sales) will be asked to ensure a **responsible person for compliance information** acting in their behalf is in located the EU. These businesses will then incur additional one-off costs for the selection of party able to fulfil the function of representative and the set-up of the relative contract. Additional costs concern only a portion of businesses and do not imply a discrimination of third country businesses vis-à-vis other business, as they actually remedy to

the current unbalanced situation where EU and third countries businesses with a presence in the EU can be reached by authorities while others cannot.

Economic operators in the supply chain would **find more easily relevant compliance information** on products they purchase from other operators. Stepped-up compliance information and information by market surveillance authorities would in addition give them more **legal certainty**.

Finally the preferred option contains a Common European Portal though which businesses could provide information to EU consumers on **voluntary measures** regarding their products. This measure would help businesses to comply with their existing obligations to inform consumers free of charge. It would not create new reporting obligations or administrative burden.

Consumers and other end-users

In the public consultation 75% of respondents indicated that consumers and other end-users would be negatively affected by problems of non-compliance (of which 25% even to a significant extent). The measures in the preferred option should help to reduce the magnitude these problems:

Consumer and other, professional end-users of products that are subject to EU harmonisation legislation will benefit from the more and more effective enforcement against non-compliant products and increased level of protection that will result from the initiative. **Fewer non-compliant products** that circulate in or enter the Single Market, implies that consumers would be less likely to purchase such products inadvertently and they would be less exposed to the potential harm that could be caused by such non-compliant products (e.g. adverse health or safety impacts, property losses, higher energy consumption, incorrect measurement of quantities traded).

The increased visibility of enforcement efforts, including by publication of restrictive measures, would create a **higher awareness** among consumers and professional end-users about the risks of non-compliant products.

ANNEX 4: METHODS AND ANALYTICAL MODELS USED IN PREPARING THE IMPACT ASSESSMENT

The absence of detailed, reliable and systematic statistics on enforcement activity and compliance rates across sectors and Member States makes it difficult to provide quantified estimates of the scale of positive impacts on compliance that could results from the policy options[2]. The impact assessment relies on triangulation of the results from the public and other targeted consultations, analysis of data reported by Member States, results from joint enforcement actions, where relevant data or cases from related policy areas, case-studies and literature, and ultimately expert judgement.

Member States have implemented the market surveillance provisions of Regulation (EC) n° 765/2008 many different, specific forms, in terms of organisational structures, level of deployed resources (financial, human and technical), market surveillance strategies and approaches, powers of inspection, and sanction and penalties for product non-compliance[3]. In relation to choices of enforcement regimes, the OECD (2006) concludes that it is highly unlikely that any single model of practices and procedures will provide the most cost-effective means of achieving a high degree of compliance[4]. That being said a 'mix' of best-practice principles for enforcement and inspection can be proposed (OECD 2014)[5] [6] and could serve as a basis to benchmark policy actions[7].

---

2 Few authoritative models are available on effectiveness of market surveillance. The UNECE's ongoing work on a Market Surveillance Model Initiative attempts to arrive at a quantitative modelling tool for MSA's to assess the effectiveness of their market surveillance actions. At present however the research does not allow concluding unequivocally what constitutes an effective market surveillance system.https://www.unece.org/fileadmin/DAM/trade/wp6/documents/2009/wp6_09_GMS_012E.pdf; http://www.unece.org/index.php?id=43283#/

3 Technopolis, Ex-post evaluation of the application of the market surveillance povisions of Regulation (EC) n° 765/2008, 2017.

4 Best practices for consumer policy: Report on the effectiveness of enforcement regimes, DSTI/CP(2006)/21Final, OECD, 2006.

5 OECD, 2014 http://www.oecd.org/gov/regulatory-policy/enforcement-inspections.htm

6 Further refinements could be considered e.g. including elements from ISO standard criteria for bodies performing inspections; see also Annex 12.

7 Similarly in the area of competition policy, the OECD has developed competition law and policy indicators measure the strength and scope of competition regimes and are the foundation for assessing the impact of competition regimes. OECD, 2013, http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ECO/WKP(2013)96&docLanguage=En

ANNEX 5: GENERAL MARKET STATISTICS

1. MARKET ANALYSIS

The market analysis and the detailed statistics were based on the reference list of sectors included in the annex of "Template for drafting a national market surveillance programme pursuant to article 18(5) of Regulation (EC) No 765/2008"[8]. In order to focus on the variables to be included in the analysis, the appropriate NACE divisions have been identified in an attempt to create a correspondence between the list of harmonised sectors and economic sectors / products included in the market analysis. All results should be considered as an estimate, as some divisions might contain one or more classes for which harmonised product rules do not exist.

The analysis for manufacturing had a two-stage approach:

- An analysis a sectorial level oriented towards the macro dimension, looking at:
  - The number of economic operators that are active within the economic sectors for which EU harmonised product rules exist (harmonised sectors);
  - The current contribution of the harmonised sector to the EU economy;
- An analysis at product level focused on the value of harmonised products that are traded within the EU Single Market.

Around 1,850 harmonised products have been identified that represent around 46% of all products (around 4,000) included in the PRODCOM list. The value of harmonised products traded within the EU Single Market has been on average €2,478 billion during the period 2008 – 2014, this corresponds to around 69% of the overall value of traded manufacturing products. This value has been computed considering the following values for the identified harmonised products: value of sold production – Value of Extra EU Exports + Value of Extra EU Imports. 30% of the value of harmonised products (€756 billion) is related to goods imported from non-EU countries. The intra EU imports of products for which harmonised product rules exist represent also 66% of the value of the overall (intra-EU) imports of manufacturing goods (€1,183 billion).

All data were extracted from three databases:

- Structural business statistics (SBS)[9] provided by EUROSTAT to describe the structure of harmonised sectors and measure their economic performance;
- Prodcom - Statistics by Product[10] provided by EUROSTAT to estimate the value of non-harmonised products;
- EU trade since 1988 by Standard International Trade Classification (SITC)[11] provided by EUROSTAT to estimate the value of intra EU trade of harmonised products.

8 http://ec.europa.eu/DocsRoom/documents/20141
9 http://ec.europa.eu/eurostat/web/structural-business-statistics
10 http://ec.europa.eu/eurostat/web/prodcom/overview
11 http://ec.europa.eu/eurostat/web/international-trade-in-goods/data/database

The statistics for trade looked at the number of economic operators that are active within the economic sectors for which EU harmonised product rules exist and the current contribution of the harmonised sector to the EU economy.

Data was extracted from the SBS database[12] based on NACE Rev. 2 classification. In particular the following were considered:

- Business demographic variables (number of enterprises)
- Input related variables: labour input (number of people employed)
- Output related variables (i.e. value added).

2. DETAILED STATISTICS (MANUFACTURING)

2.1 Analysis at sectorial level

It is important to underline that since data are available at NACE division level (Digit 2 – NACE code), all results should be considered as an upper estimate, as some divisions might contains one or more classes for which harmonised product rules do not exist.

Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2] – EU 28

Last update: 17.02.2017

Extracted on: 20.02.2017

Source of data: Eurostat

INDIC_SB: Number of enterprises

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
C13 - Manufacture of textiles	64,422	61,087	61,940	60,798	59,821	59,285	61,311
C14 - Manufacture of wearing apparel	140,824	130,704	130,292	125,953	125,029	122,901	123,399
C15 - Manufacture of leather and related products	40,770	37,337	36,523	36,692	36,418	36,240	36,624
C20 - Manufacture of chemicals and chemical products	28,932	28,634	28,770	28,206	28,320	28,331	28,560
C21 - Manufacture of basic pharmaceutical products and pharmaceutical preparations	3,827	4,604	3,814	3,903	4,021	4,176	4,124
C22 - Manufacture of rubber and plastic products	67,811	66,006	66,872	65,097	63,360	62,182	62,484
C23 - Manufacture of other non-metallic mineral products	106,758	101,683	103,673	101,687	98,020	95,457	95,314
C24 - Manufacture of basic metals	17,789	17,513	18,017	18,371	17,343	17,068	17,183

12 http://ec.europa.eu/eurostat/web/structural-business-statistics/data/database

C25 - Manufacture of fabricated metal products, except machinery and equipment	380,680	369,561	392,794	391,034	382,816	373,925	382,277
C26 - Manufacture of computer, electronic and optical products	46,449	45,045	44,385	42,627	41,447	41,807	41,681
C27 - Manufacture of electrical equipment	50,812	50,636	52,315	51,242	50,204	48,510	48,320
C28 - Manufacture of machinery and equipment n.e.c.	103,368	97,445	98,230	96,621	92,938	91,981	91,692
C29 - Manufacture of motor vehicles, trailers and semi-trailers	21,174	19,818	20,189	20,178	19,481	19,338	19,678
C30 - Manufacture of other transport equipment	14,442	14,393	14,588	14,423	14,004	13,766	14,209
C32 - Other manufacturing	138,155	136,943	146,585	146,016	147,609	149,306	155,086
Total	**1,226,213**	**1,181,409**	**1,218,987**	**1,202,848**	**1,180,831**	**1,164,273**	**1,181,942**

Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2] – EU 28

Last update: 17.02.2017

Extracted on: 20.02.2017

Source of data: Eurostat

INDIC_SB: Turnover or gross premiums written

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
C13 - Manufacture of textiles	84,512	69,784	75,988	79,997	74,677	74,605	76,525
C14 - Manufacture of wearing apparel	87,910	72,976	72,808	75,678	69,500	67,917	70,754
C15 - Manufacture of leather and related products	47,269	38,525	43,289	47,082	48,698	45,340	53,633
C20 - Manufacture of chemicals and chemical products	480,385	418,208	495,208	541,016	544,910	539,577	537,109
C21 - Manufacture of basic pharmaceutical products and pharmaceutical preparations	188,831	208,889	211,024	214,725	227,031	226,752	237,383
C22 - Manufacture of rubber and plastic products	284,629	237,886	267,637	293,898	287,066	288,755	295,398
C23 - Manufacture of other non-metallic mineral products	253,900	208,533	204,657	220,901	207,513	201,079	204,754

C24 - Manufacture of basic metals	428,242	266,576	335,619	390,939	365,273	339,896	340,584
C25 - Manufacture of fabricated metal products, except machinery and equipment	493,358	403,229	435,087	471,949	468,254	460,153	469,450
C26 - Manufacture of computer, electronic and optical products	327,877	268,583	292,428	273,853	278,275	273,776	289,714
C27 - Manufacture of electrical equipment	296,774	255,789	280,483	303,628	294,145	289,359	289,758
C28 - Manufacture of machinery and equipment n.e.c.	613,887	508,448	545,318	618,338	631,858	622,272	640,140
C29 - Manufacture of motor vehicles, trailers and semi-trailers	801,102	624,875	739,934	839,818	846,599	866,735	924,548
C30 - Manufacture of other transport equipment	163,374	157,901	163,471	161,232	174,014	177,649	194,201
C32 - Other manufacturing	98,301	94,216	104,660	112,103	113,696	111,907	116,735
Total	**4,650,349**	**3,834,416**	**4,267,611**	**4,645,156**	**4,631,508**	**4,585,771**	**4,740,685**

Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2] – EU 28

Last update: 17.02.2017

Extracted on: 20.02.2017

Source of data: Eurostat

INDIC_SB: Value added at factor cost

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
C13 - Manufacture of textiles	23,613	19,654	21,793	22,159	21,126	21,153	21,899
C14 - Manufacture of wearing apparel	23,938	19,393	19,463	20,439	18,717	18,645	19,670
C15 - Manufacture of leather and related products	11,644	9,707	11,713	12,299	12,643	11,455	14,235
C20 - Manufacture of chemicals and chemical products	102,247	91,775	110,988	111,538	106,492	104,991	114,710
C21 - Manufacture of basic pharmaceutical products and pharmaceutical preparations	66,717	71,581	73,512	76,397	83,653	69,035	80,447
C22 - Manufacture of rubber and plastic products	80,103	70,299	77,118	81,576	80,394	81,228	85,064
C23 - Manufacture of other non-metallic mineral products	79,114	63,147	63,076	65,644	60,577	58,843	62,149
C24 - Manufacture of basic metals	80,324	46,718	60,626	63,847	57,498	56,862	61,843

C25 - Manufacture of fabricated metal products, except machinery and equipment	163,659	137,121	149,191	158,766	159,229	158,946	167,101
C26 - Manufacture of computer, electronic and optical products	82,029	64,528	77,613	71,914	73,555	72,591	77,918
C27 - Manufacture of electrical equipment	83,068	74,717	85,277	86,529	85,176	84,388	85,666
C28 - Manufacture of machinery and equipment n.e.c.	182,609	150,111	172,592	191,675	190,700	190,137	199,542
C29 - Manufacture of motor vehicles, trailers and semi-trailers	133,857	99,018	140,797	154,252	150,137	157,813	181,251
C30 - Manufacture of other transport equipment	47,474	42,657	46,306	47,304	51,057	53,608	54,229
C32 - Other manufacturing	35,970	34,872	39,503	42,506	41,559	37,541	43,333
Total	**1,196,366**	**995,298**	**1,149,568**	**1,206,842**	**1,192,512**	**1,177,235**	**1,269,055**

Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2] – EU 28

Last update: 17.02.2017

Extracted on: 20.02.2017

Source of data: Eurostat

INDIC_SB: Number of persons employed

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
C13 - Manufacture of textiles	730,477	635,594	602,122	638,431	611,137	602,942	608,060
C14 - Manufacture of wearing apparel	1,288,220	1,108,524	1,078,032	1,046,414	1,005,144	973,918	969,762
C15 - Manufacture of leather and related products	455,967	393,606	412,550	424,091	421,773	423,887	433,945
C20 - Manufacture of chemicals and chemical products	1,076,079	1,031,277	1,169,929	1,172,142	1,159,566	1,147,688	1,146,472
C21 - Manufacture of basic pharmaceutical products and pharmaceutical preparations	422,206	436,363	491,390	454,206	540,069	497,736	542,522
C22 - Manufacture of rubber and plastic products	1,563,742	1,436,169	1,618,215	1,650,655	1,619,321	1,622,869	1,649,665
C23 - Manufacture of other non-metallic mineral products	1,440,147	1,293,147	1,333,697	1,342,452	1,278,170	1,231,496	1,224,781
C24 - Manufacture of basic metals	1,055,689	943,086	1,006,950	1,015,355	991,598	963,838	962,384

C25 - Manufacture of fabricated metal products, except machinery and equipment	3,557,995	3,343,947	3,599,634	3,655,127	3,598,328	3,569,223	3,604,522
C26 - Manufacture of computer, electronic and optical products	1,127,975	1,002,575	1,136,659	1,095,643	1,126,657	1,108,699	1,089,980
C27 - Manufacture of electrical equipment	1,433,374	1,332,254	1,466,551	1,488,681	1,459,910	1,449,203	1,432,494
C28 - Manufacture of machinery and equipment n.e.c.	2,941,171	2,727,707	2,840,648	2,902,308	2,920,152	2,917,483	2,912,683
C29 - Manufacture of motor vehicles, trailers and semi-trailers	2,162,516	1,984,939	2,167,171	2,236,181	2,289,826	2,297,415	2,365,720
C30 - Manufacture of other transport equipment	631,983	625,854	717,065	707,530	706,256	713,710	735,450
C32 - Other manufacturing	798,121	755,245	871,055	895,623	882,347	866,872	881,221
Total	**20,685,662**	**19,050,287**	**20,511,668**	**20,724,839**	**20,610,254**	**20,386,979**	**20,559,661**

If the size of enterprises is considered, micro and SMEs active in harmonised sectors represent **more than 99% of the manufacturing** in these sectors.

Value added at factor cost – EU 28

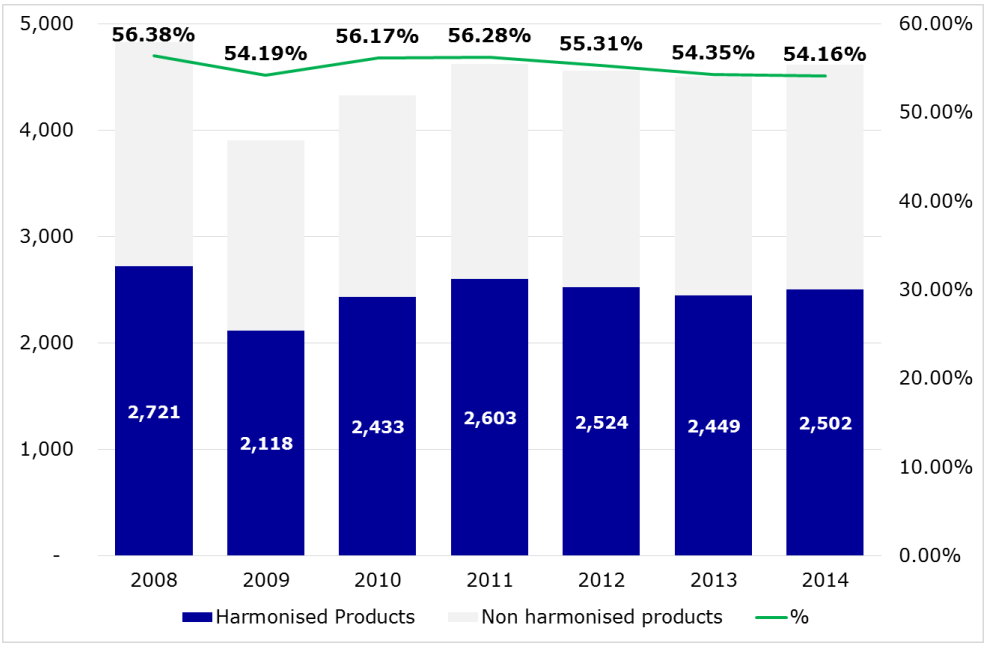
Size of enterprises	**Harmonised Sectors**		**Manufacturing**		**a/b**
	Total (€b) (a)	**%**	**Total (€b)**	**%**	**%**
Micro enterprises (0-9 employees)	**49.02**	6%	84.64	7%	**4%**
SMEs (10 – 249 employees)	**323.54**	38%	451.88	39%	**28%**
Large enterprises (> 249 employees)	488.56	57%	627.25	54%	42%
Total	861	100%	**1,164 (b)**	100%	74%

Turnover or gross premiums written

Size of enterprises	**Harmonised Sectors**		**Manufacturing**		**a/b**
	Total (€b) (a)	**%**	**Total (€b)**	**%**	**%**
Micro enterprises (0-9 employees)	146.15	4%	251.03	5%	3%
SMEs (10 – 249 employees)	1,091.72	33%	530.30	34%	24%
Large enterprises (> 249 employees)	2,067.94	63%	2,782.93	61%	45%
Total	3,306.81	100%	4,564.26	100%	72%

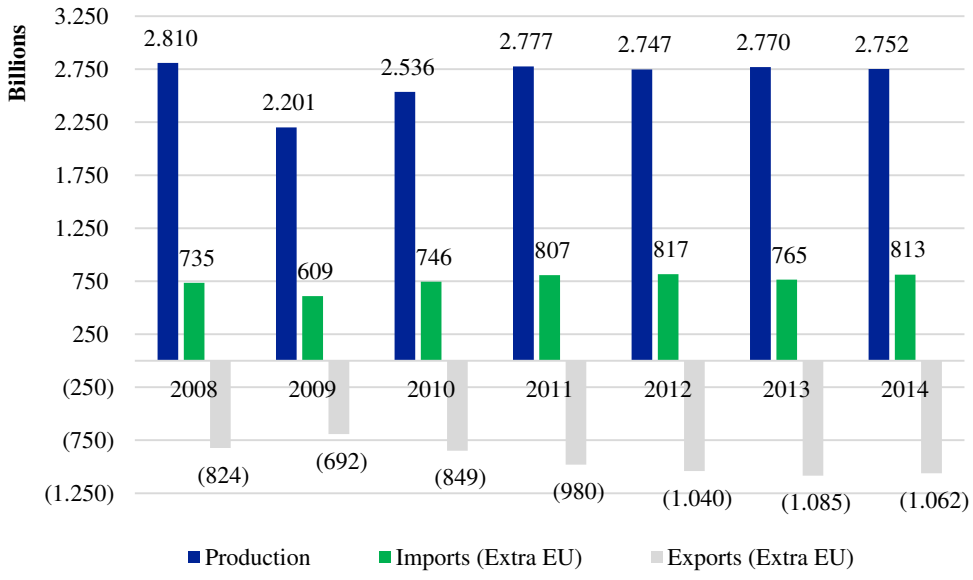
2.2 Analysis at product level

Value of harmonised products circulating within the European Single Market (2008-2015), € billions, EU28



Source: Prodcom – statistics by product, EUROSTAT (2016)

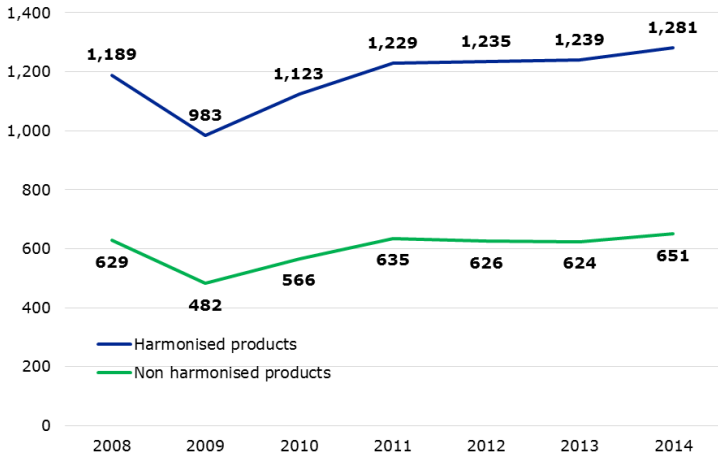
Trade of harmonised products: sold production and trades with non EU countries (2008-2015, EU-28), € billions

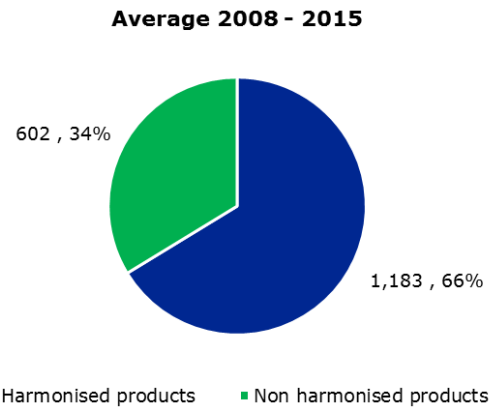


Source: Prodcom – statistics by product, EUROSTAT (2016)

The intra EU imports of products for which harmonised product rules exist represent also 66% of the value of the overall (intra-EU) imports of manufacturing goods (€1,183 billion).

Value of intra EU imports: harmonised products vs non-harmonised products (annual value and annual average 2008-2015, EU-28, EUR billion)





Source: EU trade since 1998 by SITC, EUROSTAT (2016)

3. DETAILED STATISTICS (RETAIL)

Annual detailed enterprise statistics for trade (NACE Rev. 2 G) [sbs_na_dt_r2] – EU 28

Last update	13/01/17
Extracted on	03/02/17
Source of data	Eurostat
INDIC_SB	Number of enterprises

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
Sale of cars and light motor vehicles	178,747	184,435	182,110	189,127	189,835	192,212	198,430
Sale of other motor vehicles	11,335	12,724	12,724	14,000	14,089	14,471	14,781
Sale of motor vehicle parts and accessories	106,823	106,823	110,000	113,509	114,560	115,432	117,558
Wholesale on a fee or contract basis	533,922	533,922	579,659	590,000	588,690	583,523	583,431
Agents involved in the sale of timber and building materials	37,435	38,049	38,956	38,431	37,572	36,506	36,436
Agents involved in the sale of machinery, industrial equipment, ships and aircraft	38,544	41,284	41,692	41,651	41,753	40,197	40,872
Agents involved in the sale of textiles, clothing, fur, footwear and leather goods	49,822	49,762	50,496	50,220	49,179	48,185	44,449
Agents involved in the sale of a variety of goods	142,182	135,424	165,673	170,242	171,493	174,055	178,561
Wholesale of textiles	24,988	23,220	23,497	22,758	22,462	22,225	23,284
Wholesale of clothing and footwear	68,821	62,802	62,940	62,722	63,872	61,021	62,079
Wholesale of electrical household appliances	34,560	32,761	30,907	29,851	29,166	28,772	28,476
Wholesale of china and glassware and cleaning materials	17,235	18,202	18,427	17,744	17,335	16,516	16,455

Wholesale of perfume and cosmetics	18,380	18,472	18,951	18,663	19,829	21,471	21,624
Wholesale of furniture, carpets and lighting equipment	25,681	24,692	24,695	24,742	24,028	24,606	24,579
Wholesale of watches and jewellery	11,935	12,350	13,136	12,976	12,905	13,709	13,904
Wholesale of other household goods	87,579	85,197	89,707	90,205	86,849	87,462	85,658
Wholesale of information and communication equipment	59,241	60,000	60,000	61,081	60,706	61,256	62,322
Wholesale of agricultural machinery, equipment and supplies	22,507	19,782	21,633	21,774	22,499	23,468	22,696
Wholesale of machine tools	13,141	13,726	14,076	14,602	13,982	13,782	14,190
Wholesale of mining, construction and civil engineering machinery	9,779	9,910	10,173	10,152	10,167	11,226	10,247
Wholesale of machinery for the textile industry and of sewing and knitting machines	2,858	2,858	2,858	2,451	2,483	2,400	2,242
Wholesale of other office machinery and equipment	10,965	11,003	11,163	11,761	10,971	10,584	10,733
Wholesale of other machinery and equipment	93,560	99,363	101,202	102,338	103,453	103,095	105,612
Wholesale of wood, construction materials and sanitary equipment	116,192	116,095	115,587	114,767	114,114	113,312	113,775
Wholesale of hardware, plumbing and heating equipment and supplies	41,977	45,723	44,955	46,211	46,407	46,350	46,781
Wholesale of chemical products	26,356	26,565	27,411	27,733	27,877	27,479	27,590
Non-specialised wholesale trade	111,279	105,209	115,548	124,286	122,994	121,357	123,297
Retail sale in non-specialised stores with food, beverages or tobacco predominating	437,034	427,551	435,256	438,670	429,818	423,029	415,256
Other retail sale in non-specialised stores	116,445	126,887	135,908	143,923	140,986	135,023	132,956
Retail sale of information and communication equipment in specialised stores	99,768	99,768	99,768	94,571	90,497	90,324	88,931
Retail sale of textiles in specialised stores	77,278	80,110	78,152	77,169	73,302	70,118	68,096
Retail sale of hardware, paints and glass in specialised stores	141,868	138,500	135,325	131,903	131,402	125,655	125,191
Retail sale of electrical household appliances in specialised stores	54,634	55,483	54,486	50,055	46,912	44,204	42,244
Retail sale of furniture, lighting equipment and other household articles in specialised stores	178,372	173,255	168,405	168,813	161,615	154,629	150,479
Retail sale of games and toys in specialised stores	18,993	18,339	19,129	19,276	17,140	18,319	18,378
Retail sale of clothing in specialised stores	350,599	351,688	347,417	341,450	332,799	320,873	315,221

Retail sale of footwear and leather goods in specialised stores	80,338	79,912	81,694	77,665	77,288	71,463	70,910
Retail sale of medical and orthopaedic goods in specialised stores	20,530	21,124	21,191	22,633	24,348	24,781	23,925
Retail sale of cosmetic and toilet articles in specialised stores	47,566	47,566	47,807	48,367	45,409	44,906	45,968
Retail sale of watches and jewellery in specialised stores	70,068	69,637	67,830	69,145	68,839	68,397	67,582
Retail sale via stalls and markets of textiles, clothing and footwear	121,912	130,551	133,446	132,158	131,658	130,878	120,710
Retail sale via stalls and markets of other goods	102,578	94,904	94,904	119,407	119,535	124,217	153,413
Retail sale via mail order houses or via Internet	59,661	70,000	70,000	122,818	144,729	164,936	179,219
Total	**3,873,488**	**3,875,628**	**3,978,894**	**4,082,020**	**4,055,547**	**4,026,424**	**4,048,541**

* When there is no information, data from previous or following year is taken.

Annual detailed enterprise statistics for trade (NACE Rev. 2 G) [sbs_na_dt_r2] – EU 28

Last update	13/01/17
Extracted on	03/02/17
Source of data	Eurostat
INDIC_SB	Value added at factor cost

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
Sale of cars and light motor vehicles	67,556	59,527	63,046	67,581	61,671	60,965	69,474
Sale of other motor vehicles	8,684	5,275	5,886	6,675	6,105	6,816	6,946
Sale of motor vehicle parts and accessories	23,000	22,241	25,119	29,348	25,700	26,012	27,100
Wholesale on a fee or contract basis	41,000	37,052	41,353	44,490	43,524	44,001	43,897
Agents involved in the sale of timber and building materials	2,530	2,240	2,254	2,413	2,264	2,224	2,577
Agents involved in the sale of machinery, industrial equipment, ships and aircraft	6,819	5,860	6,388	6,623	7,230	7,158	7,936
Agents involved in the sale of textiles, clothing, fur, footwear and leather goods	3,650	2,667	3,654	3,832	3,223	3,482	3,765
Agents involved in the sale of a variety of goods	8,364	6,739	7,886	8,654	7,780	7,611	7,533
Wholesale of textiles	4,414	4,145	4,466	4,659	4,355	4,549	4,278
Wholesale of clothing and footwear	20,830	22,133	20,777	23,313	22,125	22,992	24,002
Wholesale of electrical household appliances	18,668	18,081	16,616	17,071	17,826	16,065	17,519
Wholesale of china and glassware and cleaning materials	4,455	5,102	5,608	5,890	5,568	4,981	7,350

Wholesale of perfume and cosmetics	10,035	12,061	12,718	11,610	12,318	12,925	11,118
Wholesale of furniture, carpets and lighting equipment	6,633	6,491	6,326	6,685	6,305	6,261	6,415
Wholesale of watches and jewellery	2,358	2,844	3,146	2,679	2,679	2,597	3,121
Wholesale of other household goods	26,320	26,350	25,446	27,097	25,028	29,780	27,950
Wholesale of information and communication equipment	42,378	42,000	42,000	47,049	48,338	49,000	50,000
Wholesale of agricultural machinery, equipment and supplies	8,450	7,511	7,021	8,836	9,318	10,040	9,815
Wholesale of machine tools	5,043	4,386	4,769	5,366	5,118	5,053	5,986
Wholesale of mining, construction and civil engineering machinery	6,949	5,380	5,167	6,078	6,037	6,065	6,230
Wholesale of machinery for the textile industry and of sewing and knitting machines	489	310	310	410	416	462	412
Wholesale of other office machinery and equipment	5,523	5,351	5,178	4,954	5,273	5,142	5,207
Wholesale of other machinery and equipment	52,298	49,163	54,040	56,977	59,083	56,241	61,163
Wholesale of wood, construction materials and sanitary equipment	39,682	34,768	34,575	37,777	33,676	35,559	36,833
Wholesale of hardware, plumbing and heating equipment and supplies	26,881	23,367	24,255	26,602	26,564	25,080	26,525
Wholesale of chemical products	13,889	13,673	16,141	16,181	16,282	16,576	16,903
Non-specialised wholesale trade	28,079	27,894	25,700	28,000	25,292	25,771	30,243
Retail sale in non-specialised stores with food, beverages or tobacco predominating	122,400	122,400	130,000	130,000	137,560	140,000	140,000
Other retail sale in non-specialised stores	23,684	23,684	23,684	23,684	23,684	23,684	23,684
Retail sale of information and communication equipment in specialised stores	13,105	12,605	11,798	11,000	11,796	10,441	10,723
Retail sale of textiles in specialised stores	2,984	3,014	2,894	2,483	2,470	2,562	2,653
Retail sale of hardware, paints and glass in specialised stores	22,614	21,146	21,496	22,529	20,773	20,603	21,594
Retail sale of electrical household appliances in specialised stores	7,470	6,646	6,370	6,258	5,747	5,691	5,842
Retail sale of furniture, lighting equipment and other household articles in specialised stores	24,437	22,694	23,843	24,201	22,495	22,343	22,853

Retail sale of games and toys in specialised stores	2,326	2,277	2,034	2,225	2,458	2,341	2,428
Retail sale of clothing in specialised stores	44,884	44,259	45,143	45,775	44,605	45,029	48,892
Retail sale of footwear and leather goods in specialised stores	8,516	9,608	10,411	9,619	9,907	9,653	10,005
Retail sale of medical and orthopaedic goods in specialised stores	4,073	4,217	4,254	4,609	4,948	5,245	5,134
Retail sale of cosmetic and toilet articles in specialised stores	8,799	7,339	8,149	8,003	7,589	8,707	9,710
Retail sale of watches and jewellery in specialised stores	6,600	6,070	6,994	7,491	7,603	6,907	7,587
Retail sale via stalls and markets of textiles, clothing and footwear	1,249	988	1,329	1,389	1,149	956	956
Retail sale via stalls and markets of other goods	1,137	1,137	1,137	816	941	941	1,026
Retail sale via mail order houses or via Internet	9,670	11,335	11,919	12,828	13,613	14,383	17,793
Total	**788,920**	**752,028**	**781,296**	**819,757**	**806,432**	**812,894**	**851,175**

* When there is no information, data from previous or following year is taken.

Annual detailed enterprise statistics for trade (NACE Rev. 2 G) [sbs_na_dt_r2] – EU 28

Last update	13/01/17
Extracted on	03/02/17
Source of data	Eurostat
INDIC_SB	Turnover or gross premiums written

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
Sale of cars and light motor vehicles	760,059	668,009.6	679,116.8	708,070.4	673,520.8	664,399.5	719,247.3
Sale of other motor vehicles	60,586	43,837.2	47,761.5	49,151.9	48,233.9	50,932.8	53,036.6
Sale of motor vehicle parts and accessories	139,000	127,835.9	148,145.7	168,249.0	166,000.0	166,923.7	172,000.0
Wholesale on a fee or contract basis	257,000	219,541.9	236,260.9	260,064.7	264,805.1	256,545.4	250,000.0
Agents involved in the sale of timber and building materials	9,312	6,668.8	7,307.3	7,537.8	7,779.7	7,566.7	7,639.0
Agents involved in the sale of machinery, industrial equipment, ships and aircraft	18,382	15,462.4	17,339.7	17,995.2	17,588.2	19,086.6	21,414.8
Agents involved in the sale of textiles, clothing, fur, footwear and leather goods	8,982	7,232.6	8,619.5	9,363.1	8,213.9	9,173.3	9,545.7
Agents involved in the sale of a variety of goods	55,127	48,388.1	50,080.9	56,239.7	56,788.1	55,583.9	52,125.2
Wholesale of textiles	26,859	24,083.2	26,976.5	27,547.6	28,128.7	26,161.3	27,127.3

Wholesale of clothing and footwear	118,896	119,916.3	114,266.3	130,209.0	135,707.4	132,652.0	143,308.2
Wholesale of electrical household appliances	172,804	159,310.6	159,189.8	149,874.2	152,911.3	149,499.5	141,651.1
Wholesale of china and glassware and cleaning materials	26,885	29,288.6	33,515.8	32,680.3	34,042.0	34,548.2	38,172.1
Wholesale of perfume and cosmetics	47,781	55,992.5	54,903.9	56,442.6	57,157.7	59,595.0	55,697.8
Wholesale of furniture, carpets and lighting equipment	43,104	36,819.2	37,328.0	39,905.5	39,427.9	37,175.0	38,934.6
Wholesale of watches and jewellery	14,692	14,715.4	17,317.6	21,205.6	21,205.6	18,641.9	18,065.7
Wholesale of other household goods	168,284	164,405.1	174,628.3	177,353.3	173,752.5	174,316.9	179,279.3
Wholesale of information and communication equipment	332,397	310,000.0	310,000.0	357,979.1	364,816.5	360,000.0	360,000.0
Wholesale of agricultural machinery, equipment and supplies	58,873	52,592.1	53,452.8	64,026.0	68,393.8	68,500.6	71,033.2
Wholesale of machine tools	26,146	22,268.1	25,526.1	28,416.0	27,703.6	27,629.6	29,705.1
Wholesale of mining, construction and civil engineering machinery	42,523	31,106.1	32,182.7	36,297.4	36,234.9	34,161.1	36,993.6
Wholesale of machinery for the textile industry and of sewing and knitting machines	2,840	2,839.7	2,839.7	2,173.8	2,358.4	2,411.1	2,049.6
Wholesale of other office machinery and equipment	26,130	25,766.7	26,040.0	26,261.7	25,125.9	24,913.4	24,939.5
Wholesale of other machinery and equipment	276,610	242,974.4	271,384.6	293,913.8	301,142.1	296,082.2	303,652.5
Wholesale of wood, construction materials and sanitary equipment	277,752	239,684.3	243,814.8	260,567.9	253,973.9	249,293.5	254,307.1
Wholesale of hardware, plumbing and heating equipment and supplies	141,866	131,370.9	141,598.4	150,673.2	150,968.7	142,687.1	144,918.2
Wholesale of chemical products	138,675	120,981.4	139,625.1	156,687.8	165,402.0	167,646.4	168,352.4
Non-specialised wholesale trade	236,577	218,941.2	225,000.0	240,000.0	241,507.9	255,000.0	269,941.8
Retail sale in non-specialised stores with food, beverages or tobacco predominating	922,634	900,000.0	900,000.0	1,000,000	1,021,082	1,000,000	1,000,000
Other retail sale in non-specialised stores	122,943	122,942.8	122,942.8	122,942.8	122,942.8	122,942.8	130,000.0

Retail sale of information and communication equipment in specialised stores	75,369	72,212.4	72,263.0	70,000.0	74,263.1	67,974.0	63,639.1
Retail sale of textiles in specialised stores	12,524	11,630.9	11,479.9	10,646.6	10,657.8	10,874.0	10,751.2
Retail sale of hardware, paints and glass in specialised stores	114,070	107,369.7	110,566.0	114,271.1	108,946.1	104,572.1	108,612.3
Retail sale of electrical household appliances in specialised stores	49,044	44,843.3	42,180.2	40,734.3	42,969.2	41,748.8	42,142.4
Retail sale of furniture, lighting equipment and other household articles in specialised stores	117,991	107,725.5	112,689.8	113,486.7	111,455.2	107,604.8	109,553.2
Retail sale of games and toys in specialised stores	12,363	11,831.5	12,265.1	12,381.0	11,809.1	11,949.2	12,244.7
Retail sale of clothing in specialised stores	187,702	178,158.1	188,552.6	194,066.9	193,236.8	191,531.3	203,719.3
Retail sale of footwear and leather goods in specialised stores	39,713	39,680.3	42,589.9	40,791.7	42,940.8	42,491.9	43,596.8
Retail sale of medical and orthopaedic goods in specialised stores	13,725	13,883.0	13,724.0	14,854.4	15,804.0	16,202.1	16,383.6
Retail sale of cosmetic and toilet articles in specialised stores	40,369	36,889.0	39,766.9	40,347.2	38,177.4	40,631.9	42,699.7
Retail sale of watches and jewellery in specialised stores	25,777	23,015.6	26,052.5	29,965.0	32,248.4	29,324.5	30,926.4
Retail sale via stalls and markets of textiles, clothing and footwear	5,111	3,642.5	4,773.4	5,126.5	4,276.5	3,735.5	3,735.5
Retail sale via stalls and markets of other goods	5,266	5,266.3	5,266.3	5,266.3	3,674.8	3,674.8	3,820.1
Retail sale via mail order houses or via Internet	65,438	67,942.7	67,942.7	67,942.7	67,942.7	67,942.7	67,942.7
Total	**5,298,181**	**4,887,066**	**5,057,278**	**5,411,710**	**5,425,318**	**5,354,327**	**5,482,905**

* When there is no information, data from previous or following year is taken.

Annual detailed enterprise statistics for trade (NACE Rev. 2 G) [sbs_na_dt_r2] – EU 28

Last update 13/01/17

Extracted on 03/02/17

Source of data Eurostat

INDIC_SB Number of persons employed

NACE_R2/TIME	2008	2009	2010	2011	2012	2013	2014
Sale of cars and light motor vehicles	1,492,200	1,462,700	1,399,400	1,416,400	1,366,000	1,330,500	1,335,452
Sale of other motor vehicles	124,200	120,600	120,900	122,000	119,900	123,600	121,601
Sale of motor vehicle parts and accessories	670,000	685,000	674,800	707,400	704,900	706,300	706,230
Wholesale on a fee or contract basis	971,600	1,006,700	1,004,400	1,046,000	1,040,500	1,017,600	1,016,957
Agents involved in the sale of timber and building materials	70,400	69,100	63,900	64,000	63,800	62,500	67,616
Agents involved in the sale of machinery, industrial equipment, ships and aircraft	94,500	105,000	95,100	97,100	100,000	100,400	104,794
Agents involved in the sale of textiles, clothing, fur, footwear and leather goods	84,000	88,100	88,000	90,500	89,400	87,400	80,224
Agents involved in the sale of a variety of goods	236,900	236,800	259,100	276,900	262,900	262,500	263,389
Wholesale of textiles	123,900	122,500	121,100	120,400	121,600	108,800	105,145
Wholesale of clothing and footwear	381,400	399,300	367,900	382,800	377,900	365,700	370,853
Wholesale of electrical household appliances	297,800	275,600	266,900	262,600	255,600	243,500	243,175
Wholesale of china and glassware and cleaning materials	101,600	108,800	109,700	107,400	103,100	98,800	94,825
Wholesale of perfume and cosmetics	169,600	188,200	194,400	186,100	181,100	194,800	187,787
Wholesale of furniture, carpets and lighting equipment	154,000	144,900	142,300	138,500	135,800	134,200	133,442
Wholesale of watches and jewellery	51,100	56,300	56,100	55,900	54,200	56,500	54,802
Wholesale of other household goods	530,200	577,300	553,700	544,400	509,200	521,600	508,582
Wholesale of information and communication equipment	575,500	566,800	574,400	599,900	588,800	585,500	580,000
Wholesale of agricultural machinery, equipment and supplies	152,300	165,700	166,600	174,700	180,100	182,300	186,016
Wholesale of machine tools	79,800	86,200	86,700	91,000	87,200	81,900	85,640
Wholesale of mining, construction and civil engineering machinery	99,400	93,200	88,300	92,400	91,600	88,200	88,167
Wholesale of machinery for the textile industry and of sewing and knitting machines	11,900	10,900	10,900	10,400	10,300	9,200	8,219

Wholesale of other office machinery and equipment	100,900	103,400	101,600	99,300	95,200	94,300	94,688
Wholesale of other machinery and equipment	776,000	823,000	848,000	864,100	856,700	847,000	869,238
Wholesale of wood, construction materials and sanitary equipment	933,300	942,800	892,000	921,100	897,800	865,700	849,093
Wholesale of hardware, plumbing and heating equipment and supplies	483,100	507,100	499,700	536,800	514,500	502,500	483,719
Wholesale of chemical products	197,700	207,400	206,500	212,300	209,000	210,200	203,281
Non-specialised wholesale trade	691,200	685,500	655,800	663,000	673,500	665,700	649,412
Retail sale in non-specialised stores with food, beverages or tobacco predominating	5,452,100	5,818,600	5,609,600	5,778,100	5,780,700	5,783,100	5,803,517
Other retail sale in non-specialised stores	1,064,200	996,000	1,037,600	1,101,400	1,069,300	1,060,700	1,068,017
Retail sale of information and communication equipment in specialised stores	469,200	465,100	453,100	440,000	422,300	405,700	396,919
Retail sale of textiles in specialised stores	191,800	191,400	186,300	180,600	180,100	177,300	170,033
Retail sale of hardware, paints and glass in specialised stores	801,200	769,900	780,300	798,100	765,400	724,200	736,456
Retail sale of electrical household appliances in specialised stores	290,900	291,700	268,800	255,900	251,400	240,500	231,517
Retail sale of furniture, lighting equipment and other household articles in specialised stores	858,700	836,000	838,000	815,900	807,100	763,000	766,580
Retail sale of games and toys in specialised stores	97,400	97,400	101,800	98,900	94,600	94,700	95,506
Retail sale of clothing in specialised stores	1,938,100	1,881,000	1,931,300	1,934,000	1,884,600	1,862,700	1,910,139
Retail sale of footwear and leather goods in specialised stores	423,100	434,300	439,100	433,100	426,700	423,700	419,150
Retail sale of medical and orthopaedic goods in specialised stores	124,900	133,500	134,200	145,500	151,900	159,400	155,627
Retail sale of cosmetic and toilet articles in specialised stores	351,700	345,600	345,300	342,500	322,600	338,000	342,605
Retail sale of watches and jewellery in specialised stores	243,600	241,100	245,300	259,500	267,000	248,200	253,418
Retail sale via stalls and markets of textiles, clothing and footwear	170,100	145,400	162,200	159,000	157,900	154,200	142,466
Retail sale via stalls and markets of other goods	201,400	114,100	121,900	134,100	135,400	137,700	168,107
Retail sale via mail order houses or via Internet	253,500	275,200	315,200	358,700	411,900	440,200	487,773
Total	**22,586,400**	**22,875,200**	**22,618,200**	**23,118,700**	**22,819,500**	**22,560,500**	**22,640,177**

* When there is no information, data from previous or following year is taken.

Regarding the distributive trade by employment, it is important to underline that since data are available at NACE division level (Digit 3 – NACE code), all results should be considered as an upper estimate, as some divisions might contains one or more classes for which harmonised product rules do not exist.

Distributive trades by employment size class (NACE Rev. 2, G) [sbs_sc_dt_r2] – EU 28

Last update	**14.12.16**
Extracted on	**20.02.17**
Source of data	**Eurostat**

Number of enterprises	**2012**	**2013**	**2014**	**Average**	**Percentage**
From 0 to 1 person employed	2.577.519	2.604.470	2.645.964	2.609.318	56,84%
From 2 to 9 persons employed	1.732.022	1.673.011	1.663.731	1.689.588	36,81%
From 10 to 19 persons employed	171.057	164.476	166.101	167.211	3,64%
From 20 to 49 persons employed	86.371	83.625	84.028	84.675	1,84%
From 50 to 249 persons employed	34.862	33.078	32.741	33.560	0,73%
250 persons employed or more	5.993	5.930	5.929	5.951	0,13%
				4.590.303	

Turnover or gross premiums written	**2012**	**2013**	**2014**	**Average**	**Percentage**
From 0 to 1 person employed	394.997	390.950	389.927	391.958	5,22%
From 2 to 9 persons employed	1.072.535	1.020.808	1.088.970	1.060.771	14,12%
From 10 to 19 persons employed	672.167	639.121	645.621	652.303	8,68%
From 20 to 49 persons employed	999.342	945.590	970.937	971.956	12,94%
From 50 to 249 persons employed	1.571.164	1.552.925	1.591.293	1.571.794	20,93%
250 persons employed or more	2.773.586	2.872.213	2.940.377	2.862.059	38,11%
				7.510.841	

Value added at factor cost	**2012**	**2013**	**2014**	**Average**	**Percentage**
From 0 to 1 person employed	47.510	48.323	45.848	47.227	5,07%
From 2 to 9 persons employed	169.918	164.883	173.642	169.481	18,18%
From 10 to 19 persons employed	90.665	89.106	91.725	90.499	9,71%
From 20 to 49 persons employed	116.624	115.022	120.987	117.544	12,61%
From 50 to 249 persons employed	159.881	170.064	181.826	170.590	18,30%
250 persons employed or more	327.393	311.574	371.255	336.741	36,13%
				932.082	

Number of persons employed	2012	2013	2014	Average	Percentage
From 0 to 1 person employed	2.426.329	2.419.255	2.470.014	2.438.533	9,66%
From 2 to 9 persons employed	6.183.691	5.958.154	5.976.103	6.039.316	23,93%
From 10 to 19 persons employed	2.341.761	2.230.178	2.255.139	2.275.693	9,02%
From 20 to 49 persons employed	2.705.197	2.624.023	2.629.549	2.652.923	10,51%
From 50 to 249 persons employed	3.370.595	3.245.546	3.241.023	3.285.721	13,02%
250 persons employed or more	8.498.570	8.541.047	8.607.334	8.548.984	33,87%
				25.241.169	

ANNEX 6: GENERAL OVERVIEW OF THE EU MARKET SURVEILLANCE FRAMEWORK FOR ON NON-FOOD PRODUCTS

Under Regulation (EC) No 765/2008 national market surveillance authorities have clear obligations to proactively control products made available on the market, to organise themselves and ensure coordination between themselves at the national level and to cooperate at the EU level[13]. Economic operators have the clear obligation to cooperate with the national market surveillance authorities and to take corrective action where necessary. National market surveillance authorities have the authority to take sanctions which can include the destruction of products.

Regulation (EC) No 765/2008 integrates the provisions of Regulation 339/93 on control of products from third countries. Such controls are now part and parcel of market surveillance activities and Regulation (EC) No 765/2008 obliges national market surveillance and customs authorities to cooperate in order to ensure a seamless system. Such controls must be carried out in a non-discriminatory manner in line with the WTO rules and under the same rules and conditions as set out for internal market surveillance controls.

It should be noted, however, that most sector legislation contains provisions on the obligations of economic operators vis-à-vis market surveillance authorities and specific procedures and measures when products are found to be non-compliant:

MARKET SURVEILLANCE PROVISIONS IN EU LEGISLATION		
MARKET SURVEILLANCE MEASURES AND STRUCTURES	**REGULATION (EC) No 765/2008**	**SECTOR LEGISLATION**
MARKET SURVEILLANCE 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**

13 The General Product Safety Directive also contains requirements on market surveillance. The relationship between Regulation (EC) No 765/2008 and the General Product Safety Directive is described in detail in the Working Paper of 3 March 2010 available at: http://ec.europa.eu/consumers/safety/prod_legis/docs/20100324_guidance_gspd_reg_en.pdf

MARKET SURVEILLANCE PROVISIONS IN EU LEGISLATION		
MARKET SURVEILLANCE MEASURES AND STRUCTURES	**REGULATION (EC) No 765/2008**	**SECTOR LEGISLATION**
Procedure for compliant products which present a risk to health and safety	**No**	**Yes**
MARKET SURVEILLANCE STRUCTURES		
General requirements for market surveillance	**Yes**	**No but legislation refers to Regulation (EC) No 765/2008**
Information obligations about market surveillance authorities		
Obligations of the Member States as regards organisation of market surveillance		
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**

The European Commission has the responsibility to facilitate the exchange of information between national authorities (in relation to their national market surveillance programmes, their risk assessment methodologies, etc.) in order to ensure that market surveillance is effectively EU-wide and that Member States can pool together their means.

1. WHY DO WE NEED MARKET SURVEILLANCE?

Member States have to take appropriate measures to prevent the making available on the market and use[14] of non-compliant products. Market surveillance aims at ensuring that products fulfil the applicable requirements providing a high level of protection of public interests such as health and safety in general, health and safety in the workplace, protection of consumers, protection of the environment and security while ensuring 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 Union rule. Market surveillance entitles

14 Subject to specific Union harmonisation legislation.

citizens to an equivalent level of protection throughout the single market, regardless of the origin of the product. Further, market surveillance is important for the interest of economic operators, because it helps to eliminate unfair competition.

Market surveillance activities are not directed exclusively towards the protection of health and safety but are additionally undertaken with the aim of enforcing Union legislation which seeks also to safeguard other public interests, for example by means of regulating the accuracy of measurement, electromagnetic compatibility, energy efficiency, consumer and environment protection, following the principle of "high level of protection" as laid down in Article 114 (3) TFEU.

Member States must ensure effective surveillance of their market. They are required to organise and carry out the monitoring of the products made available on the market or imported. Member States have to take appropriate measures to ensure that the provisions of Regulation (EC) No 765/2008, of Directive 2001/95/EC and of the other Union harmonisation legislation, as well as non-harmonised, national legislation, in force are respected in the EU and, in particular, to prevent the making available on the market and use of non-compliant and/or unsafe products.

Market surveillance should enable unsafe products or products which otherwise do not conform to applicable requirements set out in Union harmonisation legislation to be identified and kept or taken off the market and unscrupulous or even criminal operators punished. It should also act as a powerful deterrent[15]. For that purpose Member States must:

- correctly implement the provisions of the relevant legislation and allow for sanctions proportional to any infringements;

- survey the products (whatever their origin) introduced on their market in order to ensure that they have been subjected to the necessary procedures, that the marking and documentation requirements have been respected and that they have been designed and manufactured in accordance with the Union harmonisation legislation requirements.

In order to be effective, the market surveillance effort should be uniform across the Union. This is all the more important considering that each point of the Union's external border constitutes an access point for a great quantity of products from third countries. If market surveillance is "softer" in some parts of the Union than others, weak spots are created which threaten the public interest and create unfair trade conditions. Consequently, there must be effective market surveillance along the entire length of the Union's external borders.

In order to guarantee the necessary objectivity and impartiality, market surveillance must be undertaken by the authorities of the Member States. Certain checks (e.g. tests, inspections) can be delegated to other bodies, but the official authorities must retain full responsibility for the decisions taken following these checks. Controls carried out within the framework of market surveillance may be carried out at different times during the life-cycle of a product,

15 According to Article 16 of Regulation (EC) No 765/2008 "Market surveillance shall ensure that products covered by Union harmonisation legislation which, when used in accordance with their intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained, are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements set out in Union harmonisation legislation are withdrawn or their being made available on the market is prohibited or restricted and that the public, the Commission and the other Member States are informed accordingly. Member States shall ensure that effective measures can be taken in relation to any product category subject to Union harmonisation legislation".

following its placing on the market, such as distribution, putting into use or final use. It can, therefore, be exerted in various locations, e.g. importers establishments, wholesale or retail distributors, hire companies, users, etc.

2. CONTROLS BY MARKET SURVEILLANCE AUTHORITIES

Market surveillance authorities shall check the compliance of the product with the legal requirements applicable at the moment of the placing of the market or, if relevant, putting into service.

Thus, market surveillance does not formally take place during the design and production stages, which is before the manufacturer has taken formal responsibility for the conformity of the products, usually by affixing the CE marking. However, nothing prevents market surveillance authorities and economic operators to collaborate during the design and production phase. Such collaboration may help taking preventive actions and identifying as early as possible safety and conformity issues.

Other exceptions to the principle that market surveillance can only take place after the manufacturer has taken formal responsibility for the products are trade fairs, exhibitions and demonstrations. Most Union harmonisation legislation allows the showing and display of non-CE marked products at trade fairs, exhibitions and demonstrations, provided that a visible sign clearly indicates that the products may not be marketed or put into service until they have been made to comply, and that adequate measures are taken during demonstrations, where appropriate, to ensure the protection of public interests. Market surveillance authorities must monitor that this obligation is respected.

For market surveillance to be efficient, resources should be concentrated where risks are likely to be higher or non-compliance more frequent, or where a particular interest can be identified. Statistics and risk assessment procedures can be used for this purpose. To be able to monitor products on the market, market surveillance authorities must have the power, competence and resources:

- to regularly visit commercial, industrial and storage premises;
- to regularly visit, if appropriate, work places and other premises where products are put into service[16];
- to organise random and spot checks;
- to take samples of products, and to subject them to examination and testing and
- to require, upon reasoned request, all necessary information.

The first level of control are documentary and visual checks, for example regarding the CE marking and its affixing, the availability of the EU declaration of conformity, the information accompanying the product and the correct choice of conformity assessment procedures. More profound checks may be however necessary to verify the conformity of the product, for example regarding the correct application of the conformity assessment procedure, the

16 This is important for products (for example machinery and pressure equipment) that are directly, after being manufactured, installed and put into service at the premises of the client.

compliance with the applicable essential requirements, and the contents of the EU declaration of conformity.

In practice, individual market surveillance activities can focus on certain aspects of the requirements. Besides market surveillance activities that have as their explicit aim the verification of products made available on the market, other public mechanisms exist that, although not directly designed for that aim, can nevertheless have as a consequence the uncovering of non-compliance[17]. Labour inspectorates that check safety at the workplace, for example, can discover that the design or construction of a machine, or personal protective equipment bearing the CE marking, is not in conformity with the applicable requirement[18].

Information on the compliance of a product at the moment when it was placed on the market can also be obtained during in-use inspections, or by analysing the factors that caused an accident. Complaints from consumers or other users about the product, or from manufacturers or distributors about unfair competition can also provide information for market surveillance purposes.

Monitoring of products made available on the market may be divided between several authorities on the national level, for example functionally or geographically. Where the same products are subject to control by more than one authority (for example customs and a sectoral authority, or local authorities), coordination between services within a Member State is necessary.

Voluntary initiatives, such as product certification or application of a quality management system, cannot be put on the same footing as market surveillance activities carried out by an authority. Still, they can contribute to the elimination of risks and non-compliances. However, market surveillance authorities must be impartial regarding all voluntary marks, labels and arrangements, and they may only be taken into consideration, in a transparent and non-discriminatory way, for the risk and compliance assessment. Accordingly, products should not be excluded from market surveillance operations even if they have been subject to voluntary certification or other voluntary initiatives.

Union harmonisation legislation provides for two different tools that enable market surveillance authorities to receive information on the product: the EU declaration of conformity and the technical documentation. These must be made available by the manufacturer, the authorised representative established within the Union or under certain circumstances by the importer[19].

Other natural or legal persons, such as distributors cannot be obliged to make these available[20]. However, they are expected to assist the market surveillance authority in obtaining them. Further, the market surveillance authority may request the notified body to provide information on the conduct of conformity assessment for the product in question.

---

17 According to the Directive on high-speed rail systems, each Member State authorises the putting into service of the structural subsystems in their territory. This is a systematic mechanism to monitor the compliance of subsystems and their inter-operability constituents.

18 Member States are obliged, according to the Directive on the introduction of measures to encourage improvements in the safety and health of workers at work (89/391/EEC), to ensure adequate controls and supervision.

19 Under Decision No 768/2008/EC, module B, Notified Bodies are required to provide, upon request from Member States, European Commission or other Notified Bodies a copy of the technical documentation.

20 Unless the EU Declaration of Conformity is required to accompany the product, in which case the distributor should provide the market surveillance authorities with such document.

The EU declaration of conformity must be made available for the market surveillance authority without delay upon reasoned request[21]. It shall accompany the product where required so by specific Union harmonisation legislation. It can be made available for surveillance purposes in each of the Member States, for instance, by means of administrative cooperation.

The technical documentation must be made available to the market surveillance authority within a reasonable period of time, in response to a reasoned request. The authority cannot request it systematically. In general, it can be requested during random checks made for market surveillance purposes, or when there are grounds for a concern that a product does not offer the level of protection required in all respects.

More detailed information (for example certificates and decisions from the notified body) can, nevertheless, be requested in cases of doubt about the conformity of the product to the applicable Union harmonisation legislation. The full technical documentation should be requested only where clearly necessary, and not, for example, when only a detail has to be checked.

This request has to be evaluated in accordance with the principle of proportionality and, thus, taking into account the need to ensure the health and safety of persons or other public interests foreseen in the applicable Union harmonisation legislation, as well as to protect the economic operators from unnecessary burden. Furthermore, failure to present the documentation in response to a reasoned request by a national market surveillance authority, within an acceptable delay, may constitute sufficient grounds for doubting the conformity of the product with the essential requirements of the applicable Union harmonisation legislation.

In the case of a reasoned request it is sufficient for the manufacturer to provide the part of the technical documentation related to the claimed non-conformity and appropriate for demonstrating whether the issue has been dealt with by the manufacturer. Therefore, the request for translation of technical documentation should be limited to these parts of the documentation. If the market surveillance authority considers a translation necessary, it must clearly indicate the part of the documentation to be translated and allow reasonable time for this to take place. No further conditions may be imposed on the translation, such as a requirement of a translator accredited or recognised by the public authorities.

National authority might accept a language they understand and which is different from the national language(s). The language chosen could be a third language, if accepted by that authority.

It must be possible to make the technical documentation available in the Union. However, it does not need to be kept inside the Union, unless otherwise provided for in the applicable Union harmonisation legislation. The requirement for making it available does not mean that the person who bears this responsibility has to store it himself[22], as long as he is capable of presenting it on request from the national authority. The name and address of the person storing the documentation does not need to be expressly mentioned on the product or on its

21 The reasoned request does not necessarily mean a formal decision by an authority. According to Article 19 (1), paragraph 2 of Regulation (EU) No 765/2008, "market surveillance authorities may require economic operators to make such documentation and information available as appear to them to be necessary for the purpose of carrying out their activities". For a request to be reasoned it is sufficient the market surveillance authority explains the context in which the information is requested (e.g. inspection on specific characteristics of the products, random checks, etc.)

22 For example storing the technical documentation may be delegated to the authorised representative.

packaging, unless otherwise specified. Further, the technical documentation can be kept and sent to market surveillance authorities in paper or electronic form, which allows it to be made available within a period of time commensurate with the risk or non-compliance in question. Member States must ensure that everyone receiving information about the contents of the technical documentation during market surveillance activities is bound to confidentiality according to principles laid down in the national legislation.

3. CONTROL OF PRODUCTS FROM THIRD COUNTRIES BY CUSTOMS

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 the making available of non-conforming or unsafe imported from third countries on 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[23]. 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.

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 co-operation 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.

23 These guidelines are available at: http://ec.europa.eu/taxation_customs/resources/documents/common/publications/info_docs/customs/product_safety/guidelines_en.pdf

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 three 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.

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'[24]. 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

24 If following the refusal of release for free circulation by customs the products are declared for customs-approved treatment or use other than release for free circulation, and provided the market surveillance authorities have no objections, the same wording must be added, under the same conditions, to the documents relating to that treatment or use.

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.

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'[25].

- 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.

- The customs authorities have not been notified of any action taken by the market surveillance authorities.

If, within three 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 three 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 three 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.

25 Also in this case, if following the refusal of release for free circulation by customs the products are declared for customs-approved treatment or use other than release for free circulation, and provided the market surveillance authorities have no objections, the same wording must be added, under the same conditions, to the documents relating to that treatment or use.

4. MEMBER STATES RESPONSIBILITIES

4.1 National infrastructures

Market surveillance is the responsibility of public authorities. This is, in particular, to guarantee the impartiality of market surveillance activities. Each Member State can decide upon the market surveillance infrastructure, for example there is no limitation on the allocation of responsibilities between authorities on a functional or geographical basis as long as surveillance is efficient and covers the whole territory. Member States organise and carry out market surveillance through the establishment of market surveillance authorities[26]. Market surveillance authorities are the authorities of a Member State responsible for carrying out market surveillance on their territory. Surveillance of the market by public authorities is a fundamental element for the good implementation of Union harmonisation legislation.

Member States must ensure that the public is aware of the existence, responsibilities and identity of national market surveillance authorities, and of how those authorities may be contacted. They must also ensure that consumers and other interested parties are given an opportunity to submit complaints to the competent authorities and that these complaints are followed up appropriately.

Member States must entrust market surveillance authorities with the powers, resources and knowledge necessary for the proper performance of their tasks. This is to monitor products made available on the market and, in case of products presenting a risk or other form of non-compliance, to take appropriate action to remove the risk and enforce conformity. As regards personnel resources, the authority has to have, or have access to, a sufficient number of suitably qualified and experienced staff, with the necessary professional integrity. The market surveillance authority should also be independent, and carry out its activities in an impartial and non-discriminatory way. Further, the market surveillance authority should carry out market surveillance respecting the principle of proportionality, for example action must be in accordance with the degree of risk or non-compliance and the impact on the free circulation of products may not be more than is necessary for achieving the objectives of market surveillance.

The market surveillance authority may subcontract technical tasks (such as testing or inspection) to another body, provided that it retains the responsibility for its decisions, and provided there is no conflict of interest between the other body's conformity assessment activities carried out of behalf of economic operators and compliance assessment provided to the market surveillance authority. In doing so the market surveillance authority should exercise great care to ensure that the impartiality of the advice it receives is beyond reproach. The responsibility for any decision to be taken on the basis of such advice should reside in the market surveillance authority.

4.2 National Market Surveillance Programmes (NMSP) and reviews of activities

National authorities are obliged by Article 18(5) of the Regulation (EC) No 765/2008 to establish, implement and periodically update and communicate their NMSP[27]. Programmes may be general and/or sectoral. They should ensure that the overall EU market surveillance

26 A list of market surveillance authorities appointed by the Member States can be found at: http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm

27 A similar provision can be found in the GPSD.

framework is respected. Member States must also communicate the programmes to other Member States and to the Commission and make them accessible to the public via internet, without information that could hamper the effectiveness of the programme if made public. The purpose of these programmes is to allow the other countries' authorities, as well as citizens in general, to understand how, when, where and in which areas market surveillance is carried out. National programmes then contain information on activities planned to improve the general organisation of market surveillance at national level (e.g. mechanisms of coordination between different authorities, resources attributed to them, working methods, etc.) and initiatives in specific areas of intervention (e.g. product categories, risk categories, types of users, etc.)[28]. Both types of information are necessary.

The Commission helped Member States by proposing common templates to lay out their programmes. The use of all relevant templates is recommended to ensure completeness of information provided. This also facilitates the comparability of national market surveillance programmes in specific product or legislation areas and makes it possible for market surveillance authorities to plan cross-border cooperation in areas of common interest.

When establishing national market surveillance programmes, market surveillance authorities should take the needs of customs into account. Programmes should take into consideration the balance between proactive and reactive control activities and any other factors which may influence enforcement priorities. Resource capabilities must be ensured at the border for this purpose.

According to Article 18(6) of the Regulation (EC) No 765/2008, the functioning of market surveillance activities needs to be periodically reviewed and assessed by Member States, at least every four years. The results of this assessment are then communicated to the Commission and other Member States and made available to the public[29].

4.3 Public information

Considering that the aim of market surveillance is to provide a high level of protection of certain public interests, informing the public is an essential element of market surveillance. Therefore, Member States should ensure openness to the public and to interested parties and should ensure public access to the information available to the authorities on product conformity. In accordance with the principle of transparency, information available to the authorities of the Member States or the Commission relating to risks to health and safety or other public interests protected under EU harmonisation legislation posed by products should in general be available to the public, without prejudice to the restrictions required for protecting patents and other confidential business information as well as preserving personal data, and for monitoring and investigation and prosecution activities.[30]

The public should be aware of the existence, responsibilities and identity of national market surveillance authorities, and of how those authorities may be contacted. Also national market surveillance programmes and reviews of activities carried out have to be made available to the public by way of electronic communication and, where appropriate, by other means.

---

28 The public national market surveillance programmes can be consulted here: http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm

29 The national reviews and assessments can be found here: http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm

30 See General Product Safety Directive, whereas n. 24 and 35 and Article 16; see also Regulation (EC) 765/2008, Article 19(5).

Among the measures that market surveillance authorities have to take, is the obligation to alert users within their territories within an adequate timeframe of hazards they have identified relating to any product so as to reduce the risk of injury or other damage particularly when the economic operator responsible fails to do so.

5. MARKET SURVEILLANCE PROCEDURES

Market surveillance is carried out through the implementation of a sequence of procedures whose aim is to ensure that an effective and consistent system of market surveillance is established across the EU. Market surveillance authorities follow these procedures when dealing with products presenting a risk to the health and safety or persons or to other aspects of public interest protection, according to Article 16(2) of Regulation (EC) No 765/2008 and in line with Articles R31 and R32 in Annex 1 of Decision No 768/2008/EC, and with products presenting a serious risk requiring rapid intervention, according to Articles 20 and 22 of Regulation (EC) No 765/2008.

An initial event suggesting to market surveillance authorities that a product presents a risk to the health or safety of persons or to other aspects of public interests may trigger the need for closer scrutiny of the product. It may be an accident, the reception of complaints, ex officio initiatives of market surveillance authorities (including custom authorities' control of products entering the EU) as well as information from economic operators on products presenting a risk. When there are sufficient reasons to believe that a product presents a risk, market surveillance authorities carry out an evaluation of compliance with the requirements of the relevant Union harmonisation legislation. They have to perform appropriate checks (both documentary and physical/laboratory checks, as necessary) on the characteristics of the products, duly taking into account the reports and conformity assessment certificates issued by an accredited conformity assessment body provided by the economic operators.

Market surveillance authorities carry out a risk assessment in order to verify if products present a serious risk. According to Article 20(2) of the Regulation an appropriate risk assessment "takes account of the nature of the hazard and the likelihood of its occurrence".[31]

If a product presents a risk to the health or safety of persons or to other aspects of public interests, market surveillance authorities must request without delay to relevant economic operators to:

- take any action to bring the product into compliance with the applicable requirements laid down in the Union harmonisation legislation and/or;
- withdraw the product and/or;
- recall the product and/or;
- stop or restrict supplying the product within a reasonable period.

In case the risk is deemed to be "serious", market surveillance authorities must adopt a rapid intervention following the specific provisions of Articles 20 and 22 of the Regulation.

31 See the Rapid Alert System Guidelines for a more precise definition of "risk" and "serious risk".

The economic operators must ensure that the corrective action is taken throughout the EU. The market surveillance authorities must also inform the relevant notified body (if any) on the decision taken. In case of serious risk requiring a rapid intervention, the market surveillance authority may adopt restrictive measures without waiting for the economic operator to take corrective action to bring the product into compliance. According to Article 21 of the Regulation, the measures adopted by market surveillance authorities have to be proportionate and communicated to the relevant economic operator without delay. The market surveillance authorities must also consult the economic operator prior to the adoption of the measures and, if such consultation is not possible because of the urgency of the measures to be taken, the operator must be given the opportunity to be heard as soon as possible. The market surveillance authorities must withdraw or amend the measures taken if the economic operator demonstrates that he has taken effective action.

When non-compliance is not limited to the national territory, market surveillance authorities must inform the Commission and the other Member States about the results of the compliance evaluation and about the actions required of the economic operator or the measures adopted. In case of serious risk, market surveillance authorities notify to the Commission through the RAPEX system of any voluntary or compulsory measure according to the procedure laid down in Article 22 of the Regulation and/or Article 12 of the GPSD. In the case of products that do not present a serious risk, the Commission and the other Member States will be informed by means of the information support system indicated in Article 23 of the Regulation and/or Article 11 of the GPSD. Market surveillance authorities have to verify that adequate corrective measures have been taken. Otherwise, they adopt appropriate provisional measures, informing the Commission and the other Member States with the procedures detailed above.

In order to broaden the effectiveness of the market surveillance activity launched by the notifying Member State, the other Member States are called upon to follow up on the notification by verifying whether the same product has been made available on their territories and by adopting appropriate measures. They should inform the Commission and the other Member States according to the procedures of the initial notification.

Under Union harmonisation legislation aligned to Decision No 768/2008/EC if the Commission and the other Member States do not raise any objection within a certain period, the restrictive measures are deemed justified and must be adopted without delay by the Member States. In the case of non-compliance due to shortcomings in harmonised standards, the Commission informs the relevant standardisation bodies and brings the matter before the Committee set up under Article 22 of Regulation (EU) No 1025/2012. In light of the Committee's opinion, the Commission can decide to: a) maintain the reference to harmonised standards in the OJEU; b) maintain with restrictions the reference to the harmonised standards in the OJEU; c) withdraw the reference to the harmonised standards in the OJEU. The Commission also informs the relevant European standardisation organisation and, if necessary, requests the revision of the harmonised standards concerned.

If objections are raised, the safeguard mechanism will apply.

Additional information on the procedure allowing Member States to exchange information on measures adopted against products presenting a risk and, if appropriate, for their assessment by the European Commission is provided in sections 7.5.1 and 7.5.2.

6. CORRECTIVE MEASURES – BANS – WITHDRAWALS – RECALLS

According to Union harmonisation legislation, Member States are required to ensure that products are made available on the market only if they comply with the applicable requirements. The latter include both the essential requirements, and a number of administrative and formal requirements. When competent national authorities discover that a product is not in compliance with the provisions of the applicable Union harmonisation legislation, they must take action to ensure it is brought into conformity or taken off the market.

The corrective action depends on the risk or non-compliance and, thus, must be in accordance with the principle of proportionality. Non-conformity to essential requirements must be considered as a substantial non-compliance, because this may lead to the product presenting a potential or actual risk to the health and safety of persons or to other aspects of public interest. In case of a serious risk, Article 20 of Regulation (EC) No 765/2008 sets out the need of prohibiting products from being made available on the market, withdrawing or recalling products.

If a product covered by Union harmonisation legislation is not CE marked, it is an indication that the product does not comply with the essential requirements or the conformity assessment procedure has not been applied and, consequently, the product may endanger the health and safety of persons or harm other public interests protected by that legislation. Only if, following further investigation, the product proves to be compliant with the essential requirements, the absence of the CE marking is to be considered as a formal non-compliance (i.e. the product does not present a risk).

Unless there are reasons to believe that the product presents a risk, there are cases where non-compliance with a number of administrative or formal requirements are defined as formal non-compliance by Union harmonisation legislation. That is the case for the incorrect affixing of the CE marking as regards, for instance, the design, size, visibility, indelibility or legibility, can usually be considered as a formal non-compliance. Examples of typically formal non-compliance could also be the situations where other conformity markings provided for in the Union harmonisation legislation are incorrectly affixed, or where the EU declaration of conformity cannot be provided for immediately or it does not accompany the product when this is mandatory, or the requirement to accompany other information provided for in sectoral Union harmonisation legislation is complied with insufficiently, or, where applicable, the identification number of the notified body has not been affixed to the CE marking.

Enforcement of conformity can be achieved by obliging the manufacturer, the authorised representative, or other responsible persons (importers, distributors), to take required measures. Corrective action can also take place if the necessary measures are taken (for example the product is modified or withdrawn from the market), either as a result of consultations carried out by the market surveillance authority or as a result of formal or informal warnings. In all cases the market surveillance authority must establish accompanying measures to ensure that conformity is enforced. PROSAFE "Guidelines for Businesses to manage Product Recalls & Other Corrective Actions"[32] have been designed to assist businesses to ensure, whenever necessary, the appropriate corrective actions and follow-up

32 http://ec.europa.eu/consumers/archive/safety/rapex/docs/corrective_action_guide_march2012.pdf

once a product has been already made available on the EU market or is coming from third countries.

Actions to prohibit or restrict the placing on the market may first be temporary to allow the market surveillance authority to obtain sufficient evidence about the risk or other substantial non-compliance of the product.

In case of formal non-compliance only (i.e. without a risk), the market surveillance authority should first oblige the manufacturer, or the authorised representative, to make the product intended to be placed on the market and, if necessary, the product already on the market, comply with the provisions and to remedy the infringement within a reasonable time period. If no result can be achieved, the market surveillance authority has to, ultimately, take a further step to restrict or prohibit the placing on the market of the product and, if necessary, to ensure that it is also withdrawn or recalled from the market.

Any decision taken by national market surveillance authorities to restrict or prohibit the placing on the market or the putting into service, to withdraw or recall the products from the market must state the exact grounds on which it is based. The party concerned – in particular, the manufacturer, or the authorised representative established in the Union – must be notified. They must also be informed about remedies available under the national law in force in the Member State in question, and of the time limits to which such remedies are subjected.[33]

Unless the matter is urgent (for example the product presents a serious risk), the manufacturer, or the authorised representative established in the Union, should have an opportunity to be consulted in advance, before the competent authority takes action to restrict the free circulation of products. In practice, it should be considered as sufficient when the manufacturer or the authorised representative has been provided with an opportunity to react.[34] However, it should not delay the proceedings, if the manufacturer or the authorised representative remains passive.

The decision to restrict the free movement of a CE marked product in case of non-compliance with the essential requirements usually invokes the safeguard clause procedure. This procedure is aimed to enable the Commission to keep an overview of such measures, to consider whether or not they are justified and to ensure all Member States take similar measures in relation to the same products. A manufacturer, the authorised representative, or other economic operator may consider himself to have suffered a loss as a result of an inappropriate national measure that restricted the free movement of a product. In such a case he could be entitled to claim damages under the jurisdiction of the Member State which initiated the procedure and accordingly the Commission, at the end of a safeguard clause procedure, where the national measure is considered as non-justified. This may raise the question whether or not a liability case for incorrect implementation of EU law could take place.

33 See Directives relating to simple pressure vessels, toys, machinery, personal protective equipment, non-automatic weighing instruments, active implantable medical devices, gas appliances, potentially explosive atmospheres, medical devices, recreational craft, lifts refrigeration appliances, pressure equipment, ecodesign requirements for energy-related products and in vitro diagnostic medical devices.

34 An explicit provision to consult has been included in Article 21 of Regulation (EC) No 765/2008, as well as in the Directives relating to medical devices and in vitro diagnostic medical services.

7. SANCTIONS

Regulation (EC) No 765/2008 requires Member States to ensure the correct implementation of its provisions and to take appropriate action in the event of infringement. The Regulation requires penalties to be proportionate to the seriousness of the offence and constitute an effective deterrent against abuses.

It is up to the Member States to lay down and implement the mechanism for enforcing the provisions of the Regulation in their territories. According to Article 41 of the Regulation, "the penalties provided for shall be effective, proportionate, and dissuasive and may be increased if the relevant economic operator has previously committed similar infringement".

In addition, Union harmonisation legislation aligned to Decision No 768/2008/EC includes as well a provision requiring Member States to lay down penalties for infringements by economic operators of that particular legislation.

Sanctions are imposed by means of fines, whose sums vary from one Member State to the other. They may also include criminal sanctions for serious infringements.

The most common legal instruments providing for sanctions are general product safety acts and/or sector specific legislation. However, in some Member States sanctions are provided in CE Marking acts, customs code or acts on conformity assessment system.

8. COOPERATION BETWEEN THE MEMBER STATES AND THE EUROPEAN COMMISSION

Cooperation and coordination of action among national authorities is indispensable to obtain effective and consistent surveillance of the Single Market. The EU legal framework provides a number of tools to achieve this goal. The safeguard mechanism included in Union harmonisation legislation obliges to share information about restrictive measures adopted by national authorities so that, if appropriate, follow up action can be taken by other authorities. Mutual assistance based on Regulation (EC) No 765/2008 allows authorities to enforce request of information vis-à-vis economic operators located in another Member State. Administrative cooperation groups (ADCOs), the ICSMS database, the RAPEX Rapid Alert System constitute essential tools to exchange information and optimise work sharing among authorities.

8.1 Safeguard mechanisms

The safeguard clause procedure, based on Article 114(10) TFEU and included in most sectoral Union harmonisation legislation, authorises Member States to take restrictive measures in relation to products presenting a risk to health and safety or other aspects of public interests protection and obliges them to notify those measures to the Commission and other Member States. The safeguard clause procedure is designed to provide a means to inform all national market surveillance authorities about dangerous products, and, accordingly, to have the necessary restrictions extended to all Member States, so as to ensure an equivalent level of protection throughout the EU. Furthermore, it allows the Commission to take a position on the national measures restricting the free movement of products with a view to ensuring the functioning of the internal market.

It is to be noted that the safeguard procedure is distinct from the RAPEX Rapid Alert System procedure because of their different notification criteria and different methods of application[35].

Where, having performed an evaluation, a Member State finds that a product is non-compliant or a product is in compliance but presents a risk to the health or safety of persons or to other aspects of public interest protection, it must require the relevant economic operator to take all appropriate measures to ensure that the product concerned, when made available on the market, no longer presents that risk, to withdraw the product from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

This procedure will be applicable, unless it is established that the risk does not affect a whole series of products manufactured, however limited the series, or that the risk is not due to the product itself but to its misuse, that is, when not used in accordance with their intended purpose or under conditions which can be reasonably foreseen and when not properly installed and maintained.. For an isolated error, limited to the territory of the Member State that has discovered the non-compliance, there is no need to invoke the safeguard clause, since there is no need to take action at EU level. In addition, the risk must be due to the product itself and not to its misuse.

Conformity can be enforced if the national authority requests the manufacturer or the authorised representative to take the necessary measures, or if the product is modified or voluntarily withdrawn from the market. Unless a formal decision is taken in these cases, to prohibit or restrict the making available on the market of the product or to have it withdrawn from the market, the safeguard clause procedure is not invoked. In case there is no compulsory measure; there is no need to invoke the safeguard clause[36].

However, if an economic operator does not take adequate corrective action within the period indicated by a market surveillance authority, the market surveillance authorities have to take all appropriate provisional measures to prohibit or restrict the product's being made available on their national market, to withdraw the product from that market or to recall it.

8.2 The application of safeguard mechanisms step by step

The application of the safeguard clause requires that the competent national authority takes a compulsory measure to restrict or forbid the making available on the market and, possibly, the putting into service of the product, or has it withdrawn from the market where the relevant economic operator does not take adequate corrective action himself. The contents of the decision should relate to all products belonging to the same type, batch or series. It must also have binding legal effect: it is followed by sanctions, if not respected, and can be subject to an appeals procedure. Court decisions, which restrict the free movement of CE marked product within the scope of the relevant Union harmonisation legislation, do not invoke the safeguard clause. However, where administrative proceedings initiated by the surveillance authority

35 The safeguard clause procedures under the Union harmonisation legislation apply independently from Rapid Alert System. Accordingly, Rapid Alert System does not necessarily have to come into play before the safeguard clause procedure is applied. However, the safeguard clause procedure has to be applied, in addition to Rapid Alert System, when a Member State takes a decision to permanently prohibit or restrict the free movement of harmonised products on the basis of a danger or other serious risk presented by the product.

36 Even if it may not constitute a safeguard clause, the market surveillance authorities shall inform the Commission and other Member States of actions taken against non-compliant products where the non-compliance is not restricted to the national territory (see Art. R31(2) of Annex I of Decision No 768/2008/EC.

must be, according to the national law, confirmed by a court, such court decisions are not excluded from the safeguard clause procedure.

The findings that justify the national measure are established either by the market surveillance authority on its own initiative or based on information received from a third party (such as consumers, competitors, consumer organisations, labour inspectorates). Further, the national measure must be based on evidence (for example tests or examinations) that constitutes sufficient proof of errors in the product design or the manufacture to indicate a foreseeable potential or actual danger or other substantial non-compliance, even when the products are correctly constructed, installed, maintained and used in accordance with their intended purpose or in a reasonably foreseeable way. There is a grey zone between correct and incorrect maintenance and use, and it can be considered that, to a certain extent, products should be safe, even if maintained and used for their intended purpose in an incorrect way that can reasonably be expected. In evaluating this, the data supplied by the manufacturer on the labelling, in the instructions, in the user's manual or in promotion materials are to be taken into consideration.

The reason for taking restrictive measures may result, for instance, from differences or failures in the application of essential requirements, incorrect application of harmonised standards or shortcomings in them. The surveillance authority can add or specify other motives (for example failure to comply with good engineering practice) when invoking the safeguard clause, provided that they are directly linked with these three reasons.

Where non-compliance with harmonised standards that give a presumption of conformity is established, the manufacturer, or the authorised representative, must be requested to provide evidence about compliance with essential requirements. The decision of the competent authority to take corrective action must always be based on an established non-compliance with the essential requirements.

The measures taken by authorities have to be proportionate with the seriousness of the risk and the non-compliance of the product and have to be notified to the Commission.

As soon as a competent national authority restricts or forbids the free movement of a product in such way that the safeguard clause is invoked, the Member State must immediately notify[37] the Commission indicating the reasons and justification for the decision.

The information has to include all available details, in particular:

- name and address of the manufacturer, the authorised representative, and in addition – if necessary – the name and address of the importer or other person responsible for making the product available on the market;
- the data necessary for the identification of the product concerned, the origin and the supply chain of the product;
- the nature of the risk involved and the nature of the national measures taken;

37 This notification should be made via ICSMS. A link between the ICSMS database and the GRS RAPEX IT tool will prevent double encoding of information by national authorities for the purposes respectively of the safeguard clause process and rapid alerts according to Article 22 of the Regulation (EC) No 765/2008.

- a reference to the Union harmonisation legislation, and in particular to the essential requirements, against which the non-compliance has been established;

- a comprehensive assessment and evidence to justify the measure (for example harmonised standards or other technical specifications used by the authority, the test reports and identification of the testing laboratory). In particular, the market surveillance authorities must indicate whether the non-compliance is due to either:

  – failure of the product to meet requirements relating to the health or safety of persons or to other aspects of public interest protection; or

  – shortcomings in the harmonised standards conferring a presumption of conformity.

- the arguments put forward by the relevant economic operator;

- If possible, the notification should also include:

- a copy of the declaration of conformity;

- the name and number of any notified body that intervened in the conformity assessment procedure, if applicable;

- a copy of the decision taken by the Member State authorities.

Where objections are raised against a measure taken by a Member State[38], or where the Commission considers a national measure to be contrary to Union harmonisation legislation, the Commission must without delay enter into consultation with the Member States and the relevant economic operator or operators and must evaluate the national measure. On the basis of the results of this evaluation, the Commission decides whether the national measure is justified or not.

The Commission addresses its decision to all Member States and immediately communicates it to them and the relevant economic operator or operators.

If the national measure is considered justified, all Member States must take the measures necessary to ensure that the non-compliant product is withdrawn from their market, and must inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned must withdraw the measure.

Where the national measure is considered justified and the non-compliance of the product is attributed to shortcomings in the harmonised standards, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 concerning the formal objection to harmonised standard.

38 Union harmonisation legislation aligned to Decision No 768/2008/EC provides for a safeguard procedure which applies only in the event of disagreement between Member States over measures taken by a Member State. The aim is to ensure that proportionate and appropriate measures were taken when a non-compliant product is present in their territory and that similar approaches are taken in the different Member States. While in the past a notification of a risk of a product was notified, Commission had to open a case and elaborate an opinion, now, this burden has been removed and a safeguard case is only opened if a Member State or Commission objects to the measure taken by the notifying authority. Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission is required, except where non-compliance can be attributed to shortcomings of a harmonised standard.

Member States other than the Member State initiating the procedure must without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the product concerned, and, in the event of disagreement with the notified national measure, of their objections. Member States must ensure that appropriate restrictive measures are taken in respect of the product concerned, such as withdrawal of the product from their market, without delay.

Where, within a certain period of time of receipt of the information, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure should be deemed justified.

Conversely, should the Commission see no justification for the national action that invoked the safeguard clause, it will ask the Member State to withdraw its action and take immediate appropriate steps to re-establish the free movement of the products in question on its territory.

Whether the action taken by the Member State is considered justified or not, in either case, the Commission keeps the Member States informed of the progress and the results of the procedure.

Once the decision is taken by the Commission, it can be legally challenged by Member States on the basis of Article 263 TFEU. The economic operator directly concerned by the Decision may also challenge it on the basis of article 263 TFEU.

If the initiating Member State does not withdraw the measure in case of non-justification, in this case, the Commission will consider initiating the infringement procedure provided for by Article 258 TFEU.

9. MUTUAL ASSISTANCE, ADMINISTRATIVE COOPERATION AND EXCHANGE OF INFORMATION AMONG MEMBER STATES

The proper application of Union law depends on a smooth administrative cooperation to ensure uniform and efficient enforcement of Union legislation in all Member States. The obligation to cooperate is in line with Article 20 of the Treaty on European Union (TEU) which states that Member States must take all appropriate measures to fulfil their obligations[39], and with Article 24 of Regulation (EC) No 765/2008. Although technical harmonisation has created a single market, where products move over national borders, market surveillance is carried out on a national basis. Administrative cooperation mechanisms between nation- al surveillance authorities, therefore, need to be developed to increase the efficiency of surveillance, to minimise the effect of different surveillance practices and to reduce the overlapping of national surveillance operations. Cooperation between market surveillance authorities can also spread good surveillance practice and techniques across the Union, as it allows national authorities to compare their methods with those of other authorities, for example in the framework of comparisons and joint surveys or study visits. In addition, cooperation can be useful for exchanging views and solving practical problems.

39 An explicit obligation for administrative cooperation is laid down in the Directives relating to pressure equipment and in vitro diagnostic medical devices: Member States are required to take appropriate measures in order to encourage/ensure that the authorities responsible for implementing the Directive cooperate with each other, and provide each other (and the Commission) with information in order to assist the functioning of the Directive.

Administrative cooperation calls for mutual trust and transparency between national surveillance authorities. Member States and the Commission need to be informed about the way enforcement of Union harmonisation legislation, in particular market surveillance of products is organised throughout the single market. This includes information about national authorities in charge of market surveillance for the different product sectors, and about national market surveillance mechanisms to clarify how monitoring of products made available on the market takes place and what corrective actions and other activities the surveillance authority is entitled to use.

Transparency is also necessary regarding the national rules on confidentiality. For the achievement of effective market surveillance in the Union, it is important that national surveillance authorities assist each other. On request, a national authority should make information available and provide other assistance. Without prior request, a national authority may consider sending to the other national authorities all relevant information concerning operations that constitute, or are likely to constitute, breaches of Union harmonisation legislation, which may have an impact on the territory of other Member States. In addition, the national authorities should communicate to the Commission any information they consider relevant, spontaneously or in response to a reasoned request from the Commission. The Commission may then communicate this information to the other national authorities when considered necessary.

Cooperation and mutual assistance according to Article 24(2) of Regulation (EC) No 765/2008 are, in particular, necessary to ensure that action can be taken against all those who are responsible for a non-compliant product being made available on the market. In some cases the authority of the Member State, where the manufacturer, the authorised representative, or other responsible person is established, needs to be contacted. This is to enforce requests of information made to these economic operators, for example to require the EU declaration of conformity or some specified details from the technical documentation, or to request information concerning the distribution chain, and not followed up by them. The Member State under whose jurisdiction the notified body operates (where applicable) needs to be contacted as well. When a national authority acts due to information it has received from another national body, it should report back to this authority on the outcome of the action.

Moreover, market surveillance would be more efficient, at the Union level, if the national surveillance authorities could agree on how to allocate their resources in such a way that a maximum number of different product types could be covered in each sector. To avoid duplication of product tests, or other investigations for market surveillance purposes, national authorities should exchange summary reports of these tests. This can be done by using the Information and Communication System for Market Surveillance (ICSMS). National surveillance authorities should also consider whether or not there is a special need to carry out technical analyses or laboratory tests when another surveillance authority has already done so, and the results are available to those authorities or may at their request be placed at their disposal[40]. It might also be useful to exchange results of periodic inspections on equipment in service, to the extent that they provide information on the compliance of products when they were placed on the market.

Information exchanged between national surveillance authorities has to be covered by professional confidentiality, according to the principles of the national legal system in

40 See Judgement of the Court, cases 272/80 and 25/88.

question, and it has to enjoy the protection extended to similar information under national law. Where a Member States has rules permitting free access by persons to information held by surveillance authorities, this fact must be revealed at the time of the request to another surveillance authority, or during the exchange of information if no such request occurs. If the sending authority indicates that the information involves matters of professional or commercial confidentiality, the receiving authority should ensure that this can be provided for. Otherwise the sending authority is entitled to withhold the information. Coordination and exchange of information between national surveillance authorities need to be agreed by the parties involved and taking into account the needs of the sector concerned. The following principles could be taken into consideration, where appropriate:

- appointing a national communication point or correspondent for every sector, which would coordinate internally as appropriate;

- agreeing about the types of cases for which the communication of surveillance information would serve a useful purpose;

- developing a common approach to issues such as the classification of risks and hazards and their coding;

- identifying of the details which should be communicated in each case, including the request for further information;

- accepting the obligation to respond to enquiries within a given time scale[41];

- transmitting information (requests and responses), as simply as possible, by e-mail, or through a telematic system operated by the Commission (ICSMS) or an external body, and by using standard multi-language forms;

- taking advantage of up-to-date data recording techniques so that enquiries can be easily undertaken and

- treating the information received in complete confidence.

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. Administrative cooperation between national authorities carrying out market surveillance is taking place in the following sectors: measuring instruments and non–automatic weighing instruments (WELMEC), low voltage equipment (LVD ADCO), Eco-Design ADCO Group, electromagnetic compatibility (EMC administrative cooperation), machinery, medical devices (Vigilance Working Group and COEN – Compliance and Enforcement Group), PEMSAC (The Platform of European Market Surveillance Authorities for Cosmetics), Toy-ADCO (The Administrative Cooperation Group of toys), telecommunications terminal equipment (TCAM), recreational craft, personal protective equipment, ATEX equipment, Radio and Telecommunications Terminal Equipment (R&TTE), Cableways (CABLE), Energy Labelling (ENERLAB), Gas Appliances (GAD), Lifts (LIFTS), Marine Equipment (MED), Noise,

41 An information request does not infringe the right of a national authority to take whatever measures are needed to ensure compliance with Union harmonisation legislation within its jurisdiction.

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. There are also groups dealing with more horizontal issues such as PROSAFE (the product safety forum of Europe), the Expert Group on Internal Market for Products (IMP-MSG), a horizontal committee where, for instance, general questions related to the implementation and enforcement of Union harmonisation legislation, such as horizontal aspects of market surveillance, are discussed. The network of the authorities of the Member States competent for product safety, set up under the GPSD, regularly discusses administrative cooperation issues of general interest.

10. RAPID ALERT SYSTEM FOR NON-FOOD PRODUCTS PRESENTING A RISK

The Rapid Alert System used for non-food products allows 31 participating countries (all EEA countries) and the European Commission to exchange information on products presenting a risk to health and safety or other protected interests and on the measures taken by these countries to do away with that risk.

Article 12 of the GPSD provides a legal basis for a general and horizontal system for the rapid exchange of information on serious risks arising from the use of products (RAPEX, Rapid Alert System).

The Rapid Alert System covers consumer and professional products[42]. It is applicable to non-harmonised products and products covered by the Union harmonisation legislation alike[43].

The Rapid Alert System works according to the detailed procedures laid down in annex II to the GPSD and in the Rapid Alert System guidelines[44].

With the entry into force of Regulation (EC) No 765/2008, the scope of the Rapid Alert System system was extended to risks other than those affecting health and safety (i.e. risks for the environment and in the work place, security risks) and also to products intended for professional (as opposed to consumer) use. Member States should ensure that products which present a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, are recalled, withdrawn or that their being made available on their market is prohibited, and that the Commission is informed without delay through Rapid Alert System under Article 22 of Regulation (EC) No 765/2008.

On 16 December 2009, the Commission adopted Decision 2010/15/EU[45] laying down the new guidelines for the management of the Rapid Alert System. Since guidelines were written before 1 January 2010 they refer explicitly only to notifications based on the GPSD. Nevertheless they are the main reference also for notifications based on Regulation (EC) No 765/2008 (see Article 22(4) therein) – professional products and risks other than health and safety.

---

42 Under Article 22 of Regulation (EC) No 765/2008, the Rapid Alert System applies to products covered by Union harmonisation legislation.

43 In the field of medicinal products and medical devices, there is a specific information exchange system.

44 Adopted as Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product safety Directive, OJEU L 22, 26.11.2010, p. 1. The Commission is in the process of drafting an EU wide Risk Assessment Methodology which builds on the RAPEX guidelines, developed within the framework of the GPSD and extends risks assessment to products that can harm the health and safety of professional users or other public interests.

45 Decision 2010/15/EU is available at: http://ec.europa.eu/consumers/safety/rapex/docs/rapex_guid_26012010_en.pdf

The Rapid Alert System procedure is as follows:

- When a product (e.g. a toy, a childcare article or a household appliance) is found, for instance, to be dangerous, the competent national authority takes appropriate action to eliminate the risk. It can withdraw the product from the market, recall it from consumers or issue warnings. Economic operators can take such measures also voluntarily which has to be reported by the competent authorities as well. The National Contact Point then informs the European Commission (through IT system GRAS-Rapid Alert System [46]) about the product, the risks it poses and the measures taken by the authority or the economic operator to prevent risks and accidents.

- The Commission disseminates the information that it receives to the National Contact Points of all other EU and EEA countries. It publishes weekly overviews of products posing a risk and the measures taken to eliminate the risks on the Commission's Rapid Alert System website[47].

- The National Contact Points in each EU and EEA country ensure that the authorities responsible check whether the newly notified product is present on the market. If so, the authorities take measures to eliminate the risk, either by requiring that the product is withdrawn from the market, by recalling it from consumers or by issuing warnings.

The safeguard clause procedures under the Union harmonisation legislation apply in addition to the Rapid Alert System. Accordingly, the Rapid Alert System does not necessarily have to come into play before the safeguard clause procedure is applied. However, the safeguard clause procedure has to be applied, in addition to the Rapid Alert System , when the Member State takes a decision to permanently prohibit or restrict the free movement of CE marked products on the basis of a danger or other serious risk presented by the product.

11. ICSMS

ICSMS (Information and Communication System for Market Surveillance) is an IT tool that provides for a comprehensive communication platform between all the market surveillance authorities.

ICSMS consists of an internal (accessible only to market surveillance authorities) and a public area.

11.1 Role

ICSMS offers fast and efficient communication means for market surveillance authorities to exchange information within a short space of time. ICSMS allows information on non-compliant products (test results, product identification data, photographs, economic operator information, risk assessments, accident information, information on measures taken by surveillance authorities etc.) to be quickly and efficiently shared between authorities.

46 General Rapid Alert System for the RAPEX notifications. GRAS-RAPEX replaced RAPEX-REIS (Rapid Exchange Information System for the Rapid Alert System application and extended the scope of Rapid Alert System to professional products and to other risks than health and safety.

47 http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm

The aim is not only to avoid cases where an unsafe product taken off the market in one country to be on sale for a long time in another country but mainly to have a market surveillance policy tool that allows to establish a co-operation mechanism among authorities.

While being aware of the fact that the mere reliable exchange of information is crucial for the market surveillance, it must be acknowledged that the added value of ICSMS stems from its capacity to be the platform for the implementation of the European market surveillance policy.

In this respect whenever a national authority wants to exchange information about a product under investigation with other authorities in order to share resources (e.g. for product checks), carry out common actions or consult other authorities, it must input into ICSMS the relevant information. This must be done as early as possible and certainly well before the decision to adopt measures for products found to present a risk. E.g. if a national authority cannot determine the level of the risk presented by a relevant product and carries out investigations, it must use ICSMS in order to communicate with the competent authorities of the other Member States.

ICSMS is not limited only to non-compliant products, but it gives information also regarding all products checked by authorities even if the result of the checks would be that no non-compliances have been found. This helps authorities avoiding any double (or multiple) checking of products.

Thus the ultimate role of ICSMS is to help the European Union to fulfil one of its major political objectives; i.e. to ensure reliability and coherence in the implementation and enforcement of the European legislation) in order for operators and citizens to benefit from the original intention of full access to the Internal Market.

In particular ICSMS helps market surveillance authorities to:

- proceed to quick and in-time exchange of information on market surveillance measures;
- coordinate their activities and inspections more effectively, especially by focusing on products which have not been inspected or tested yet;
- share resources and have thus more time to concentrate on other products which have yet to be tested;
- carry out wide-scale market interventions wherever products of a dubious nature are concerned using the latest information and avoid thus duplicate and multiple inspections;
- elaborate best practices;
- ensure that market surveillance is efficient and of even rigour in all Member States and avoid thus distortion to competition;
- establish an encyclopaedia of EU market surveillance intelligence.

11.2 Structure

The internal area is destined for market surveillance authorities, customs authorities and the EU. It contains all information available (product description, test results, measures taken etc.). Only ICSMS account holders may access this area.

The public area is destined for consumers, users and manufacturers. The information which is visible to the public provides only the data, which reference the product and its non-compliance and not any internal documents (i.e. information exchange between authority and importer/manufacturer).

ICSMS enables specific searches for non-compliant products. Confidentiality aspects are protected by a system of access authorisations.

Each market surveillance authority can input data about investigated products, which are not already in the database and add information (e.g. additional tests results, measures taken) to an already existing product information file.

The Commission ensures the proper functioning of ICSMS. The use of ICSMS is free of charge.

12. SUMMARY TABLE OF PROVISIONS OF REGULATION (EC) NO 765/2008 RELATED TO MARKET SURVEILLANCE BY MEMBER STATES

Stakeholder	Chapter	Article	Requirement
Member States	Chapter III – EU market surveillance framework and controls of products entering the EU market	16	General obligation to carry out market surveillance and take restrictive measures for product found to be dangerous or in any case non-compliant in relation to any product categories subject to EU harmonisation law and to inform the European Commission and other Member States.
		17	Inform the EC of their national MSAs and their areas of competence.
			Ensure that the public is aware of the existence of national MSAs.
		18	Establish appropriate communication and coordination mechanisms between their national MSAs.
			Establish adequate procedures in order to: - follow up complaints or reports on issues relating to products that may cause risks; - monitor accidents and harm to health which are suspected to have been caused by those products; - verify that corrective action has been taken; - follow up scientific and technical knowledge concerning safety issues.
			Entrust MSAs with the powers, resources and knowledge necessary for the proper performance of their tasks
			Ensure that MSAs exercise their powers in accordance with the principle of proportionality.
			Establish, implement and periodically update their market surveillance programmes.
			Draw up either a general market surveillance programme or sector-specific programmes covering the sectors in which they conduct market surveillance, communicate those programmes to the other MS and the Commission and make them available to the public.
			Periodically review and assess the functioning of their surveillance activities (at least every four year) and communicate the results to the EC, other MS and to the public.
		20	Ensure that products which present a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, are recalled, withdrawn or that their being made available on their market is prohibited, and that the Commission is informed without delay.
		21	Ensure that any measure taken to prohibit or restrict the product's being made available on the market, to withdraw it from the market or to recall it, is proportionate and states the exact grounds on which it is based.
			Communicate restrictive measures without delay to the relevant economic operator, together with the remedies available under the law of the MS concerned and

Stakeholder	Chapter	Article	Requirement
			the time limits to which such remedies are subject.
			Hear the economic operator concerned prior to adoption of restrictive measure
			Withdraw or amend any restrictive measure adopted if the economic operator demonstrates that he has taken effective action.
		22	If considers that the reasons which prompted the restrictive measure or the effects of the measure go beyond its territory, shall immediately notify the Commission of that measure using the market surveillance and information exchange system RAPEX.
			If a product presenting a serious risk has been made available on the market, notify the Commission of any voluntary measures taken and communicated by an economic operator.
		23	Provide the EC with information at their disposal and not already provided on products presenting a risk regarding, in particular, identification of risks, results of testing carried out, provisional restrictive measures taken, contacts with the economic operators concerned and justification for action or inaction.
			Safeguard the confidentiality of the information content.
		24	Ensure efficient cooperation and exchange of information between their MSAs and those of other MS, the EC and the relevant EU agencies. Mutual assistance to supply each other information or documentation and to carry out appropriate investigation or any other measures.
		25	Ensure that their competent authorities participate fully in the training, exchange of experience and best practices, joining the common projects, information campaigns, joint visit programmes.
	Chapter VI – Final provisions	41	Lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the provisions of this Regulation and take all measures necessary to ensure that they are implemented.
Market Surveillance Authorities	Chapter III – EU market surveillance framework and controls of products entering the EU market	19	Perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples.
			May require economic operators to make documentation and information available for the purpose of carrying out their activities, and, where it is necessary and justified, enter the premises of economic operators and take the necessary samples of products. MSA may destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary.
			Take due account of test reports or certificate presented by economic operators attesting conformity issued by an accredited conformity assessment body.
			Take appropriate measures to alert users within their territories within an adequate timeframe of hazards they have identified relating to any product so as to reduce the risk of injury or other damage.

Stakeholder	Chapter	Article	Requirement
			Cooperate with economic operators regarding actions which could prevent or reduce risks caused by products made available by those operators.
			In case of decision to withdraw a product manufactured in another Member State, inform the economic operator concerned.
			Carry out its duties independently, impartially and without bias and observe confidentiality in order to protect commercial secrets or to preserve personal data pursuant to national legislation.
			Observe confidentiality where necessary in order to protect commercial secrets or to preserve personal data pursuant to national legislation, subject to the requirement that information be made public under this Regulation to the fullest extent necessary in order to protect the interests of users in the EU.
		26	Cooperate with the competent authorities of third countries with a view to exchanging information and technical support, promoting and facilitating access to European systems and promoting activities relating to conformity assessment, market surveillance and accreditation.
		27	In case of more than one authority is responsible for market surveillance they cooperate with each other, by sharing information relevant to their functions and otherwise as appropriate.
		28	Evaluate the product suspended by the external border controls Authorities. If the product does not present a serious risk to health, safety and other public interest or cannot be regarded as being in breach of EU harmonisation legislation, it shall be released.
		29	Take measures to prohibit that a dangerous product is placed on the market and require the authorities in charge of external border controls to include a commercial invoice accompanying the product and on any other relevant accompanying document.
			Take appropriate action, including the prohibition of the marketing of the product, in case it does not comply with EU harmonisation legislation and require the authorities in charge of external border controls to include the a specific endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document.
			Destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary and proportionate.
			Provide external border controls authorities information on product categories in which a serious risk or non-compliance has been identified.
External border controls Authorities	Chapter III – EU market surveillance framework and controls of products entering the EU market	27	In case of more than one authority is responsible for external border controls, they cooperate with each other, by sharing information relevant to their functions and otherwise as appropriate.
			Carry out appropriate checks on the characteristics of products on an adequate scale, in accordance with the principles set out in Article 19(1), before those products are released for free circulation. Suspend release of a product for free circulation on the internal market when the product (a) displays characteristics which give cause to believe that the product, when properly installed, maintained and used, presents a serious risk to health, safety, the environment or any other public interest, (b) is not accompanied by the written or electronic documentation required by the relevant EU harmonisation legislation or is not marked in accordance with that legislation (c) the CE marking has been affixed to the product in a false or misleading manner and immediately notify the MSAs of any such suspension.

Stakeholder	Chapter	Article	Requirement
			Ensure that any requirements they may impose with regard to the storage of products or the parking of vehicles used for transport are not incompatible with the preservation of perishable products.
			Ensure efficient cooperation and exchange of information among external border controls Authorities.
		28	Release a suspended product if, within three working days of the suspension of release, external border controls Authorities have not been notified of any action taken by the MSAs, and provided that all the other requirements and formalities pertaining to such release have been fulfilled.

ANNEX 7: UNION HARMONISATION LEGISLATION ON NON-FOOD PRODUCTS IN THE EU (2016) AND COMPLIANCE COSTS

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 pre-packaged 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 hot-water 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;

(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;

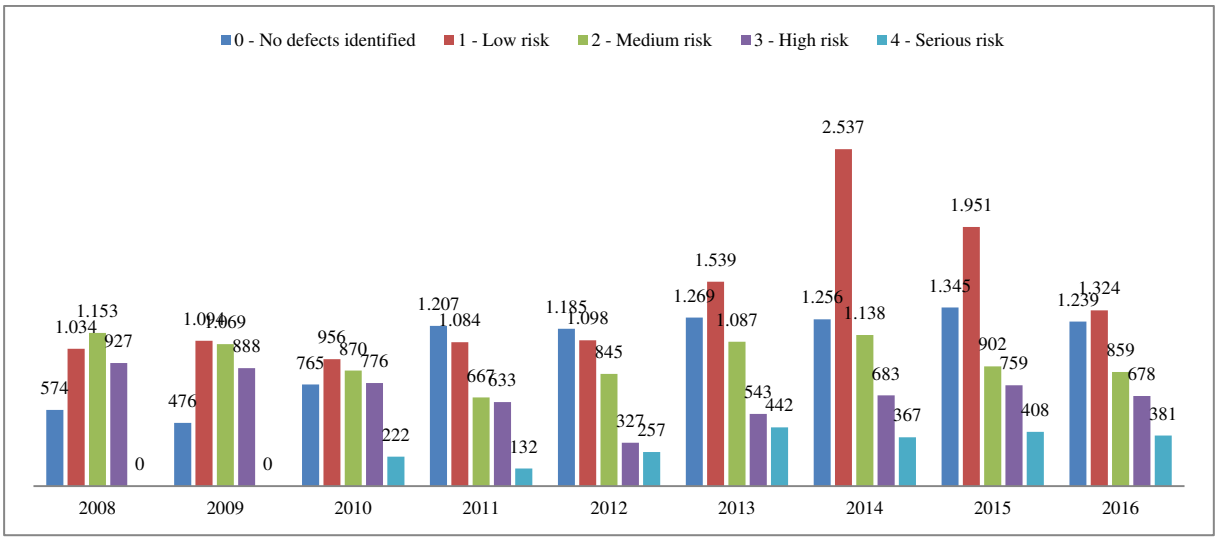
(67) Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC;

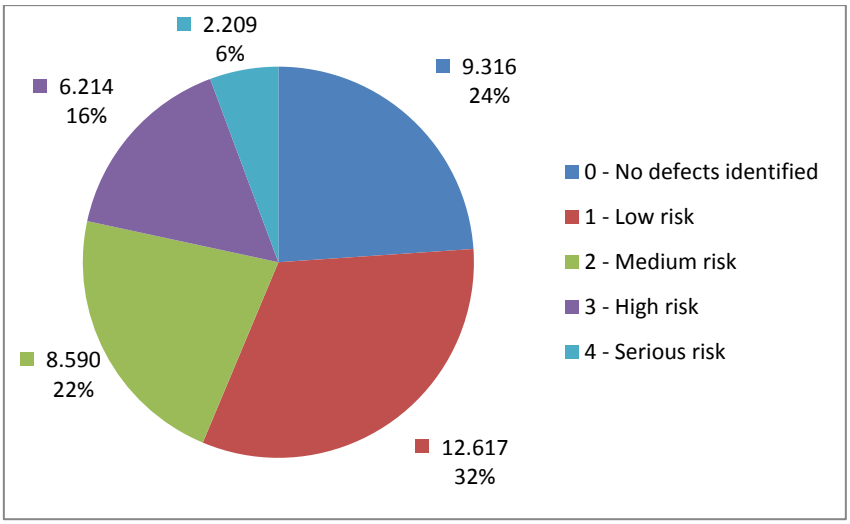
(68) Directive (EU) 2016/802 of the European Parliament and of the Council of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels.

2. EVIDENDE OF NON-COMPLIANCE AT EU LEVEL

2.1 Data from the Information Communistation System for Market Surveillance (ICSMS)

	0 - No defects identified	1 - Low risk	2 - Medium risk	3 - High risk	4 - Serious risk
2008	574	1.034	1.153	927	0
2009	476	1.094	1.069	888	0
2010	765	956	870	776	222
2011	1.207	1.084	667	633	132
2012	1.185	1.098	845	327	257
2013	1.269	1.539	1.087	543	442
2014	1.256	2.537	1.138	683	367
2015	1.345	1.951	902	759	408
2016	1.239	1.324	859	678	381
	9.316	**12.617**	**8.590**	**6.214**	**2.209**





GUIDELINE	RISK	COUNT
2000/14/EC Outdoor Noise Emissions Directive	0 - no defects identified	179
	1 - Low risk	151
	2 - Medium risk	70
	3 - High risk	17
	4 - Serious risk	9
	5 - not specified	142
2000/9/EC Cableways Directive	1 - Low risk	1
	2 - Medium risk	1
	3 - High risk	1
	5 - not specified	2
2001/95/EC General Product Safety Directive (GPSD)	0 - no defects identified	1418
	1 - Low risk	1790
	2 - Medium risk	2645
	3 - High risk	2673
	4 - Serious risk	510
	5 - not specified	8225

GUIDELINE	RISK	COUNT
2002/95/EC Restriction Use of Hazardous Substances Directive (RoHS)	0 - no defects identified	236
	1 - Low risk	69
	2 - Medium risk	68
	3 - High risk	8
	4 - Serious risk	16
	5 - not specified	190
2002/96/EC Waste Electrical & Electronic Equipment Directive (WEEE)	0 - no defects identified	28
	1 - Low risk	64
	2 - Medium risk	23
	3 - High risk	5
	4 - Serious risk	13
	5 - not specified	58
2003/2003/EC Fertilizers Directive	5 - not specified	1
2004/108/EC Electromagnetic Compatibility Directive (EMC)	0 - no defects identified	163
	1 - Low risk	2068
	2 - Medium risk	133
	3 - High risk	82
	4 - Serious risk	62
	5 - not specified	357
2004/22/EC Measuring Instruments Directive (MID)	0 - no defects identified	15
	1 - Low risk	11
	2 - Medium risk	14
	3 - High risk	3
	5 - not specified	10
2004/42/EC Deco-paint Directive	1 - Low risk	1
	2 - Medium risk	1
	5 - not specified	2
2004/49/EC Railway Safety Directive	5 - not specified	2

GUIDELINE	RISK	COUNT
2006/42/EC Machinery Directive	0 - no defects identified	475
	1 - Low risk	601
	2 - Medium risk	541
	3 - High risk	365
	4 - Serious risk	145
	5 - not specified	704
2006/66/EC Batteries and Accumulators Directive	0 - no defects identified	1
	1 - Low risk	1
	2 - Medium risk	2
	3 - High risk	2
	4 - Serious risk	2
	5 - not specified	3
2006/95/EC Low Voltage Directive (LVD)	0 - no defects identified	2053
	1 - Low risk	2566
	2 - Medium risk	3367
	3 - High risk	2426
	4 - Serious risk	568
	5 - not specified	6586
2007/23/EC Pyrotechnic Articles Directive	0 - no defects identified	41
	1 - Low risk	17
	2 - Medium risk	13
	3 - High risk	4
	4 - Serious risk	8
	5 - not specified	143
2007/45/EC Pre-packed Products Directive	1 - Low risk	1
2007/46/EC Motor Vehicles Directive	4 - Serious risk	1
	5 - not specified	2
2009/105/EC Simple Pressure Vessel Directive	0 - no defects identified	14

GUIDELINE	RISK	COUNT
	1 - Low risk	44
	2 - Medium risk	18
	3 - High risk	5
	4 - Serious risk	7
	5 - not specified	32
2009/125/EC Energy Related Products Directive	0 - no defects identified	774
	1 - Low risk	156
	2 - Medium risk	431
	3 - High risk	4
	4 - Serious risk	7
	5 - not specified	627
2009/142/EC Gas Appliances Directive (GAD)	0 - no defects identified	40
	1 - Low risk	60
	2 - Medium risk	84
	3 - High risk	78
	4 - Serious risk	9
	5 - not specified	195
2009/23/EC Non-Automatic Weighing Instruments Directive	0 - no defects identified	2
	1 - Low risk	7
	2 - Medium risk	3
	3 - High risk	2
	5 - not specified	2

GUIDELINE	RISK	COUNT
2010/30/EU Energy Labelling Directive	0 - no defects identified	27
	1 - Low risk	53
	2 - Medium risk	52
	3 - High risk	9
	4 - Serious risk	7
	5 - not specified	54
2010/35/EC Transportable Pressure Equipment Directive	0 - no defects identified	5
	1 - Low risk	2
	3 - High risk	2
	4 - Serious risk	1
	5 - not specified	15
2010/62/EU Tractor Directive	0 - no defects identified	1
	2 - Medium risk	1
2011/65/EU Restriction of Hazardous Substances RoHS	0 - no defects identified	230
	1 - Low risk	81
	2 - Medium risk	115
	3 - High risk	7
	4 - Serious risk	13
	5 - not specified	99
2012/19/EU Waste Electrical & Electronic Equipment Directive	0 - no defects identified	3
	1 - Low risk	1
	2 - Medium risk	1
	3 - High risk	1
	4 - Serious risk	2
	5 - not specified	7

GUIDELINE	RISK	COUNT
67/548/EEC Dangerous Substances Directive	0 - no defects identified	7
	1 - Low risk	88
	2 - Medium risk	80
	3 - High risk	29
	4 - Serious risk	1
	5 - not specified	115
75/324/EEC Aerosol Dispensers Directive	0 - no defects identified	20
	1 - Low risk	38
	2 - Medium risk	45
	3 - High risk	2
	5 - not specified	42
76/211/EEC Pre-packed Products Directive	5 - not specified	1
76/768/EEC Cosmetics Directive	0 - no defects identified	5
	1 - Low risk	25
	2 - Medium risk	7
	3 - High risk	5
	4 - Serious risk	23
	5 - not specified	202
76/769/EEC Marketing and Use Directive	0 - no defects identified	10
	1 - Low risk	36
	2 - Medium risk	98
	3 - High risk	205
	5 - not specified	142
87/357/EEC Consumer Products appearing to be other than they are Directive	3 - High risk	1
	4 - Serious risk	13
	5 - not specified	7

GUIDELINE	RISK	COUNT
88/378/EEC Toy Directive	0 - no defects identified	983
	1 - Low risk	1289
	2 - Medium risk	1063
	3 - High risk	1348
	4 - Serious risk	135
	5 - not specified	2808
89/106/EEC Construction Products Directive	0 - no defects identified	58
	1 - Low risk	24
	2 - Medium risk	15
	3 - High risk	2
	5 - not specified	308
89/336/EEC Electromagnetic Compatibility Directive (EMC)	0 - no defects identified	250
	1 - Low risk	1321
	2 - Medium risk	248
	3 - High risk	172
	4 - Serious risk	9
	5 - not specified	130
89/686/EEC Personal Protective Equipment Directive (PPE)	0 - no defects identified	650
	1 - Low risk	1292
	2 - Medium risk	669
	3 - High risk	156
	4 - Serious risk	39
	5 - not specified	649
91/414/EEC Plant Protection Products Directive	0 - no defects identified	1
	2 - Medium risk	1
	3 - High risk	1
	5 - not specified	1
93/15/EEC Civil Explosives Directive	2 - Medium risk	1

GUIDELINE	RISK	COUNT
	5 - not specified	7
93/42/EEC Medical Devices Directive	0 - no defects identified	6
	1 - Low risk	7
	2 - Medium risk	4
	3 - High risk	1
	4 - Serious risk	2
	5 - not specified	53
94/11/EC Footwear Directive	0 - no defects identified	1
	5 - not specified	1
94/25/EC Recreational Craft Directive	0 - no defects identified	13
	1 - Low risk	35
	2 - Medium risk	12
	3 - High risk	5
	5 - not specified	44
94/62/EC Packaging and Packaging Waste Directive	0 - no defects identified	2
	1 - Low risk	12
	5 - not specified	3
94/9/EC Equipment for Use in Potentially Explosive Atmospheres (ATEX)	0 - no defects identified	4
	1 - Low risk	6
	2 - Medium risk	20
	3 - High risk	5
	4 - Serious risk	4
	5 - not specified	15

GUIDELINE	RISK	COUNT
95/16/EC Lift Directive	1 - Low risk	18
	2 - Medium risk	5
	3 - High risk	8
	4 - Serious risk	1
	5 - not specified	9
96/98/EC Marine Equipment Directive	5 - not specified	6
97/23/EC Pressure Equipment Directive	0 - no defects identified	51
	1 - Low risk	58
	2 - Medium risk	78
	3 - High risk	47
	4 - Serious risk	12
	5 - not specified	64
97/68/EC Directive on Emissions of off-road engines	0 - no defects identified	2
	2 - Medium risk	4
	3 - High risk	1
	5 - not specified	3
98/37/EC Machinery Directive	0 - no defects identified	268
	1 - Low risk	627
	2 - Medium risk	1246
	3 - High risk	915
	4 - Serious risk	12
	5 - not specified	633

GUIDELINE	RISK	COUNT
98/8/EC Biocidal Products Directive	0 - no defects identified	27
	1 - Low risk	193
	2 - Medium risk	103
	3 - High risk	12
	4 - Serious risk	3
	5 - not specified	201
99/36/EC Transportable Pressure Equipment Directive	0 - no defects identified	3
	2 - Medium risk	2
	3 - High risk	5
	5 - not specified	6
99/45/EC Dangerous Preparations Directive	0 - no defects identified	61
	1 - Low risk	561
	2 - Medium risk	426
	3 - High risk	132
	4 - Serious risk	10
	5 - not specified	621
99/5/EC R&TTE - Radio and Telecommunications Terminal Equipment Directive	0 - no defects identified	143
	1 - Low risk	1800
	2 - Medium risk	88
	3 - High risk	109
	4 - Serious risk	13
	5 - not specified	277
Commission Delegated Regulation (EU) No 1059/2010 energy labelling of household dishwashers	0 - no defects identified	1
	1 - Low risk	6

GUIDELINE	RISK	COUNT
Commission Delegated Regulation (EU) No 1060/2010 energy labelling of household refrigerating appliances	0 - no defects identified	8
	1 - Low risk	17
	2 - Medium risk	7
	5 - not specified	2
Commission Delegated Regulation (EU) No 1061/2010 energy labelling of household washing machines	0 - no defects identified	1
Commission Delegated Regulation (EU) No 1062/2010 energy labelling of televisions	0 - no defects identified	2
	1 - Low risk	5
	5 - not specified	1
Commission Delegated Regulation (EU) No 626/2011 energy labelling of air conditioners	0 - no defects identified	1
	1 - Low risk	2
	2 - Medium risk	1
	5 - not specified	4
Commission Delegated Regulation (EU) No 65/2014 energy labelling of domestic ovens and range hoods	1 - Low risk	1
	5 - not specified	5
Commission Delegated Regulation (EU) No 665/2013 energy labelling of vacuum cleaners	0 - no defects identified	4
	1 - Low risk	2
	3 - High risk	1
	5 - not specified	1
Commission Delegated Regulation (EU) No 874/2012 energy labelling of electrical lamps and luminaires	0 - no defects identified	12
	1 - Low risk	35
	2 - Medium risk	42
	3 - High risk	5
	5 - not specified	5

GUIDELINE	RISK	COUNT
Construction Products Regulation (EU) No 305/2011	0 - no defects identified	10
	1 - Low risk	5
	2 - Medium risk	1
	3 - High risk	4
	4 - Serious risk	2
	5 - not specified	34
Directive 2009/48/EC on the safety of toys	0 - no defects identified	1239
	1 - Low risk	585
	2 - Medium risk	369
	3 - High risk	542
	4 - Serious risk	293
	5 - not specified	1376
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 (recast) Text with EEA relevance	1 - Low risk	3
	2 - Medium risk	16
	3 - High risk	2
	4 - Serious risk	1
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 (recast) Text with EEA relevance	0 - no defects identified	6
	1 - Low risk	8
	2 - Medium risk	6
	3 - High risk	1
	5 - not specified	3
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 Text with EEA relevance	2 - Medium risk	3

GUIDELINE	RISK	COUNT
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 av2ilable on the market of electrical equipment designed for use within certain voltage limits Text with EEA relevance	0 - no defects identified	44
	1 - Low risk	31
	2 - Medium risk	112
	3 - High risk	83
	4 - Serious risk	39
	5 - not specified	3
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 Text with EEA relevance	0 - no defects identified	9
	1 - Low risk	3
	5 - not specified	1
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 Text with EEA relevance	1 - Low risk	3
	3 - High risk	1
Non Harmonised Product / No directive applies	0 - no defects identified	96
	1 - Low risk	73
	2 - Medium risk	53
	3 - High risk	36
	4 - Serious risk	16
	5 - not specified	63
REGULATION (EC) No 1007/2011 Textiles Regulation	0 - no defects identified	14
	3 - High risk	2
	4 - Serious risk	2
	5 - not specified	6
REGULATION (EC) No 107/2009 ecodesign for simple set-top boxes	0 - no defects identified	5
	2 - Medium risk	2
REGULATION (EC) No 1222/2009 Tyre Labelling	0 - no defects identified	12
	1 - Low risk	3
Regulation (EC) No 1223/2009 on cosmetic	0 - no defects identified	129

GUIDELINE	RISK	COUNT
products	1 - Low risk	37
	2 - Medium risk	49
	3 - High risk	50
	4 - Serious risk	15
	5 - not specified	25
Regulation (EC) No 1223/2009 on cosmetic products - Article 23	0 - no defects identified	12
	2 - Medium risk	1
	4 - Serious risk	2
	5 - not specified	55
Regulation (EC) No 1272/2008 Classification, Labelling & Packaging (CLP)	0 - no defects identified	74
	1 - Low risk	174
	2 - Medium risk	149
	3 - High risk	108
	4 - Serious risk	43
	5 - not specified	237
REGULATION (EC) No 1275/2008 ecodesign for electrical and electronic household and office equipment	0 - no defects identified	110
	1 - Low risk	11
	2 - Medium risk	13
	5 - not specified	11
Regulation (EC) No 1907/2006 (REACH)	0 - no defects identified	402
	1 - Low risk	306
	2 - Medium risk	556
	3 - High risk	322
	4 - Serious risk	119
	5 - not specified	982

GUIDELINE	RISK	COUNT
REGULATION (EC) No 244/2009 ecodesign for non-directional household lamps	0 - no defects identified	20
	1 - Low risk	26
	2 - Medium risk	32
	4 - Serious risk	1
	5 - not specified	8
REGULATION (EC) No 278/2009 ecodesign for external power supplies	0 - no defects identified	266
	1 - Low risk	61
	2 - Medium risk	105
	5 - not specified	26
REGULATION (EC) No 528/2012 Biocidal Products	0 - no defects identified	5
	1 - Low risk	53
	2 - Medium risk	32
	3 - High risk	18
	4 - Serious risk	1
	5 - not specified	31
REGULATION (EC) No 640/2009 ecodesign for electric motors	1 - Low risk	6
	5 - not specified	2
REGULATION (EC) No 642/2009 ecodesign for televisions	0 - no defects identified	8
	1 - Low risk	6
REGULATION (EC) No 643/2009 ecodesign for household refrigerating appliances	0 - no defects identified	7
	1 - Low risk	1
	2 - Medium risk	6
REGULATION (EC) No 648/2004 Detergents	0 - no defects identified	6
	1 - Low risk	24
	2 - Medium risk	6
	3 - High risk	1
	5 - not specified	10

GUIDELINE	RISK	COUNT
REGULATION (EC) No 689/2008 Export and Import of Dangerous Chemicals	1 - Low risk	2
Regulation (EC) No 765/2008 Accreditation & Market Surveillance	0 - no defects identified	56
	1 - Low risk	44
	2 - Medium risk	16
	3 - High risk	3
	4 - Serious risk	9
	5 - not specified	52
REGULATION (EC) No 850/2004 Persistent Organic Pollutants	0 - no defects identified	15
	1 - Low risk	3
	2 - Medium risk	3
	3 - High risk	2
	4 - Serious risk	3
	5 - not specified	17
REGULATION (EU) No 1015/2010 ecodesign for household washing machines	0 - no defects identified	1
REGULATION (EU) No 1194/2012 ecodesign for directional lamps, light emitting diode lamps and related equipment	0 - no defects identified	12
	1 - Low risk	27
	2 - Medium risk	35
	5 - not specified	2
REGULATION (EU) No 206/2012 ecodesign for air conditioners and comfort fans	0 - no defects identified	1
	1 - Low risk	2
	2 - Medium risk	2
	5 - not specified	1
REGULATION (EU) No 617/2013 ecodesign for computers and computer server	0 - no defects identified	1
	5 - not specified	6
REGULATION (EU) No 66/2014 ecodesign for domestic ovens, hobs and range hoods	2 - Medium risk	6
	5 - not specified	5
REGULATION (EU) No 666/2013 ecodesign	0 - no defects identified	5

GUIDELINE	RISK	COUNT
for vacuum cleaners	1 - Low risk	2
	3 - High risk	1
	5 - not specified	3
REGULATION (EU) No 932/2012 ecodesign for household tumble driers	0 - no defects identified	2

2.2 Reviews and assessments of the functioning of market surveillance activities

Member States reviewed and assessed the functioning of their market surveillance activities carried out for the 2010 to 2013 period. These reports were drafted pursuant to Article 18(6) of Regulation (EC) 765/2008.

http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation_en

The Commission combined the provided information into a single report.

http://ec.europa.eu/DocsRoom/documents/15241/attachments/1/translations

A more detailed analysis of data provided by member States is contained in Annex 9 section 5.

2.3 Joint market surveillance authorities in different sectors

- Toys intended for children under 3 years

  http://www.prosafe.org/images/Documents/JA2013/JA2013_Toys_Final_Technical_Report_24-02-2016.pdf

- LED lighting equipment

  http://ec.europa.eu/DocsRoom/documents/9868

- Active electric energy meters and heating meters

  http://ec.europa.eu/DocsRoom/documents/20422

- Electromagnetic Compatibility

  http://ec.europa.eu/DocsRoom/documents/9869

  http://ec.europa.eu/DocsRoom/documents/8064

- Radio and Telecommunications Equipment

  http://ec.europa.eu/DocsRoom/documents/9922

http://ec.europa.eu/DocsRoom/documents/7718

http://ec.europa.eu/DocsRoom/documents/13343

- REACH and CLP

  https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects

3. COSTS OF COMPLIANCE

3.1 Terminology

ATEX	Directive on Equipment and protective systems intended for use in potentially explosive atmospheres
CPR	Construction Products Regulation
EMC	Electromagnetic Compatibility Directive
GAD	Gas Appliances Directive
IM	Internal Market
LD	Lifts Directive
LVD	Low Voltage Directive
MD	Machinery Directive
MID	Measuring Instruments Directive
OED	Outdoor Equipment Directive
PED	Pressure Equipment Directive
PPE	Personal Protective Equipment Directive
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical substances Regulation
R&TTE	Radio and Telecommunications Terminal Equipment Directive
RoHS	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment
SPVD	Simple Pressure Vessels Directive

3.2 Introduction

This section outlines the process by which industry complies with the legislation and attempts to identify and quantify the costs incurred in compliance[48]. More specifically, the analysis has

48 For further details, see Commission Staff Working Document SWD(2014)23.

attempted to estimate the costs of compliance with Union harmonisation legislation faced by firms. This task has been undertaken through case studies of specific product groups. The table below lists the product groups covered by the case studies.

No	Product	Applicable Legislation
Harmonised product groups		
1	Electric motors	Core Directives - LVD, EMC, ATEX Other applicable IM legislation: REACH, RoHS, Ecodesign
2	Laptops	Core Directives - R&TTE, LVD and EMC Other applicable IM legislation: Ecodesign, RoHS, Packaging and Packaging Waste Directive
3	Domestic refrigerators and freezers	Core Directives - LVD, EMC Other applicable IM legislation: REACH, Ecodesign, Energy labelling, RoHS, Regulation on materials in contact with foodstuff
4	Lifts for persons	Core Directives - Lifts[49], LVD and EMC
5	Gardening equipment	MD, EMC, Outdoor noise, Non-road mobile machinery Emissions, RoHS, REACH
6	Fuel dispensers	MID, LVD, EMC
7	Air conditioners	MD, EMC, LVD, CPR, RoHS, Energy Labelling, PED[50], Ecodesign, Regulation 2000/2037/EC on Ozone Depleting Substances Regulation 2006/842/EC on Fluorinated Greenhouse Gases Regulation 2007/1494/EC on Labelling Requirements
8	Integrated circuits	LVD, EMC, ATEX, RoHS

For each of these product groups, the relevant legislation was reviewed, sectoral data on market size and structure was analysed and firms were interviewed in depth in order to identify the processes followed in compliance and the costs incurred. Data on costs was then analysed using the Standard Cost Model in order to draw conclusions around the cost of

49 The Machinery Directive applies to lifts for goods and to other types of lifts not covered by the Lifts Directive, the Cableways Directive applies to lifting appliances installed in outdoor mountain or urban sites.

50 The SPVD is also applicable but only to certain types of air conditioners.

compliance. Finally, macro-economic impacts were assessed through the application of a macro-economic model.

Attempting to quantify the costs of compliance is clearly not without its challenges:

- **Establishing the baseline:** whilst many firms have provided an indication of the situation prior to the introduction of Union harmonisation legislation, none were able to provide quantitative data on costs, given the time that has elapsed; similarly, it has not seemed useful to compare current costs against a hypothetical scenario in which no Union harmonisation legislation exists;

- **Availability of data:** data on costs can clearly be commercially sensitive and many firms were unwilling to participate or reluctant to provide data; even where firms were willing, many simply did not collect data relating to certain costs of compliance; it was relatively straightforward to obtain data on the level of human resources working directly on compliance with administrative obligations, whereas data on product design and development and testing was less available;

- **Disaggregation of data:** for most of the products in question, several pieces of IM legislation are applicable; moreover, most of the firms interviewed produced a range of products or models for both EU and global markets; it thus became difficult to isolate the cost of compliance with particular pieces of legislation from other costs and to relate those costs solely to production for the EU28 market;

- **Establishing the "business-as-usual" scenario**, namely the costs that would be incurred in the absence of legislation; many firms found it difficult to accurately estimate the proportion of costs that they would incur in the absence of legislation, i.e. as part of the normal process of product design, development and testing.

A distinction should be made between administrative and substantive compliance costs:

- **Administrative costs** - relate to the costs of preparing documentation and direct fees; and

- **Substantive compliance costs** - relate to any specific investments firms must make in order to comply with the law.

It is widely recognised that there may be nuances and an unclear demarcation between the two types of costs because such costs are part of a continuum. Most notably, in the case of testing carried out as part of conformity assessment modules to comply with Union harmonisation legislation, the aim is neither to obtain an authorisation or certification. Rather, it is to demonstrate compliance with the essential requirements. Nevertheless, the guidelines suggest that conformity assessment should still be treated as a substantive compliance cost, even if the current definition does not exactly fit this area. However, some elements of the conformity assessment process are administrative, such as preparing the technical file and issuing the Declaration of Conformity. Therefore, the following methodological distinctions were made:.

Type of costs	One-off costs	Recurring costs
Administrative costs	• Familiarisation with Union harmonisation	• Development and updating of technical files

	legislation and standards • Notified Bodies fees for Union harmonisation legislation and mandatory testing	• Production of a DoC and CE marking • Conformity assessment: preparation of technical files in parallel with testing activities
Substantive compliance costs	• Modifications to product design (during new product development phase/ R&D) • Modifications to product design once products have been placed on the market • Costs of temporarily or permanently withdrawing products from the market	• Conformity assessment: preparation of technical files in parallel with testing activities testing for conformity with the applicable modules defined in Union harmonisation legislation

Source: CSES

The extent of administrative and substantive compliance costs was estimated for four stages in the process of compliance with Union harmonisation legislation:

- Preparatory actions and familiarisation with the applicable legislation and relevant administrative obligations for economic operators
- Substantive compliance: Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations
- Conformity assessment procedures and the preparation of relevant technical documentation
- Declaration of Conformity or other statement of compliance and CE marking

Costs incurred at each stage are now presented in the sub-sections that follow. Although a common approach was adopted to the cases, in some instances it has been difficult to compare findings from the different cases due to the data limitations already described. Cost are estimated at sectoral level, for firms of different size and for public authorities.

3.3 Preparatory actions and familiarisation with the legislation

Familiarisation with Union harmonisation legislation and the respective requirements is an important and ongoing task for all firms. Even though the amount of time that firms spend on familiarisation was found to vary, most firms indicate that they spend quite a lot of time on such activities, commonly 15-20% of the total in terms of human resources.

Many large firms have staff specialising in regulatory compliance (commonly around 2-4 staff). Since monitoring legislation is part of their everyday business, as part of the familiarisation process, they follow and input to EU policy and legislative-making processes. The firms interviewed recognised that it was in their direct interest to participate in shaping the form, content and implementation of Union harmonisation legislation. Furthermore, many of the large firms interviewed are actively involved in standards development processes. They

are involved in discussions at the policy level and have a clear view of relevant developments, and of the dates for the introduction of new requirements or changes to relevant technical standards.

Among small firms, there is more of an ad-hoc approach to the familiarisation step, i.e. whenever there are major legislative developments or changes to standards, SMEs seem to find out about what changes are being introduced. They then assess whether any modifications are necessary for existing products or for new product development. SMEs find out about forthcoming changes through a number of information sources, particularly the relevant national and/ or EU industry associations – which charge a membership fee but provide updates on relevant legal developments.

Some firms interviewed also maintain a database that identifies the relevant legislation and relevant/applicable standards for each of their products. Once developed, however, such a database is useful across different business functions since an overview of legal requirements is required by laboratory staff involved in testing, production engineers and product development departments. Some larger firms were found to have developed a more sophisticated database / information management system that goes beyond a simple spreadsheet. However, this can be costly and time consuming both to set up and to maintain. A suggestion was made that it would be very helpful if there were an online database or web portal where product group specific information about compliance, such as forthcoming legislative developments and the dates of updates to standards coming into effect was provided.

Firms in a few product sectors covered also referred to costs for staff attending training courses, either organised internally or through the use of external consultants. The true cost of such training is difficult to identify, since it may often be incorporated into wider staff training activities. In the case of petrol pumps, one company suggested that it accounted for 15% of the total costs of familiarisation, whilst another suggested a figure of 25%.

In small firms, the familiarisation step typically accounted for less than one full time equivalent (FTE), but sometimes additional external support was needed. For larger firms, given their engagement in EU policy and legislative-making processes and standardisation-related activities, the costs are often much higher, usually around 3-4 FTE (although in one case, as many as 15 staff were involved, although only part of their time was involved in familiarisation). This reflected a much more active approach to monitoring and shaping the development of Union harmonisation legislation and technical standards.

Among other preparatory actions that involve cash costs for firms are the purchase of harmonised standards which, in the majority of cases, represent the preferred route to ensuring conformity with the applicable requirements. The costs of the purchase and/or update of standards for a specific product group does not account to more than €2,000 on an annual basis, and in many cases less than €1,000.

The amount of time for familiarisation varies depending on the year and what type of legislation has been introduced. For instance, long-established Union harmonisation legislation was seen as much less burdensome during this step, compared with the introduction of new legislation. For example, for the laptops case, a significant resource input was required to input to the preparation of RoHS and once adopted, to ensuring that companies were RoHS-ready. In the case of air conditioners and air conditioning systems, the Ecodesign implementing regulations required substantial familiarisation time.

Currently, SMEs and large firms obtain information about Union harmonisation legislation, technical standards and administrative requirements from a variety of sources, such as the legislative authorities, suppliers, industry and trade associations, market surveillance authorities, etc. However, among SMEs and especially micro firms, there is a low level of knowledge about Union harmonisation legislation, and the specific requirements for different economic operators in the value chain (manufacturers, importers and distributors). Therefore, there seems to be a need to ensure that there is an easily identifiable "first port of call" available for firms in each Member State, particularly SMEs, to find out more about which Union harmonisation legislation is applicable to their products and which standards could be applied to meet the essential requirements. Although the European Enterprise Network could potentially help in providing a signposting function, the European Information Centres (EICs) can only provide very general advice and are non-specialised, as is the case for the SOLVIT network, whereas PCPs have at least some specialist knowledge, since they are often located within national Ministries that are responsible for different national competent authorities.

Quite a number of manufacturers that took part in the case studies stated that one of the most significant challenges in respect of the familiarisation step is keeping track of changes in legislation and updates to standards, since there is a high cumulative frequency of changes. They suggested that an online web portal could be developed at EU level funded by the Commission to provide a single reference point for firms to find out more about which legislation applies to their product, and what changes are being made to legislation and updates to standards.

3.4 Substantive compliance with Union harmonisation legislation

Having understood and familiarised themselves with the applicable essential requirements under Union harmonisation legislation for their product, firms then need to comply with these requirements (often using a voluntary technical standard) and with the appropriate conformity assessment procedures and CE marking requirements.

Either in the case of the development of new or modification of existing product models, this typically includes a period of largely overlapping research and development activities and product testing, the latter providing feedback on the former. The main cost drivers are the costs of human resources (research, engineers), materials, investment in testing facilities and in the costs of testing. Ensuring compliance with the requirements is sometimes the main driver of R&D and testing activities or may be only one among a number of considerations in new product development. The aim is to satisfy market demand and to ensure product quality. Thus, the share of these costs associated with meeting legal requirements (substantive compliance costs) can vary greatly. This is reflected in the input provided through the interview programme and case studies.

Aspects related to product safety may be linked to specific legal provisions but many firms indicate that such activities would take place even in the absence of Union harmonisation legislation. In most case studies, the firms responded that testing for the Machinery Directive, Lifts Directive, Low Voltage Directive or the EMC Directive is largely part of their business as usual costs, i.e. what firms would do irrespective of whether European harmonised product legislation was in place. For instance, lift manufacturers undertake their own extensive product testing both during development and installation so as to ensure high levels of quality and safety. In most cases, these checks, which are often part of internal quality management systems, readily encompass the minimum essential requirements set out in the legislation.

In contrast, firms very often consider that none of the costs of compliance with environmental (emissions, noise, energy efficiency) requirements are business-as-usual costs. An exception identified in this regard (material handling equipment) indicated that the share of investment in R&D and testing activities directly linked to Union harmonisation legislation has recently increased from a typical 10-20% to more than 60% of the total R&D budget. . Another exception is the energy efficiency of domestic refrigerators and freezers [cf. case study].

The main reason indicated is the need to ensure compliance with Non-road Mobile Machinery Emissions and the Outdoor Noise Directives, both of which require dedicated testing facilities (the costs of a sound chamber to test for outdoor noise can be more than €1 million). However, there are also benefits and potential trade-offs with products' performance, requiring additional product design costs. In comparison, firms in the gardening equipment sector – a sector also covered by the NRMM and the Outdoor Noise Directives - indicated that 10-35% of product development and testing costs could be avoided in the absence of Union harmonisation legislation.

Another Directive considered by some stakeholders as having created significant compliance costs for SMEs is the Ecodesign Directive, under which implementing regulations are adopted in relation to specific product groups. The evaluation of the implementation of the Ecodesign Directive in 2012[51] suggested sizeable costs for R&D, testing facilities and possible changes in production. The Ecodesign implementing regulations however only require redesign of the worst-performing products.

A survey organised by the Finnish Industry Association indicated that, on average, for each firm the one-off costs of setting up the necessary test labs were around €200,000 with an additional 1-2 FTE for relevant personnel. In the case of SMEs that use external labs to assess conformity, the cost per product is, according to information from the impact assessments, around €1,000 per product model-family. The testing of products also includes investment in testing facilities. Large firms usually invest in their own testing facilities while smaller firms use external labs more commonly, often those of accredited organisations that provide certification services (Notified Bodies). The costs involved are higher, but smaller firms often have no choice because they cannot afford the major upfront investment to set up a suitable laboratory and to purchase testing equipment.

Whether directly or indirectly linked to legal provisions, an important point identified through a number of the case studies (laptops, lifts) is that a high percentage of substantive compliance costs are integrated into firms' product design cycle. Large manufacturers account for a very significant market share and since they follow legislative-making processes leading to the adoption of Union harmonisation legislation, they are typically aware well in advance of the adoption of the legislation what the requirements are likely to be, and they can therefore factor these in to R&D and design processes well in advance of the legislation coming into effect. A number of firms therefore indicated that even the costs for compliance with the Ecodesign implementing regulations could be significantly reduced when firms are given significant lead times and can integrate the design and testing activities into their normal product development cycle[52]. It should be noted however that the product development cycle varies among sector. For example, in the case of laptops it is typically no

51 CSES(2012), Evaluation and review of the Ecodesign Directive, http://ec.europa.eu/enterprise/policies/sustainable-business/ecodesign/review/index_en.htm

52 It should be noted that the product development cycle varies among sector. For example, in the case of laptops it is typically no more than 6 months, while in the case of air-conditioners it can be up to 3 years.

more than 6 months, while in the case of air-conditioners it can be up to 3 years. Product development cycles are usually considered in the regulatory process establishing Ecodesign implementing regulations.

In contrast, frequent changes to requirements and standards can lead to sizeable costs for industry. It was also noted that regulatory changes for IM legislation are less frequent than changes to environmental legislation. However, the interaction between (and cumulative regulatory impacts of) Union harmonisation legislation on the one hand and environmental legislation on the other can sometimes lead to additional administrative costs for industry.

While in general many safety-related directives are not viewed as particularly costly, frequent changes to the requirements or relevant standards can have cost implications requiring the sudden withdrawal and redesign of products. While it was not argued that individual pieces of Union harmonisation legislation change too frequently (usually legislation is reviewed once every 10 years) since multiple legislation is applicable to a given product, and legislative review processes are carried out at different times, there is an almost constant process of monitoring for revisions. This is especially the case for technical standards, where amendments to standards can be especially frequent.

An example of the implication of changes to standards was provided in the laptop case study where a large multinational had to withdraw a specific desktop PC model that did not meet Amendment 1 of standard IEC 60950-1, a standard set of electronic safety requirements. Similarly, a manufacturer of air-conditioners estimated that it will need to use 75% of its development resources over a 12-18 month period to make necessary adjustments to meet the recently introduced requirements for fans under the Ecodesign Directive.

After the initial adjustments are made, the burdens associated with the Directive are expected to significantly reduce. A lift manufacturer suggested that any technical adaptation required by the legislation would cost around €500k-€1m in terms of new product development. Such costs would relate to ensuring conformity of design, a physical examination of 8-10 different product platforms to be certified but also additional documentation for the conformity assessment process, costs for sales companies, training for sales and production staff, updating sales literature.

Moreover, economic operators referred to additional risks arising for R&D and early stage product development investment if they do not know how Union harmonisation legislation will develop over time, and the form that its implementation may take in future. It is difficult to provide typical values of substantive compliance costs across the whole industry. They vary depending on the product category and the firm strategy. The following table provides some illustrative examples from the case studies.

Product category	**Example(s)**
Domestic Refrigerators	A large firm typically spends 1-1.5 year FTE / firm, 80-90% of which is allocated to product development and product quality testing. Another large firm indicated that a typical product development project - leading to the development of a basic model with multiple variants – takes 3 years and requires and a budget of up to €100 million.

Gardening equipment	A large firm producing close to one million units indicated that around 3% of annual R&D budget of €50-60 million that is invested to the development of a new product is directly related to ensuring compliance with internal market legislation (circa €4 million). A small firm producing 15,000 units indicated investments for product design of €200-300k
Pumps and dispensers	A large producer of pumps and dispensers (over 1000 employees) estimated total compliance costs of €3.2m over the last five years, €2m on changes to product design and €1.2m to production processes.

3.5 Conformity assessment procedures

The conformity assessment procedure most commonly followed by manufacturers interviewed was the Supplier's Declaration of Conformity (SDoC). Among the steps needed as part of conformity assessment are carrying out product testing, the preparation of the technical file and the preparation of the DoC and the required information manual and CE marking. For product groups that have legislation that requires mandatory third party testing, an inspection by Notified Bodies and appropriate certification is required.

According to the common requirements set out in Decision 768/2008/EC, following the placing on the market, this information needs to be kept for 10 years following the placing on the market and to be updated whenever there are changes. This can require significant time and resources, for instance, checking and updating DoCs every few months, as and when legislation and standards are updated.

Significant time is often dedicated to the collection of information from suppliers of specific components or finished products. The estimated time for the preparation of a technical file for a gardening equipment product ranges from 40-100 hrs. The costs for conformity can vary depending on the need or not for third party certification. The data from the case studies suggests that the annual budget of firms for services of Notified Bodies is in the range of €30-80k, around €4,000 for certification of a single product and representing 20-25% of the total estimated costs for compliance. Similar figures were provided by manufacturers of fuel dispensers. Manufacturers of fuel dispensers – a product that requires third party certification - estimated that Notified Bodies fees represented 55% of the conformity assessment costs, 35% relating to initial inspections and 20% to periodic inspections. Data from the evaluation of the Gas Appliances Directive[53] also refer to certification costs in the range of €1000/product. However, the input from a number of firms (gardening equipment, air conditioners, refrigerators) is that firms use NBs services to support them in testing and ensuring compliance even when third party certification is not mandatory.

The provision of relevant information in the instruction manuals and translation costs are also part of the administrative costs. Data for translation costs of these manuals to cover all EU countries ranged around €3,000 for each gardening equipment model. It should be noted here that every change to relevant standards or requirements lead to costs for the replacement of manuals. A producer of domestic appliances selling around 2 million units indicated that

53 RPA (2011), Ex-Post Evaluation of the Gas Appliances Directive: http://ec.europa.eu/enterprise/dg/files/evaluation/03_2011_finalreport_gas_en.pdf

every time there is new legislation new information manuals need to be printed. The estimated cost at an annual basis was around €100,000k/year.

Sectors covered by the Outdoor Noise Directive (e.g. gardening equipment) need also to submit information included in the DoC to the national and European authorities. Estimates from the gardening equipment case were that it took approximately 80 hours for the 20 different models in its production line. The REACH Regulation and the RoHS Directive do not directly affect firms in the manufacturing sector that are downstream users. The main task is the collection of information from suppliers so as to ensure that no substances of high concern are included in any component.

Some large manufacturers may test components but more typically, the approach followed is to request and collect appropriate certificates from suppliers, to allocate part of a FTE on an annual basis for this activity. According to the recent review of the REACH Regulation[54], 50-70% of downstream users of chemicals (mostly in the non-food manufacturing industry with the exception of chemicals and plastics) have experienced an increase in the costs of managing information along the supply chain, typically in the form of additional workload for existing staff (small firms) or the hiring of extra staff (large firms).

As in the case of product design and testing, additional costs may also arise from the changes to regulatory requirements and the updating of relevant standards. There is a need to adopt information manuals and technical files. This can be particularly problematic for small firms that do not have the structures and mechanisms to follow developments on an on-going basis. The feedback provided suggests that it is mainly these changes that create important adjustment costs rather than the actual information obligations. This is seen as particularly problematic for small firms.

Frequent changes make the legal environment unpredictable but also introduce costs – sometimes sizeable – for firms that try to follow all development and to fit their information collection systems to the information obligations. The feedback provided suggests that it is mainly these changes that create important adjustment costs rather than the actual information obligations. This is seen as particularly problematic for small firms. It was noted that regulatory changes for Union harmonisation legislation are less frequent than changes to environmental legislation. However, the interaction between and cumulative regulatory effects associated with the two can sometimes lead to additional administrative costs for industry.

A further finding was that although economic operators may not always be able to quantify costs, most firms were able to comment on the level of staffing involved and the broad cost parameters. There were however concerns regarding those areas of the regulatory framework where there is potential future uncertainty for economic operators with regard to the future costs of compliance, such as REACH. Given the very significant level of investment and long lead times required in order to bring some types of new products to market, there are concerns that the situation may change in the interim with potentially very high costs for industry.

A large global components manufacturer in the electronics sectors expressed concern as to whether particular chemicals would still be in use in 10 years' time, and whether if not, substitute products are likely to be available. Product R&D operates according to long lead

54 CSES (2012), Functioning of the European chemical market after the introduction of REACH http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/chemical_market_en.htm

times and significant investment in the product development cycle is required to bring new innovative products to market. Economic operators, especially larger companies operating globally have to be inherently forward-looking in assessing how the regulatory landscape will evolve over time.

The firm interviewed commented that "there is a great deal of legal uncertainty from a downstream user perspective. There is a substance called gallium arsenide and currently microchips cannot be made without it, but there is no viable substitute product. The substance is currently being reclassified under the CLP 5th ATP. There is a risk that the substance could be fast-tracked to being subject to an authorisation, which would impose major costs on industry. If a particular substance requires authorisation or is banned, then this could really disrupt the supply chain, and lead to legal uncertainty. REACH is delivering in terms of identifying harmful substances, but there should be a greater focus on assessing the impacts on impacts on downstream users."

3.6 Estimates of costs at sectoral level

On the basis of data inputs from firms across the eight sectors examined, we estimated compliance costs – administrative and substantive – at a sectoral level. In the table that follows, we provide summary information drawing on the data from the case studies focusing on:

- Total annual compliance costs (excluding business as usual costs) and their share in the sector turnover;
- The main cost drivers (phases of the process, type of activity) of administrative costs.

Various caveats should be added before presenting the summary findings with regard to the costs of compliance of Union harmonisation legislation across 8 harmonised product groups. Firstly, there were difficulties in obtaining reliable quantitative data on cost parameters across all variables. Secondly, there were specific issues and assumptions made regarding cost drivers for each case study. These are indicated in the footnotes for the Table below that provide an aggregate of sectoral cost estimates for each case and explained in greater detail in the respective case studies.

The total estimated annual costs of compliance of Union harmonisation legislation across the 8 harmonised product cases were estimated at €342 million.

Product group	**Total annual compliance costs for the sector and share in annual turnover (%)**	
Electric motors	€ 33.2 million	0.3% of annual turnover
Laptops	€ 28.1m	2.0% of annual turnover
Domestic refrigerators/freezers	€ 86.0 million	0.4% of annual turnover
Lifts	€ 26.0 million	0.9% of annual turnover
Gardening equipment	€ 98.5 million	3.9% of annual turnover**
Petrol pumps	€ 12.2 million	1% of annual turnover
Air conditioners	€ 50.1 million	1% of annual turnover
Integrated circuits	€ 7.7 million	<0.1% of annual turnover
Total	€ 342 million	

*Notes (i) the reasons for this outlier are explained in the case study on gardening equipment (ii) reference should be made to the footnotes in the case studies setting out the quantitative findings in all cases, since the assumptions made underlying the data, any gaps and imputations used for particular cases needs to be spelled out.

It is also important to note that it has not always been possible to clearly distinguish between administrative and substantive compliance costs in the quantitative assessment. There are grey areas where the delineation between different types of costs is unclear. For example, while conformity assessment costs are classified as being substantive costs, there are aspects of conformity assessment where administrative costs are incurred in parallel, such as the preparation of a technical file. Where possible to do so, a differentiation between the two was made in individual case studies.

This being said, we can still observe wide divergence in compliance costs between different harmonised product groups. In most cases, total annual estimated compliance costs do not exceed 1% of annual turnover. The notable exceptions in this regard were gardening equipment (3.9%) and laptops (2.0%). The explanatory factors as to why compliance costs were higher in these sectors were explored through the research. In the case of gardening equipment, the higher level of compliance costs was mainly because of the costs associated with environmental Union harmonisation legislation (the Outdoor Noise Directive, non-road mobile emissions). In contrast to safety-related requirements which are very often considered to be "business as usual", costs of compliance with environmental legislation are considered additional for the firms in the sector and, according to most firms, rather demanding, particularly in terms of the testing required.

For gardening equipment, administrative costs were found to be only a small part of total compliance costs. This seems to be the case generally for many consumer products (gardening equipment, domestic refrigerators and air conditioners). Substantive compliance costs are the main driver of compliance costs because important aspects of product design and testing for safety are not considered by firms to be business-as-usual costs. In comparison, in the case of the lifts and electric motors, both products primarily addressed at professional users, substantive compliance costs (product design and testing) are generally considered to be business as usual and, as a result, the main focus of firms is on the administrative costs of the legislation,

In the case of laptops, the estimates provided may over-estimate the total compliance costs associated with Union harmonisation legislation. Since the industry is dominated by a small number of global manufacturers, it was difficult for them to provide compliance costs disaggregated by geographic region because they tend to design products for global markets and sometimes for multiple – or at least dual – regulatory requirements with some customisation of the product itself to local markets.

Ecodesign was perceived as costly by some manufacturers that took place in the electric motors case study. However, there was found to be a difference between perception amongst industry about the main cost drivers in terms of the type of legislation, and the actual costs. The Ecodesign Regulations do not require all products to be redesigned, only the lowest-performing electric motors (typically 20% of existing models). Since other major global jurisdictions, such as the US, already had strict requirements, many motors already complied and the Ecodesign regulations has simply prevented the dumping of poorly efficient electric motors on the EU market. Compliance costs only equated to 0.3% of turnover in the electric motors sector.

3.7 Compliance costs by firm size

There were differences between firms in the level of compliance costs (administrative, substantive) by firm size, although this was difficult to substantiate based on the limited

numbers of SMEs that agree to take part in the study. SMEs were found to experience significantly higher costs / unit for regulatory compliance compared with large firms that are better able to spread the costs across a high number of units. SMEs also appear to have a higher percentage of staff involved in compliance-related activities (familiarisation, testing) than large firms, although few are able to have individual staff members working full-time on compliance. Micro and small firms were also more likely to have to rely solely on external third party conformity assessment since many do not have their own in-house laboratory and testing facilities.

SMEs are also at a comparative disadvantage because large firms follow EU legislative-making and standardisation development processes more closely. As a result, they are more aware about proposed changes to Union harmonisation legislation in advance and can factor in anticipated regulatory requirements prior to new IM regulatory requirements coming into effect at the product design stage, which lowers substantive compliance costs. Even if the number of SMEs that participated in the case studies was limited, the quantitative findings on compliance cost differentials were substantiated by a number of SME and industry associations in particular sectors (e.g. lifts, air conditioning).

The administrative burdens of compliance with Union harmonisation legislation were sometimes found to be disproportionate for micro enterprises. For instance, any manufacturer wishing only to place a product on the domestic market must still comply with Union harmonisation legislation (including DoC and CE marking requirements) if their product is in the harmonised sectors. An example cited by a European SME association of the burdens were the Finnish woodcutters, where micro enterprises of 2 persons only producing products for the local domestic market had to go through the conformity assessment procedures and to CE mark, even though the products were sold untreated. Nevertheless, they are still subject to the REACH Regulation.

3.8 Costs for public authorities of monitoring product safety and regulatory enforcement

Quantification of expenditure on national support mechanisms, structures and activities to support the implementation of Union harmonisation legislation, such as on market surveillance, was impossible. However, some data was available in this regard through previous studies and impact assessments.

As far as public authorities are concerned, the available estimates on the number of product safety enforcement activities provided by national authorities suggest that a total of 3,000-4,000 product inspectors across EU28 are engaged in market surveillance and regulatory enforcement activities, with an annual budget of enforcement activities in the range of €100-150 million[55]. These figures are quite a high estimate, as they include enforcement activities relating to non-harmonised products. In addition, in order to assess the overall costs of the implementation of Union harmonisation legislation, other costs related to national implementation are the human resource costs for policy coordination through the role of national competent authorities, for instance, in the transposition of Union harmonisation legislation, in the appointment of Notified Bodies, etc.

The feedback provided points to market surveillance as being the most resource-intensive

55 Commission Staff Working Document - Annexes to the Impact Assessment Accompanying the document : Product Safety and Market Surveillance Package, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2013:0033(52):FIN:en:PDF

aspect of the implementation of Union harmonisation legislation for public authorities. From the small number of Member States that provided data on the resources allocated to Union harmonisation legislation, more than 80% appears to be allocated to market surveillance activities. Compared to the situation prior to the introduction of the Union harmonisation legislation, national authorities may have experienced some cost savings. According to the evaluation of the MID, for instance, many authorities indicated a substantial decrease in their workload in terms of dealing with applications for national certification. This reduction was most notable in countries with a small number of manufacturers of measuring instruments or where measuring instruments are imported on the basis of certification undertaken in other countries.

3.9 Conclusions on the costs of compliance with Union harmonisation legislation for industrial products

Whilst most manufacturers could highlight the most costly compliance steps and pieces of legislation, few were able to quantify the costs incurred at each step with any accuracy. However, as the overall volume of Union harmonisation legislation has grown, it was clear that the task of ensuring compliance with legislation and technical requirements set out in harmonised standards is resource-intensive.

A certain proportion of compliance costs were 'BAU' and would have been incurred by industry regardless as to whether there was a European regulatory framework in place. Many firms have well-developed internal safety testing procedures as part of quality assurance procedures and use third party testing for reputational reasons, even where not mandatory.

In all sectors, the process of adaptation to new technical requirements can be costly for manufacturers short-term, particularly when the transition period is relatively short. In the long-run, substantive compliance costs fall over time as manufacturers become more familiar with the requirements of the legislation. Industry is highly familiar with compliance requirements for long-established directives, such as the Machinery Directive, Low Voltage Directive and EMC Directive. Since the technical standards and administrative requirements are well-known, these can be factored in to design requirements from the outset.

Some legislation is more costly than others to implement. Ecodesign implementing regulations were often mentioned as costly, both because of the need for changes to be made to the worst-performing products. However, it should be noted that under Ecodesign Regulations, this does not mean redesigning all existing models, rather only the worst-performing, typically 20% of existing models. Moreover, products that have already been placed on the market are not effected by ecodesign; components and parts are not a specific aspect: ecodesign requirements are generic to the whole product. Substantive costs vary by sector. In sectors characterised by rapid technological innovation, the substantive requirements can usually be "designed into" the product; in that sense, the legislation sets parameters regarding what is possible without increasing the costs of design and production.

In other sectors, substantive costs tend to account for a relatively high proportion of total compliance, depending on the duration of the product lifecycle. For example, it is more difficult for manufacturers of products with a long lifecycle because they are more likely to have to make modifications – or to identify alternatives or substitutes - to products already on the market. This is more costly than factoring these into the initial design phase during the R&D process.

It is also worth noting that there has been a gradual accretion of Union harmonisation legislation in the previous 25 years and this has led to cumulative effects of regulatory compliance. While it has long been the case that multiple pieces of legislation may be applicable to a given product, when the New Approach was first adopted, it was perhaps not foreseen that the body of internal market legislation would grow to the level that it has. Moreover, the past decade has seen the introduction of a number of Union harmonisation directives and regulations that apply horizontally across all product groups (e.g. REACH, RoHS, Ecodesign and Energy Labelling). The cumulative effects of regulatory compliance stem from the fact that manufacturers of industrial products must comply with a growing body of internal market and environmental legislation. It is the cumulative frequency of these changes and updates to legislation itself and to (voluntary) technical standards that result in cumulative effects and impose additional costs, for instance, familiarisation time to keep track of changes, integrating new requirements into R&D and the product design phase, making modifications to products already on the market.

Findings from the case studies

- Familiarisation with the legislation accounts for a significant proportion of the total costs of compliance, estimated at around 15-20% for many firms. Much of these costs are in the form of staff time, around 2-4 FTEs in a typical large firm and >1 FTE in an SME.
- Ensuring compliance with IM legislation is sometimes a key driver of R&D and testing activities or may be only one among a number of considerations in new product development
- Testing equipment can account for massive costs that manufacturers might not otherwise incur. These affect SMEs disproportionately, as the cost is spread over at lower volume of production.
- In the long-run, a high proportion of substantive compliance costs are integrated into firms' product design cycles and are therefore negligible. In that sense, the legislative requirements tend merely to set parameters around what is possible rather than imposing additional substantive compliance cost
- In contrast, frequent changes to legislative requirements and standards can impose sizeable adaptation costs on industry, albeit one-off and short-term in nature.
- A significant proportion of the costs of conformity assessment relates to the task of collecting information from suppliers, preparing technical files, checking and updating DoCs and maintaining technical files for 10 years. Such costs are greatly increased when there are changes to the legislation or the standards.
- The costs of conformity assessment depend very largely on the need for third-party certification. Certification of a single product typically costs around €4k in NB fees, though annual certification of systems would be much higher.
- In most sectors the costs of compliance do not exceed 1% of annual turnover, provided that much of the costs of product design and testing for safety can be considered business-as-usual costs.

- SMEs experience higher compliance costs relative to their turnover, though few have individual staff members solely devoted to compliance. They are also more likely to rely on external third-party conformity assessment and less likely to follow and participate in the process of developing legislation and standards at EU level.

- Market surveillance activities are estimated to occupy 3,000-4,000 product inspectors across EU28 at a cost of around €100-150m per annum. This accounts for around 80% of the total cost to national authorities of developing, implementing and enforcing IM legislation.

- The gradual accretion of IM legislation has required manufacturers to comply with a growing body of internal market and environmental legislation. Frequent updates to legislation itself and standards risk imposing cumulative costs, for instance, related to familiarisation time to keep track of changes, integrating new requirements into R&D and the product design phase, making modifications to products already on the market, updating DoCs, etc.

3.10 Case studies

3.10.1 Case Study 1 – Electric motors

Introduction

The product group examined in this case study is electric motors. The rationale for the selection of these product groups was that:

- Electric motors are covered by a large number of Union harmonisation Directives and Regulations;

- There is a large number of professional users in the sector;

- The sector represents a high share of total manufacturing (see industry structure below). Hence demand for electric motors is closely related to manufacturing processes and investments in the manufacturing industry[56].

The case study is based on desk research and interviews with two national industry associations representing manufacturers of electric motors and nine in depth interviews with manufacturers of electric motors operating in Europe, four large size manufacturers, one medium and four small.

Product definition and description of structure of the sector

Product definition

The product group examined in this case study is electric motors. An electric motor is a device which converts electric energy into mechanical energy[57]. These types of motors are widely used in machine tools, household appliances, power tools and other electrical

56 Report 'Trends and segments for electric motors' by the Dutch Center for Encouraging import from Developing Countries (CBI) – 2011. http://www.cbi.eu/system/files/marketintel/Trends_and_segments_for_electric_motors.pdf

57 Definition taken from 'EUP Lot 11 Motors' by de Almeida, Ferreira, Fong and Fonseca (2008). See http://www.eup-network.de/fileadmin/user_upload/Produktgruppen/Lots/Final_Documents/Lot11_Motors_FinalReport.pdf

appliances and equipment. There are two main types of electric motors. These are the so-called AC and DC motors. Around 50% of the demand in the European Union is for AC motors. Further distinctions can be made by output in kW or by type of motor (single-phase, multi-phase).

Electric motors are covered under PRODCOM code 27.11 that includes the following 21 different sub-categories:

- 27111010 - Electric motors of an output <= 37.5 W (including synchronous motors <= 18 W, universal AC/DC motors, AC and DC motors)
- 27111030 - DC motors and generators of an output > 37,5 W but <= 750 W (excluding starter motors for internal combustion engines)
- 27111053 - DC motors and generators of an output > 0,75 kW but <= 7,5 kW (excluding starter motors for internal combustion engines)
- 27111055 - DC motors and generators of an output > 7,5 kW but <= 75 kW (excluding starter motors for internal combustion engines)
- 27111070 - DC motors and generators of an output > 75 kW but <= 375 kW (excluding starter motors for internal combustion engines)
- 27111090 - DC motors and generators of an output > 375 kW (excluding starter motors for internal combustion engines)
- 27112100 - Universal AC/DC motors of an output > 37,5 W
- 27112230 - Single-phase AC motors of an output <= 750 W
- 27112250 - Single-phase AC motors of an output > 750 W
- 27112300 - Multi-phase AC motors of an output <= 750 W
- 27112403 - Multi-phase AC motors of an output > 0,75 kW but <= 7,5 kW
- 27112405 - Multi-phase AC motors of an output > 7,5 kW but <= 37 kW
- 27112407 - Multi-phase AC motors of an output > 37 kW but <= 75 kW
- 27112530 - Multi-phase AC traction motors of an output > 75 kW
- 27112540 - Multi-phase AC motors of an output > 75 kW but <= 375 kW (excluding traction motors)
- 27112560 - Multi-phase AC motors of an output > 375 kW but <= 750 kW (excluding traction motors)
- 27112590 - Multi-phase AC motors of an output > 750 kW (excluding traction motors)
- 27112610 - Alternators of an output <= 75 kVA

- 27112630 - Alternators of an output > 75 kVA but <= 375 kVA
- 27112650 - Alternators > 375 kVA but <= 750 kVA
- 27112670 - Alternators of an output > 750 kVA.

Industry structure

Enterprises

According to data from Eurostat there were around 14,000 enterprises in the electric motors sector in the period of 2008 – 2010, which were concerned with the manufacturing of these motors. As mentioned before this concerns NACE code is 27.11 (Manufacture of electric motors, generators and transformers), which is broader than only electric motors.

Table 7-1: Number of enterprises – electric motors, generators and transformers sector (NACE 27.11)

2008	2009	2010
14,697	14,272	14,544

Source: Eurostat, Structural Business Statistics.

The following table shows the production value for the years 2009 and 2010. It shows a sharp increase from 2009 and 2010. This is not in line with the number of employees, which stayed stable around 2.5 million during the same time period.

Table 7-2: Production value (in million €) – electric motors, generators and transformers (NACE 27.11)

2009	2010
45,530.38	53,606.02

Source: Eurostat.

Products

Based on the Eurostat PRODCOM data for 2009, the total market size for electric motors was around 733.5 million units or EUR 10.5 billion in production value[58]. In the following table an overview is provided of the different PRODCOM indicators and their export/import value for the year 2009. In Europe 293.2 million electric motors, generators and transformers were produced. The corresponding production value was 12.3 billion euro's. The sector has exported a value of 4.2 billion, while imports amounted to 2.4 billion. This confirms the view that most motors are still produced in (Western) Europe given the highly automated production processes present in those countries[59]. Table 7-A1 in the Annex gives a detailed description of all codes and the production, import and export values.

58 Including production and import, excluding export.
59 Report 'Trends and segments for electric motors' by the Dutch Center for Encouraging Import from Developing Countries (CBI) – 2011. http://www.cbi.eu/system/files/marketintel/Trends_and_segments_for_electric_motors.pdf

Table 7-3: Production, import and export value – electric motors, generators and transformers (2009), PRODCOM CODES: 2711010 to 27112670[60]

	Quantity (units)	Values (€)
Production	293,264,097	12,309,392,520
Import	543,812,581	2,433,820,520
Export	103,498,097	4,261,409,780
Total EU market (Production + imports - exports)	733,578,581	10,481,803,260

Source: Eurostat PRODCOM.

Tables 7-4 and 7-5 show numbers of units sold and value data for the four most common technologies of motors. 91% of all electric motors sold in Europe in 2010 are small power range motors, namely under 750W. In this year, only 0.01% of the motors sold had a very large power range, 9% were medium range motors.[61]

Table 7-4: Electric motors and generators sold by type in EU27 (thousand units, 2010)

Technology	Power range					
	≤ 750 W		> 0,75 ≤ 375 kW		> 375 kW	
	units	%	units	%	Units	%
DC Motors and Generators	12,176	56	4,417	21	1	5
AC Single-Phase	67,019	29	6,379	30	n/a	n/a
AC Multi-Phase	11,700	5	10,175	49	28	95
Universal	23,288	10	n/a	n/a	n/a	n/a
Total	230,123	100	20,970	100	30	100

Source: EuP lot 30: Electric Motors and Drives (2012)

Table 7-5: Revenue data for electric motors and generators by type EU27 (millions €s, 2010)

Technology	Power range					
	≤ 750 W		> 0,75 ≤ 375 kW		> 375 kW	
	Value €	%	Value €	%	Value €	%
DC Motors and Generators	1,762	39	515	11	64	5

60 The table in the appendix provides an overview of the data of per PROD-COM CODE.
61 Source: EuP lot 30: Electric Motors and Drives (2012), table 2-3 and 2-4 - http://www.eco-motors-drives.eu/Eco/Documents_files/EuP-Lot30-Task-2-2-Dec-2012.pdf

AC Single-Phase	1,365	30	805	17	n/a	n/a
AC Multi-Phase	805	18	3,384	72	1,142	95
Universal	576	13	n/a	n/a	n/a	n/a
Total	4,508	100	4,705	100	1,207	100

Source: EuP lot 30: Electric Motors and Drives (2012).

Analysis of applicable legislation and standards

Electric motors are covered by seven different pieces of legislation. This legislation is divided into three categories:

- Health and safety (Low Voltage Directive, Machinery, RoHS Directive on hazardous chemicals, REACH, ATEX directive),
- Electromagnetic compatibility (EMC Directive); and
- Energy consumption (Eco-design and the respective implementing measures)

The following directives are applicable to electric motors:

- Low Voltage Directive: LVD is applicable to all electric motors, except extra low voltage and high voltage;
- Machinery Directive: the MD is applicable for high voltage electric motors (high voltage electric motors are considered as partly completed machinery). It should be mentioned that in general electric motors are used in machines, for which the MD is applicable. So, although the MD is not applicable to most electric motors, MD is applicable to the machines with electric motors;
- Directive on Electromagnetic Compatibility (EMC): EMC is applicable to all electric motors. Some interviewees mentioned that EMC is not relevant to electric motors, because electric motors do not cause disturbances. There only might arise problems when other components are added (such as control units).
- ATEX: ATEX is only applicable to electric motors that are used in specific areas (explosive atmospheres).
- RoHS: Refers to the use of chemicals (such as lead).
- Reach: Refers to the use of chemicals (such as copper lamination).
- Ecodesign: Ecodesign is applicable to a large part of the electric motors (see below).

The table in the appendix provides an overview of relevant Union harmonisation legislation for the electric motors, including the basic administrative requirements.

The most important directives is terms of impacts are considered to be the Ecodesign (EuP for IEC-motors) and ATEX. ATEX (if applicable) is considered the most burdensome since it requires third party certification.

Ecodesign is a relatively new Directive in relation to electric motors. Electric motors which have to comply with the Ecodesign directive are called IE-motors or IEC-motors. For these motors there are rules for energy efficiency. EC Regulation 640/2009 implements the European Ecodesign Directive for electric motors. It contains requirements for the design of electric motors. The Regulation was published on 23 July 2009 and entered into force on 12 August 2009. There are several efficiency levels in the regulation. Minimum requirements are IE2 from 2011, IE3 or IE2 combined with a variable speed drive (VSD) for motors above 7.5 kW from 2015 and IE3 or IE2+VSD for motors above 0.75 kW from 2017. Because of the clear timetable enterprises can anticipate on the new efficiency levels. Also international standards are developed before a new level comes into force. Every new level means for enterprises that they have to design new electric motors, which stimulates innovation. Some interviewee noticed that the new efficiency levels are used in the market as a commercial tool.

Analysis of costs of compliance

Introduction

The information presented in this section is based on the in-depth interviews with nine manufactures of electric motors. The firms range in terms of size and production volume. From six respondents data on administrative costs were collected, four large size manufacturers, one medium and one small.

Table 7-6: Basic information on the firms interviewed

Firm	Specific/main product	Firm size	Annual sales from product	Main markets
A	Electric motors	Large (>1000 employees)	3,500,000 units	--
B	Electric motors	Large (>1000 employees)	25,000 units	100% of sales in the EU
C	Electric motors	Large (>500 employees)	900,000 units	80% of sales in the EU
D	Electric motors	Large (>500 employees)	260,000 units	60% of sales in the EU
E	Electric motors	Medium (250-500 employees)	600,000 units	98% of sales in the EU
F	Electric motors	Small (<250 employees)	15,000 units	80% of sales in the EU
G	Electric motors	Small (<250 employees)	40,000 units	100% of sales in the EU
H	Electric motors	Small (<250 employees)	20,000 units	100% of sales in the EU
I	Electric motors	Small (<250 employees)	20,000 units	100% of sales in the EU

Before we briefly discuss the process steps some remarks need to be pointed to understand the typical situation for electric motors:

- In this case study we identified seven directives which are applicable to electric motors. But in general not all directives are applicable to all electric motors. The applicable directives for electric motors differ between companies, depending on which type of motors they produce. For example, the ATEX directive is only applicable to motors which are used in explosive atmospheres.

- Lots of companies do not produce bare electric motors. Often frequency converters, controllers, software, etc. are added to the electric motors. These added components are often also covered by legislation individually or in combination with the electric motor. For example, some interviewees mentioned that electric motors themselves do not produce interferences and the EMC directive actually is not very relevant, but when frequency converters or controllers are added this causes interferences which make the EMC directive very relevant. Another interviewee mentioned that the Machinery directive was not applicable to the electric motors they produce, but that their customers use the electric motors in their machines. These machines are covered by the Machinery directive. This leads to customer requirements with regard to the supplier of the electric motors in line with the Machinery directive. In general, interviewees indicated that it is difficult for them to distinguish between the processes to comply with the obligations for the electric motors and the processes to comply to the obligations for the added components, because for the manufacturers it is one integrated process.

- Most of the directives relevant for electric motors exit already for a relative long time. They do not change that much and companies are used to comply with these directives. It is incorporated in their processes. Only the Ecodesign implementing regulation is relatively new and has at the moment the largest impact on companies. The regulation requires that electric motors, covered by the regulation, have to reach certain levels of energy efficiency in several steps. For some manufacturers/models [as indicated in section 1.6 the requirements are not more stringent than elsewhere in the world and do not mean that all models need to be redesigned, only a number of them. Typically ecodesign means redesign for 20% of the existing models. Since other jurisdictions such as the US already had strict requirements, many motors already complied and the ecodesign regulation simply stopped the dumping of the poor efficiency ones on the EU market], this does not require simple adjustment of existing models, but complete electric motors have to be redesigned. When asking about internal market legislation for electric motors, most interviewees start with the Ecodesign regulation, because this regulation is the current issue and has the major impact on the companies. Other directives are more viewed as business as usual. The Ecodesign regulation causes extra costs for the companies, but on the other hand most interviewees use the new requirements as strategic issues in their markets. They recognize the impact of electric motors on energy use in the world and that improving the energy efficiency of electric motors is very important. They try to be the first with the development of more efficient motors in the market.

The following steps can be identified in the process of placing electric motors to the market:

- Familiarisation with applicable/relevant obligations

- Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations
- Conformity assessment procedures and relevant documentation
- Declaration of conformity or other statement of compliance and CE marking

Familiarisation with applicable/relevant obligations

To comply with the applicable internal market legislation companies need to have knowledge of the applicable directives and of the standards. As mentioned, the applicable directives for electric motors differ between companies, depending on which type of motors they produce. For example, the ATEX directive is only applicable to motors which are used in explosive atmospheres and the Ecodesign directive is not applicable to all motors because this directive includes several exceptions.

In general, the companies are linked to information sources on Directives and on standards or they have their own system. For example a smaller Dutch producer is a member of the NEN-connect network. This is a digital platform which shows the different standards and directives which are of interest for producers of electric motors. The platform sends an automatic message when the standards are updated and changes need to apply. When this message arrives, the firm examines the change and decides if they have to change their design. Furthermore, companies buy standards and get all technical features to comply with.

One interviewee mentioned that they participate in standardisation groups to be informed in a very early stage about the backgrounds of the legislation and standards. For them these backgrounds are necessary for the correct application of the requirements.

The average costs for familiarisation with applicable/relevant obligations of the interviewed companies amount to approximately 0.2% of turnover. More than 90% of these costs are cost of human resources.

Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations

For developing new electric motors and production processes the companies have to comply with the requirements of relevant directives. For most directives working in accordance with the relevant standards is incorporated in the development, testing en production processes of the enterprises. At the moment the Ecodesign implementing regulation requires that electric motors are more and more energy efficient in several steps. To comply with these efficiency requirements enterprises have to redesign some models [as indicated in section 1.6 the requirements are not more stringent than elsewhere in the world and do not mean that all models need to be redesigned, only a number of them. Typically ecodesign means redesign for 20% of the existing models. Since other jurisdictions such as the US already had strict requirements, many motors already complied and the ecodesign regulation simply stopped the dumping of the poor efficiency ones on the EU market. Although this causes extra costs,

several respondents mentioned that these developments also offer new opportunities in their markets.

For most producers of electric motors testing is the most costly step to comply with the relevant Directives. But on the other hand most interviewees would also test a lot when there were no directives and standards. This is needed to develop and sell safe products. This is especially the case for ATEX-motors because these motors are used in explosive atmospheres.

The average costs for compliance with requirements (product design and testing) of the interviewed companies amount to approximately 0.6% of turnover. 74% of these costs are cost of human resources, 23% are costs for testing equipment and 3% are costs for third parties.

Conformity assessment procedures and relevant documentation

This step is concerned with preparing technical documentation, which causes costs for employees of the enterprises, and with conformity assessment. Conformity assessment is especially related to inspection of notified bodies. This is the step that causes most of the external costs. This is especially relevant for ATEX-motors. For ATEX- motors it is mandatory that a notified body inspects the designs of these motors and test motors to get the required marking. This is only needed when companies produce motors that are to be used in explosive atmospheres.

The average costs for conformity assessment procedures and relevant documentation of the interviewed companies amount to approximately 0.3% of turnover. 57% of these costs are cost of human resources, 32% are costs for third parties and 11% are costs for testing equipment.

Declaration of conformity or other statement of compliance and CE marking

Drawing up declarations of conformity and CE marking is not viewed a big issue for the interviewees. Compared to the other steps this is a minor step, not very complex and not very costly. The average costs for declaration of conformity or other statement of compliance and CE marking of the interviewed companies amount to approximately 0.1% of turnover. More than 90% of these costs are cost of human resources.

Business as usual

Companies were asked to differentiate between Business As Usual cost (BAU) and cost specifically due to the internal market regulation. Part of the activities obliged by IM legislation companies would perform anyway. For example, a firm may carry out product testing so as to check the quality and safety of products. Such costs are known as ‘business as usual’ (BAU) costs. Respondents mentioned that the largest shares of the activities that cause the administrative costs are business as usual. If there were no directives and standards the enterprises would have their own quality and safety standards. To meet these standards companies also have to test their products. Some enterprises mentioned that without directives they would spend less on some external tests (costs of third parties). On average, 73% of the costs of human resources spent on compliance activities is considered as business as usual by the interviewed companies. For the costs of third parties this average is 67% and for the costs of testing equipment 87%.

Assessment of costs of Union harmonisation legislation for the whole sector

Data collection

Based on the information provided by interviewees, the average costs of complying with Union harmonisation legislation have been estimated. Out of six respondents, data on costs were collected, four large size manufacturers, one medium and one small. In principle the respondents are manufacturers. But some of them also have some trading activities (import of motors). Cost data have been collected for activities relating to electric motors, especially manufacturing, but the respondents could not distinguish between the compliance costs for the manufactured and the imported motors. The data collection was focussed on the costs to comply with the following legislation: Low Voltage Directive, Machinery Directive, the Directive on Electromagnetic Compatibility (EMC), ATEX, RoHS, Reach and Ecodesign.

The six interviewed companies were asked to give estimates of the costs of human resources, costs of third parties and costs of testing equipment for total compliance activities (top down approach). Also data on time and tariff were asked (bottom up approach), but this did not result in sufficient usable data. For the testing equipment the costs for the last five years are collected to calculate the average cost per year. Next the interviewees were asked to distribute these costs of human resources, costs of third parties and costs of testing equipment over the identified steps of the compliance process (familiarisation, compliance with requirements, conformity assessment, DoC and CE marking and other) and they were asked which parts of these costs are considered as business as usual.

Estimation of costs

All costs are collected as totals for enterprises. The cost estimates for the whole sector are based on turnover. All costs were calculated as percentages of turnover and this was then used to weight the results. The data collected with two SMEs did not show clear differences – in terms of costs as a percentage of turnover - as compared to the data for large enterprises. Therefore, there were no grounds for making a distinction in the calculations. In other words, it has been assumed that the compliance costs as a percentage of turnover are the same for large enterprises and for SMEs.

Based on the results from the six respondents, in Table 7-7 the estimates of compliance costs for the sector of electric motors are presented as percentages of turnover. The costs were standardised by calculating averages of the percentages. To estimate the compliance costs for the whole sector of electric motors we followed the following steps:

- for each type of costs (cost of human resources, costs of third parties and costs of testing equipment) the costs were calculated as a percentage of the turnover of electric motors, averaged over respondents (first row in Table 7-7)

- the distribution of the costs over the different process steps is again an average of the estimated distribution from the respondents, as a percentage of the annual compliance costs (see distribution over process steps in Table 7-7)

- we then determined the average percentages of business as usual (as percentage of annual compliance costs, per cost type), to distinguish between the total compliance costs and the regulatory burden related to the internal market legislation (last 2 rows in table 7-7).

Table 7-7: Estimate of average compliance costs (%)

	Cost of human resources for total compliance activities	Costs of third parties	Costs of testing equipment	Total
Annual costs (% of turnover)	0.95%	0.13%	0.18%	1.26%
Of which (% of annual costs; is the distribution over process steps)				
- Familiarisation	19.17%	8.50%	2.50%	15.65%
- Compliance with requirements (product design and testing)	49.00%	15.00%	80.00%	50.16%
- Conformity assessment	16.67%	71.50%	16.67%	22.15%
- DoC and CE marking	13.50%	5.00%	0.83%	10.79%
- Other	1.67%	0.00%	0.00%	1.26%
And of which (% of annual costs)				
- Business As Usual (BAU)	73.33%	68.00%	86.67%	74.76%
- Regulatory burden	26.67%	32.00%	13.33%	25.24%

Source: CSES study

To calculate an estimate of the overall costs for the whole sector we used the value of the total EU market according to Eurostat PRODCOM, namely € 10,5 billion in 2009 (see table 7-3). Applying the percentages in table 7-7, led to the figures presented in the table 7-8.

Table 7-8: Estimate of compliance costs for the whole sector of electric motors (€)

	Cost of human resources for total compliance activities	Costs of third parties	Costs of testing equipment	Total
Total Annual costs	€ 99,175,627	€ 13,159,638	€ 19,368,345	€ 131,703,610
Distribution over process steps:				
- Familiarisation	€ 19,008,662	€ 1,118,569	€ 484,209	€ 20,611,440
- Compliance with requirements (product design and testing)	€ 48,596,057	€ 1,973,946	€ 15,494,676	€ 66,064,679
- Conformity assessment	€ 16,529,271	€ 9,409,141	€ 3,228,057	€ 29,166,470
- DoC and CE marking	€ 13,388,710	€ 657,982	€ 161,403	€ 14,208,094

- Other	€ 1,652,927			€ 1,652,927
- Business As Usual (BAU)	€ 72,728,793	€ 8,948,554	€ 16,785,899	€ 98,463,246
- Regulatory burden	€ 26,446,834	€ 4,211,084	€ 2,582,446	€ 33,240,364

Source: CSES study

Overall conclusions

The case study examined alternative and direct current electric motors. Total EU market for electric motors in 2009 was 733.5 million units and €10.5 billion in value. 91% of all electric motors sold in Europe in 2010 are small power range motors, namely under 750W.

Electric motors are covered by seven different pieces of Union harmonisationlegislation covering aspects of health and safety (Low Voltage Directive, Machinery, ATEX), electromagnetic compatibility (EMC), energy consumption (Ecodesign Directive) and chemicals use (RoHS Directive on hazardous chemicals, REACH).

Based on the information collected during the study it is estimated that the total annual costs of compliance with Union harmonisation legislation for the firms in the sector are around €130 million, although more than 70% of this is considered to be part of business as usual, namely costs incurred even in the absence of legislation. The estimated net annual costs directly linked with the legislation are around €33 million, no more than 0.3% of the annual turnover of the sector. Substantive compliance costs are significant (around 50%) of the total and are primarily linked with ensuring compliance with the Ecodesign and the ATEX Directives. Still, there are also important costs for familiarisation with the legislation (15%) and conformity assessment procedures, including in particular the costs for notified bodies in relation to the ATEX Directive.

Sources of information

Publications

- Report 'Trends and segments for electric motors' by the Dutch Center for Encouraging import from Developing Countries (CBI) – 2011. www.cbi.eu/system/files/marketintel/Trends_and_segments_for_electric_motors.pdf
- Report 'Trends and segments for electric motors' by the Dutch Center for Encouraging import from Developing Countries (CBI) – 2011. www.cbi.eu/system/files/marketintel/Trends_and_segments_for_electric_motors.pdf
- Almeida, Ferreira, Fong and Fonseca (2008), 'EUP Lot 11 Motors'. www.eup-network.de/fileadmin/user_upload/Produktgruppen/Lots/Final_Documents/Lot11_Motors_FinalReport.pdf
- Anibal de Almeida, Hugh Falkner, João Fong and Keeran Jugdoyal (November 2012), 'EuP lot 30: Electric Motors and Drives, 2nd Draft'. www.eco-motors-drives.eu/Eco/Documents_files/EuP-Lot30-Task-2-2-Dec-2012.pdf

- Eurostat PRODCOM

Interviews:

- 2 with national industry associations
- 9 interviews with enterprises (especially producers); from 6 respondents data on administrative costs were collected.

Annex

Production, import and export value per PROD-COM CODE

Table 7-A1: Production, import and export value – electric motors, generators and transformers (2009), PROD-COM CODES: 2711010 to 27112670

PRODCOM CODE/ INDICATORS	Export values (000s)	Import values (000s)	Production Quantity (000s)	Production Value (000s)	Total
27111010 - Electric motors of an output <= 37.5 W (including synchronous motors <= 18 W, universal AC/DC motors, AC and DC motors)	429,581,300	814,922,340	74,545,678	825,041,147	1,210,382,187
27111030 - DC motors and generators of an output > 37,5 W but <= 750 W (excluding starter motors for internal combustion engines)	278,747,230	386,366,040	104,390,496	1,407,085,735	1,514,704,545
27111053 - DC motors and generators of an output > 0,75 kW but <= 7,5 kW (excluding starter motors for internal combustion engines)	49,647,610	55,532,980	6,000,000	261,370,719	267,256,089
27111055 - DC motors and generators of an output > 7,5 kW but <= 75 kW (excluding starter motors for internal combustion engines)	31,837,520	15,936,700	1,000,000	200,000,000	184,099,180
27111070 - DC motors and generators of an output > 75 kW but <= 375 kW (excluding starter motors for internal combustion engines)	41,158,050	20,115,000	21,021	45,698,243	24,655,193
27111090 - DC motors and generators of an output > 375 kW (excluding starter motors for internal combustion engines)	43,932,440	36,989,480	1,600,000	61,635,219	54,692,259
27112100 - Universal AC/DC motors of an output > 37,5 W	140,273,990	121,276,880	21,783,407	495,727,677	476,730,567
27112230 - Single-phase AC motors of an output <= 750 W	120,770,450	129,836,810	56,520,199	1,195,803,791	1,204,870,151
27112250 - Single-phase AC motors of an output > 750 W	50,438,620	49,425,060	6,300,000	132,175,642	131,162,082

PRODCOM CODE/ INDICATORS	Export values (000s)	Import values (000s)	Production Quantity (000s)	Production Value (000s)	Total
27112300 - Multi-phase AC motors of an output <= 750 W	191,938,140	77,272,170	10,000,000	667,498,083	552,832,113
27112403 - Multi-phase AC motors of an output > 0,75 kW but <= 7,5 kW	324,722,000	133,198,120	6,359,618	1,455,629,073	1,264,105,193
27112405 - Multi-phase AC motors of an output > 7,5 kW but <= 37 kW	198,759,480	62,888,110	1,189,773	663,563,780	527,692,410
27112407 - Multi-phase AC motors of an output > 37 kW but <= 75 kW	110,315,070	43,175,790	192,619	304,180,879	237,041,599
27112530 - Multi-phase AC traction motors of an output > 75 kW	91,719,690	11,825,180	14,000	300,000,000	220,105,490
27112540 - Multi-phase AC motors of an output > 75 kW but <= 375 kW (excluding traction motors)	171,106,750	49,028,550	54,834	422,095,148	300,016,948
27112560 - Multi-phase AC motors of an output > 375 kW but <= 750 kW (excluding traction motors)	111,558,390	24,443,830	21,331	454,592,720	367,478,160
27112590 - Multi-phase AC motors of an output > 750 kW (excluding traction motors)	630,921,610	55,401,750	11,593	1,003,373,605	427,853,745
27112610 - Alternators of an output <= 75 kVA	114,769,970	85,838,450	3,142,975	326,940,309	298,008,789
27112630 - Alternators of an output > 75 kVA but <= 375 kVA	63,040,220	29,373,550	66,725	177,975,375	144,308,705
27112650 - Alternators > 375 kVA but <= 750 kVA	75,541,500	10,966,450	18,434	135,533,843	70,958,793
27112670 - Alternators of an output > 750 kVA	990,629,750	220,007,280	31,394	1,773,471,532	1,002,849,062
Electric Motors, generators and transformers	**€4 ,261,409,780**	**€2,433,820,520**	**293,264,097 units**	**€12,309,392,520**	**€10,481,803,260**

Source: Eurostat PRODCOM database, all values (€s, units) are in thousands

Summary of Union harmonisation legislation covering electric motors

Table 7-A2: Summary of Union harmonisation legislation covering electric motors

Name of legislation	Main issue addressed	Who is responsible?	Requirements for economic operators
LVD 2014/35/EU Directive on low voltage machines	Health & Safety (low voltages machines)	Technical documentation should be provided by the manufacturer. Declaration of conformity procedures	According to the directive, all products should meet the safety requirements set out in annex I.

Name of legislation	Main issue addressed	Who is responsible?	Requirements for economic operators
		and CE marking can be followed by both the manufacturer or his authorized representative (art. 8)	-Testing according to relevant standards -Development of technical file -Declaration of conformity and CE marking -Mark with information (type, voltage, etc,) -Installation instructions and manual for final consumer (with translations)
Machinery 2006/42/EC Directive on machinery	Health & Safety (machinery)	Manufacturers or his authorized representative (art. 5)	- Ensure satisfaction of health and safety requirements Annex I - Technical file (Annex VII) -Provide necessary information (instruction) - Conformity procedures (art. 12, art. 13 for not finished machines) - CE marking (art. 16) - EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery - Construction file and risk assessment which contains: (i) a list of the essential health and safety requirements applied and fulfilled (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks,

Name of legislation	Main issue addressed	Who is responsible?	Requirements for economic operators
			(ii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards, (iv) any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorized representative, (v) a copy of the assembly instructions for the partly completed machinery
EMC 2014/30/EU Directive on Electromagnetic Compatibility	Electromagnetic compatibility	Manufacturer (and, for the CE marking his authorized representative)	- fulfill the protection requirements mentioned. -Testing according to standards -Development of technical file -EC Declaration of conformity and CE marking -Installation instructions and manual for final consumer -Meet essential requirements -Other marks and information
ATEX 2014/34/EU Directive on Equipment and protective systems intended for use in potentially explosive atmospheres[62]	Health & Safety (equipment and protective systems intended for use in potentially explosive atmospheres)	The directive carries obligations for the person who places products on the market and/or puts products into service, be it the manufacturer, his authorized	-Risk assessment -Products should meet the health and safety requirements as set out in the Directive; -Meet the required testing to relevant

62 http://ec.europa.eu/enterprise/sectors/mechanical/files/atex/guide/atex-guidelines_en.pdf

Name of legislation	Main issue addressed	Who is responsible?	Requirements for economic operators
		representative, the importer or any other responsible person	standards -Development of technical documentation for testing purposes -CE Marking
RoHS (2011/65/EC) Restriction use of hazardous substances	Use of hazardous chemicals (Health and environment – art. 1)	Manufacturers are mainly responsible (art. 7) Secondly, art. 8 lists responsibilities of authorized representatives. Thirdly, art. 9 lists obligations of importers. Lastly, art. 10 lists obligations for distributors.	-Assure no substances listed in annex II are used (art. 4) The following measures are required from the manufacturers: -Assure production in line with requirements directive (art. 4 and 7a) -Collect compliance statement from suppliers (material declarations) -Technical file with supplier declarations and own analysis tests (internal production control, art. 7b) -Declaration of conformity (art. 7c) -Declaration of conformity to be kept for 10 years (art. 7d) -CE marking of the product -Procedures for production to remain in conformity (art. 7e) -Register of non-confirming and recalled products and informing distributors (art. 7f) -Identification mark on each product (art. 7g and 7h) -Take measures if they have reason to believe non-conformity (art. 7i)

Name of legislation	Main issue addressed	Who is responsible?	Requirements for economic operators
			-Provide information if so requested by a competent national authority (art. 7j)
REACH (1907/2006/EC) Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals	Use of chemicals (Health and safety)	Manufacturing, authorized representative (art. 4) or importer.	Collect statement from suppliers stating that he is in compliance with requirements (REACH compliance statement) Register and notification of the substances to the Agency.
Eco-Design Directive 2009/125/EC and Implementing Regulation 640/2009 (Design and sustainability)	Energy consumption/ efficiency	Manufacturer or his authorized representative is in general responsible. However, art. 4 of the directive lists specific requirements for the importer if the manufacturer is not established within the community.	Meet the ecodesign requirements as described in Annex I (art. 3 regulation) -Testing (conformity assessment – art. 4 regulation) -Declaration of Conformity and CE marking (art. 3&5 regulation) -Complying with the mentioned conformity procedure in the appendix, -Information in instruction manual for minimizing energy-use -Comply to the proper energy efficiency levels (IE2 or 3) -Instructions for consumers on sustainable use

3.10.2 Case study 2 – Laptops

Introduction

The aim of the product cases is to assess how Union harmonisation legislation for industrial products affects economic operators (manufacturers, importers and distributors). The applicable Union harmonisation legislation specific to each product is mapped out and the costs of regulatory compliance (administrative and substantive) in meeting Union harmonisation regulatory requirements are then assessed.

The rationale for the selection of laptops[63] as a product group was that:

- A key issues highlighted in the specifications was how far Union harmonisation legislation is 'fit for purpose' in facilitating – or at least not hindering - process / product innovation. Since laptops are characterised by a high level of innovation and technological change, they provide scope to explore this issue.

- Laptops are dominated by a small number of global manufacturers. This allows us to consider how Union harmonisation legislation affects multinational companies that produce laptops for both the European internal market and other markets globally.

The case study was carried out using desk research and interviews. With regard to data sources, the main sources used were Eurostat SBS (2 digit NACE code level) and Prodcom data (8 digit NACE), sectoral studies and market research reports.

Product definition and description of structure of the sector

Information and data on market size and structure for the laptop industry is presented. Recent industry developments and market trends are also summarised.

Product definition and data availability

The product group within scope is laptops (also commonly referred to as notebooks). Other types of IT products, such as palm-top organisers, desktops and printers are outside the scope.

Eurostat SBS and Prodcom data extends more widely than laptops alone[64] and covers the manufacture of computers and peripheral equipment. It was therefore only possible to obtain data at a sufficient level of disaggregation for some variables. In order to supplement Eurostat data and to compensate for data gaps, we have also made use of industry data from industry associations and other market data available through previous studies.

Market size and structure

The size and structure of the laptops market is now considered. The main variables presented are the number of enterprises, employees and production value, and the value of imports and exports. According to data from the PRODCOM database[65], the total market for laptops is around €24.6 billion. Market studies available provided similar estimates (€24.4 billion)[66]. According to the same data source, a total of 79 million laptops units are sold annually within the EU.

63 Laptops can be defined as a portable computer to be operated for extended periods of time without a direct connection to an AC power source.

64 NACE codes 2620 includes: Laptop PCs and palm-top organisers, Point-of-sale terminals, ATMs and similar machines capable of being connected to a data processing machine or network Desk top PCs and Laptop PCs and palm-top organisers, among other categories of peripherals.

65 It is not clarified by the definition but it is also possible that this category covers portable tablets.

66 Data from the 2011 Euromonitor report for computers.

Table 7-9: EU laptop market size (2011) – estimate based on PRODCOM data for product code 26201100 - Laptop PCs and palm-top organisers

Exports quantity (million units)	Value of exports (billion €s)	Imports quantity (million units)	Imports value (billion €s)	Production quantity (pairs)	Production value (billion €s)	**Consum-ption volume (million units)**	**Consum-ption value (billion €s)**
8.8	3.3	80	25.6	7,800,000	2.25	**79**	**24.6**

Source: Eurostat Prodcom data

A leading EU industry association suggested a lower figure for laptops alone. According to industry data, the current market size for laptops can vary significantly and is about 32 million - 48 million units per annum. This is a more accurate figure since palm-top organisers were not examined. PRODCOM data confirms that laptops manufacturing is mainly carried out outside the EU, commonly in East Asia. The value of imports into the EU is more than 9 times greater than of imports.

Global laptop producers are commonly involved throughout the value and distribution chain (e.g. from initial design, through to manufacturing and direct distribution to consumers and businesses). In recent years, since the price of laptops has gone down considerably, manufacturers have had to adjust the value chain. Accordingly, there is strong reliance of manufacturers on ODMs (Original Designed Manufacturers). ODMs are suppliers that supply parts or final parts for laptops and under the modular approach to complying with IM regulations (see later in this case), may assume responsibility for the compliance of the particular product modules/ parts that they produce.

Industry structure and employment

A small number of major global laptop producers dominate manufacturing and distribution activities. It was estimated that there are only about 20 large firms in total and industry data shows that five multinationals have approximately a 60% share of the global market (Hewlett-Packard, Dell, Acer, Lenovo and Toshiba).

Additional information about market share in Europe was obtained by searching the Amadeus database (now called ORBIS) of Bureau Van Dijk on laptops. This confirmed that top manufacturers have a very high market share. For example, HP has an estimated 21.5% share of the market, ACER 11.4%, Lenovo: 11.4% and Asus 11.2%. Data for other firms was not available.

Looking beyond the leading global manufacturers, there are also SMEs in the laptops sector. These build bespoke desktops and notepads in relatively small volume (as little as a few hundred units). Data from Eurostat's Structural Business Statistics were of limited use since NACE code 2620 "Manufacture of computers and peripheral equipment" extends well beyond laptops. This shows that there were 6,963 enterprises in 2008. An alternative data source was the ORBIS database (Bureau Van Dijk) which provides information on active enterprises in Europe.

The ORBIS database lists a total of 7094 firms under NACE code 2622 for 2013 – similar to the Eurostat figure. However, a keyword search with the "economic activity description" field with the term "laptops" produced a list of 66 manufacturers. 3 of these are large firms and the

remaining 63 are SMEs. 8 of these firms were the headquarters of firms and the remainder were branches and included as one or more subsidiaries of the large manufacturers. In total, on the basis of the information collected, we consider that the number of firms resulting from the use of the ORBIS database provides a realistic estimate of the number of firms affected by internal market legislation.

In terms of employment, the total computers and peripheral equipment sector employed almost 1.1m people across Europe in 2008. There had been a reduction in employment to 884,000 by 2010. However, this relates to the whole of NACE 2620 (including desktops, palmtop organisers and many other types of IT equipment). The European industry association interviewed confirmed that the number of employees in the laptops sector involved in manufacturing is very low. Nevertheless, laptops are an important industry, when combining different aspects of the value chain from manufacturing through to distribution (wholesale, retail) and aftersales and servicing activities.

Key industry trends and challenges

This case does not allow for a detailed review of key industry trends and challenges. However, recent developments and key features of the laptop industry are worth noting. These are, in summary:

- The importance of economies of scale and scope to be competitive, with a high level of market concentration in manufacturing and distribution among a handful of leading global firms.
- A decline in laptop sales and prices in a maturing industry. Increasing competition from product groups such as tablets, smart phones and the advent of alternative data storage solutions such as cloud computing, which reduces the need for high computing power in portables.
- Convergence between the mobile phone and ICT markets (including the entrance of new manufacturers that have diversified away from Smart Phones into tablets and notebooks.
- Strong capacity for innovation and technological change[67].
- Changes to the business model and organisation of the value chain within the laptop industry:
    - Increased use of ODMs in manufacturing processes.
    - Leading brand names moving away from selling hardware alone to combining these with add-on services such as technical support.

67 Examples of technological change are increased processing power with reduced power consumption through investment in energy-efficient technologies

Analysis of applicable Union harmonisation legislation and standards

Summary of applicable legislation

A mapping exercise was undertaken to identify relevant applicable Union harmonisation legislation for laptops. In summary, the main legislation that is applicable is:

- The Low Voltage Directive (LVD)
- Electromagnetic Compatibility Directive (EMC)
- Radio equipment Directive
- RoHS Directive (2011/65/EC)Ecodesign for Energy-related products Directive (ErP) 2009/125/EC
- REACH Regulation (EC 1907/2006)
- Packaging and packaging waste (2004/12/EC)

The detailed mapping of applicable legislation is provided as an annex. This summarises the main issues addressed through the legislation (e.g. product safety, energy-efficiency), the key administrative requirements for manufacturers and examples of relevant (voluntary) technical standards. The mapping of the legislation was based on desk research and discussions with individual manufacturers. It should be noted that environmental legislation applicable to laptops such as the WEEE Directive (design for end of life and recyclability) is outside the scope.

Overall, the Union harmonisation regulatory framework affecting laptops was regarded by interviewees as being relatively stable in terms of the core applicable legislation. For instance, the EMC Directive has been in place since 1989 and although this was recast in 2004, there were no major changes. The LVD is one of the oldest Single Market Directives and was adopted even before the "New" or "Global" Approach came into being in the early 1970s. The R&TTE Directive has been in place since 1999.

However, further successive Union harmonisation regulations applicable to laptops have been adopted in the last decade, such as the RoHS Directive and REACH Regulation and the setting of Ecodesign requirements for energy-related products (ErPs). Firms interviewed stated that the introduction of new IM regulations have had a much greater impact on the industry than their predecessors.

There are currently general requirements common to electrical products used in households and offices, and concern standby and off-mode electric power consumption and Power consumption for information technology equipment (ITE). However, specific requirements will soon apply following the adoption of Regulation 617/2013 (Ecodesign requirements for computers and computer servers), of which some requirements will be mandatory from 1 July 2014 and others from 1 July 2016. In addition, there exists a voluntary energy labelling for laptops used as office equipment, called 'Energy Star'. This is an endorsement label for the most efficient appliances developed by the US, which is also applied in the EU for office equipment).

Conversely, standards are always changing and being updated, which requires technical work both during the development stage and in order to comply with new or updated technical requirements.

Alternative routes to regulatory compliance - laptops

There are two alternative routes to regulatory compliance for laptops. If a laptop is defined by the manufacturer as a **"radio product"**, then the Radio Equiment Directive alone can be applied. Since the Directive incorporates requirements relating to electrical safety and checking for Electromagnetic Compatibility, this means that the LVD and EMC Directives themselves do not need to be applied, since this would be duplicative.

However, if the laptop is considered to be a piece of "**electrical equipment"** containing a radio part within it, then a modular approach can be followed in which the R&TTE, LVD and EMC Directives are treated separately for compliance purposes. This can be especially beneficial for manufacturers in a situation in which different manufacturers and / or ODM suppliers are responsible for producing different parts of the product since they can then assume responsibility for the compliance of specific product modules rather than for the whole product. An explanation as to how these approaches work in practice, and the advantages and disadvantages of each approach from the perspective of manufacturers is highlighted in the following table.

Table 7-10: A modular approach to compliance with IM regulations

Compliance route	Description	Compliance requirements – analysis of differences	Advantages and disadvantages
Radio Equipment Directive alone	Complying with Union harmonisation regulations using the RED only. This means that the whole laptop is treated as a single radio product.	• DoC must be placed together with the product • Product must be CE marked Notification requirements for non-harmonised radio frequencies Laptops with Wifi Radio Module Class 1 and 2 must include an alert mark next to the CE mark	Advantages • Only one Directive is applicable rather than three • Legal clarity - responsibility for whole product is sole responsibility of manufacturer Disadvantages • Cannot divide up compliance responsibilities between different components / parts manufacturers. • Additional labelling marking requirements compared to the EMC-D/LVD (e.g. alert mark next to

			CE mark, information on restrictions of use, etc…). • Making information available for the user which are not required for the LVD and the EMC (e.g. DoC placed with the product).
A modular approach - RED, EMC and LVD Directives applied separately	Modular approach - the laptop itself is treated as a non-radio product and the RED is only applied to the radio module. Other parts of the laptop are subject to the EMC and the LVD	DoC must be placed together with radio module Only the radio module would potentially need the alert sign (Class 2) Notification requirements for radio frequencies (only for radio module part)	Advantages • Division of responsibility for compliance between manufacturers responsible for different components / parts of laptop • Manufacturer producing other parts of laptop under LVD and EMC don't need to consider requirements specific to the R&TTE Directive e.g. alert sign, DOC with product[68] • Manufacturers of other parts do not need to provide a DoC to user (only upon request by a MSA)

Feedback is now provided by manufacturers interviewed about their views on the overall Union harmonisation regulatory framework and their experiences of complying with Union harmonisation legislation. There are different views among industry as to which approach is preferable. Firms interviewed all appreciated the flexibility afforded by Union harmonisation legislation to determine whether to follow the RED alone, or to adopt a modular approach as and when appropriate. Interview feedback is now considered on this matter.

Firm C treats laptops as a single radio product and complies with the RED alone and assumes responsibility for the product's compliance. The LVD and EMC Directives are not applicable

68 A DoC only needs to be provided with the product by manufacturer responsible for radio part (since only R&TTE Directive has this requirement).

because the essential requirements under these Directives are already included within the RED. *"The main benefit of a modular* approach was dividing up responsibility among manufacturers for different parts of the laptop, depending on the module concerned. However, as a manufacturer, we prefer to take sole responsibility for regulatory *compliance".* This was considered as beneficial when considering their obligations towards consumers and in terms of minimising risks.

Conversely, in Firm A and Firm B, the modular approach is followed and compliance with the LVD, EMC and RE Directives respectively is addressed separately. The modular approach was considered to be more efficient in a situation in which multiple manufacturers are involved in producing the end product since the manufacturer of each part is able to assume responsibility for their specific part. In a competitive market place, it was considered that suppliers need to take responsibility for the quality of their product lines and it was believed that this had helped to strengthen standards in the components market.

In Firm A, a different member of the regulatory compliance team deals with each of these Directives and conformity assessment testing is also carried out separately by different teams. The firm pointed out that under the modular approach, the manufacturer of the final product retains ultimate responsibility for product compliance. In the full version of the DoC[69], a list of all modules that can be used for each product model is provided. This has been made available online by all leading laptop manufacturers. The modular approach was however seen as an effective mechanism for optimising regulatory compliance processes and procedures, with advantages in allocating responsibility to different manufacturers at different modules/ stages in the production process.

Firm A commented that *"Since due diligence needs to* be carried out on each product, the modular approach allows us to provide better information to Market Surveillance Authorities about how compliance has been achieved through each product module. If an MSA asks for further information or raises questions about a product, then the manufacturer or ODM supplier concerned that carried out conformity assessment tests and produced technical documentation relating to that specific module can provide technical information as to how regulatory compliance has been a*chieved under that module".*

According to an industry association, most but not all laptop manufacturers follow the modular approach. This depends on the manufacturer's business model and how the manufacturing of laptops is organised. Some laptops are designed and manufactured by a single manufacturer, whereas others are produced by multiple manufacturers and ODM suppliers, each responsible for different parts / modules and components within the laptop. For example, Firm C is directly involved in all aspects of manufacturing and does not generally outsource production (although it may source components from suppliers), whereas most firms in the sector (including Firms A and B) use an increasing amount of outsourcing to ODM suppliers for manufacturing. This trend has been accelerated by downward pricing pressure for laptops and competition from smartphones, tablets and cloud computing.

Analysis of costs of compliance with Union harmonisation legislation

This section contains:

69 In the laptops industry, it has been agreed that an abbreviated version of the DoC is provided together with the product with more detailed regulatory compliance information provided online.

- A summary of how laptop manufacturers meet Union harmonisation compliance requirements from a business process point of view, highlighting any differences in approach between manufacturers.

- An estimate of the costs of complying with Union harmonisation regulations (administrative and substantive compliance costs)

Interview programme

In order to carry out the quantitative research, four interviews have been carried out with global manufacturers (three with laptops manufacturers and one with a leading manufacturer of chips and processors)[70]. In addition, two discussions were carried out with a European industry association. An overview of the firms interviewed is provided in the following table:

Table 7-11: Overview of firms interviewed - laptops

Firm	Product category	Firm size	Annual sales from product in the EU
A	Laptop manufacturer	Large	3 million units/ annum. Market share - 19-20% of EU market
B	Laptop manufacturer	Large	4 million units/ annum. Market share – 25-26% of EU market
C	Laptop manufacturer	Large	NA - but circa 8-10% of EU market
D	Components manufacturer	Large	NA - but no. of laptop chips and components numbered in the millions/ annum

Although there were challenges in persuading firms to take part, the firms interviewed are all globally recognised players in the laptops industry and account for a market share of c.a. 50-55% of the total market. There are an estimated total of 15m annual laptop sales in Europe. Unlike for other products, no SMEs were interviewed, since the laptops industry is dominated by large manufacturers (see Section 2).

Overview – how do laptops manufacturers manage regulatory compliance?

In this section, a description is provided of the way in which laptops manufacturers manage compliance with Union harmonisation regulations. Five main steps were identified in harmonised product sectors in order to place products on the EU market. These five steps were defined for all the harmonised product cases and have been used as the basis for carrying

70 There were difficulties in persuading more firms to participate. Some companies approached were concerned about commercial sensitivities, while others did not believe that they would be able to collect such complex data at the product level because they produce so many different product platforms.

out discussions with manufacturers to ascertain information about how they manage compliance processes and the costs involved:

- Familiarisation with the applicable/relevant obligations – preparatory actions
- Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations
- Conformity assessment procedures and relevant documentation
- Declaration of conformity or other statement of compliance and CE marking
- Other activities related to obligations posed by authorities

The way in which manufacturers manage each of these five steps and feedback received on the type of costs involved is now provided.

Reference should also be made to the previous section, which highlighted that there are alternative routes to achieving compliance for laptops. Clearly, whether a given manufacturer has decided to follow the R&TTE-D alone, or a modular approach in which they comply with the RED, EMC-D and the LVD-D separately will have implications in terms of the way in which manufacturers organise their business processes relating to compliance and testing.

Step 0 – Engagement in EU policy and legislative-making processes and in standardisation-related activities

The firms interviewed recognised that it was in their direct interest to participate in influencing the form, content and implementation of Union harmonisation legislation. Since large manufacturers dominate the laptops sector, they commonly participate directly in EU legislative-making and standardisation development processes, for instance by taking part in working groups meetings on particular Directives and in standardisation processes. They also make an indirect contribution, for instance, by providing feedback through the main European industry association, Eurodigital, who in turn participate in EU regulatory processes and in consultations on specific Union harmonisation regulations.

The aim of this participatory approach is to ensure that industry feedback influences and shapes the form of new Union harmonisation legislation. Taking part in policy and legislative-making processes enables firms to better anticipate regulatory developments affecting laptops well in advance of the entry into force of Union harmonisation legislation. It also allows industry to shape the requirements for manufacturers, which is especially important when the potential burden could be significant and other appropriate but equally effective solutions are possible. Among the examples of legislation where industry input was felt to be especially important were RoHS, REACH and the drawing up of Eco-design implementing regulations.

Firm B agreed that active participation in EU regulatory development processes was vital and stressed that they invest considerable time in monitoring key developments well in advance of new regulations and technical standards being adopted and coming into force. Firm C commented that *"*In order to ensure that we are effective in managing compliance, we take part in the policy-making process and this facilitates our understanding of how regulatory requirements should be interpreted and implemented. It is important to have both direct and indirect communication channels with legislators (e.g. participating in industry associations,

responding to public consultations, attending meetings and workshops, direct email contact *etc.)".*

The preparatory phase prior to legislation and standards being adopted requires human resources. Firm B commented that they worked approximately 75% FTE on Union harmonisation legislation and that they spent a lot of time following new regulatory developments. This requires attending 6 industry meetings in Brussels per year of 2 days' duration, contributing to the preparation of industry responses to proposed EU regulatory developments, etc.

However, although this does take some time and resource commitment on the part of industry, the scale of administrative costs incurred should be set in context. It is in industry's strong interest to monitor EU regulatory developments and standardisation processes closely as part of an active approach to managing compliance with Union harmonisation regulations. This helps manufacturers to better anticipate how changes in the regulatory regime applying to the products that they manufacture is likely to affect their industry. This can in turn help to reduce substantive compliance costs by ensuring that upcoming or new requirements are factored into the product design process from the outset.

Moreover, large global manufacturers also employ thousands (and sometimes tens of thousands) of staff and can spread the cost of engaging in EU policy and legislative-making processes across sales volumes that amount to millions of units per year in the EU. Although there are only a few laptop manufacturers that are SMEs, such firms may find it more difficult to dedicate resources to Step 0.

Step 1 - Familiarisation with applicable legislation and relevant information obligations.

Taking part in the early stages of the formulation of legislation as part of preparatory work to help laptops manufacturers better anticipate forthcoming legislative developments, updates to technical standards, etc. (Step 0) is closely linked to Step 1, which is concerned with familiarisation with the applicable legislation and relevant information obligations once Union harmonisation regulations have been adopted.

Manufacturers invest considerable human resources in familiarisation with the applicable regulatory and administrative requirements. Since the sector is dominated by approximately 10 large global manufacturers, these firms have dedicated regulatory compliance departments who not only work on familiarisation, but brief their colleagues in other departments as to (i) which legislation is applicable (ii) which technical standards could be utilised (iii) whether there are any forthcoming regulatory changes likely that need to be considered in product design (iv) preparatory work needed on documentation (mainly the preparation of a DoC and of a technical file for each product.

There was a lot of variance in the percentage of time firms estimated that familiarisation took as a proportion of total time spent by internal staff over the 5 process steps. For instance, Firm A estimated that about 10% of staff time was devoted to familiarisation, whereas the equivalent figure for Firm C was 15%. For Firm B, however, this was estimated at 40% (Firm D did not provide an estimate).

Such divergence among manufacturers will depend on the role and perceptions of the interviewee and how the amount of time spent on compliance is divided between different compliance activities and business functions. Since in many cases, the interviewee was

located in Europe, and was themselves involved in monitoring regulatory developments, they did not always have the details of the amount of human resources involved in testing activities for compliance, which are often carried out in a different Member State or outside the EU. It was interesting to note that requesting data from colleagues particularly those located outside Europe was seen as challenging and would take considerable time and that the quality of the information eventually provided may not be well thought through.

More generally, it was difficult to quantify how many staff are working on compliance for any given product group, since most laptop manufacturers produce a wide range of electrical and IT products. Regulatory compliance teams typically work across a number of different product groups, are overseeing different applicable Union harmonisation regulations, as well as differences in the technical standards which are specific to particular product groups. This means that it is often difficult to estimate precisely how much staff time is spent on familiarisation broken down to a particular product group. This was the case for instance with Firm C, which has a team of 13 FTE staff working on compliance with Union harmonisation regulations and a further 13 FTE staff with EU environmental regulations.

Laptop manufacturers interviewed noted that they spent much less time on familiarisation in regard to long-established IM legislation, such as the LVD and EMC Directives, where the requirements have not changed that fundamentally in 20-30 years. They spent much more time preparing their firms to meet new regulatory requirements stemming from recently adopted IM legislation. Examples cited in this regard from the past few years were the RoHS Directive (RoHS II was adopted in 2011), the REACH Regulation (which entered into force on 1st June 2007). For instance, Firm D, a global manufacturer of microchips and compressors commented that there had been a lot of preparatory work for RoHS and REACH. There was a need for specialist compliance staff to liaise internally across different business functions such as R&D in order to ensure that the firm was fully compliant and REACH-ready.

The introduction of new implementing regulations for Ecodesign specific to laptops was viewed by firms interviewed as being likely to require significant familiarisation time. An Ecodesign implementing measure was adopted in 2013 for computers and servers in June 2013[71]. Laptops manufacturers already have some familiarity with Ecodesign requirements through the requirements on Standby and Off-mode (Regulation EC 1275/2008) which apply to electronic devices generally.

.Lastly, in order to help industry to minimise the burden of EU legislation, the development of guidance materials was seen as invaluable in saving time for familiarisation costs. For instance, a components manufacturer in the laptops industry commented that the development of guidance for Ecodesign requirement on standby and off-mode was especially important, given the technical complexity involved. However, aspects related to standby and off-mode for laptops are now included in the new ecodesign regulation for computers and computer servers and no longer in the horizontal regulation on standby and off-mode.

Step 2 - Changes to processes or changes to product design and production processes

Like other industrial products, laptop manufacturers have to incorporate regulatory requirements into R&D and product design processes. However, it was difficult to obtain cost

71 COMMISSION REGULATION (EU) No 617/2013

estimates from manufacturers. In instances when data was not available at all, the main reasons were that:

- Where manufacturers carry out conformity assessment testing internally, the testing often takes place in laboratories outside Europe for global consumer products such as laptops. Since laboratories work on products designed for the global market, data on testing costs specific to European Union harmonisation regulations is often not collected by the manufacturer.

- Laptops manufacturers are increasingly reliant on ODM suppliers to carry out testing at the product design stage. ODM suppliers do not usually break down their prices to reveal the specific costs of regulatory compliance (and associated conformity assessment tests) since they provide their client(s) with a total estimated price.

- Manufacturer that make extensive use of ODM suppliers carry out random "spot" testing of products as part of quality control procedures but only at the point when a product model is already on the market (e.g. checking of product batches about to be shipped).

Industry found it difficult to quantify expenditure on substantive design costs. Firm A pointed out that the business model makes it difficult for laptops manufacturers to disaggregate costs. "There is lot of global leveraging and in the notebook business a lot of manufacturing is outsourced this work is, the certification are more and more included in the final price offer and not always quantified, if it is quantified, the price is on global scale mixing a lot of items. In addition, there are difficulties in calculating the leveraged cost of testing modules, which nowadays are carried out on an outsourced basis by OEM suppliers. Consumer notebooks are now totally managed by the outsourcing partner and therefore we totally lost control of that type of costs especially as annual aggregate and related to EU. Somehow by passing the ball we avoid to ask to avoid the risk to have our outsourced partner to revise the agreements, assuming that it is their task to keep tests costs low".

Even in those instances when data was available to the manufacturer, they were unwilling to share this data because it was considered to be commercially sensitive. Although some data imputations have been made by our team (see table quantifying these costs), the feedback received was mainly qualitative.

It was observed that **by anticipating changes to Union harmonisation regulations, firms are able to help minimise substantive compliance costs**. As noted above, large firms follow EU regulatory development processes closely, and are usually aware about changes to Union harmonisation legislation and administrative requirements well in advance of these becoming mandatory and also follow standards development processes. Since laptop products are designed with knowledge of current requirements under Union harmonisation regulations (and those likely in future) in mind, and the core legislation has been relatively stable in the past decade, this helps to avoid lots of changes to produce design or to products already on the market due to changes in requirements.

Another observation from the research was that some types of costs, such as substantive changes to product design once products have already been placed on the market in the EU are probably lower for laptops than for say air conditioners due to **differences in the product development lifecycle and the duration of the product's lifecycle post-placement on the**

market. Whereas for an air conditioner, this lifecycle is typically 10-12 years (see Ecodesign Preparatory Studies[72]), for laptops it is around 2-4.

If changes are required due to changes in Union harmonisation regulations (and/ or updates to voluntary technical standards), these are usually identified well in advance by laptop manufacturers. Any necessary changes can therefore be factored into the design phase when new product models under development, which helps to reduce substantive compliance costs.

It is less common – though not unknown - for laptops to have to be temporarily withdrawn from the market or for modifications to have to be made to existing models. Rather, new laptop platforms under development take these changes into account directly and existing models are simply phased out in line with their planned product timeframe.

Some examples of substantive costs were however identified over and above the initial R&D and product design phase. For instance, interviewees stated that the introduction of some Union harmonisation regulations had resulted in them incurring substantial additional costs, even if these were difficult to quantify. For instance, under REACH, there was a need for chip makers supplying laptop manufacturers to invest in R&D to identify and test possible substitute chemicals for use in the production of micro-chips.

The **most costly pieces of Union harmonisation regulations were perceived as being those IM regulations introduced in the past five – ten years**. This is partly because new Union harmonisation regulations require more familiarisation time, but mainly because whereas the classical New Approach Directives were concerned with product safety, more recent regulations have more environmental and health-focused requirements in their objectives (e.g. concerned with restricting the use of dangerous chemicals, hazardous substances, and ensuring improved levels of energy efficiency).

There may therefore be a need under these regulations to make significant changes and to plan for these changes, for instance, in respect of product design and specifications, the type of components and parts used, the substances and chemicals used, etc.

Both Firm B and Firm D regarded the introduction of RoHS and REACH as having been burdensome for laptops manufacturers and components makers (e.g. of chips and micro-processors) respectively. Firm D commented that while recognising the environmental benefits, there were significant costs associated with achieving REACH compliance. These are examined in Table 7-12.

Table 7-12: Industry concerns about legal uncertainty for downstream users under REACH regulation

A concern among industry in relation to the REACH regulation was that there was perceived legal uncertainty as to which substances might be outlawed in future following substance evaluation or subject to restrictions and authorisation requirements. These concerns are particularly acute in terms of the potential cost implications from a downstream user perspective. There is not only uncertainty as to whether chemicals that are currently critical for some laptops components could be banned or restricted, and replacing

72 Preparatory studies for Eco-design Requirements of EuPs, Lot 3 Personal Computers (desktops and laptops) and Computer Monitors, IVF Industrial Research and Development Corporation, 2007 (for the European Commission's DG TREN)

them with alternatives could potentially be costly.

This was viewed as especially problematic by Firm D. For instance, the substance, gallium arsenide, is widely used and without it microchips cannot be produced. However, there is no viable product substitute. The substance is currently being reclassified under the CLP Regulation as part of the Adaptations to Technical Progress (ATP) to the CLP. This specific substance is currently also being assessed under the Community rolling action process substance evaluation by Latvia. However, there are presently no common criteria for undertaking substance evaluation in order to fast-track particular chemicals. In Firm D's view, before banning or requiring authorisation for substances that could really disrupt the supply chain, there should be a more detailed impact assessment for downstream users.

Since REACH is at a relatively early stage in the process of identifying harmful chemicals that need to be subject to authorisation, restrictions and phased out, there is considerable legal uncertainty and unpredictability for downstream users at the present time. Currently, manufacturers cannot plan for the future effectively and this was said to impose costs.

Firm D noted that since a technology-driven development cycle from basic R&D through to high-volume manufacturing takes 10 years. Planning is therefore needed as to which substances can be legally used under Union harmonisation regulations for the next 15-20 years and investment decisions need to be taken about semi-conductor production facilities which can be very high-cost. Such legal uncertainty may deter investment.

There can also be substantive compliance costs associated with **ensuring that products already placed on the market meet requirements set out in updated harmonised technical standards**, even though there is a transition period before new standards must be used for products and products that have used the former standard to be slowly phased out. For instance, in the area of electrical safety, in March 2013, a large multinational announced that it had temporarily withdrawn a desktop PC product from the market because it was not compliant with Amendment 1 of IEC 60950-1, an updated standard on electrical safety. The firm concerned was reported to be redesigning the product in order to allow it to continue to be sold in future.

Table 7-13: Differences in the cost of modifying products to reflect the updating of standards – a comparison between Europe and the US

There are differences between Europe and the US as to whether products can remain on the market once new and updated technical standards have been introduced. Firm B commented that the differences between the US and European regulatory systems affects the costs of modifying products in order to update technical standards, once these are placed on the market.

In the EU, there is a transition period during which manufacturers that apply harmonised standards must update products in accordance with the new technical standard, usually within 2-3 years of a product being placed on the market. This imposes costs on the European laptops industry compared with other geographic regions. In contrast, in the US, once a product is already on the market[73], then even if a new, updated technical standard has

73 There is no direct equivalent to the concept of "placing a product on the EU's internal market" as set out in Decision 768/2008

been introduced, products using the old standard can continue to be legally sold in the US . However, any new products in the development pipeline are required to conform with the new, updated standard.

Step 3 - Conformity assessment procedures and relevant documentation.

The applicable **conformity assessment** modules that need to be followed will depend on which alternative route to compliance the manufacturer has decided to select. As set out in detail in Section 3, if the modular approach is applied, then appropriate testing will need to be carried out for the EMC-D, LVD-D and the RED respectively, whereas if the product is classified as a radio product, then only the CA procedures applicable under the RED will need to be applied[74].

The laptop manufacturers interviewed use the Suppliers' Declaration of Conformity (SDoC) as the main conformity assessment route to meet the essential requirements for applicable IM regulations. Many manufacturers also choose to use a third party to carry out testing in respect of some IM directives, although this is not mandatory. This is a common approach (for instance for the LVD to check electrical safety) since many manufacturers prefer to use external conformity assessment bodies either to carry out all the testing or to check a sample of products that have already been checked by the manufacturer using internal testing. This approach was seen as helpful in minimising risks and in reassuring consumers, which is important, since there are reputational management issues at stake.

Industry confirmed that the flexibility of carrying out conformity assessment internally using the SDoC was appreciated. Since the majority of laptops are produced by global manufacturers using large in-house testing facilities, it was felt that manufacturers could ensure product safety equally as well as third party conformity assessment. Firm B commented that *"there is no evidence that SDoC makes products any less safe compared with* the use of mandatory third party testing, so long as the system is underpinned by robust *market surveillance".*

There were difficulties in obtaining data on the costs of internal and external Conformity Assessment Procedures, for the reasons already set out in Step 2 (e.g. commercial sensitivity of data, internal testing costs not shared between different business divisions globally, difficulty in obtaining accurate data when testing carried out outside EU by manufacturer or when outsourced to ODMs).

Nevertheless, some estimates on the annual costs of external conformity assessment, were obtained. For instance, Firm A estimated that across the 30-40 different product platforms launched annually on the EU market, it spends approximately 800000– 1m EUR per year on third party conformity assessment. In addition, it estimated that in-house testing costs approximately 10000 EUR / regulatory model. A distinction was drawn here between a "regulatory model" on which compliance is built and a "marketing model" i.e. a firm may develop many different models for marketing purposes, but there are a much smaller number of basic platforms on which basic compliance is built. However, it was not possible to obtain

74 The conformity assessment procedures that are applied by manufacturers under the R&TTE-D are in summary (II) Internal production control (iii) Internal production control plus specific apparatus tests (IV) Technical construction file and (V) Full quality assurance).

estimates of the one-off and recurring costs of internal laboratories and testing and of the purchase equipment.

The applicable conformity assessment mechanism is defined in each implementing measure and conformity is generally based on internal design control or on a quality assurance management system. Implementing measures may also make provision for modules, but this is typically Module A unless explicitly stated otherwise. In the case of the forthcoming Ecodesign requirements for computers and computer servers (Regulation 617/2013), when these start to apply, the applicable conformity assessment procedure will be the internal design control system set out in Annex IV of the Ecodesign Directive or the management system for assessing conformity set out in Annex V of the Directive.

Since large firms dominate the laptops market, no SMEs were able to be interviewed. Some feedback was nevertheless obtained on SMEs. According to the industry association, Eurodigital, it can be challenging for SMEs to test products for Ecodesign requirements. Firm D, which is a global manufacturer of chip and micro-processors confirmed that it assists smaller manufacturers in carrying out testing to meet Ecodesign requirements, which currently apply only to standby power mode), but will be replaced by requirements applying to computers and computer servers as a whole through Ecodesign implementing regulation 617/2013.

Feedback was received from two global laptops manufacturers on the costs of standards. It was pointed out that a distinction needs to be made between harmonised standards and wider standards and technical specifications that are used by the industry but which are not directly linked to complying with Union harmonisation legislation.

Although the purchase of harmonised standards is voluntary, since the leading laptops manufacturers follow these standards, they are regarded as being part of the overall costs of compliance (even if they only account for a small percentage of the overall costs). There are just a few harmonised standards that meet the essential requirements set out in Union harmonisation legislation and are included in the Declaration of Conformity (DoC) for laptops. In analysing costs, only the purchase of these harmonised standards should be considered. The same standards can often be applied not just to other types of laptop models but also to other product devices horizontally. For instance, ETSI EN 300 328 relates to 2,4GHz WiFi technology, regardless as to whether the device concerned is a laptop or an MP3 player. We therefore asked firms to estimate the proportion of the costs of standards solely relating to laptops and to IM legislation.

Firm A stated that the cost of purchasing a single standard, especially those related to the EMC and to electrical safety under the LVD is typically around 80 EUR. There are cheaper prices when obtaining updates for standards that have already been purchased. A manufacturer of laptops will typically follow some 30-40 standards in total (of which only a few are harmonised standards needed to build compliant products). However, as noted above, once a complete set of standards has been purchased, these can then be used across multiple laptop models.

An alternative option for large manufacturers is to purchase a company license, which then gives them the right to purchase a certain number of single licenses (typically 50 licences for all IEC standards purchased). The cost is approximately 40,500 EUR, which is a one-off cost, but which can be used to cover multiple laptop products (and other devices). The cost of purchasing standards specific to the laptops segment of Firm A were estimated to be in the

order of 5000 EUR per year across multiple product models. The cost is higher for large firms than for SMEs because SMEs can purchase standards with a single user license, whereas to share the knowledge internally, large firms must by a company license, or at the least a license for multiple users.

One of the interviewees commented that "companies need to operate smartly in terms of the way in which they deal with buying standards otherwise they may waste money, even if the cost of standards is a relatively small part of the whole. The cost of buying standards is not normally attributed to the cost of an individual product, rather that the purchase of a complete set of standards is needed in order to build multiple laptop platforms". In this respect, there are similarities to the costs of purchasing laboratory equipment in that this is a pre-requisite and part of the "set up" costs for being a manufacturer in the sector.

According to the interviewee in Firm A, "some European Standardization Organisations such as ETSI adopt a more industry-friendly approach since the standards that they develop are free (in effect, they are paid for by industry who pay to participate in the standards development process for ETSI standards. The amount payable is dependent on the type of membership, the size of the company, and the participation that it has in the standards development process". Firm C noted that *"some companies are more CENELEC*-oriented and either purchase individual standards or have a subscription, whereas others are more ETSI-oriented and pay subscriptions to be involved in the standardization process (as standards are indeed freely available). Other laptops manufacturers are involved in the development of both CENELEC and ETIS standards, so the cost of their participation in standardisation making proc*esses (and in purchasing standards) is higher".*

Step 4 - Declaration of Conformity (DoC) or other statement of compliance and CE marking.

Producing documentation - the DoC and the technical file

In common with other industrial products, having first carried out conformity assessment procedures, laptop manufacturers are required to produce a DoC and technical file and to keep this updated for 10 years following placement on the market.

The preparation of the DoC itself is straight forward since this involves producing a sheet of A4 setting out the applicable Union harmonisation regulations, and commonly also a list of the voluntary harmonised standards that have been applied in order to meet the essential requirements. However, there are administrative costs associated with the regulatory checking and updating of DoCs due to the high cumulative frequency of regulatory changes, both legislative and those resulting from updates to harmonised technical standards. Decision 768/2008 states that DoCs shall be kept "continuously updated".

Internal systems and procedures need to be put in place to ensure that these documents are updated regularly. Updating DoCs between two and four times each year – depending on the firms' internal procedures – is a significant burden in terms of human resource costs. Industry noted that although producing an individual DoC was not difficult, the cumulative effects can be burdensome, since global firms have hundreds of different product models (and variants of each product model) and each DoC then has to be kept under continual review.

In Firm A, the dedicated European compliance team working on Union harmonisation regulations includes 4 staff solely involved in the development and updating of compliance

documentation, with regular internal review procedures put in place for (i) checking, maintaining and updating DoCs and (ii) checking that technical files are as complete as possible. This was regarded as resource-intensive.

There was a perception that there is now a longer timeframe to check that product documentation is administratively compliant with the applicable Union harmonisation regulations. It was noted that while it previously took 5 days to undertaken an internal procedures to review DoCs and technical documentation and check that these are up to date, the procedure now takes up to 20 days. This was attributed to Union harmonisation legislation becoming more numerous and complex, for instance, as a result of the introduction of the RoHS, EuP and Ecodesign Directives.

Although some firms viewed the requirement to provide a paper copy of the DoC together with the product under the RED as burdensome, the administrative costs are not that significant thanks to an agreement with TCAM for manufacturers to use the so-called "short form of a Declaration of Conformity". This is an abbreviated compliance statement localised in all languages and a weblink is provided to the full declaration which is available in English only, but can be translated at the specific request of MSAs.

Translation requirements for DoCs – uncertainty for manufacturers?

Two laptops manufacturers interviewed commented that they faced legal uncertainty since it is unclear whether there is a formal requirement that DoCs should be translated into local languages or should continue to provide a local language version of a DoC upon request as has been the case for many years.

The wording in the NLF has led to uncertainty for industry as to what translation requirements apply to DoCs in order to meet compliance requirements. There is ambiguity in the wording in Decision 768/2008 which states that "The DoC shall be translated into the language or languages required by the Member State in which market the product is placed or made available". This ambiguous wording causes uncertainty for the laptop industry, which had previously produced DoCs in English only. One firm commented that *"If a translation* requirement were to become compulsory, this would be administratively burdensome. Also, for whose benefit would this be, since regulatory compliance information – unlike an instruction booklet which is directly is concerned with consumer safety –is only to help facilitate the work of MSAs". The argument put forward is that it is cheaper for global businesses to produce DoCs in English only and the benefits of translating the DoC are minimal given that the applicable legislation is well known and is available translated in all EU languages.

A further concern related to translation was that since the NLF, upon reasoned request by a Market Surveillance Authority (MSA), part of the technical file may be required to be translated. While the reasons for this were understood, since many test reports and other important information for MSAs may not even be in a European language, there were concerns that this could constitute a significant administrative burden for manufacturers. The problem is that there is no clear definition as to what constitutes a "reasoned request".

Step 5 - Other activities related to Union harmonisation information obligations.

Traceability requirements

The Commission has strengthened traceability requirements for industrial products in order to better enable MSAs to trace the provenance of products and to be able to contact the manufacturer to obtain regulatory compliance information, and parts of the technical file such as tests reports more easily. In Decision 768/2008, there is a specific requirement for products (at least for the packaging) to provide addressee information for the manufacturer and importer(s).

The move towards strengthening traceability is understandable since so many products are manufactured in third countries and MSAs need to be able to contact the manufacturer that produced the product more easily. However, industry has concerns about the administrative burdens that this might impose and also the constraints on product design if such information has to be provided on the product itself.

However, both the industry association and two firms were concerned about the potential administrative burdens of traceability requirements and the difficulty of conforming with such requirements, while at the same time producing attractive, consumer-appealing products. This point extends beyond laptops alone to other products such as smart phones. It was argued that traceability requirements may risk compromising product aesthetics from an industrial design point of view (in instances where labelling has to be provided on the product itself). E-labelling was viewed as a possible solution to avoiding having to have too much information on products and packaging.

A further issue identified relating to information obligations related to marking requirements under the RED. This affects laptops using Class II Wifi devices.

Table 7-14: Marking requirements affecting laptops using Class II wifi devices

Alongside the CE mark, an additional alert mark (a circle with an exclamation mark in the middle) has to be provided on laptops next to the CE mark. This was regarded by Firm C, which follows the R&TTE-D alone as unnecessary first because the CE mark should already cover all safety-related aspects of products and secondly since the alert mark is not understood by consumers. Although the costs involved in adding labels to products are small, the multiplication of labelling requirements (linked to IM regulations and product safety, but also energy-efficiency, waste disposal) has cumulative effects. For example, it places constraints on manufacturers as to where the marking and labelling information should be placed in order to ensure compliance, and may serve to detract from producing an appealing product (again, this depends whether there is scope to put such information discretely on the product e.g. on the underside of the product, under the battery, etc).

Assessment of costs of Union harmonisation legislation for the whole sector

In this section, the costs of complying with Union harmonisation legislation in the laptops sector are assessed. The data is based on data and supporting qualitative information provided by four manufacturers. Although the analysis is based on a small number of firms, these can be considered as representative, since they collectively account for a significant share of the

market. In the case of laptops, the three firms that took part collectively account for 45-50% of the market and all four participants are global manufacturers.

There were challenges in carrying out the analysis since there were data limitations as regards the costs of product testing, for reasons already explained in our assessment of the five steps in Section 4. Nevertheless, it was possible to arrive at quantitative estimates, since some manufacturers were able to provide more detailed information than others.

Extrapolation of costs and cost saving from the firms to the sector

The following table summarises the costs per unit and total estimated costs for industry. A list of key assumptions made is provided in footnotes. The cost estimates take into account information provided by the firms that took part in relation to the five process steps described in Section 4.

The costs are related to turnover. In the first column, we seek to distinguish between different types of costs. The distinction between one-off and recurrent costs has been taken into account in the analysis, and some costs, such as the costs of purchasing laboratory equipment have been annualised[75].

Table 7-15: Summary of main costs of compliance for laptops manufacturing industry

Types of cost	Unit of measurement	Unit cost[76]	Total quantity	Total costs (annualised)
Compliance with admin. requirements				
Familiarisation	(Manufacturers / cost per year)	€ 402,000	10[77]	€ 4,020,000
Preparation of DoC and technical documentation	Manufacturers / cost per year)	€ 1,206,000	10	€ 12,060,000
Standards purchase	No. of standards	€ 80	30-40	€ 5000[78]

75 These costs were annualised in order to arrive at comparable annual costs, using a system similar to firms' accounting for depreciation. For some questions, we also asked questions in the SCM questionnaire about how much they spent on testing equipment over a 5 year period, which had to be annualised.

76 All unit costs are based on the interviews with at least 3 respondents answering each figure.

77 Turnover is used to upscale the parameter estimates. The average respondent has a market share of about 10%. The same approach was adopted for the DoCs.

78 Approximately 30-40 standards need to be purchased in order to develop a compliant laptop product. However, once purchased, these standards can then be used across multiple product platforms. We have assumed an average annualised cost of 5000 EUR since larger firms may purchase a group license rather than buy standards individually.

Types of cost	Unit of measurement	Unit cost[76]	Total quantity	Total costs (annualised)
Substantive compliance and Conformity assessment (internal)[79]				**€ 9,000,000**
R&D and Product design	Models	€ 800,000	10[80]	€ 8,000,000
Testing (internal)	Models	€ 5,000	200[81]	€ 1,000,000
Testing equipment[82]				No data
Conformity assessment (external)				**€ 3,000,000**
Consultancy/advisory services (product design)				€ 0
3rd party Conformity Assessment by notified bodies	Models	€ 15,000	200	€ 3,000,000
Total (excluding testing equipment)				**€ 28,080,000**

The total estimated costs of regulatory compliance by the laptops industry are in the order of 28m EUR on an annualised basis. However, it should be noted that there was difficulty in obtaining data from firms on all the variables (for reasons explained in our assessment of the five steps in Section 4 and in some cases, further expanded upon below). For example, there were difficulties in obtaining estimates of BAU and for the purchase of testing and laboratory equipment.

Business as Usual (BAU) costs were not taken into account in the calculations (these are the costs that firms would be undertaking anyway regardless as to whether internal market legislation was in place, for instance product performance testing and safety testing as part of internal quality management procedures). The main problem was the lack of consistency in

79 Here, substantive compliance costs are concerned with building in compliance requirements to product design during new product development phase and where necessary, making modifications to products that have already been placed on the market.

80 Based on one respondent and its market share, the total number of models was estimated at 200. The average respondent runs 20 models, so the quantity is 10 (200/20).

81 Number of models (see above footnote). The same is done for 3rd parties.

82 No data was available on the costs of purchasing testing equipment because for commercial sensitivity reasons, the firms concerned were unwilling to share this data.

the estimates provided by firm and the absence of firms being willing to provide quantitative estimates generally in two cases.

Among the two firms that did provide data, there was divergence in interpretation among firms as to whether compliance costs meet the requirements of Union harmonisation legislation. Firm A estimated that approximately 30% of the time spent by internal staff on regulatory compliance would be necessary anyway as part of the internal planning and quality management procedures necessary to ensure a safe product and to produce documentation about the product and safety elements. Conversely, Firm C commented that *"since all* compliance-related activities are ultimately related to Union harmonisation legislation, there *is no element of compliance costs that can be considered as BAU".*

Some costs are one-off costs, whereas other costs are recurring. Other types of costs are more nuanced, and represent a combination of one-off and recurring costs. Examples of costs that are clearly one-off include the purchase of laboratory and testing equipment, R&D costs, third party conformity assessment costs and the purchase of standards. Other costs are evidently recurrent, such as the recalibration of testing equipment. However, the picture is more nuanced for other types of compliance costs, which are both one-off and recurring. For example, the cost of the preparation of a DoC and technical documentation mainly occurs prior to a product being placed on the market. However, in addition to these one-off costs, there are also recurring costs linked to the need to update and maintain a DoC for 10 years post-placement on the market. In addition, there is a need to update technical documentation, for instance, to reflect new spare parts and components that are introduced as replacements once a product is already on the market. As regards product design, the costs are mainly one-off, but there could also be recurrent costs if regulatory changes are made and modifications to product design are needed once the product is on the market.

With regard to the total estimate of firm size, although the total number of firms in the industry was estimated to be approximately 60, the top 10 firms account for a very high market share, so the calculations have been made based on compliance cost data provided by leading global firms and then extrapolated. It was estimated that compliance with administrative requirements amounts to 57.2% of total costs (14.3% for the familiarisation stage and 42.9% for the preparation of technical documentation associated with the product and the DoC. Another major cost was the substantive compliance costs associated with the R&D and product design phase to ensure that compliance requirements are factored into new product development. These were significant and estimated to be circa 8m EUR per annum (28.5% of the total).

No substantive compliance costs were identified linked to withdrawing laptops from the market and making modifications to products due to changes in regulatory requirements and/ or in technical standards among the firms that participated (although one or two examples of product withdrawals resulting from regulatory requirements were identified through the desk research. The low incidence of product withdrawals and design modifications reflects the fact that leading global; manufacturers are fully aware of regulatory changes well in advance of these being introduced, and factor these into the R&D and design phase. This is made possible due to the fact that there are relatively short development lead times for laptops, so current models on the market do not have to be replaced, since they rapidly become old models and are superseded by new models that are compliant with new regulatory requirements.

A further significant cost was carrying out conformity assessment. Although the SDoC procedure was usually followed by manufacturers, as noted earlier, several interviewees stated that they made use of a combination of in-house laboratory and testing facilities and external conformity assessment services. This depended on the individual Directive concerned. For instance, it was common to outsource at least some aspects of testing for standards relating to the LVD to a third party, since these relate to electrical safety.

As noted earlier, it was difficult to obtain data on the costs of setting up testing laboratories (one-off costs) and on the recurrent annual costs of recalibration. The reasons for the absence of data were explained earlier and include the commercial sensitivity of the data, the lack of data availability internally within organisations because the information is not shared between different business divisions globally and because testing costs are hidden due to the use of OEM and ODM suppliers.

The costs of internal testing were estimated to be 3.5% and the costs for external testing in the region of 10.7% of the total regulatory costs of compliance. However, the estimates of internal testing costs are probably an under-estimate and reflect the staff time involved in carrying out testing and some laboratory costs. The quantification exercise took into account information concerning the 'Business as Usual' (BAU) scenario, i.e. the estimated percentage of compliance costs linked to IM regulations that related to activities that the firm would undertake anyway irrespective of whether there was Union harmonisation legislation.

Overall Conclusions

- Laptop manufacturers appreciate the flexibility provided by Union harmonisation legislation and the fact that there are alternative routes to achieving regulatory compliance (following the RED alone vs. a modular approach).

- The compliance costs for manufacturers that follow several individual pieces of Union harmonisation legislation under the modular approach are broadly similar to the costs of following a single Directive (RED), since similar product safety tests are required under the RED (e.g. to ensure electrical safety, electro-magnetic compatibility).

- A modular approach can however be advantageous in allowing compliance responsibilities to be divided up between different manufacturers specific to the part of the laptop that they produce and the corresponding applicable module, while the manufacturer retains ultimate responsibility for compliance of the final whole product.

- There were difficulties in obtaining data on substantive compliance costs during the R&D and product design phase, especially for testing costs. This was due to commercial sensitivity reasons in some cases, and the extensive use of ODM and OEM suppliers by most laptop manufacturers in others.

- Qualitative feedback suggests that substantive costs are lower for laptops than for certain other types of industrial products (e.g. air conditioners) when regulatory changes are introduced because the lifecycle of a laptop model is shorter. Therefore, new requirements can be built into the development and customisation of new models, rather than having to adapt or replace components or to adapt product platforms used as the basic building block for developing new products variants.

- There is strong support among manufacturers for the increased provision of compliance information to Market Surveillance Authorities (MSAs) and users/ consumers electronically and for e-labelling. This may offer scope for efficiency savings and a reduction in the administrative costs of updating compliance information.

- There are concerns that since the adoption of the NLF, there is legal uncertainty for manufacturers resulting from the ambiguous wording in Decision 768/2008 as to the translation requirements for DoCs.

- Since the DoC is primarily intended for MSAs rather than for users/ consumers, if this requirement were to be interpreted in a stricter way in future, then there is a risk that this would result in considerable additional administrative costs. The current practise is that the translation of DoCs is only available upon request by MSAs.

- Divergent requirements for DoCs between Union harmonisation regulations can cause uncertainty when manufacturers are shipping mixed products in large containers, some of which require a DoC together with the product under the RED, while other products do not because they do not contain a radio part. There is a risk that different administrative requirements for different types of products may confuse customs authorities and lead to unnecessary and costly delays.

Sources of information

References

- Eurostat Structural Business Statistics Database and PRODCOM
- Data from the 2011 Euromonitor report for computers.
- Lot 3 Personal Computers (desktops and laptops) and Computer Monitors Final Report (Task 1-8)
- Guidance documents on the LVD and EMC Directives

Interviews

- Interviews with 4 global manufacturers, 3 of laptops and one of computer chips
- Several interviews with the European industry association, Digital Europe.

Annex 1 –Mapping of Union harmonisation Legislation (Laptops)

Table 7-16: Mapping of applicable Union harmonisation legislation and administrative requirements for manufacturers

Name of legislation	Main issues addressed (safety, environment, other)	Main administrative requirements for manufacturers	Relevant standards (note: illustrative only)
Core legislation			
Low Voltage Directive	Health & Safety	Supplier's Declaration of	EN 60950-1:2006

(LVD) -	(electrical)	Conformity (SDoC) Testing according to relevant harmonised standards or alternative means of achieving presumption of conformity Preparation of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations)	Information technology equipment - Safety -- Part 1: General requirements
Electromagnetic Compatibility Directive (EMC)	Electromagnetic compatibility	Testing according to relevant harmonised standards or alternative means of presumption of conformity Development of technical file Declaration of conformity and CE marking	Electrical safety standards IEC 60950 (IT equipment safety), EN 60950 (and American standard UL 60950)[83]. EN 55024:2010 IT equipment (Immunity characteristics) Limits and methods of measurement CISPR 24:2010 EN 61000-3-2:2006 - Part 3-2: Limits for harmonic current emissions (equipment input current <= 16 A per phase) EN 55022, (Radiated emissions), IEC 61000-2-2 and IEC 61000- 3-3, EN 61000-3-3:2008 - limitation of voltage changes, voltage fluctuations and flicker

83 These standards are similar and can be considered broadly harmonised.

			in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection IEC 61000-3-3:2008[84].
Radio equipment Directive	Radio bandwidth frequency	Manufacturers must carry out testing to ensure that RE devices do not cause any harm to PST Networks and do not violate power and frequency spectrum allocations on a country by country basis. Declaration of conformity and CE marking	The RED is applicable to laptops that include radio devices e.g. modems and/or wireless communications interfaces (e.g. WiFi, Bluetooth). EN 55024:2010 Information technology equipment - Immunity characteristics - Limits and methods of measurement CISPR 24:2010 EN 55022:2010 Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement CISPR 22:2008 (Modified)
RoHS Directive (2011/65/EC)	Use of hazardous chemicals	Collect compliance statement from suppliers (material declarations) Technical file with supplier declarations and own analysis tests Declaration of conformity to be kept for 10 years	Although the 2002 RoHS Directive did not require CE marking, the new 2011 Directive does so.
Ecodesign for Energy-related Products Directive (ErP) 2009/125/EC.	Ecodesign requirements		The ErP establishes a framework for setting Ecodesign requirements for energy-related products (ErPs). Through product-specific Implementing Measures, mandatory, Ecodesign requirements are set.

84 When designing a computer or laptop, EMC technical standards influence the design phase because they set the parameters as to what is possible or not.

			Two implementing measures are currently applicable under the ErP. External power supplies that are shipped with the notebook (Regulation 278/2009/EC with regard to ecodesign requirements for no-load condition electric power consumption and average active efficiency of external power supplies) General requirement applicable to electrical electronic office equipment on standby and off-mode power consumption (Regulation 1275/2008/EC with regard to Ecodesign requirements for standby and off-mode electric power consumption of electrical and electronic household office equipment. The above are applicable to general electrical products. However, for laptops these implementing regulations will be superseded by Regulation 617/2013 (Ecodesign requirements for computers and computer servers) which will be mandatory from 01.07.2014.
Wider applicable legislation where CE marking does not apply			
REACH Regulation (EC 1907/2006)	Use of chemicals	REACH compliance statement from suppliers	
Packaging and packaging waste (2004/12/EC)	Packaging	Declaration of Conformity	

Annex 2 - Voluntary environmental labels

In addition to Union harmonisation legislation, there are a number of voluntary environmental labels at European and national levels relevant to laptops such as the EU Ecolabel for portable computers[85]. Examples of the requirements in order to qualify and be able to display energy efficiency markings on products are that "Power management settings should be 10 minutes to screen off (display sleep); 30 minutes to computer sleep".

There are also national voluntary labelling schemes within the EU such as Blue Angel (Der Blaue Engel), a German certification system for environmentally-friendly products and services and Nordic Swan, the official sustainability Ecolabel for the Nordic countries. There are also international voluntary energy-efficiency labels such as Energy Star (US), which is for office equipment also applied in the EU. Other schemes include TCO Certified, an international sustainability certificate for IT products which incorporates a range of criteria to ensure that the manufacturing, use and recycling of IT products is carried out in an environmentally-friendly, socially responsible and sustainable manner. Such labelling initiatives have strong potential to promote resource efficiency, and are often adhered to by major manufacturers, even if there is no regulatory requirement to do so. There are links here with IM regulations that require manufacturers to assess the energy efficiency of products, notably the Ecodesign implementing regulation for computers and computer servers, for which the setting of the requirements took into account the work done for the development of Energy Star.

3.10.3 Case study 3 – Domestic Refrigerators and Freezers

Introduction

The product groups examined in this case study are refrigerators and freezers for domestic use, also known as cold appliances. The rationale for the selection of these product groups was that:

- Refrigerators and freezers are covered by a large number of Union harmonisation Directives and Regulations, 8 in total;
- The sector is dominated by a few (around 20) large manufacturers; and
- The conclusions drawn from an assessment of these specific products could be used to draw conclusions on the compliance costs for a broader category of electric domestic appliances since most of the products within this group are covered by the same pieces of legislation.

The case study is based on desk research, the interview with the EU industry association representing manufacturers of refrigerators and freezers (CECED) and three detailed interviews with manufacturers of domestic appliances, one medium size firm (350 employees and total turnover of 150 million) and two large multinationals selling over 2million units and occupying more than 2000 employees. The final text of the analysis was reviewed by CECED that provided additional comments. However, this should not be considered as an endorsement of the conclusions from the side of CECED.

85 The Ecolabel for portable computers can be awarded for desktops or laptops with a system unit, display and keyboard combined in a single case which can be used with an internal battery. This product group also covers devices equipped with touch screen keyboard.

Product definition and description of the sector

Product definition (products included/excluded)

The product group examined in this case study are refrigerators and freezers for domestic use, also known as cold appliances. According to standard EN 153 they are "electric mains-operating refrigerating appliances". According to standard EN 15502:2006 refrigerating appliances are "factory-assembled insulated cabinets with one or more comportments and of suitable volume and equipment for household use, cooled by natural conversion or a frost-free system whereby the cooling is obtained by one or more energy consuming means". There are two main type of refrigerating appliances, compression type and absorption type. The main appliance categories are:

- Simple refrigerators (no freezer compartment);
- Refrigerator-freezer (with at least one refrigerator and one freezer compartment);
- Food freezers; and
- Frozen-food storage cabinets

Data on the market size of the specific product group are derived mainly from Eurostat PRODCOM database and are complemented by market studies. In the PRODCOM database the specific products are covered under the code 27.51.11 (Refrigerators and freezers of household type) with the following subcategories:

- 27511110 - Combined refrigerators-freezers, with separate external doors
- 27511133 - Household-type refrigerators (including compression-type, electrical absorption-type)
- 27511135 - Compression-type built-in refrigerators
- 27511150 - Chest freezers of a capacity <= 800 litres
- 27511170 - Upright freezers of a capacity <= 900 litres

According to PRODCOM database data for 2011 the total market for refrigerators was close to 24.6 million units with a value of the market of EUR 4.8 billion sold/annum. Other data sources suggest a somewhat smaller market size of 17-20 million[86] cold appliances sold on an annual basis. Refrigerators represent around 42% of the market, combined units 38% and freezers 20%.

The majority of domestic refrigerators are electric powered. However, gas refrigerators and freezers (of the absorption type) are also available used either as mobile (e.g. for camping, recreation vehicles and boats) or fixed at home. Data on the specific market segment are not available since PRODCOM codes do not differentiate depending on the source of power. According to the Evaluation of the gas appliances Directive[87] there are a few large firms in

86 Topten (2012), Cold appliances: recommendations for policy design May 2012, http://www.topten.eu/uploads/File/Recommendations_Cold_May%202012.pdf

87 RPA (2011), Ex-Post Evaluation of the Gas Appliances Directive- Final report

Europe producing gas refrigerator. The 2005 preparatory study for the development of Ecodesign implementing measures for domestic refrigerators and freezers[88] refers to a total of 0.7-0.8 million of absorption refrigerators sold annually in Europe, 0.3 million of which were gas refrigerators. A according to the competitiveness report of the gas appliances sector they do not have a noteworthy role in the total market.[89]

Available PRODCOM data also indicate that the total volume of production within Europe is around 15 million units with a value of €3.8 billion. Of these, 3.4 million units are exported (value of €0.9 billion) while there are also around 12.7 million units imported from third countries (estimated value of €1.9 billion). Thus, according to the PRODCOM, imported refrigerators represent around 50% of the market of refrigerators and freezers. However, it should be noted that a significant part of leading refrigerators and freezers brand are designed in Europe but manufactured outside Europe and subsequently imported.

Industry structure

Concerning the structure of the industry, Eurostat Structural Business Statistics are not particularly helpful. The relevant NACE statistical code covers the whole range of domestic appliances (27.51 - Manufacture of domestic appliances[90]) and as a result they do not allow developing an accurate picture of the sector (e.g. number of firms, turnover, employment). Nonetheless, there were 2,200 enterprises[91] active in the manufacturing of electric domestic appliances (annual turnover of 41 billion and close to 195 thousand people employed in 2011), 31,000 wholesalers of electric appliances (€159 billion turnover and 267,000 people employed). Some guidance on the share of the refrigerators and freezers sub-sector may be provided by PRODCOM data according to which refrigerators and freezers represented around 15% in terms of value sold of all domestic appliances[92]. This would imply a total number of 29,000 employees in the manufacturing of refrigerators and freezers.

Table 7-17: Data on market size and industry structure for cold appliances

Parameter	Data
EU Market size	PRODCOM (2011): € 4.8 billion (24.6 million units) Market reports: 17-20 million (2010)
Production volume/value in Europe	PRODCOM (2011): € 4.8 billion (15 million units)
Imports	PRODCOM (2011): €1.9 billion (12.7 million units)
Exports	PRODCOM (2011): €0.9 billion (3.4 million units)
Number of enterprises (2010)	Market reports: 10 large multinational firms with multiple brands cover around 85% of EU market sales

88 ISIS (2007), Preparatory studies for Ecodesign Requirements of EuPs – Lot 13: Domestic refrigerators and freezers – Final report

89 Ecorys (2009), Study on the Competitiveness of the EU Gas Appliances Sector - Within the Framework Contract of Sectoral Competitiveness Studies – ENTR/06/054 - Final Report, http://ec.europa.eu/enterprise/sectors/pressure-and-gas/files/study_competitiveness_eu_gas_appliances_final_en.pdf

90 Besides refrigerators and freezers this category includes a range of appliances including: dishwashers and washing machines, vacuum cleaners, hair dryers, radiators and heaters, microwave ovens, electric ovens, grills and toasters, coffee makers, electric cookers, food grinders and mixers, electric blankets.

91 The data from Eurostat refer to individual enterprise units, many of which are subsidiaries of the few large manufacturers that dominate the refrigerators market and are present in most EU national markets.

92 All products for which the first 4 digits of the PRODCOM code is 2751.

Parameter	Data
	Eurostat: Manufacturing (NACE 27.51): 2,212 (all electric domestic appliances); Wholesale (NACE 46.43): 30,900; Retail (47.54): 54,500
Number of employees (2010)	NACE 27.51: 194,200 (all electric domestic appliances) Wholesale (NACE 46.43): 267,000 Retail (47.54): 269,000

Source: Eurostat

According to data from Euromonitor market research for 2012, 10 large size companies – most of them present in the market with multiple brands – represent more than 85% of the market in Western and Eastern Europe. At the product/brand-name level the market is rather fragmented since only 1%[93] of the models are sold under the same name in all EU markets.

Additional information for the number of firms can be derived from the ORBIS database of Bureau Van Dijk. From the total of 2,568 enterprises active in the 27.51 a search within the economic activity description field using the keywords "refrigerators" OR "freezers" produced 101 records. The list included all major producers as well as smaller manufacturers some of which are active in the commercial refrigerators and freezers market. A market share list from Euromonitor market research database suggested that 22 manufacturers capture 98% of the market in Western Europe and 90% in Eastern Europe (including non-EU countries). Thus, we consider that a total number of 100 firms provide an upper limit in terms of firms affected by the relevant IM legislation for refrigerators and freezers.

Analysis of applicable Union harmonisation legislation and standards

Desk research and the input from firm interviews identified the list of applicable pieces of Internal Market legislation, the basic administrative requirements and the relevant harmonised standards that can be used by manufacturers to meet the essential requirements. According to the input from industry 95-99% of manufacturers do make use of the standards in the case of refrigerators, and more general for domestic appliances.

Refrigerators are covered by 9 different pieces of Union harmonisation legislation covering a range of aspects:

- **Health and safety** (Low Voltage Directive, Regulation on materials and articles that come in contact with food, RoHD Directive on hazardous chemicals,). In the case of gas refrigerators and freezers the Gas appliances Directive is applicable. Furthermore, the Pressure Equipment Directive applies for those refrigerators and freezers that include piping and other pressure vessels (compressors, containers of refrigerants, heat exchangers) with internal pressure above 0,5 bar.

- The General product safety Directive is also applicable but does not introduce additional requirements to refrigerators since these are covered by the other more specific pieces. It does introduce however other obligations, mainly of administrative nature;

93 Electra report - Twenty solutions for growth and investment to 2020 and beyond, http://ec.europa.eu/enterprise/sectors/electrical/files/electrareport_en.pdf

- **Electromagnetic compatibility** (EMC Directive); and
- **Energy consumption and noise** (Eco-design and Energy labelling Directives and the respective implementing measures).

In addition, certain requirements arise from the F-GAS Directive concerning the use of fluorinated gases used in refrigerators, as downstream users of chemicals included in articles under REACH Regulation and also in relation to the use of packaging (Packaging Directive). We should also note that the WEEE Directive is also applicable to refrigerators - and is identified as rather burdensome for manufacturers - but it is a piece of legislation that is outside the scope of this study.

Table 7-18: Summary of Union harmonisation legislation covering refrigerators and freezers and the relevant standards

Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
LVD	Health & Safety (electrical, flammable refrigerants)	Testing according to relevant standards or alternative solutions Development of technical file Declaration of conformity and CE marking Include information ensuring that the product can be used safely and in applications for which it was made	IEC/EN 60335-1 IEC/EN 60335–2- 24
Directive 2009/142/EC on Appliances Burning Gaseous Fuels (GAD)	Health and safety of gas appliances	Testing according to relevant standards or alternative solutions Development of design documentation Declaration of conformity and CE marking	EN 732

Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
General product safety Directive	Health & Safety	Provide identification of the product by a product reference Carry out sample testing of products, keep a register of complaints and keeping distributors informed of such monitoring (voluntary) Inform authorities of dangerous products and actions taken to prevent risk Co-operate with the authorities upon request	
Pressure equipment Directive	Health & Safety	Testing according to relevant standards or alternative solutions Development of design documentation Declaration of conformity and CE marking	EN 378-2:2008+A2:2012[94] EN 12178:2003[95] EN 12263:1998[96] EN 12284:2003[97] EN 14276-1:2006+A1:2011[98] EN 14276-2:2007+A1:2011[99]
Regulation on materials and articles that come in contact with foodstuff 1935/2004 and Regulation 10/2011 on plastic materials and articles intended to come into contact with food	Health & Safety	Chemical analysis and migration tests of the materials used (in cabinet, door, shelves and accessories) Establish information collection system providing information on the source of materials (traceability) Declaration of compliance	

94 Refrigerating systems and heat pumps - Safety and environmental requirements - Part 2: Design, construction, testing, marking and documentation
95 Refrigerating systems and heat pumps - Liquid level indicating devices - Requirements, testing and marking
96 Refrigerating systems and heat pumps - Safety switching devices for limiting the pressure - Requirements and tests
97 Refrigerating systems and heat pumps - Valves - Requirements, testing and marking
98 Pressure equipment for refrigerating systems and heat pumps - Part 1: Vessels - General requirements
99 Pressure equipment for refrigerating systems and heat pumps - Part 2: Piping - General requirements

Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
EMC 2004/108/EC	Electromagnetic compatibility	Testing according to standards Development of technical file Declaration of conformity and CE marking	EN 55014-1 EN 55014-2 EN 61000
Eco-Design Directive 2009/125/EC (Implementing Regulation 643/2009 related to domestic cold appliances)	Noise	Testing Declaration of Conformity and CE marking Information in instruction manual for minimising noise	IEC 60704-1 IEC 60704-2-14 IEC 60704-3 ISO 8960
	Energy consumption/ efficiency	Testing Technical file with results of studies and explanations of design choices made and the management system Declaration of Conformity to be kept for 10 years and CE marking Information in instruction manual for minimising energy-use	EN 62301 - IEC 60301 EN 153/ EN ISO 15502
Energy Label Directive 2010/30/EU and implementing Regulation 1060/2010	Energy consumption/ efficiency	Testing according to harmonised standard Technical file with results of studies and explanations of design choices made and the management system Development of product fiche Placing of energy label	IS015502
F-GAS on fluorinated gases 842/2006	Climate change	Information on the gas contained in the instruction manual and relevant label on product	

Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
RoHS (2011/65/EC)	Use of hazardous chemicals	Collect compliance statement from suppliers (material declarations) Technical file with supplier declarations and own analysis tests Declaration of conformity to be kept for 10 years	
REACH	Use of chemicals	Collect statement from suppliers stating that he is compliance with requirements REACH compliance statement	
Packaging and packaging waste (2004/12/EC)	Packaging	Declaration of Conformity	Standard EN 13427

The analysis and the discussions with manufacturers did not indicate the presence of conflicting requirements that could be seen as creating either or uncertainty or problematic trade-offs in relation to the design of the product.

Turning to the administrative requirements, a number of applicable pieces of Union harmonisation legislation (LVD, EMC, Eco-design and Energy-Label, Regulation concerning articles in contact with foodstuff, RoHS) require the development of a technical files following testing, which in most cases is done according to the specific technical standard. The discussions did not point to any conflicts or overlapping activities in relation to the development of these technical files. The main concern is the size of these files and the work required to develop and update them. It is also often difficult to keep all the required information and to get from suppliers the complete technical files. Suppliers sometimes send only parts of the technical file (e.g. the test reports, energy consumption reports) or do not provide technical information at all (only the DoC) due to concerns about confidentiality and this means that certain testing needs to be redone.

The General Product Safety Directive also introduces certain requirements including the mandatory product identification or the voluntary conduct of tests of marketed products and the keeping of a register of complaints.

The review of the requirements of the Declaration of Conformity indicate minor differences in terms of the terminology used (e.g. under the LVD there is a reference to the "description of the product" whereas under the EMC, the "identification of the apparatus") or similar but the same requirements in terms of the information to be provided (e.g. under LVD it is required to provide the date when the CE mark was affixed to the product whereas under the EMC, the date that the declaration of conformity was signed). However, the discussions so far did not suggest any conflicts or problems for the manufacturers.

Analysis of costs of compliance with Union harmonisation legislation

The information presented in this section is based on the in-depth interviews with 3 manufactures, one small and two large size firms[100].

Table 7-19: Basic information on the firms interviewed

Firm	Firm size	Annual sales from product in the EU	Main markets
A	Small (ca. 350 employees)	Ca. 350 thousand units	Ca. 100% of sales in the EU
B	Large (>1000 employees)	2 million units	Ca. 100% of sales in the EU
C	Large (>4000 employees)	1.8 million units	80% of sales in the EU

On the basis of the discussion with firms the process followed by manufacturers of refrigerators to ensure compliance with the Union harmonisation legislation includes:

- familiarisation with the applicable Union harmonisation legislation and the respective requirements, identification and purchase of relevant standards and in some cases other preparatory actions in training of staff.
- introduction of changes to the product design and the production process to ensure compliance with the requirements
- conformity assessment procedures including the relevant testing and the development of the technical file, the use of notified bodies for certification if/when required, preparation of declaration of conformity (DoC), CE marking and placing in the market
- other activities in response to requests of the market surveillance activities

Preparatory actions: Familiarisation with relevant legislation and purchase of standards

A common practice among most economic operators (not only manufacturers but also distributors) is to develop a database where all applicable legislation is indicated, the relevant harmonised standards are listed along with links to the technical file which demonstrates how the essential requirements are met (see below). The databases are continuously updated to reflect changes in the legislation, to standards or any information related to the technical files. In the case of both small firm A and large C around 1 FTE is allocated solely to the management and update of the database which covers all domestic appliances products produced by the firm. Additional staff working in product development and testing makes use of the database and contribute to maintaining and storing information in the database.

Sophisticated relational databases are also used among larger size companies[101] in order to manage the complexity of keeping track with Union harmonisation legislation, standards and amendments, but equally ensuring that relevant links are kept under each product group to technical documentation required by the firm itself for monitoring regulatory compliance, risk management and quality assurance purposes.

100 It has not been possible to collect data from a manufacturer of gas refrigerators. However, some data on costs of the gas appliances were available in the evaluation of the Gas appliance Directive and are included in the relevant sections of the report.

101 In 2012, the firm interviewed had a turnover of EUR 150 million and 350 employees. Around 10% of the turnover came for the sales of refrigerators. The firm is a subsidiary of a larger enterprise

The majority of manufacturers in the sector rely on the use of European harmonised standards in order to meet the essential requirements. In the case of refrigerators the number of mandatory harmonised standards is around 20 but additional standards (e.g. related to quality management) are also often used by firms. While there is no fixed period for revisions of those standards, their average life span is around 6-8 years. Data from two firms indicate that the average annual expenditure for purchase and/or update of technical standards is usually in the range of €700-1,000.

Compliance with the applicable Union harmonisation legislation

Ensuring compliance with the applicable Union harmonisation legislation often requires changes to existing product design or new product development. Furthermore, the introduction of new products requires product design work and testing to ensure that the new products are in compliance with requirements.

The small size firm A indicated that in total around 7-8 engineers work full time in product design and quality for all products in the production line, around 10% of which focusing on refrigerators (0.8 FTE). However, since Firm A outsources most of the manufacturing to OEM suppliers in third countries, suppliers absorb most of the compliance costs in their own design process prior to production. Nonetheless, around 0.5-1 FTE is allocated to the testing of all products which includes testing according to harmonised standards and also reliability checks on a periodical basis. Tests for the EMC and LVD Directives take place in the firm's premises while other tests are conducted outside. It was estimated that the total annual costs for testing and certification for all products produced account to €200k/year including the expenditure for testing equipment with costs for refrigerators around €20-30K for the 20-30 models of refrigerators that are placed in the market on an annual basis (around €1k/model).

For large firms B and C, 5% of the total number of employees in the specific product line is working on product development activities, around 100 for firm B and close to 300 for Firm C. For the development of a new product Firm B usually spends 1-1.5 year (i.e. 100-150 FTE), 80-90% of which is allocated to the product development and product quality testing. Firm C indicated that a typical product development project - leading to basic model with multiple variants – has duration of 3 years and a budget of up to €100 million. For the large size firm B, testing for product quality and internal market legislation are rather closely linked and it was not possible to get specific estimates of testing costs.

Thus, some of the above costs are not directly linked to Union harmonisation legislation and firms select to incur as part of their own product quality strategy. However, it was not possible to get estimates of the shares of costs that should be linked to IM legislation. For Firm C more than 60% of the total costs are linked with product design activities, around 50% of which (€30 million) is directly linked to compliance with Internal market legal requirements.

Among the different tests, the firms made reference to those related to RoHS which require an examination of the substances in the materials used for fridge appliances. Firms B and C stated that the most costly tests linked to the IM legislation are those related to the Ecodesign Directive for energy efficiency and noise. A typical noise chamber costs around €1 million while for the costs of equipment for energy efficiency testing for the Ecodesign Directive – which is used for a range of products – are around €100 k. Of course, these are generally one-off investments on equipment that may last for more than 5 or 10 years. The tests for EMC and LVD Directives were also considered as costly due to equipment costs but no specific

figures were made available. According to Firm B a rather problematic point appears to be the tests concerning the Regulation on the materials and articles the come in contact with foodstuff. The current provisions of the legislation are considered as rather unclear (making reference to materials that "may" come in contact with foodstuff) and often lead firms to perform a broader range of tests than what could be the case if the provisions were more specific.

Conformity assessment procedures

The last part of the process includes the preparation of the technical file, the inspection of the notified bodies and certification, preparation of the DoC and the required information manual and the placing of the CE marking.

The results of the necessary tests is also brought together in a technical file and the remaining documentation, parts of which also need to be translated to English. According to Union harmonisation legislation this information needs to be stored for at least 10 years and updated whenever there are changes. Significant time is often dedicated for the collection of information from suppliers of specific components or finished products.

While not necessary for all the pieces of applicable Union harmonisation legislation, Firm A uses the services of a third party (Notified body) for conformity assessment. This is part of the firm's risk management strategy and introduces costs that are higher than those necessary to meet the minimum requirements imposed by Union harmonisation legislation. The costs for certification for all products is included in the €200k/year indicated earlier.

Large Firm B indicated that around €100k is spent on an annual basis for third party services that most often go beyond the minimum required (e.g. testing of production facilities) while Firm C tries to keep the costs of third party to the minimum and spends no more than €10-20k for third party certification. Firm C also stated that there are 3 FTE working on the preparations of DoCs and ensuring that CE marking is appropriately applied in all products. In total, while a specific figure was not provided, Firm C estimated that the conformity assessment procedures and preparation of documentation represents no more than 15% of the total budget allocated to the development of a new model. Firm C also indicated that the requirement for placing an energy label on each appliance adds a cost of around €1/appliance.

Firm A suggested that there is some confusion in relation to the information and level of detail to be included in the DoCs and whether legislation and the relevant standards need to be included but this was not shared by the representatives of large Firms B and C. Still, even for small Firm A this part does not represent a sizeable cost. The firms interviewed did not indicate any problem with the requirement for a single declaration. However, CECED indicated that some of manufacturers may find it problematic as they have separate departments each having responsibility for preparing conformity statements within their own competence. In such case, the requirement for a single DoC may introduce some costs for changes to structures and procedures. Unfortunately, none of the firms was able to provide more specific estimates of the time and resources allocated to these activities. However, on the basis of the information provided this did not appear to represent sizeable part of the total costs.

In relation to gas refrigerators falling under the Gas Appliances Directive, the evaluation of the Directive found that the introduction of GAD led to additional costs, particularly with regard to testing/certification and labelling/CE marking. 102 However, the costs of testing and certification for all types of gas appliances – not only gas refrigerators – were estimated at around 0.1% of the annual sales value of gas appliances. Response to market surveillance authorities

Market surveillance authorities make requests for technical information and possibly for testing of products approximately once a month although this varies significantly among countries. The amount of time dedicated to respond to enquiries from market surveillance authorities varies depending on the nature of the request (e.g. what information is required from the technical file, which Directive the request relates to, or whether information in relation to conformity of all applicable legislation has been asked for). Typically, authorities give to firms 10 days to respond to requests. The Ecodesign, RoHS, EMC and energy labelling Directives are those for which there are most often requests for information by the market surveillance authorities. A common perception is that big firms tend to be asked more frequently than SMEs to provide technical information. The large firm interviewed indicated that the related resources dedicated are difficult to estimate but are generally part of the work of the 10 FTE dedicated to compliance.

Business as usual

All firms indicated that they would probably conduct large part of the tests, primarily those related to product safety, even in the absence of the legislation and that production quality management would still be part of internal procedures irrespective of the regulatory framework requirements. Even parts of the costs for tests from third parties could be considered as part of a business as usual (no Union harmonisation legislation) scenario. Even more demanding product reliability tests – that are voluntary under the GPSD - are often conducted by established firms that want to ensure the quality of their products. Similarly, given that issues such as energy efficiency are the focus of consumer organisations related tests would also have to take place – even if not demanding – in the absence of relevant requirements under the Ecodesign and Energy labelling Directive. Thus, large parts of the testing costs incurred – on average up to 50% - are considered as business as usual. Even the product design is in most respects not driven by the legislation but primarily by the general product development process. The main concern for manufacturers is when requirements introduced do not provide sufficient lead time in which case these design costs cannot be integrated in the product design cycle.

Assessment of costs of Union harmonisation legislation for the whole sector

On the basis of the information provided we have attempted to estimate the costs of compliance for the whole refrigerators sector. The provided figures include the information concerning the Business as usual scenario. Assumptions have been made concerning the number of firms affected since, besides the 10 large firms indicated by EGMF there are also a number of smaller size manufacturers particularly in the professional market segment. As indicated in section 2, the calculations for the whole sector were based on an estimated number of 100 firms, an annual turnover of €4.8 billion and a number of units sold/year of €24.6 million.

102 RPA (2011), Ex-post evaluation of Directive 2009/142/EC on appliances burning gaseous fuel, http://ec.europa.eu/enterprise/dg/files/evaluation/03_2011_finalreport_gas_en.pdf

The table overleaf summarizes the analysis of the costs for different aspects. The main point is that the estimated cost for compliance activities for the whole of the domestic refrigerators and freezers sector is around €160 million/year. Around 60% of this (€86 million) is considered as directly resulting from the internal market legislation while the remaining 40% are costs that would most probably occur even in the absence of legislation. Total substantive compliance costs – product designs related activities, testing and testing equipment – are estimated between 80-90% of the total compliance costs while administrative costs (information collection, preparation of technical files, DoC) represent 10-20%.

Table 7-20: Summary of main costs of compliance for domestic refrigerators industry

	Unit of measurement	**Average cost/unit**	**Total quantity**	**Industry wide costs/year**
Own human resources occupied on compliance activities				
Total	Per annual turnover	2.9% of turnover	€4.8 billion	€140 million
Familiarisation with legislation				5-10%
Share of product design and testing activities				80-90%
Conformity assessment (technical file preparation, information manual, DoC and CE marking)				5-10%
Share of human resources costs in absence of IM legislation (BaU)				40%
Net human resources compliance costs				€86 million
Costs of testing equipment				
Total	Per annual turnover	0.33% of turnover	€4.8 billion	€16 million
Share of expenses even in absence of IM legislation		Ca. 48%		
Net costs for testing equipment				€8.3 million
Costs of third parties				
Total	Per annual turnover	0.5% of turnover	€4.8 billion	€2.6 million
Net third party costs – only for IM		60%		€1.8 million
Total annual compliance costs	**Per firm**	**€1.59 million**	**100**	**€158.6 million**

Total net compliance costs		**€ 0.86 million**	**100**	**€86 million**
Substantive compliance costs				80-90%
Administrative costs				10-20%
Share in total industry turnover				**0.2%**
Basic assumptions:	Total units sold: 24.6 million/year Market size: €4.8 billion Number of firms affected: 100 (20 large and 80 small)			

Overall conclusions

The product groups examined in this case study are refrigerators and freezers for domestic use, also known as cold appliances. The total market for refrigerators in 2011 was close to 24.6 million units with a value of the market of EUR 4.8 billion sold/annum. Refrigerators represent around 42% of the market, combined units 38% and freezers 20%. The total volume of production in Europe is around 15 million units with a value of €3.8 billion while imports represent around 50% of the market. Significant part of leading refrigerators and freezers brand are designed in Europe but manufactured outside Europe and subsequently imported. In total, around 10 large size companies – most of them present in the market with multiple brands – represent more than 85% of the market in Western and Eastern Europe and 22 manufacturers capture 98% of the market in Western Europe and 90% in Eastern Europe (including non-EU countries).

Cold appliances are covered by 9 different pieces of IM legislation that cover health and safety aspects (Low Voltage Directive, Regulation on materials and articles that come in contact with food, RoHD Directive on hazardous chemicals), electromagnetic compatibility (EMC Directive), energy consumption and noise (Ecodesign and Energy Labelling Directive). The Gas appliances Directive and Pressure Equipment Directive are also applicable to a small share of cold appliances.

The analysis suggests that cost for compliance activities for the whole of the domestic refrigerators and freezers sector is around €160 million/year, representing no more than 0.2% of annual turnover. Around 60% of this (€86 million) is considered as directly linked to the implementation of the internal market legislation while the remaining 40% are costs that would most probably occur even in the absence of legislation (business as usual). Substantive compliance costs – costs related to product design, testing and testing equipment – are estimated between 80-90% of the total compliance costs while administrative costs (information collection, preparation of technical files, DoC) represent 10-20% of the total. The compliance costs are driven primarily by the compliance with environmental legislation (mainly the Ecodesign Directive) which, in contrast to health and safety aspects, is not considered as business as usual.

Sources of information

References

- Eurostat Structural Business Statistics Database and PRODCOM

- Euromonitor Market research data on consumer appliances
- Text of applicable IM legislation and relevant standards
- Guidance documents of LVD and MC Directives
- Input from one medium and one large manufacturer/importer of refrigerators and freezers.

Interviews

- Interview with industry association: CECED
- 3 interviews with manufacturers of refrigerators/freezers

3.10.4 Case study 4 - Lifts

Introduction

This case study assesses how Union harmonisation legislation affects different economic operators involved in the manufacture, import and distribution of lifts for persons (covered under the Lifts Directive). In order to help shed light on the interaction between different types of Union harmonisation legislation, and issues around whether there are sufficiently clear demarcations between such legislation, it also however addresses other types of lifts covered through the Machinery Directive 2006/42/EC, including lifting hoists, lift platforms and escalators and certain types of lifts for goods not covered by the Lifts Directive. The applicable Union harmonisation legislation specific to each product is mapped out and the administrative costs – and to the extent possible substantive compliance costs – in meeting these regulatory requirements are then assessed.

The rationale for the selection of lifts was that:

- The lifts sector, while dominated by four large firms, has a large number of small and medium-sized enterprises ("SMEs");
- The lifts sector has longstanding experience of implementing Union harmonisation legislation since the first Lifts Directive was adopted in 1995;
- The Lifts Directive is one of nine Directives that formed part of the Alignment Package. It is important to examine stakeholder views on how the alignment process has had an impact on strengthening the coherence of Union harmonisation legislation; and
- The case demonstrates the advantages of having a clear delimitation in Union harmonisation legislation in defining the borderline between different Directives in order to ensure legal clarity for economic operators.

The case study is based on interviews of EU-level and national industry associations, manufacturers and installers of lifts and manufacturers of safety components for lifts, as well as analysis of key legislative documents and published reports.

Product definition and structure of the sector

The lift industry is dominated by four very large companies (Kone, Otis, Schindler, ThyssenKrupp Elevator), of which three are European (one non-EU) and one from the USA. These four companies and their subsidiaries have a high combined share of the European market, estimated at 60%.

The lifts industry has undergone substantial changes as a result of globalisation, with evidence of increased industry consolidation in statistics on market structure.[103] The estimated size of the lifts market in Europe, according to the Europe SME lifts association (EFESME) was about €15 billion in in 2009. However, this extends beyond manufacturing and the placing of products on the market (covered by IM legislation). Lift manufacturing and installation only accounts for one third of the total market size, while the remainder is made up of after-sales services (maintenance 41%, repair 7%, and modernisation 18%). The total number of lifts in operation in the EU was estimated at about 4.7 million units. Further data has been obtained for 2009 from NACE and PRODCOM on the size and structure of the lifts industry. "Lifts and escalators" fall within the NACE classification "manufacture of lifting and handling equipment".

NACE data shows that there are over 9,500 enterprises in the lifts sector, the great majority of which are SMEs, although there has been a decline in the number of lifts companies in the 2008-2010 period (the latest period for which data was available), reflecting on-going industry consolidation processes.

Table 7-21: Number of enterprises – lifts sector

Nace Code	2008	2009	2010
28.22	9,970	9,720	9,525

Source: Eurostat

The production value of lifts is shown in the following table. The data shows that in parallel with the economic and financial crisis there was a major downturn in the lifts industry but that the production value has since stabilised.

Table 7-22: Production value of the lifts sector (€ thousands)

Nace Code	2008	2009	2010
28.22	59,072.38	42,603.23	43,688.83

Source: Eurostat

In the following table, Prodcom data shows that a total of about 255,000 lifts (and skip hoists) were produced in Europe in 2012, of which the majority were electrical lifts and the remainder hydraulic.[104]

103 http://www.lift-report.de/index.php/news/361/373/Industry-report---Lifts-and-escalators-an-industry-in-flux

104 It should be noted that skip hoists are not lifts and are not subject to the Lifts Directive. However, Eurostat does not provide further disaggregation of Prodcom data.

Table 7-23: Sales volumes for lift manufacturing industry (2012)

	Units	Median price (€)	EU27 production value (€000)
Sales volumes			
28221630 (electrically-operated lifts and skip hoists)	133,000	18,242	2,157,000
28221650 (lifts and skip hoists excluding electrically-operated)	122,000	14,207	802,766
Total sold volume	255,000	-	2,959,766

Source: Eurostat

Manufacturing in the lifts sector is strongly export-oriented and has generated a significant volume of exports, although the interviews found that a lot of manufacturing that used to take place within the EU has been moved to lower-cost producer countries outside the EU. The table below provides a summary.

Table 7-24: Production value – lifts sector (2010)

	Export values (000s)	Import values (000s)	Production Value (000s)	Apparent consumption (Production+ Imports- Exports)
28221630 - Electrically operated lifts and skip hoists	599,774,450	37,947,640	2,343,821,623	1,781,994,813
28221650 - Lifts and skip hoists (excluding electrically operated)	165,383,210	17,338,000	628,899,470	480,854,260
Total	**765,157,660**	**55,285,640**	**2,972,721,093**	**2,262,849,073**

Source: Eurostat

With regard to employment, various industry surveys indicate a total European workforce in the lifts for persons sector (manufacturing, installation and servicing) of between 15,000-18,000 people.[105]

Analysis of applicable Union harmonisation legislation and standards

This section maps out relevant Union harmonisation legislation since the study seeks to

105 Elevators and Escalators - A Global Strategic Business Report 10/12

provide estimates of the costs associated with complying with Union harmonisation legislation (dividing these costs into administrative costs and substantive compliance costs). Reference is also made to applicable environmental legislation where this has a major impact on manufacturers of industrial goods. However, in the quantitative analysis, we do not seek to quantify the impact of such legislation, rather only Union harmonisation legislation for industrial products.

In the first table, relevant applicable Union harmonisation legislation for lifts for persons is mapped out. The table shows that, unlike some of the other product cases, the lifts sector is subject to relatively few pieces of Union harmonisation legislation.

Table 7-25: Legislation applying to lifts

Applicable legislation	Scope of products included	Main administrative requirements for economic operators
Lifts Directive	Lifts for persons, persons and goods or goods alone (if the carriers is accessible) with speeds of more than 0.15 m/s	• Conformity assessment - obligation of the installer of lifts or manufacturer of safety components • Produce a DoC (note: DoC required for both installation of lifts and for each safety component) • Keep technical documentation copies of EC type-examination certificates and their additions for a period of 10 years from the date on which the safety component was last manufactured or the date on which the lift was placed on the market • 'CE' marking - must be visibly affixed to lifts or to certain safety components of lifts • Rules relating to manufacturing apply to both installers of lifts and to manufacturers of lift safety component (or authorized representatives)
		<u>All economic operators</u> Traceability obligations - identify name of installer, manufacturer, name / ID number of Notified Body having carried out conformity assessment **<u>Installers and manufacturers</u>** Conformity assessment remains the obligation solely of the installer or the manufacturer of safety component **<u>Importers</u>** • Verify that the manufacturer of safety

Applicable legislation	Scope of products included	Main administrative requirements for economic operators
		components has carried out the applicable conformity assessment procedure and has drawn up a technical documentation. • Verify that the safety components for lifts are correctly marked and accompanied by the required documents. • Keep a copy of the DoC and indicate their name and address on the product, or where this is not possible on the packaging or the accompanying documentation.
EMC Directive	Applies to lifts for persons	Testing products for Electromagnetic Compatibility interference Conformity assessment procedure for apparatus mandatory CE marking on apparatus required in accordance with Annex V.
Machinery Directive 2006/42/EC	Lifts for goods only Slow-moving lifts (speed less than 0.15 m/s) Construction site hoists Lifting platforms for persons with impaired mobility	<u>Manufacturers</u> • Ensure conformity assessment procedure for lifting machinery carried out • Produce a DoC (note: DoC required for both installation of lifts and for manufacture of each safety component) • Keep technical documentation copies of EC type-examination certificates and their additions for a period of 10 years 'CE' marking - must be visibly affixed to lifts or to certain safety components of lifts • Construction file and risk assessment. The latter should contain: (i) a list of the essential health and safety requirements applied and fulfilled; (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks;

Applicable legislation	Scope of products included	Main administrative requirements for economic operators
		(iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards; (iv) any technical report giving the results of the tests carried out either by the installer or manufacturer or by a body chosen by the manufacturer or his authorised representative; and (v) a copy of the assembly instructions for the partly completed machinery.

The Lifts Directive covers Lifts for persons (and goods). Article 1(1) states that the lifts to which the Directive applies are those "serving buildings and constructions". The Directive is clear as to whether spare parts and components are included, since it covers both lifts and safety components for lifts, both of which must be CE-marked. Likewise, other Directives that apply to different types of lifts such as Directive 2000/9/EC relating to Cableways (e.g. chair lifts, drag lifts) also applies to safety components and also to sub-systems.

A number of different types of lifts are **excluded from the Directive's scope**, namely:

- lifting appliances whose speed is not greater than 0,15 m/s;
- construction site hoists;
- cableways; including funicular railways;
- lifts specially designed and constructed for military or police purposes;
- lifting appliances from which work can be carried out;
- mine winding gear;
- lifting appliances intended for lifting performers during artistic performances;
- lifting appliances fitted in means of transport;
- lifting appliances connected to machinery and intended exclusively for access to workstations including maintenance and inspection points on the machinery; and
- rack and pinion trains, escalators and mechanical walkways.

The legislation applies to goods alone if the carrier is accessible i.e. a person may enter it without difficulty, and fitted with controls situated inside the carrier or within reach of a person inside the carrier. Other types of lifts to carry goods are included within the scope of the Machinery Directive 2006/42/EC.

Analysis of costs of compliance with Union harmonisation legislation

Feedback was obtained on how companies in the lifts sector ensure compliance with the relevant Directives (listed in Table 7-25 above). In order to ensure their compliance with the legislation, the large manufacturers tend to employ specialist staff at their research and development centres and production sites, as well as in their distributing companies (typically nationally-based) that are responsible for installation, service and maintenance. Compliance must be ensured at the design and development stage (typically a one-off task for each new or revised product) as well as at the installation stage for each individual lift unit. It should be noted that the EU legislation only relates to new products; service, maintenance and renovation (including of lifts pre-dating the Lifts Directive) is covered by national legislation that differs from country to country.

Lifts differ from many other industrial products in that compliance has to be undertaken in three main phases, which may take place at different sites in different countries. New lift models are, firstly, designed to take into account Union harmonisation legislation. For the big four manufacturers, design tends to be undertaken at specialist research and development (R&D) centres, given the obvious economies of scale. For example, one of the firms interviewed has eight R&D centres globally, of which three are in the EU. Second, new lifts must be manufactured to comply with the legislation. Again, the manufacturing of lifts may often be done centrally to make use of economies of scale. The same firm has multiple global production sites, of which three are in the EU. Last, the installers of lifts must ensure that installed products satisfy a proper conformity assessment undertaken on site before they become operational. In contrast to the design and manufacturing of lifts, installation is typically done by nationally-based firms given the need for proximity. The four large firms have operating companies or authorised distributors in each of the 27 Member States and in many other countries worldwide. SMEs clearly differ from the four global players in that respect, since design and production is more likely to take place at the same site.

At each phase, the task of ensuring compliance is very different. Designing a new lift product or model is clearly a lengthy task, undertaken some considerable period before the product is placed on the market. The design process involves intensive testing, whether required by the legislation or not. At the design stage, the requirements of the legislation must be taken into account and thus limit the options for design but without creating a specific additional stage in the process; the requirements are "designed in" to the product. The manufacture of lifts in compliance with the legislation is relatively straightforward, provided that the product has been designed to comply and provided that the lift is made according to the specification. However, the installation of lifts tends to require numerous refinements to ensure the lift functions well within its environment. These refinements result in a corresponding need for repeated checks to ensure compliance with the legislation, as well as with health and safety requirements in general.

The particular nature of this production chain also creates specific costs and benefits compared to other products. There is the need for specialist staff that have expert knowledge of the legislation at all sites, i.e. the locations where R&D, production and installation take place. This is in contrast to a product such as mobile phones, for which there is no separate "installation" phase; once such products leave the production site, the manufacturer can be sure that the product is compliant (unless it is tampered with at a later stage). Compliance is thus a "decentralised" task, creating the need for communication between disparate sites at different points in the production chain, e.g. for feedback from installers to designers about the practical difficulties faced in complying with the legislation at the point of installation.

However, the nature of the product (i.e. physically large and fixed in a certain location) facilitates enforcement of the regulation and market surveillance; products can be tracked and traced much more easily than other products, making it hard for rogue or ill-informed manufacturers to place non-compliant products on the market. Similarly, end-users are unlikely to purchase non-compliant products inadvertently, e.g. via a website.

The size of the four largest manufacturers enables them to employ specialist compliance staff in-house. As a result, the general approach in the lifts industry is to gain approval of the installer's full quality assurance system under Module H, which avoids the need for EC type-approval of each unit installed. However, the system used tends to vary according to the nature of the building; other Modules tend to be used for unusual buildings. Two of the companies interviewed pointed out that they would tend to comply with the harmonised standards as much as possible, reflecting the fact that the Lifts Directive covers a very specific product, unlike some other directives. Compliance with harmonised standards also makes exporting easier to third countries that have unilaterally adopted the EU standards (e.g. many of the Asia-Pacific countries) and also simplifies maintenance.

Feedback from industry associations was that European standards play an important role in supporting the compliance of SMEs with EU legislation, since almost all SME producers of lifts use ropes and follow such technical standards. However, the four large manufacturers do not use standards in order to comply with the essential requirements, since they use belts. There is a reluctance among the biggest industry players to be involved in standardisation because of concerns about maintaining competitive edge and because newer types of lifts are patented.

Preparatory actions: familiarisation with relevant legislation and purchase of standards

For the two large companies interviewed, the process of **familiarisation with legislation** was not unduly costly. Their very large size makes it affordable to employ staff specialising in EU and other legislation. For example, such staff are a very small part of the workforce for the big four players with more than +40,000 employees worldwide. Moreover, the availability of specialist staff allows the large companies to be well-connected to the European Commission and to participate in various forums and working groups at EU level, which helps familiarisation.

The greatest costs related to familiarisation with the legislation tend to occur when there are changes in the harmonised standards or in the interpretation of those standards, e.g. by national authorities. One interviewee reported that the cost of familiarisation with applicable requirements was not particularly costly, nor was purchasing the relevant standards. (Standards in the UK typically cost between £50 and £300 each). However, reviewing the existing harmonised standards could take time, as could the process of familiarisation across a large company, given the need for constant communication of the information obligations of the legislation to a much wider group of people. For example, the requirements of the legislation are just one part of the knowledge required by those installing lifts; those staff would not necessarily be as pro-active as the compliance officers in ensuring that their knowledge remained up-to-date, hence the need for continued communication as well as regular training. None of the companies interviewed incurred costs in using external consultants to support preparatory work.

Compliance with the applicable Union harmonisation legislation

Changes to the requirements of the legislation or to the standards have the greatest potential to impose costs on manufacturers where they require changes in **processes and product design**. Indeed, the nature of lifts requires very considerable investment to be undertaken in the design and development of new products over long time-periods. Where changes occur in the legislation on a regular basis or at short notice, they have the potential to impose substantial costs on manufacturers.

However, the companies interviewed pointed out that the costs of adapting processes and product design are much less where changes in the legislation are announced some time before they come into effect. In general, lift products are continually evolving, e.g. in response to technological innovations and the R&D centres of the large companies are constantly seeking to improve their products, whether through new models or new versions of existing models. The development process involves constant checking of prototypes to ensure safe and effective functioning, as well as compliance with the legislation. Whilst such checks are time-consuming, they are seen as part of the overall development cost. Indeed, it becomes hard to separate out the cost of checking compliance with the legislation from the cost of other checks. As one interviewee stated, "the product specification is not costly as you have to do it anyway; in that sense, the Directive just limits your options, it doesn't create costs".

Conformity assessment procedures

The companies interviewed were unanimous in highlighting the additional costs imposed by **conformity assessment procedures** both in development and installation. The development of a new or revised model tends to require continual refinements to the product. When a product is designed, it has to be considered by a notified body and go back each time it is revised (as part of the overall development process). Manufacturers/installers are required to retain the product certification at each stage of development, which creates a cost. It would appear therefore that it is not so much the cost of the developing a product that conforms to the legislation which is burdensome but the cost of checking conformity. Such costs tend to be additional and therefore costly. As noted above, approval of the installer's full quality assurance system under Module H avoids the need to have each individual unit checked.

Within the conformity assessment procedure, it would appear that the main costs are imposed by the requirement to collect all information required for technical reports. For example, collecting information from third party suppliers of components can be particularly burdensome due to the lifecycle of the product. The compilation of test reports is equally important and burdensome but tends to be viewed as a "business as usual" cost, since the manufacturers operate their own test procedures and compile test reports in any case. Similarly, product identification requirements (e.g. serial number) and the maintenance of technical information for at least ten years tend also to be seen as "business as usual" costs, in the latter case, because the life-cycle of a lift is 25-30 years. It may be possible to reduce some costs by allowing increased use of electronic documentation.

The large manufacturers tend to undertake their own tests themselves, using in-house staff and following quality assurance systems approved under Module H. Clearly, such costs are significant, given the need for full-time staff. However, the cost of notified bodies tends to be modest; one manufacturer reported that third party notified body inspections are only used to verify its quality assurance system. No company reported their own internal reviews of technical documentation to be particularly burdensome, given the availability of in-house

staff; one of the companies mentioned that such reviews were undertaken by the global headquarters. In the case of lifts, periodic inspections of installed products are the responsibility of the customer and, in any case, fall under national rather than EU legislation.

Declaration of Conformity and CE marking

Overall, the **Declaration of Conformity and CE marking** do not appear particularly burdensome for manufacturers, except for the requirement to keep information up to date, e.g. in relating to changes in the harmonised standards or in the legislation. Since each lift installed represents a unique product, the information has to be created every time, which creates an administrative burden if the DoC is to be kept up-to-date. However, since the CE marking and DoC also have to cover the equipment and environment surrounding the lift, this step can be particularly burdensome in a minority of installations. Since, typically, the lift manufacturer will not have constructed the surrounding environment, e.g. the hoist way, the process of issuing the DoC and CE marking can prove problematic. For example, one company reported that some customers may pressure the lift installer to issue a DoC (e.g. by withholding payment) in cases where the customers themselves have not fulfilled their own obligation to develop a compliant environment for the lift.

Other activities necessary to comply with Union harmonisation legislation

None of the companies interviewed referred to costs resulting from any **other activities** required by the legislation.

Analysis of administrative costs for each relevant step indicated

Since the Lifts Directive refers to a very specific product, this Directive accounts for the majority of administrative costs. However, the administrative costs tend to be minimised by the fact that the harmonised standards of the Lifts Directive have been developed to take into account the regulatory compliance requirements applicable to lifts set out in other relevant directives, notably the Electromagnetic Compatibility Directive (EMC). This means that if a manufacturer follows the standard and carries out a conformity assessment based on the standard, they will have met their regulatory obligations across all relevant pieces of legislation.

Similarly, products covered by the Machinery Directive (e.g. escalators) and using the harmonised standards of that Directive will in meeting these requirements have also complied with the EMC requirements since they are incorporated into the standard. Two companies referred to the need to take into account the Ecodesign Directive, with respect to the buildings in which lifts are installed. One of the companies also referred to the need to comply with the ATEX Directive on occasions, i.e. in potentially explosive atmospheres.

None of the firms were able to provide detailed costs for every step in the process. However, we can make some statements based on the evidence available.

- **Familiarisation with legislation** is undertaken in-house by the large companies using specialist staff; one company stated that each of its national subsidiaries had at least one compliance officer and one final inspector, both of which would possess in-depth knowledge of the legislation and would keep themselves up-to-date; the same company estimated that the total number of compliance and inspection officers across the EU to be around 100. The other company referred to six specialist staff ("Blue collar"

operators, i.e. technicians and associate professionals) in one of its nationally-based distributing companies (in a medium-size country).

- **Processes and product design**: the large manufacturers tend to undertake their own tests, using in-house staff and following quality assurance systems approved under Module H, which serves to minimise cost; in addition, one large company suggested that changes to the legislation could incur costs of €550k-€600k if they require changes to the reference numbers for lift products.

- **Conformity assessment procedures**: The Lifts Directive is the most burdensome piece of legislation, particularly the requirement for compulsory third party conformity assessment procedures and the supporting technical documentation; this is much more detailed than the other Directives. Lift manufacturers undertake their own extensive testing of their products both in development and in installation to ensure quality and safety; in most cases, such checks can readily encompass the requirements of legislation. To a large extent, the testing required by conformity assessment would therefore tend to represent a "business as usual" cost rather than an additional cost imposed by the legislation.

- The administrative requirement related to conformity assessment procedures undertaken in the product development stage are quite high initially, but occur only once (for each model or version). The larger companies do not incur costs of notified bodies in the installation of lifts, except in special cases where those lifts do not follow the harmonised standards; one national subsidiary in a medium-sized country referred to the need to use a notified body for the certification of lift units around 3 or 4 times per year at a cost of €500 per time, i.e. €2k per year – a cost described as "minimal compared to the cost of installing lifts". The administrative burden associated with conformity assessment is quite high as inspections have to be undertaken for each new lift installed. There is also the cost of buying and maintaining testing equipment; one subsidiary of a large company reporting that cost to be around €5k per year depending on the frequency of tests.

- **Declaration of Conformity and CE marking**: in general, this task is not seen as particularly costly, except that gathering the information required for the DoC takes time. The possibility to issue a single DoC covering all Directives significantly reduces the administrative costs of this step.

Compliance costs

As for administrative costs, most compliance costs relate to the Lifts Directive, which in any case requires compliance with the EMC Directive. Again, no firm was able to provide detailed costs for every step in the process. However, we can make some general statements based on the evidence available.

Where changes occur in the legislation on a regular basis or at short notice, they have the potential to impose substantial costs on manufacturers in the design and development of products and production processes. For example, one manufacturer suggested that any technical adaptation required by the legislation would cost around €500k-€1m in terms of new product development; such costs would relate to ensuring conformity of design, a physical examination of 8-10 different product platforms to be certified, additional documentation for the conformity assessment process, costs for sales companies, training for sales and

production staff, updating sales literature.

In the long run, particularly where changes in the standards or in the legislation are introduced with sufficient notice, the costs of compliance are inseparable from the "business-as-usual" costs of designing and developing new products and production processes. It may be that the legislation or the standards exclude some options for design or production that would have delivered cost-savings, but these potential "missed savings" were not specifically mentioned by the companies interviewed.

Conclusions

It would appear that the main determinants of the level of compliance costs are the regularity and notice period of any changes in the legislation or in the harmonised standards. New or revised models are continually being designed and developed to reflect technological advances. Provided that changes are not made too frequently and are signalled well in advance, manufacturers appear able to design and develop compliant products without incurring additional compliance costs; to a certain extent, compliance is "designed in". Changes brought in at short notice can impose very significant costs, as units already in production have to be revised; this can prove particularly problematic where contracts have already been agreed with customers. Frequent changes in the legislation or, particularly, in the harmonised standards also impose a significant compliance cost by requiring extensive information and retraining of staff to ensure that "front-line" staff, e.g. lifts installers are aware of, and apply the revised standards.

For the large companies interviewed, it is clear that the administrative burden represents a somewhat modest financial cost compared to total costs/turnover, as evidenced by the number of specialist staff compared to the total workforce. SMEs may face a difficult choice between incurring the overhead involved in having specialist staff and not keeping up to date with changes in the legislation. Moreover, they rarely have the capacity to engage in the various processes at EU level related to setting standards.

Overall, it would appear that the various Directives applying to lifts are consistent and streamlined, i.e. compliance with harmonised standards of the Lifts Directive implies compliance with the other Directives. This consistency limits the costs of compliance and, particularly, the administrative burden associated with the legislation. It may therefore be safe to conclude that any negative cumulative impacts of the legislation are modest. Moreover, it is reasonable to assume that most, if not all, Member States would introduce legislation covering lifts in the absence of the Lifts Directive, given the risks to safety inherent to this product. The EU legislation may therefore have reduced compliance costs and the administrative burden by enabling the application of harmonised standards and a consistent compliance process across all Member States. However, EU legislation does not apply to services, maintenance and renovation. Any risks to safety must therefore be covered by national legislation, which will inevitably vary from country to country. It may be worthwhile for the Commission to explore the possibility of bringing service, maintenance and renovation of lifts within the scope of EU legislation or to find ways to encourage a gradual, voluntary convergence in the requirements of national legislation.

<u>Assessment of costs of Union harmonisation legislation for the whole sector</u>

On the basis of the information provided, we have attempted to estimate the costs of compliance for the installation of lift units, including electrically-operated (NACE 28221630)

and other (NACE 28221650). In offering such estimates, we have taken into account certain characteristics of the sector and of firms therein.

First, companies involved in the manufacture and installation of new lifts typically also undertake modernisation, repair and maintenance, which are not subject to EU legislation. For that reason, we have estimated costs of compliance as a proportion of production value rather than of the total revenues of such companies. Total revenues for manufacture and installation are based on multiplying median prices (sourced from PRODCOM) against the total number of units sold by each company.

Second, the estimates in the table below do not include data from manufacturers of components. Of course, the manufacturers of components must comply with the relevant legislation and this imposes a certain cost. However, those compliance costs differ in nature from the costs incurred by manufacturers and installers of lift units and are therefore excluded from the table.[106] For example, conformity assessment of new components is a one-off event, whereas each new lift unit must be assessed at the installation stage. Information from the interviews of such companies has instead informed the qualitative text above.

Third, the companies interviewed were generally unable to separate substantive compliance costs (in product design, manufacture and installation) from business-as-usual costs. All interviewees agreed that changes in the legislation or in the standards introduced at short notice tended to impose very significant substantive compliance costs. In particular, any units already in production or already manufactured but not yet installed required technical adaptations in order to be compliant with the legislation, which proved costly. However, the level of any short-term adaptation costs would depend entirely on the precise nature of the change. Moreover, manufacturers are continually innovating in search of higher quality and lower costs (not least in response to demand) and average production costs tend to be falling (e.g. due to increasing economies of scale). In this dynamic situation, the companies interviewed tended to report that, given time to adjust, they could "design in" the requirements of the legislation without necessarily incurring substantive compliance costs. None of the companies was able to state how their products would be different in the absence of legislation. For those reasons, the table below offers no estimate of substantive compliance costs.

Fourth, the companies interviewed stressed that they undertake extensive testing during the installation process for reasons of safety and quality and would do so in the absence of EU legislation. Although the conformity assessment process imposes a significant cost in terms of staff time required to check installations (e.g. under Module H) and compile technical reports, such costs tend to be inseparable from business-as-usual costs. In that sense, it might be possible to conclude that the conformity assessment process determines the format of testing during the installation without necessarily being more expensive than the tests that installation companies would undertake in the absence of EU legislation. SMEs may differ in that respect, as they are more likely to use Notified Bodies and thus incur a direct financial cost, which can be significant; of course, many reputable SMEs would submit their products for third-party testing in the absence of EU legislation, so it is impossible to determine the additional burden imposed by the legislation.

106 To a certain extent, the compliance costs incurred by manufacturers of components might be passed on to the manufacturers and installers of lift units through higher prices for components. However, it is beyond the scope of this study to determine the extent to which that happens.

The table below suggests that the costs of compliance may be around £26m p.a. for a production volume of 255,000 units. This represents around 0.89% of total revenue of €2,960m from manufacture and installation of whole units in the EU. To this cost must be added the significant but unquantifiable costs just described. However, the companies interviewed were unanimous in reporting that the cost of complying with EU legislation was less than under a "benchmark" scenario in which national legislation differed from country to country.

Table 7-26: Summary of main costs of compliance for installation of lift units

	Unit of measurement	Average cost/unit	Total quantity	Industry wide costs/year	Explanatory notes
Human resources expended on compliance					
Familiarisation with legislation	Per annual turnover	0.26%	€2,959.766 m	€7.696m	Staff responsible for participating in EU-level processes, identifying legislative requirements and informing the wider company, e.g. Codes Officers.
Informing and training staff in legislative requirements					Significant cost but impossible to quantify, typically consisting of small amounts of time spent by a large number of individuals
Product design and testing activities					Inseparable from business-as-usual costs. Significant in the short-term (i.e. adaptations to changes in the legislation or in the standards). Negligible in the long-run.
Checking compliance in design and production	Per annual turnover	0.16%	€2,959.766 m	€4.736m	Compliance and inspection officers at sites responsible for R&D & production
Conformity assessment (technical file preparation, information manual)					Inseparable from business-as-usual costs
Declaration of Conformity & CE marking	Per annual turnover	0.00%	€2,959.766 m	€0.000m	Negligible
Total human resources compliance cost				€12.432m	In addition to non-quantified costs of training, product design and testing, etc.

	Unit of measurement	Average cost/unit	Total quantity	Industry wide costs/year	Explanatory notes
Costs of testing equipment					Cost of testing for reasons of quality, health & safety are impossible from costs of testing required by the legislation. Production sites typically serve EU and global markets, therefore impossible to separate cost of testing equipment required by EU legislation from testing equipment that would be needed in the absence of legislation.
Costs of third parties					
Purchasing standards[107]	Per annual turnover	0.01%	€2,959.766 m	€0.296m	*Typical cost = €2k per company per year.*
External consultants	Per annual turnover	0.00%	€2,959.766 m	€0.000m	No reported instances of use of external consultants
Notified Bodies (Module H)	Per annual turnover	0.04%	€2,959.766 m	€1.184m	*Typical cost is €25*-30k for a national subsidiary of a major manufacturer (responsible only for installation).
Notified Bodies (fees for testing specific products)	Per unit	€200-1000	n/a	n/a	Units deviating from the standards require specific approval but typically form a very small proportion of total installations.
Total annual compliance costs	**Per annual turnover**	**0.89%**		**€26.344m**	
Total net compliance costs				n/a	Inseparable from business-as-usual costs.
Substantive compliance costs				n/a	Inseparable from business-as-usual costs.

107 As an indicative example, UK standards under the Lifts Directive are typically priced between £50 and £300. See: http://shop.bsigroup.com/.

	Unit of measurement	Average cost/unit	Total quantity	Industry wide costs/year	Explanatory notes
Administrative costs				**€26.344m**	Excludes substantive compliance costs, which are inseparable from business-as-usual costs
Share in total industry turnover				**0.89%**	
Basic assumptions:	Total units sold: 255,000 units per year (NACE: 28221630 and 28221650) Market size: € 2959.766 million (PRODCOM) Weighted median price per unit: €16,312 (NACE 28221630 and 28221650)				

Overall conclusions - lifts

Lifts for persons are a harmonised product group for which there is one overarching piece of legislation. The Lifts Directive incorporates different elements of product safety (including electrical safety) that for other product groups would be covered separately by the LVD. Other Directives, such as the EMC Directive also apply. IM legislation affecting the lifts sector was found to be coherent with no specific gaps overlaps, inconsistencies or duplication identified. The Machinery Directive 2006/42/EC (MD) applies to certain types of lifts, but the delimitation between the two Directives is clearly specified in the 2006 recast of the MD. This ensures mutual exclusivity between Directives and clarity for economic operators.

The "big four" lift manufacturers account for some 60% of the EU market, estimated at €15 billion in in 2009 (EFESME). NACE data shows that there are over 9,500 enterprises in the lifts sector, the majority of which are SMEs. A particular characteristic of the lifts sector is that the manufacturing of lifts only accounts for one third of total market size, while the remainder is made up of after-sales services (maintenance 41%, repair 7%, and modernisation 18%). Whereas manufacturing activities and initial installation are regulated through IM legislation, once installed, lifts fall under national in-service inspection regimes. The costs of lifts maintenance and the costs linked to periodic servicing once in use are a significant cost, but are note linked to European legislation.

The Lifts Directive accounts for the majority of administrative costs, although such costs are minimised by the fact that the relevant harmonised standards take into account the compliance requirements of other relevant directives, notably the Electromagnetic Compatibility Directive (EMC). This means that if a manufacturer follows the standard and carries out a conformity assessment based on the standard, they will have met their regulatory obligations across all relevant pieces of legislation. Familiarisation with legislation is undertaken in-house by the large companies using specialist staff. When developing products, the large manufacturers tend to undertake their own tests, using in-house staff and following quality assurance systems approved under Module H, which serves to minimise cost. The requirement for compulsory third party conformity assessment procedures and the supporting technical documentation tends to be the most burdensome requirement of the legislation. However, the firms emphasised that much of the required testing would be undertaken in the absence of legislation, for reasons of product safety and quality. The administrative requirement related to conformity assessment procedures undertaken in the product development stage are quite high initially, but occur only once. In contrast, the administrative requirement related to conformity assessment procedures in the installation process are higher, as as inspections have to be undertaken for each new lift installed. The task of producing the Declaration of Conformity and CE marking is not particularly costly.

Based on the research, the costs of compliance may are estimated at €26m p.a. for a production volume of 255,000 units across the EU. This represents around 0.89% of total revenue of €2,960m from manufacture and installation of whole units in the EU. However, the companies interviewed were unanimous in reporting that the cost of complying with EU legislation was less than under a "benchmark" scenario in which national legislation differed from country to country. Clearly, these costs are more onerous for SMEs than for large companies that can spread compliance costs among a large number of units.

Sources of information

References

- Eurostat Structural Business Statistics Database and Prodcom
- Text of applicable IM legislation and relevant standards
- Guidance documents of Lifts Directive and Machinery Directive
- Dispan, J. (2007), Industry report - Lifts and escalators – an industry in flux, IMU Institute Stuttgart
- Elevators and Escalators - A Global Strategic Business Report 10/12

Interviews:

- 3 EU industry associations: European SMEs in the lift industry (EFESME), European Lifts Association (ELA), European Lifts Components Association (ELCA)
- 1 national lift association
- 8 manufacturers of lifts
- 2 manufacturers of lift components

3.10.5 Case study 5 – Gardening equipment

Introduction

The case study examines gardening equipment with focus on three specific categories, chain saws, lawn mowers and brush cutters. Gardening equipment can be electric, battery powered or petrol based and they are used both by consumers and professionals. The rationale for the selection of these product groups was that:

- Lawn mowers are covered by a rather large number of Union harmonisation Directives and Regulations, 8-10 depending on the type of product;
- The sector is dominated by a few large manufacturers; and
- The conclusions drawn from an assessment of these specific products could be used to assess with some level of confidence the administrative and compliance costs to the broader category of domestic appliances since most of the products within this group are usually covered by the same pieces of legislation.

The case study is based on desk research and interviews with the EU industry association representing manufacturers of gardening equipment (EGMF) and five in depth interviews with manufacturers of gardening equipment operating in Europe, two large manufacturers, two medium and one small.

Product definition and description of structure of the sector

The focus of case study has been three types of gardening equipment, chain saws, lawn mowers and brush cutters. These categories represent the main sales volume of the broader garden machinery equipment group of products that also includes various types of trimmers, vacuums and blowers, leaf blowers, leaf collectors, motor hoes (<3 kW), scarifiers, shredders/chippers and pruners. Gardening equipment are used both by consumers and professionals although there are often differences in terms of engine power and features and some products that are typically used by professionals (e.g. garden tractors). The following paragraphs provide a more formal definition of the three products under examination on the basis of the relevant EN standards:

Lawn mowers[108]

According to EN standard EN836 a lawnmower is "a walk-behind or ride-on grass cutting machine or a machine with grass-cutting attachment(s) where the cutting device operates in a plane approximately parallel to the ground and which uses the ground to determine the height of cut by means of wheels, air cushion or skids, etc., and which utilises an engine or an electric motor for a power source. The cutting devices are either rigid cutting elements or non-metallic filament line(s) or freely pivoting non-metallic cutter(s)". A lawnmower may be a walk-behind or ride-on grass cutting machine or a machine with grass-cutting attachment(s) where the cutting device is rotating about a horizontal axis to provide a shearing action with a stationary cutter bar or knife (cylinder mower).

108 The definition comes from EN 836

Chain saws

A chainsaw (or chain saw) is a portable mechanical saw, having teeth that are linked to form an endless chain, rotated about two pivot points by a power mechanism that can be an electric motor, a gasoline engine, compressed air, hydraulic power.

Brush cutters[109]

A brush cutter is a combustion-engine driven portable hand-held unit fitted with a rotating blade made of metal or plastic intended to cut weeds, brush, small trees and similar vegetation. The cutting device operates in a plane approximately parallel to the ground.

Market size and industry structure

Data available from Eurostat PRODCOM database already provide relatively detailed data on the level of production and trade of chain saws, lawnmowers and cutters. The following PRODCOM codes fit rather well with the specific product groups under examination:

- 28241180 - Electro-mechanical hedge trimmers and lawn edge cutters
- 28304010 - Electric mowers for lawns, parks, golf courses or sports grounds
- 28304030 - Mowers for lawns, parks or sports grounds, powered non-electrically, with the cutting device rotating in a horizontal plane
- 28304050 - Motor mowers for lawns, parks or sports grounds, powered non-electrically, with the cutting device rotating in a vertical plane or with cutter bars
- 28304070 - Non-motorized mowers for lawns, parks, golf courses or sports grounds (such as push cylinder mowers) (excluding with the cutting device rotating in a horizontal plane)
- 28241123 - Electro-mechanical chainsaws
- 28241260 - Chainsaws with a self-contained non-electric motor

The data analysis suggests a total market size (production+ imports – exports) of around €2.5 billion for those categories with a total volume of 23 million chain saws, lawn mowers, trimmers and cutters sold. Imports are, according to PRODCOM, close to 60% of to total consumptions. Our interviews with manufacturers suggest that this is a reflection of the important role of non-EU producers (US firms are particularly strong in certain segment) but also the fact that many EU producers have transferred part of their production capacity outside Europe but with most of the production re-imported to the EU. Along with the US market (50% of the global sales), the European market remains the most important market for gardening equipment (35%).

109 The definition comes from EN ISO 11806

Table 7-27: PRODCOM data for Lawn mowers, trimmers, cutters and chain saws (2010)

Product code	Export quantity (000s)	Export value (millions)	Import quantity (000s)	Import value (million €s)	Production quantity (000s)	Production Value (million €s)	Total quantity (000s)	Total Value (million €s)
28241180	650	23	5,881	122	1,510	63	**6,741**	**162**
28304010	340	28	1,461	64	2,826	169	**3,947**	**205**
28304030	264	62	1,774	389	3,375	862	**4,885**	**1189**
28304050	7	11	194	88	21	36	**208**	**113**
28304070	49	4	187	6	150	23	**288**	**25**
28241123	180	16	1,317	49	517	51	**1,654**	**84**
28241260	99	13	2,817	192	2,341	564	**5,059**	**743**
Total	**1,589**	**157**	**13,631**	**910**	**10,740**	**1,768**	**22,782**	**2,521**

Source: Eurostat

Data from the European garden machinery federation (EGMF) deviate slightly from PRODCOM suggesting a EU market size of around 15.1 million gardening equipment products of which around 6 million are lawnmowers and 3 million are brush-cutters. There are also 3 million hedge-trimmers and 4.5 million chainsaws sold on an annual basis[110]. According to another study[111], around 4.5 million lawnmowers are sold annually in the EU with chain saws, hedge trimmers and lawn trimmers also being at a 7-digit level.

According to an earlier study[112] around 90% of sold lawnmowers on the European market are of the walk-behind type with cutting blade widths up to 50 cm, while the sales of ride-on is around 300,000 units.

Data from the UK[113] indicate that the consumer market represents around 60% of the total gardening products market with the remaining directed to professional users. Another study[114] raised the consumer segment in the whole of the EU to 75%. Lawn mowers represent around 40% of the consumer gardening equipment market in the UK (based on retail sales) with another 35% going to various types of power tools such as chain saws, cutters and trimmers.

110 http://www.egmf.org/en/economic-information/

111 Data from the UK indicate that the consumer market represents around 60% of the total gardening products market with the remaining directed to professional users. Lawn mowers represented around 40% of the consumer gardening equipment market in the UK (based on retail sales) with another 35% going to various types of power tools such as chain saws, cutters and trimmers.

111 According to the EGMF, its members sell in Europe more than 6 million lawnmowers, 4.5 million chainsaws, 3 million brush-cutters and 3 million hedge-trimmers on annual basis

111 http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/iastudy_noise_finrep_en.pdf

112 'Lawn Mover Noise and Vibration Control' study (Tetteroo & Bockhoff, 2006) cited in http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/iastudy_noise_finrep_en.pdf

113 http://www.britishgardenshed.co.uk/uk_market.htm

114 NOMEVAL (TNO, 2007)

Professional equipment has a relatively short lifespan of 2 years with an average usage of 150 hours per year. Consumer equipment has a lower usage rate of around 5 hours per year with a typical lifespan of several years[115].

Table 7-28: Data on market size and industry structure

Parameter	Data
EU Market size (2012)	EGMF: 10 million units for the whole Europe (39 countries) PRODCOM : 22.7 million units, € 2.5 billion
Production in EU27	PRODCOM : 10.7 million units, € 1.8 billion
Imports	PRODCOM : 13.6 million units, € 0.9 billion
Exports	PRODCOM : 1.6 million units, € 0.16 billion
Number of enterprises (2010)	20 large firms
Number of employees (2012)	30,000 employees (EGMF) 120,000 in dealers

Source: Eurostat

Industry structure

Eurostat data are not particularly useful when it comes to analysing the structure of the industry. There are two relevant NACE codes (28.24 - Manufacture of power-driven hand tools; 28.30 - Manufacture of agricultural and forestry machinery) which are much broader in scope and do not allow for meaningful conclusions.

The information provided by EGMF suggests that the consumers market is dominated by 20 large size companies that occupy around 30,000 employees. This has been the result of a significant consolidation phase in the last twenty years which has led to few large players bringing together small and medium size manufacturers while retaining the brand names and the production units across Europe. Brand awareness is relatively high among consumers, and technological barriers also make it difficult for new competitors to enter the market. The tendency is explained by the high fixed costs faced by individual product lines. According to one estimates that development costs correspond to 5% of its turnover[116]. The 13 members of EGMF- including both large multinationals and smaller size firms - cover almost 75% of the European market. The main players in the market – although this may differ in the different sub-sectors – are Husqvarna (SE), Stihl (DE), Bosch (DE), Global Garden Products (IT), MTD (US), Toro (US), John Deere (S), Stanley Black and Decker (US), Echo (DE), TTI (HK) and Makita. [117]

In the professionals market there are a few SMEs producing a wide variety of models and there are 147 brands and 1500 models for lawnmowers. Still, around 80% of the European market for professional handheld internal combustion engine powered equipment is covered

115 http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/tno_nomevalrep12-12-07_en.pdf

116 SME Test Study on possible policy options for reviewing the Noise Directive + Impact Assessment Study on possible policy options (concerning conformity assessment procedures) for reviewing the Noise Directive), http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/smetest_noise_finrep_en.pdf (p.59)

117 Data retrieved from Euromonitor international Passport database (accessed from British library)

by 4 European companies. SMEs are niche players, with specialised knowledge of specific client needs.

Analysis of applicable Union harmonisation legislation and standards

Chain saws, lawn mowers and brush cutters (gardening equipment) are covered by a large number of Union harmonisation Directives and Regulations covering a range of aspects:

- **Health and safety**: The Machinery Directive (2006/42/EC) is the main applicable legislation for all products. In the case of electricity/battery powered products requirements of the Low Voltage also apply but not the procedures and information obligations that are covered by the Machinery Directive. In the case of lawn mowers, brush cutters self-certification (Module A) can be used for conformity assessment. In the case of chain saws which are included in Annex IV, third party certification from a notified body is required.

- The **General Product Safety Directive** (2001/95/EC) is also applicable but does not introduce additional requirements to refrigerators since these are covered by the other more specific pieces of legislation. It does introduce however other obligations, mainly of administrative nature;

- **Electromagnetic compatibility**: The EMC Directive applies to all powered gardening equipment.

- **Noise**: The Outdoor Noise Directive (2000/14/EC) is particularly relevant to gardening equipment and introduces requirements concerning the sound power level which needs to be measured under specific conditions. It also requires that manufacturers submit a copy of the Declaration of Conformity (DoC) to the Member State authorities and the Commission.

- **Pollutant Emissions**: Gardening equipment have been covered by the Directive 2002/88/EC on Gaseous Emissions of non road mobile machinery (NRMM) since 2004. It covers spark ignited (SI) engines (petrol engines) up to 18 kW for engines installed in and held and non-handheld equipment such as lawn and garden machines. Certain small SI engine applications (including some trimmers) were exempted from the Stage II emission limits but these exemptions expired at the end of the first quarter of 2011. However, it should be noted that many manufacturers of gardening equipment purchase the engines from dedicated suppliers which have the responsibility to ensure compliance with the NRMM.

- **Chemicals**: Both RoHS Directives and REACH Regulation certain obligations to manufacturers of gardening equipment in terms of the chemicals included in the equipment. As downstream users, under REACH gardening equipment manufacturers need to ensure that the products do not contain substances of very high concern and, if they do, they need to pass information to their customers.

In addition, for certain type of gardening equipment products there are additional pieces of Union harmonisation legislation applicable:

- for battery based products the Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators

- for products with remote control features using wireless technology, the RED is also applicable

The following table analyses the main requirements arising for economic operators as a result of the different pieces of IM legislation and indicates the relevant harmonised and other standards applicable.

Table 7-29: Summary of Union harmonisation legislation covering refrigerators and freezers and the relevant standards

Name of legislation	Issue addressed	Requirements for economic operators	Relevant standards[118]
Machinery (2006/42/EC)	Safety	Requirements concerning safety and health of lawn mowers Information warnings and pictograms Conformity assessment on the basis of self-certification (module A) – Except for chain saws Develop technical file to be available upon request of authorities Declaration of conformity Marking of product (CE marking, name of manufacturer, type, series, year of construction)	EN 836 [119] EN ISO 5395-1/2/3 [120] EN 11681-2[121] EN ISO 11806 EN 60335-2-91/ EN 60335–2-77/EN 60335-2-107/EN 60745-2-13
LVD	Health & Safety	Testing according to relevant standards or alternative solutions (other requirements under Machinery)	EN 60335-1
General product safety Directive	Health & Safety	Provide identification of the product by a product reference Carry out sample testing of products, keep a register of complaints and keeping distributors informed of such monitoring (voluntary) Inform authorities of dangerous products and actions taken to prevent risk Co-operate with the authorities upon request	
EMC	Electromagnetic compatibility (for electric powered equipment)	Testing according to standards Development of technical file Declaration of conformity and CE marking	EN 61000-6-1 EN 61000-6-2 EN 61000-6-3 EN ISO14982

118 The list of standards is not exhaustive. Furthermore, not all standards identified are applicable to all products.
119 safety of powered lawnmowers
120 safety of electrically powered lawn mowers
121 Machinery for forestry - Portable chain saws - Safety and testing requirements

Name of legislation	Issue addressed	Requirements for economic operators	Relevant standards[118]
NRMM Emissions (97/68/EC and amendments)	Emissions of ride-on combustion engine powered lawn mowers	Application for type approval of engine or engine type Information dossier Testing of engines Approval by technical service Affix label with EC type approval marking with ID number and information on engine type and trade mark	
Outdoor noise Directive (2000/14/EC)	Noise	Meet sound level requirements (Stage II levels for most gardening equipment) Conformity assessment (Modules A and control by notified bodies, G,H) Declaration of conformity Place CE marking and marking of the guaranteed sound power level Send copy of DoC with information on measured and guaranteed sound to national authorities and the Commission (complete information in database)	EN ISO 3744[122]: **1995** ISO 10884:1995/ISO 9207:1995/ISO 11094:1991[123] EN ISO 22868[124] EN ISO 11094[125] EN ISO 4871[126]
REACH	Use of chemicals	Collect statement from suppliers stating that products are in compliance with requirements concerning chemical content of components Test the content of articles of products for substance of very high concern (not mandatory) Issue REACH compliance statement	
RoHS	Use of hazardous chemicals	Collect compliance statement from suppliers (material declarations) Develop technical file with supplier declarations and own analysis tests Declaration of conformity to be kept for 10 years	

122 Determination of sound power levels and sound energy levels of noise sources
123 Test area standard for different categories
124 noise test for internal combustion lawn mowers, brush cutters, trimmers
125 test code of airborne emissions for powered mower
126 Declaration and verification of noise emission values of machinery and equipment

Name of legislation	Issue addressed	Requirements for economic operators	Relevant standards[118]
Batteries Directive (2006/66/EC)	Heavy metal content and labelling of batteries	Forbids placing on the market batteries/ accumulators containing mercury or cadmium Design products so that batteries can be removed Information on the type of battery used Contribute to costs for establishment of battery collection schemes at national level (applies in some cases)	
Packaging and packaging waste	Packaging	Declaration of Conformity	Standard EN 13427

The review of the various requirements and the discussions with manufacturers pointed to a few issues in relation to the implementation of the legal framework and the requirements:

- large number of applicable pieces of legislation makes the whole system complex and increases legal uncertainty. The changes to the different pieces of legislation or the relevant standard in different periods also means that, quite often, firms need to introduce changes to product design, procedures, declaration forms or produced information manual which larger or smaller cost implications;

- an area of concern indicated by some firms is the problematic relationship between the Machinery and the outdoor noise Directive. A key issue indicated is that for the measurement of sound power level which falls under the Outdoor Noise Directive there is still reference to the outdated 1995 version of the ISO/EN 3744 standard while, for those products not covered by the outdoor noise, but covered by the Machinery Directive the most recent 2010 version is used. More generally, in the recent consultation[127] 80% of the respondents expressed the wish to merge the methods of measuring noise emissions required under both directives into a single Harmonised Standard;

- duplication in parts of the certification process – mainly the fees to the third parties - in the case where manufacturers sell to other firms products similar to those they sell under their own brands with only minor- cosmetic – differences (e.g. different color). For these products, which are identical with those that have already undergone conformity assessment but have a different name (model number), manufacturers are required to pay additional fees;

- firms indicate that, while there have been clear benefits from the harmonisation of the applicable legislation, there are significant problems with market surveillance which, in their view, means that much cheaper, lower quality and arguably non-compliant products circulate in the market;

127 Public consultation on the revision of Directive 2000/14/EC on noise from outdoor Equipment, http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/public-consultation/report_en.pdf

- the review of the requirements of the Declaration of Conformity indicate minor differences in terms of the terminology used or the type of information to be provided. However, the discussion with industry did not suggest important conflicts or problems. Still, the alignment process across all Directives is considered rather welcome.

Analysis of costs of compliance with Union harmonisation legislation

The information presented in this section is based on the in-depth interviews with 5 manufactures of gardening equipment. The firms range in terms of size and production volume. They also have different approaches in terms of the level of testing and other R&D activities they perform that are not a direct result of the legislation which is a reflection of their size and position in the market.

Table 7-30: Basic information on the firms interviewed

Firm	Specific product considered	Firm size	Annual sales from product	Main markets
A	Brush cutters	Large (>1000 employees)	1 million units	50% of sales in the EU
B	Lawn mowers	Large (>1000 employees)	1 million units	90% of sales in the EU
C	Lawn mowers	Medium (250-500 employees)	200,000 units	90% of sales in the EU
D	Lawn mowers	Small (<250 employees)	15,000 units	100% of sales in the EU
E	Chain saws	Medium size (250-500)	100,000 units	50% in the EU

On the basis of the discussion with firms the process followed by manufacturers of gardening equipment to ensure compliance with the Union harmonisation legislation includes:

- familiarisation with the applicable Union harmonisation legislation and the respective requirements, identification and purchase of relevant standards and in some cases other preparatory actions in training of staff.

- introduction of changes to the product design and the production process to ensure compliance

- conformity assessment procedures including the relevant testing and the development of the technical file, the use of notified bodies for certification if/when required, preparation of declaration of conformity (DoC), CE marking and placing in the market

- other activities in response to requests of the market surveillance activities

Preparatory actions: Familiarisation with relevant legislation and purchase of standards

Familiarisation with Union harmonisation legislation and the respective requirements represents a first task for all firms. Almost all firms indicated that this is not a particularly demanding part of the process and it usually corresponds to no more than 0.1-0.2 FTE of a member of the legal compliance team. However, most firms also indicated that the R&D or homologation departments try to monitor developments in the legislation and one of them even performs a scenario analysis aiming to prepare for alternative scenarios.

All firms interviewed indicated that they maintain a database of the relevant pieces of legislation which is continuously updated and also includes information in relation to the relevant/applicable standards. Maintenance and update of the database usually occupies an employee of the firms compliance/homologation department on a part-time basis. The sophistication of the database tends to be greater for larger size firms.

In relation to use of standards all firms consider them crucial in the conformity assessment process. The information provided suggest that firms typically spend €500-€2,000 on an annual basis for the purchase and update of standards and the reading licences for their various departments for a single product line (e.g. lawn mowers), for which 15-20 different standards are applicable.

Compliance with the applicable Union harmonisation legislation.

Ensuring compliance with the applicable Union harmonisation legislation often requires changes to existing product design or new product development. Furthermore, the introduction of new products requires product design work and testing to ensure that the new products are in compliance with requirements. While in most cases new product development is driven by market demand there are also cases where product development and R&D activity are primarily driven by legal requirements. More specifically, most firms indicated that the Non-Road Mobile Machinery (NRMM) and the Outdoor Noise Directives have led to significant level of investment. In the case of the NRMM, some firms purchase the combustion engines from suppliers and do not perform own research.

Large size Firm A indicated that around 3% of its annual R&D budget of €50-60 million invested to the development of a new product is directly related to ensuring compliance with internal market legislation (circa €4 million). On top of that they have made one of investments of around €10 million in tooling/equipment during the last five years. Small size firm D indicated annual costs for product design of €200-300k while medium size Firm C around €2 million. The amounts invested on product design vary depending on the firms' size but, on the basis of the data provided, the total investment on an annual basis is around €500,000 for every 100,000 units of production.

Testing of products is an important part of these costs. It includes tests directly related to the Union harmonisation legislation but also product performance and durability. For the large scale producers, these tests take place primarily in-house on an ongoing basis while for smaller firms these are often outsourced. Firm B suggested that around 15% of the budget and time of the 30 researchers and engineers working full time in the R&D department with around 30 FTE allocated to tests required by IM legislation for product homologation. The other firms indicated costs in the range of €200-700k.

Certain directives (NRMM, Outdoor noise) require specific testing facilities. Large size manufacturers may purchase for their internal controls while in other cases these may be outsourced to specialised labs. Estimates for the one-off costs for the purchase of testing equipment from large Firm A are around €30 million covering all products in the product line and all applicable Directives. €5 million were spent for chemical analysis equipment for REACH testing and €5 million for a sound chamber for outdoor noise tests. However, it should be noted that REACH related testing is not mandatory and it reflects the specific policy of this company that is not replicated among the smaller size manufacturers. Most other firms indicated smaller size investments in the range of 100-1,000,000 which were also confirmed from another data source (€0.6 million for noise measuring room).

The discussion with firms suggest that, on average, around 50% of the testing activities are directly related to Union harmonisation legislation while the remaining is part of the quality and durability testing of products. The outdoor noise and the NRMM are for most firms the pieces of Union harmonisation legislation that introduce most costs.

Conformity assessment procedures

The information provided from manufacturers is that the whole process of conformity assessment of a new product tends to last around 9 months in total. This includes the preparation of the technical file, the inspection of the notified bodies and certification, preparation of the DoC and the required information manual and the placing of the CE marking.

The estimated time for the preparation of technical file for a single product ranges from 40-100 hrs[128] with around half of the time required whenever there are significant changes to legislation.

In terms of the use of notified bodies, which is mandatory in the case of the Outdoor Noise Directive, all firms indicated that they are used even when a third party is not mandatory. The data provided suggest that the annual budget of firms for services of Notified Bodies is in the range of €30-80k, around €4,000 for a single product.

The costs for notified bodies increase for firms that produce multiple variants of the same model with the same technical characteristics. Customs authorities often do not allow the placing of products on the market if the model is not the same as that indicated in the label attached. As suggested, the current label does not allow for the provision of information that will allow to identify both the basic model and its variant. There is additional administrative work created for every new variant of the same basic model (i.e. same product with only differences in colours and brand name). This also means costs for new labels, changes to relevant references in the instruction manual and fees (around €700/product and additional time of around 4 weeks) to notified bodies every time they need to certify that the initial technical file is also appropriate for the new model.

The interaction of the CE marking with other labelling appears also somehow problematic for some of the firms and introduces costs that, in principle they need not incur. More specifically Firm B indicated that while the firm did not consider it necessary to apply for the German GS mark, it was in practice obliged in order to be able to sale in the German market as many

128 One firm indicated 300hrs but this deviated from all others.

retailers do not accept products without the GS mark. The cost for the GS mark certification of each model is around €1,200 and this needs to be renewed every 5 years for a bill of around €700. There is also a €800 annual fee charged by GS. In total, the annual bill for Firm B to get the GS mark certificate for all its lawn mower products placed in the German market is around €32,000.

Provisions of relevant information in the instruction manuals are also included in all Directives. There were no specific data provided for the time to develop the information manual. For most firms these are seen as part of the overall time for the conformity assessment process. Translation costs are also relevant here with average costs of around €3,000 for each different model.

In the case of products covered by the Outdoor Noise Directive additional information provision obligations arise since firms are required to submit information included in the DoC to the national and European authorities. One firm estimated that it can take up to 80 hours for the 20 different brush cutter models in its production line.

Certain information collection obligations arise from REACH Regulation. The main work is the collection of information from suppliers to ensure that no SVHCs are included. In the case of Firm A, around one FTE is allocated to the collection of this information from suppliers. One of the firms also conducts its own testing of the chemical content of certain components with annual costs for all products are around €500k. However, this is rather the exception. Most other firms are limited to the collection of declaration of conformity from their suppliers which is the responsibility of the purchases department.

Finally, under the NRMM there is the obligation to submit data to the national and European Database. While there are some problems with the process – sometimes difficult to update and problematic when introducing a new model with lower noise emissions – firms could not provide specific data on the specific time allocated and suggested that it is part of the work of the compliance/homologation department.

Business as usual

The discussion with firms indicates that a rather important part of the activities and the respective costs would not have taken place in the absence of the legislation. Firms estimated that, in total, between 10% and 35% of the compliance costs (substantive and administrative) would have incurred even in the absence of any legislation

Assessment of costs of Union harmonisation legislation for the whole sector

On the basis of the information provided we have attempted to estimate the costs of compliance for the whole of the gardening equipment sector. The provided figures include the information concerning the Business as usual scenario (i.e. the fact that 10-35% of the product development costs should be expected to occur irrespective). Certain assumptions have been made concerning the number of firms affected since, besides the 20 large firms indicated by EGMF, there are also a number of smaller size manufacturers particularly in the professional market segment.

The table below summarizes the main costs per unit and for the total of the industry. As is evident costs for product design and testing represent more than 85% the total costs of compliance.

Table 7-31: Summary of main annual costs of compliance for gardening equipment manufacturing industry

	Unit of measurement	Average unit cost	Total quantity	Industry wide costs/year
Familiarisation with legislation/support actions				
- human resources	per manufacturer	€ 11,520	100[129]	€ 1,152,000
- costs of purchase of standards	per manufacturer and per product line	€ 1,250	500[130]	€ 625,000
Compliance with IM-legislation requirements				
- Product (re)design and testing	per 100.000 units	€ 500,000	22.7 million/year	€ 113,500,000
Share of product design and testing costs that would apply even in the absence of the legislation				10-35%
Net product design and testing costs				**73,775,000-€102,150,000**
- Testing equipment[131]	per manufacturer	€ 100,000	100[21]	€ 10,000,000
Share of product design and testing costs that would apply even in the absence of the legislation				10-35%%
Net costs for testing equipment				**€1,000,000-€3,500,000**
Conformity Assessment				
- Preparation of technical file	per single model	€ 2,100	375[132]	€ 787,500
- Costs of notified bodies	per single product	€ 4,000	375[23]	€ 1,500,000
- requirement for new labelling	per single model (once in four years)	€ 700	375[23]	€ 262,500

129 We have assumed 20 large size firms (members of the EGMF) and 30-80 small firms
130 On the basis of an average of 5 product lines on average per manufacturer
131 Investment in testing equipment is usually one-off and last for at least 5 years. The costs provided here have been estimated on an annual basis.
132 Number based on an assumption of 15 models/firm once in four years

	Unit of measurement	Average unit cost	Total quantity	Industry wide costs/year
- translation costs	per single model (once in four years)	€ 3,000	375[23]	€ 1,125,000
Other				
- Submission of information for outdoor noise Directive	per manufacturer	€ 2,400	100[21]	€ 240,000
- Collection of REACH information	per manufacturer	€ 25,000	100[21]	€ 2,500,000
Total				**€85,467,000-111,342,000**

The estimated costs for the sector are in the range of €85-112 million/year which represent 3-5% of the total annual turnover of 2.5billion of the sector. This is a rather high share but the administrative costs – namely excluding product design and testing - are no more than 10%-15% of the total costs and less than 0.3% of the annual turnover of the sector.

Conclusions

Gardening equipment covered in this case study includes chain saws, lawn mowers and brush cutters. These categories represent the main sales volume of the broader garden machinery equipment group of products which also includes various types of trimmers, vacuums and blowers, leaf blowers, leaf collectors, motor hoes, scarifiers, shredders/chippers and pruners. The total annual market size of gardening equipment is estimated at around €2.5 billion for those categories with a total volume of 23 million sold. The consumer segment of the gardening equipment market is dominated by 20 large size companies while in the case of professional equipment there is a greater number of SMEs serving niche segments.

Gardening equipment is covered by more than 10 different pieces of Union harmonisation legislation (Directives and Regulations) covering a range of aspects including health and safety, environmental aspects (noise, pollutants, toxic from batteries).

For the whole sector the estimated annual costs are in the range of €85-112 million which represent a rather significant 3-5% of the total annual turnover of €2.5billion of the sector. This is driven by the high compliance costs associated with the environmental IM legislation (outdoor noise, outdoor emissions) both of which required changes in the design and rather sizeable costs for testing equipment (one-off) and on-going testing of products, only a small proportion of which is considered to be "business as usual" for most firms. Administrative costs – such as costs for documentation, fees to notified bodies, the preparation and updating of technical files, purchasing standards, the development of manuals - are no more than 10%-15% of the total costs and no more than 0.3% of the annual turnover of the sector.

Sources of information

References - Sources

1. http://www.egmf.org/en/economic-information/

2. 'Lawn Mover Noise and Vibration Control' study (Tetteroo & Bockhoff, 2006) cited in http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/iastudy_noise_finrep_en.pdf

3. NOMEVAL (TNO, 2007), http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/tno_nomevalrep12-12-07_en.pdf

4. http://ec.europa.eu/enterprise/sectors/mechanical/files/noise/smetest_noise_finrep_en.pdf

5. Euromonitor international: Home and Garden market analysis

Interviews

- Industry association : European Gardening equipment manufacturers associations (EGMF)

- 5 interviews with manufacturers of lawn mowers, chain saws and brush cutters

3.10.6 Case study 6 – Fuel Dispensers (Measuring Instruments)

Introduction - objectives of the study

This case study focuses on fuel dispensers which are classified as instruments and appliances for measuring, testing and navigation (hereinafter measuring instruments) and are covered under the Measuring Instruments Directive (MID). The manufacturing of fuel dispensers is also regulated by a number of other pieces of EU legislation, such as ATEX and the Petrol Vapour Recovery Directives.

The rationale for the selection of fuel dispensers was that:

- The sector, while dominated by four large firms, also includes a large number of SMEs;
- The legislation allows for the use of internationally-agreed normative documents, as an alternative to the use of harmonised standards;
- The MID is one of the Directives that form part of the Alignment Package; and
- The case has the potential to demonstrate the advantages of coherent interaction and clear demarcations between different pieces of legislation, in order to ensure legal clarity for economic operators.

The information presented in this case study was obtained from a variety of sources including Eurostat data, official EU documents, industry association documents and interviews with four major firms in the sector.

Product definition and description of structure of the sector

Product definition

Fuel dispensers are classified under NACE code 28.13 (manufacture of other pumps and compressors) and correspond solely to the PRODCOM Code 28131105: petrol and oil dispensing pumps.

Fuel dispensers are described as machines combining a pump and point-of-sale (POS) system and pumping fuel into motor vehicles. A Point of Sale (POS) system is a system for managing the sales of goods. The term refers to the software and hardware associated with check -out stands, and all of the bundled features which are included.

A modern fuel dispenser is typically divided into two main parts: an electronic part containing an embedded computer to control the action of the pump, drive the pump's displays, and communicate to a sales system; and secondly, the mechanical section which in a self-contained unit has an electric motor, pumping unit, meters, and valves to physically pump and control the fuel flow.

Market size

Fuel dispensers have an annual life cycle of 12 years and, on this basis, there are currently

around 300,000 fuel dispensers installed across the EU[133]. The size of the European market can be estimated on the basis of a total production value of around €360 million in 2012 based on a unit price of around €1,100[134]. According to PRODCOM data on fuel dispensers, around 16% of the production of Europe is exported outside EU while imports represent no more than 3% of the market.

PRODCOM data shows that a total of about 350,000 petrol and oil dispensing pumps were produced in Europe in 2012. Manufacturing in this sector is strongly export-oriented and has generated a significant volume of exports, although the interviews found that a lot of manufacturing that used to take place within the EU has been moved to lower-cost producer countries outside the EU.

Table 7-32: Production and value of petrol and oil dispensing pumps in EU27 in 2012 – PRODCOM Code 28131105

Export Quantity (Units)	Export Value (€)	Imports Quantity (Units)	Imports Value (€)	Production Quantity (Units)	Production Value (€)	Consumption Value € (Production + Imports - Exports)
347,309	148,672,970	245,102	15,171,090	349,038	357,890,334	224,388,454

Source: Eurostat

Industry structure

There are around 20 producers of fuel dispensers for petrol stations[135]. The major manufacturers include Gilbarco, Tokheim, Petrotec and Dresser Wayne with a presence across Europe and more than 60% market share[136]. The remaining manufacturers are present in only a few Member States. It is also estimated that the main companies in the sector employ around 10,000 employees without referring to importers or local distributors[137]. Altogether, the petrol pump sector employs about 14,000 to 16,000 workers[138].

Analysis of applicable Union harmonisation legislation

As noted above, the manufacture of fuel dispensers is covered by the Measuring Instruments Directive and by a number of other Directives, such as ATEX and the Petrol Vapour Recovery Directives. The table below provides a summary.

133 Figure also obtained after analysing PRODCOM annual production statistics
134 PRODCOM data from 2012
135 CSES (2010), Interim Evaluation of the Measuring Instrument Directive
136 Ibid;
137 Ibid;
138 PRODCOM data, 2010; cf. CSES (2010), Interim Evaluation of the Measuring Instruments Directive, page iii

Table 7-33: EU Legislation applicable to fuel dispensers

Applicable legislation	Issue addressed	Requirements for economic operators
Directive on Measuring Instruments (MID)	Legal metrological control	• Conformity assessment: obligation of the installer/manufacturer • Produce a DoC • Keep technical documentation copies of EC type-examination certificates and their additions for 10 years • CE marking and additional metrology marking must be visibly affixed to products
ATEX Directive	Risks relating to equipment used in potentially explosive atmospheres	• Conformity assessment – either by the manufacturer or a subcontractor of the manufacturer to a Notified Body • Produce a DoC • Keep technical documentation copies of EC type-examination certificates and their additions for a period of 10 years • CE marking must be visibly affixed to products • Additional markings of certain components for safety purposes
Petrol Vapour Recovery Directive (94/63/EC)	Reduction of emissions	• Conformity assessment with administrative fee charged by the Member State • Marking (pictogram sticker) certifying the equipment includes a petrol vapour recovery system
National Emission Ceiling Directive (2001/81/EC)	Reduction of emissions	• Same as above given that the directive relates to the reduction of emissions of volatile organic compound (VOC), i.e. petrol vapour • Administrative requirements depend on specific national measures
EMC Directive	Electromagnetic compatibility (for electric powered equipment)	• Testing products for Electromagnetic Compatibility interference • Conformity assessment procedure for apparatus mandatory • CE marking on apparatus required in accordance with Annex V.
LVD	Health and safety	• Conformity assessment – either by the manufacturer or a subcontractor of the manufacturer to a Notified Body • Develop a technical file (see Annex IV of LVD) • Produce a DoC • Keep technical documentation copies of EC type-examination certificates and their additions for a period of 10 years • CE marking must be visibly affixed to products • Provide installation instruction manual for installers

The nature of fuel dispensers is such that they require regulation covering different perspectives, notably accuracy and reliability in measurement, minimisation of the risks of explosion and protection of the environment. This inevitably requires multiple pieces of legislation, creating the risk that the overall framework is not coherent.

The interviews with the major companies in the sector suggest that the EU legislative framework pertaining to fuel dispensers has in fact become more coherent over the years,

albeit with some gaps and inconsistencies remaining. Whilst EU legislation on measuring instruments dates back to the early 1970s, MID represented a considerable simplification, since it replaced eleven previous directives, all covering different products.

The ATEX Directive was introduced in 1993. Hitherto, manufacturers were required to satisfy different national legislative requirements in each country in which they operated, whilst meeting European requirements on MID. Since the introduction of ATEX, each manufacturer has been able to gain certification from one Notified Body for its sales across the EU. MID and ATEX side-by-side have thus served to reduce barriers to the free movement of goods in the internal market – as evidenced by the process of consolidation in the industry over the last two decades, as manufacturers exploit economies of scale. Indeed, the technical parts of fuel dispensers now tend to be the same across different Member States. Moreover, the credibility of this legislative framework has also assisted manufacturers in their efforts to export to third countries. MID was also reported to be consistent and complementary to the more recent RoHS Directive.

The consistency of the legislative framework for fuel dispensers is also enhanced by the use of internationally-agreed normative documents, namely those of the International Organization of Legal Metrology (OIML). This has tended to make European products immediately marketable to third countries that apply the OIML standards. The one downside of this approach is, however, that EU manufacturers exert less influence on the specification of the standards than they do on EU standards, such as those of the ATEX Directive.

Despite this generally positive situation, there are still some inconsistencies among the applicable Directives and Regulations. More specifically, the definition of "large-scale fixed installation" within RoHS is criticised as being too vague. Definitions applicable to fuel dispensers also appear to differ between Directives, with for instance the EMC Directive treating a dispenser as a single machine, whereas MID treats it as a collection of several measuring instruments[139].The MID Annex MI-005 distinguishes between individual measuring systems (i.e. fuel dispensers) and self-service arrangements (of fuel dispensers).

There remains debate over the desirability of having an annex of the MID devoted exclusively to fuel dispensers. Annex MI-005 covers "measuring systems for continuous and dynamic measurement of quantities of liquids other than water"[140] and defines and covers all the relevant essential requirements for metrology (and refers to voluntary standards that give presumption of conformity can be more specific). It therefore can be applied to the case of fuel dispensers and, indeed, it defines flow ranges specifically for fuel dispensers. However, the industry associations and manufacturers consulted were of the view that an annex specifically devoted to fuel dispensers would be preferable and ease the process (and thus the costs) of compliance.

It was also reported by the companies interviewed that some fuel dispenser products or components covered by ATEX and PED are not covered by MID, e.g. automatic feed nozzles and pressure valves. Although these components are not directly relevant to measuring, they can have an effect on accuracy of measurement. As a result, certification requirements can differ for each piece of legislation. According to the companies and industry associations interviewed, this can lead to conflicts between approval bodies which results in an unnecessary multiplication of conformity tests and an increase in administrative work.

139 EMC Article 2 (a) (b) (c), Annex MI-005
140 Annex MI-005

A major issue is the fact that EU legislation does not address the connection between fuel dispensers and forecourt point-of-sale (POS) systems, which are not covered by EU legislation. Indeed, it was reported that it was impossible for MID-approved fuel dispensers to be connected to equipment with national certificates only such as pre-MID POS systems. . Since retailers, including small supermarkets, have contracts with POS systems providers, this can cause difficulties[141]. Moreover, the legislation does not cover the provision of regular checks and recalibration of fuel dispensers once installed; as with other New Approach Directives, MID is only concerned with the placement of a product on the market and its installation. Whilst this does not affect the free movement of products, it does affect the free movement of services, with such services tending to be provided mostly by nationally-based operators.

It was also proposed by some of the companies interviewed that the legislative framework (notably MID) needs to be extended to cover additional types of fuel dispensers, particularly compressed natural gas dispensers (CNGD), which are currently subject to national legislation. Although mutual recognition under Art 34 of the TFEU applies to CNGD, this is only valid when countries accept this. CNG is regulated under OIML R139[142] and for many years, each country has required its own type approvals. Whilst mutual recognition could be a means of allowing products to circulate freely, the risk is that national authorities to allow such products to be placed on the market in the absence of national certificates. In contrast, liquid natural gas dispensers (LNGD) are subject to MID despite accounting for lower volumes of trade. There are around 5,000 to 10,000 petrol stations equipped with CNGD while there are only around 100 stations equipped with LNGD across Europe. CNG is for cars while LNG is for trucks. CNGD are available in petrol stations along with normal MID-approved fuel dispensers and LPG dispensers, while LNGD are most likely to be found in dedicated petrol stations. Given the barriers to the circulation of CNGD products, the risk is that manufacturers face higher costs than if such products were covered by EU legislation and are be unable to exploit economies of scale in production.

Analysis of costs of compliance with Union harmonisation legislation

Analysis of the costs of compliance has been based on interviews with four large companies that serve the EU27 market and export globally, as well as two industry associations. The table provides information on the firms interviewed.

Table 7-34: Basic information on the firms interviewed

Firm	Specific/main product (if a specific sub category)	Firm size	Annual sales from product	Main markets
A	Pumps & dispensers	Large (4,000 employees)	10,000 units	50% of sales in the EU
B	Pumps & dispensers	Large (>1,000 employees)	15,000 units	82% of sales in the EU

141 There is a period of transition up till 2016, after which all new POS must be MID compliant
142 International Organisation of Legal Metrology (OIML) R139: Compressed gaseous fuel measuring systems for vehicles

Firm	Specific/main product (if a specific sub category)	Firm size	Annual sales from product	Main markets
C	Gasoline Dispensers, payment solutions for petrol stations	Large (5,400 employees globally)	Not known	60% of sales in the EU
D	Fuel management and dispensing systems, service station hardware	Large (3,200 employees)	15,000 units	33% of sales in the EU

Step 1: Familiarisation with the legislation and relevant obligations, as well as preparatory actions

For all the companies interviewed, identifying and reviewing the requirements of the legislation, the relevant standards and the resultant information obligations is a relatively costly activity. Two companies offered an estimate of the relative share of this task in the overall cost of Step 1: 50% and 60% respectively. Membership of the relevant industry associations at EU and/or national level, e.g. CECOD, is vital to this task and, of course, involves a membership fee. Whilst membership of industry associations serves a wider purpose (and is thus a business-as-usual cost), much of the rationale for and benefit of membership is related to receiving information about the legislation and the standards – and also to being able to influence the legislation and the standards at the EU level.

As well as receiving information through the industry associations, all the companies employed at least one staff member dedicating most or all of their time to this task. These individuals typically participate in the various working groups and committees relating to the legislation (e.g. through CEN) and within the relevant industry associations. Although such participation is costly, this investment of time is considered to be worthwhile by the companies, given the benefit arising, i.e. in terms of being able to influence the legislative process and receive information in good time.

For the companies interviewed, the cost of identifying the legislation and the relevant standards and reviewing its requirements mostly consisted of the staff costs of these individuals. For example, Firm A employed three staff (out of 4,000) with responsibility for overseeing compliance: one in the UK (also the European head office), one in Germany and one in Italy. Firm D employed one person in each of the 5-6 different national offices, each spending perhaps 50% of his/her time on this task. Similarly, Firm C employed between 3 and 5 heads at senior engineering level (out of a total workforce of 5,4000) to understand the legislation and train manufacturing people and QA people – as well as to undertake tasks related to other steps, i.e. checking the manufacturing process, finding practical solutions to compliance issues, gaining approvals, etc.

Training staff was seen as the next most costly element of Step 1. It is routinely provided by all the companies interviewed, for new staff and for existing staff, as and when there are changes to the legislation and/or the standards. The true cost of such training can be hard to identify, since it may often be incorporated into wider training of staff. One Firm suggested it accounted for 15% of the costs of Step 1, whilst another suggested a figure of 25%.

Use of external consultants to aid the familiarisation and preparatory process appears to vary widely between the companies interviewed. Two companies stated that they very rarely used consultants, whilst two others suggested that the use of consultants accounted for around 10% of the costs of Step 1. One Firm stated that it only used consultants when entering new national markets, which might thus explain this discrepancy. It might be safe to conclude that consultants are rarely used for the "routine" task of ensuring familiarity with the legislation but can be used when additional support is needed to identify the requirements relating to new products or new markets.

Purchasing the standards (of Directives other than MID) also presents a direct financial cost for all companies interviewed (although the MID normative documents are made available free-of-charge on the Europa website), although participation in standards committees at EU level sometimes provides access to the standards free-of-charge. For the companies interviewed – all large – the cost of standards was not seen as prohibitive. Two suggested it accounted for only 5% of the costs of Step 1. Another quoted a figure of €1.2k for each standard purchased, which was not seen as particularly burdensome relative to its revenues. However, such costs would inevitably be more burdensome for SMEs.

Two companies, as well as one EU-level industry association, highlighted that the most significant costs in Step 1 resulted from having to address differing interpretations of the legislation and of the standards in different countries. Such difficulties were said to arise not from the text of the legislation or of the standards, but from insufficiently clear guidance or, indeed, a lack of guidance. The resulting costs tended to relate to the time spent negotiating with national authorities, market surveillance authorities and Notified Bodies, as well as delays in placing products on the market (although neither firm was able to specify the precise cost, which is not therefore included in the table below).

Overall, all the companies and the industries associations interviewed highlighted the fact that most of the costs incurred in Step 1 were no higher than the previous situation in which national legislation applied. Indeed, the fact that the MID standards are also based on the internationally-agreed OIML normative documents means that there has been a degree of continuity in the processes followed, with the EU legislation reducing costs by bringing a more uniform approach. Given this situation, it would seem that the main scope for reducing costs associated with Step 1 relate to facilitating a more uniform interpretation of the legislation applying to fuel dispensers (i.e. MID, ATEX, EMC, etc.) and encouraging a more consistent application and enforcement in different Member States.

Step 2: Changes to product design and production processes to ensure compliance with substantive obligations

The nature of fuel dispensers and related products is such that design, development and manufacture require extensive testing for the purposes of safety, accuracy and reliability. It is clear that national legislation already imposed quite stringent requirements in most countries, particularly those where national standards were based on internationally-agreed normative documents. The EU legislation also places stringent requirements on manufacturers, with a consequent need for extensive testing and risk analysis, as well as subsequent changes to product design and production processes. For example, the one firm offering an estimate of substantive compliance costs, Firm B, reported that substantive compliance costs had amounted to €3.2m over the last five years (equal to around 3% of turnover), of which €2m on changes to product design and €1.2m on changes to production processes. Whilst these are one-off costs for each specific product that is certified, the fact that each large firm is

continually bringing new products to market mean each incurs such costs on an annual basis.

It is, however, impossible to separate such costs from the business-as-usual scenario, particularly in a context of on-going technological development and innovation. Indeed, reputable manufacturers of high-quality products undertake extensive testing and risk analysis of any new product in any case. To a certain extent, such activities therefore represent a business-as-usual cost. Overall, the legislation has perhaps represented more of a burden for manufacturers of poorer-quality products, who have had to operate to higher standards, with less potential to undercut other suppliers on the basis of low price.

Of the companies interviewed, all agreed that testing related to compliance with substantive obligations posed a considerable cost. Indeed, testing and risk analysis is undertaken throughout the year at all the companies interviewed, involving a mix of internal staff and external costs. Firm D suggested that testing might account for up to €1m of its annual revenue of €15m (i.e. just less than 7%). Firm B reported that testing accounted for around €500k out of annual revenues of €20m (i.e. 2.5%). Firm C reported annual testing costs of €50-€150k for each of its four European factories, i.e. €200-600k p.a. Whilst such costs are clearly significant, it is not possible to separate them from a situation in which national legislation prevails or from the "business-as-usual" cost, given the emphasis that reputable manufacturers would place on product safety, accuracy and reliability.

In general, the companies were unable to give accurate data on the cost of testing equipment related to compliance with the EU legislation. For example, Firm D stated that most testing was undertaken at the firm's main laboratory in the USA; the cost of testing for the EU market was therefore inseparable from the cost of testing products for all global markets – particularly, where international, rather than EU standards apply. Firm A reported that it spent around €40k p.a. on testing equipment for the purposes of compliance (mostly linked to the EMC Directive) in relation to sales of around 10,000 fuel pumps per annum (equivalent to an average cost of €0.25 per unit).

Firm A did, however, highlight one very specific cost arising from the legislation and which could not be considered as a business-as-usual cost. One effect of the MID has been to require calibration of fuel dispensers (e.g. to match fuels) to take place in the factory rather than on-site (i.e. at the fuel retailer's forecourt). Previously, this calibration would take place on site, with the appliance then checked by a local trading standards officer, which Firm A considered to be easier. Although the fee for the local trading standards officer was not cheap (e.g. €50 per nozzle, so €300 for a pump with six nozzles), it was paid by the customer. However, under Module B (type approval) of MID, the Notified Body now has to verify the product and the calibration has to be undertaken at the factory. This creates difficulties as the precise conditions of the installation environment (i.e. the retailer's forecourt) cannot be known and recreated in the factory. Enforcement authorities tend not to allow subsequent adjustments to be made on site, whereas previously the manufacturer could send staff to tweak the product on site. Whilst Module F allow verification and calibration at the forecourt, this option

As a result, Firm A reported that it was required to spend a lot of time in the factory, continually refining weights and measures equipment to ensure the product is legal. Overall, the legislation was reported to have introduced a liability for the manufacturer, for which no obvious practical solution had been found. The consequent cost included €120k on testing facilities for LPG, as well as around €250k in staff time over the last six years, equivalent to perhaps €100 extra per dispenser under MID compared to the previous situation.

Step 3: Conformity assessment procedures

Under the MID, manufacturers can choose from a number of conformity assessment procedures, namely Modules B+F, B+D, H1 or G. This creates a variety of approaches and therefore differing costs, with some manufacturers subject to periodic inspections of their quality systems by Notified Bodies (e.g. under Modules D and H1) and others having the conformity of specific products verified, e.g. under Modules B and F.

The companies interviewed were unanimous in reporting that the fees of Notified Bodies represented the costliest element of Step 3. The one firm that offered an estimate of the proportion of total costs in this step accounted for by Notified Bodies fees suggested a figure of 55%, of which 35% relating to initial inspections and 20% to periodic inspections. All the companies offered estimates of the financial costs of the fees of Notified Bodies and those estimates demonstrating a degree of consistency. An initial inspection of a fairly routine nature (e.g. permeation tests or other minor adjustments) was said by two companies to cost up to about €4k, whereas testing of components such as valves, motors or junction boxes was said by another firm to cost €10-20k. The same firm reported that it undertook around six of such tests each year, representing a total cost of about €100k in Notified Body fees (i.e. 0.5% of total turnover). More extensive tests for entirely new products or processes might cost €40k-50k each. In addition to the initial inspections, it is also necessary for each firm to have periodic inspections by Notified Bodies in order to retain their certification. Figures quoted by one firm included €15k-25k for both the MID and the ATEX Directives, with another firm quoting a figure of around €30k for such periodic inspections across its three European facilities for the same two Directives.

Whilst the cost of Notified Bodies' fees was reported to be high, the companies agreed on the benefits of gaining certification. One firm made a favourable comparison to the situation prevailing before the introduction of the New Approach Directives, stating that the current costs were relatively low. The same firm reported that it was able to use its MID and ATEX certification globally, in the former case because of the use of OIML standards by MID. Moreover, it was also reported that OIML certification from some EU Member States tended to have more credibility than certification gained in some third countries.

Manufacturer's own internal checks were also reported to be costly, albeit less than the cost of Notified Bodies. However, to a large extent, these tended to be a business-as-usual cost, with such checks undertaken continuously and routinely – and likely to be undertaken in the absence of legislation.

Similarly, the preparation of technical documentation in advance of conformity assessment, compilation of test reports, production identification requirements and maintenance of technical information for ten years were reported to be costly in terms of internal staff time. Indeed, one firm suggested that such activities could account for several hundred thousand euros each year in staff time, whilst another suggested that such activities could account for around 35% of the total costs of conformity assessment. Preparation of technical documentation related to ROHS was said by one firm to pose a particularly high cost. In addition, two companies reported very high costs of translation of documents related to conformity assessment, although such costs may be inextricable from the general costs of translating instruction manuals – estimated at around €100k p.a. by one firm (against sales of 10,000 units and turnover of "tens of €millions" per year).

Step 4: Declaration of Conformity and CE marking

The companies interviewed were unanimous in reporting that the Declarations of Conformity and use of the CE marking were much less costly than Steps 1, 2 and 3. However, the preparation of a Declaration of Conformity could be made more complicated – and therefore more costly – by the need to collect information, DoCs and compliance statements from suppliers of components. Depending on the number of components and of suppliers, this could in some cases be costly and manufacturers need to build such requirements into their contracts with suppliers.

The compliance statements that will be required under ROHS and REACH were expected by one firm to impose a significant cost as and when they become mandatory. However, at this stage it was not possible to estimate the cost of producing such statements.

The requirement to apply CE marking was reported by all the companies to pose very little cost. Indeed, it was easily incorporated into the manufacturing process. None reported any particular additional financial cost. However, the companies and industry associations reported some confusion around the application of CE marking. This included a lack of clarity around whether the CE marking needed to be placed only once on each pump installation or on each nozzle. It was also suggested that consumers had limited awareness of the significance of the CE marking, with national standards, such as the British Standard markings, being more widely-recognised in each country.

As with the technical documentation, translation of the Declaration of Conformity was reported to be expensive. Three of the four companies reported a very high cost of translation, whilst another reported it to be moderately high. One firm reported that it was necessary to translate Declarations of Conformity four times a year, at a cost of around €8k p.a. In order to minimise costs and the potential for error, another firm reported that it replicated the text from the various language versions of the official documentation as far as possible. Again, such translation costs are bound up with the wider cost of translating instruction manuals. However, given that fuel dispensers are sold only to businesses and not to consumers, one firm suggested that there should perhaps be flexibility over the requirement (imposed by most Member States under the terms of Article 6 of the MID) to provide such documentation in the language of the customer, provided that the customer has sufficient numbers of staff fluent in the language proposed by the manufacturer. In that way, it might be possible to reduce the number of translations required, particularly into the less-spoken EU languages where it less difficult to spread the cost of translations over a large volume of sales.

Conclusion/Summary

On average, around €800k per year are spent by major manufacturing groups on activities linked to compliance. Direct administrative compliance costs represent just over 10% of the total costs of compliance-related activities. Investments in terms of product design, manufacturing equipment represent major compliance-related expenditures (around 35-40%).

<u>Assessment of costs of Union harmonisation legislation for the whole sector</u>

On the basis of the information provided, we have attempted to estimate the costs of compliance for the whole sector. The figures in the table below include information concerning the "business-as-usual" (BAU) scenario.

Table 7-35: Summary of main costs of compliance for the firms interviewed

	Firm 1	Firm 2	Firm 3	Firm 4	Average	Total
Turnover	€ 20m	€ 20m	€ 600m	€ 15m		€ 1,091,666,667
Compliance Costs FTE						
- costs FTE yearly	€ 72,000	€ 260,000	€ 420,000	€ 330,000		
- costs FTE yearly / turnover	0.36%	1.30%	0.07%	2.20%	1%	€ 5,372,250
Business As Usual (BAU) FTE		30%	30%		30%	€ 1,611,675
Compliance costs FTE		70%	70%		70%	€ 3,760,575
Compliance Costs - third party fees	€ 41,667	€ 500,000	€ 500,000	€ 1,000,000		
- costs third parties / turnover	0.21%	2.50%	0.08%	6.67%	2.4%	€ 12,367,014
Business As Usual (BAU) third parties		50%	50%		50%	€ 6,183,507
Compliance costs third parties		50%	50%		50%	€ 6,183,507
Compliance Costs - testing equipment	€ 160,000	€ 100,000	€ 500,000			
- costs testing equipment/turnover	0.80%	0.50%	0.08%		0.46%	€ 2,773,519
Business As Usual (BAU) test equipment		20%	20%		20%	€ 554,704
Compliance costs test equipment		80%	80%		80%	€ 2,218,815
Total compliance costs	€ 273,667	€ 860,000	€ 1,420,000	€ 1,330,000		€ 20,512,782
Business As Usual (BAU)		€348,000	€476,000		41%	€ 8,349,886
Compliance costs		€512,000	€944,000		59%	€ 12,162,897
Total compliance costs as % of Turnover	1.5%	4.5%	0.25%	9%		

The assessment of costs of Union harmonisation legislation for the whole sector is based on the figures obtained from the four major companies in the sector representing 60% of the market. The figures in the far right column are an extrapolation of the data obtained from the four major firms and represent the total turnover and compliance costs for the whole of the EU petrol pumps sector.

The annual turnover for the whole sector is estimated at €1.1bn. Total compliance costs are estimated at €20.5M for all the companies in the sector, representing around 2% of their combined turnovers. For the largest of all four companies (firm 3) compliance costs represent 0.25% of the turnover. For the smallest (firm 4), compliance costs amount to around 8.5% of the total turnover. Across the four companies, around 60% of the compliance costs relate to compliance with EU Internal Market legislation.

Administrative compliance costs FTE represent around 0.5%-1% of companies' annual turnover on average. Costs range from just under €100,000 to over €400,000 for larger companies. On average, they make up 30% of Business As Usual costs to a firm on a yearly

basis. The remaining 70% relate to EU IM legislation compliance requirements.

Administrative and non-administrative compliance costs towards third-parties are of around €500,000 on average for the companies in the sector. These costs represent around 2.5% of companies' annual turnover and make up 50% of their Business As Usual costs.

Testing equipment costs for compliance activities averaged around €100,000 per firm annually. For larger companies, testing equipment can cost over €500,000. These costs are also dependent on the number of factories owned by companies. These costs represent around 0.5% of companies' annual turnover in the sector and make up 20% of Business As Usual costs. In other words, testing equipment expenditures at firm level mostly relate to the necessity to comply with the MID requirements and other environment-related requirements introduced by various EU legislative measures.

According to PRODCOM data, the production value of each individual petrol pump unit ranges between €1,000 and €2,000. This corresponds with the data obtained from the individual companies when dividing their annual turnover by the number of units they produce per year. When dividing the individual companies' annual turnover by their total compliance costs, it is possible to see that compliance costs account for between 0.25% and 9% of the production value of a single unit (See Table 7-35).

Overall conclusions

This case study focused on fuel dispensers which are machines combining a pump and point-of-sale (POS) system and pumping fuel into motor vehicles. In other words, fuel dispensers combine an electronic part containing an embedded computer measuring fuel sales and a mechanical section to physically pump and control the fuel flow.

There are around 20 manufacturers of fuel dispensers in Europe, amongst which are four major players with more than 60% of the market share in Europe and a significant presence worldwide. The total production value for petrol pumps in Europe was of around €360 million in 2012 based on a unit price of around €1,100. A total of about 350,000 petrol and oil dispensing pumps were produced in Europe in 2012. The manufacture of fuel dispensers is mainly covered by the MID and by a number of other Directives, namely: ATEX, the Petrol Vapour Recovery Directive, the EMC Directive, the Low Voltage Directive and the National Emissions Ceiling Directive. The nature of fuel dispensers is such that regulations covering different perspectives are required, notably on accuracy and reliability in measurement, minimisation of the risks of explosion and protection of the environment.

The assessment of costs of Union harmonisation legislation for the whole sector was based on the figures obtained from the four major companies in the sector representing 60% of the market. Total compliance costs are estimated at €20.5M for the four major companies in the sector, representing around 2% of their combined turnovers. Around 60% of the compliance costs relate to compliance with EU Internal Market legislation (€12M) whilst the remaining €8.5M relate to business-as-usual compliance costs.

Administrative and non-administrative compliance costs towards third-parties are of around €500,000 on average. Familiarisation costs are reported to be significant in this particular sector. This is due to the need for company to address differing interpretations of the MID legislation and of national standards in different countries. Testing equipment costs for compliance activities averaged around €100,000 per firm annually. For larger companies,

testing equipment can cost over €500,000. In summary, investments in terms of product design, manufacturing equipment represent major compliance-related expenditures (around 35-40%) for companies in the sector.

List of interviews

- 2 interviews with industry associations: CECOD, PEIMF
- 5 interviews with manufacturers
- 1 interview with the European Commission DG Enterprise and Industry

3.10.7 Case study 7 – Air Conditioners

Introduction

Common aims

The aim of the case studies is to assess the way in which Union harmonisation legislation for industrial products affects different economic operators across selected product groups. Union harmonisation legislation applicable to each product group is first mapped out and an assessment of any gaps, loopholes, inconsistencies and duplication is provided. The compliance costs in meeting these requirements are then assessed.

Specific aims of case

The rationale for the selection of air conditioners and air conditioning systems as a product group was that:

- Air conditioners and air conditioning systems are a significant industrial sector, particularly in southern European countries, with a large volume of products sold.
- There are only a relatively small number of firms overall in most market segments, and large firms dominate the market.
- The sector is one in which there is a high level of internationalisation in manufacturing and non-EU firms dominate some segments of the European market (especially for smaller and portable air conditioners). This has allowed market access issues to be considered.

The case study was carried out using a combination of desk research and interviews. The main data sources used were Eurostat SBS (2 digit NACE code level) and Prodcom data (8 digit NACE), sectoral studies and market research reports. Work carried out recently on Ecodesign requirements for air conditioners and air conditioning systems was also used, since this provides useful data on market size and structure[143].

143 For instance, the F-Gas regulation (Regulation 842/2006 on certain fluorinated greenhouse gases) relating to greenhouse gases was considered by some air conditioning stakeholders interviewed to be one of the most burdensome pieces of legislation affecting the sector.

Product definition and description of market structure

This case study focuses on air conditioners and air conditioning systems (both comfort air conditioning in buildings and portable air conditioning systems). There are a number of different types of air conditioners such as air-to-air, water-to-air, evaporatively-cooled, split and multi-split air conditioners air-to-air, water-to-air, and VRF (Variable Refrigerant flow) systems. Industrial chillers are also covered, wherever these incorporate air conditioning systems. The focus is on electrically-driven air-conditioning appliances although gas burning appliance designs placed on the market were also taken into account, since a different legal regime applies under the GAD.

Selected sub-sectors within the wider HVAC industry, and heat and industrial pumps have also been included, but only where these are part of air conditioning and heating systems. There is a trend towards convergence of cooling and heating systems so air conditioning manufacturers often produce these items.

Data and information sources

An overview of sectoral data and key trends is now provided, drawing on Eurostat Structural Business Statistics (SBS) and Prodcom data. Since Eurostat datasets can be misleading in that they present data at a very high level of aggregation, we have also drawn on market research reports. Where data gaps have been identified, for instance, an accurate estimate of manufacturing employment in the sector, we have taken feedback from industry associations and individual manufacturers into account about since they have provided insights on market size and structure, recent industry developments and market trends.

Industry structure and employment

In the first table, we provide an overview of the sector, although it should be noted however that the data is at a higher level of aggregation than for air conditioners and air conditioning systems alone. Eurostat SBS data under NACE 28.25 includes the manufacture of refrigerating or freezing industrial equipment, including assemblies of components, the manufacture of air-conditioning machines, including for motor vehicles, non-domestic fans, heat exchangers, machinery for liquefying air or gas manufacture of attic ventilation fans (gable fans, roof ventilators, etc.).

Table 7-36: Manufacture of non-domestic cooling and ventilation equipment sector (NACE 28.25)

	2008	2009	2010
Number of enterprises	9,913	8,984	9,190
Number of employees	254,200	228,800	219,700
Production value	48,083.16	37,624.77	38,645.77

Source: Eurostat's SBS

The European industry association – Eurovent – speculated that Eurostat data may also extend to firms and employment relating to the installation and maintenance of air conditioners and air conditioning systems, not only to manufacturing. Given the unreliability of official data

sources on the number of enterprises and employment, it has therefore been necessary to rely on market studies that provide industry data and on information provided by industry associations.

The **manufacturing industry for small air conditioners (<12 KwH) and comfort cooling systems is dominated by a small number of global manufacturers, especially from East Asia**. The market for single and multi-split air conditioners is dominated by Asian manufacturers and brands.[144] The five largest brands of air conditioners for domestic use in Europe are all Asian: Mitsubishi (Japan), Daikin (Japan), LG Electronics (South Korea), Hitachi (Japan) and Toshiba (Japan). Outside East Asia, a number of other international manufacturers have a strong market share of the global air conditioner market such as Amana, Carrier, Lennox and Trane (US). In BRIC economies, such as China and India, there are also large manufacturers with high sales volumes, such as Haier, Gree and Midea (China) and Blue star and Voltax (India). Chinese companies also export a lot of small air conditioning products to Europe under an array of different, less well known brands.

It was not possible to obtain accurate data on the level of employment within the sector. However, it was noted by the industry association that there is a significant level of employment – greater than in manufacturing – relating to the installation, servicing and maintenance of air conditioners and air conditioning systems. Employees in these sectors are only indirectly affected by IM legislation, they are much more affected by environmental legislation, for instance, European legislation pertaining to the F-Gas regulation and pursuant legislation[145] setting out minimum requirements and the conditions for the mutual recognition for the certification of companies and personnel.

Some data on employment in Europe by international manufacturers was however obtained. It is important to point out that although non-EU firms dominate many areas of manufacturing and although a significant proportion of manufacturing also takes place outside Europe, manufacturers originating from East Asia have made a significant investment in setting up some manufacturing facilities in Europe, which has created a significant amount of European direct employment and indirect employment (suppliers/subcontractors of e.g. pumps and fans. According to Eurovent, an EU industry association, about 5000 direct jobs have been created and an estimated 15000 indirect jobs. A significant proportion of total employment in the EU in the air conditioning sector is for the subsidiaries of large international companies. Japanese, Korean and US air conditioning companies are well-represented.

For instance, the market leader Daikin has a factory in Belgium and two in the Czech Republic. Mitsubishi Electric has a factory in Scotland, whilst Hitachi has a factory in Spain. Among the reasons why global manufacturers are investing in developing manufacturing capabilities in Europe are: proximity to market, a need to strengthen their market share in Europe and to embed their position in the European market. Consequently, these companies are keen on monitoring and participating in European decision making processes, including the development of Ecodesign and Energy Labelling regulations.

It is **difficult to obtain a clear picture by country of origin of the brands of air conditioning manufacturers** since lesser-known brands sold on European markets can be

144 Preparatory study on the environmental performance of residential room conditioning appliances (airco and ventilation), Economic and Market analysis, July 2008

145 For instance, pursuant to The F-Gas Regulation (EC) No 842/2006, Commission Regulation (EC) No 303/2008 of 2 April 2008 establishes minimum requirements and the conditions for mutual recognition for the certification of companies and personnel as regards stationary refrigeration, air conditioning and heat pump equipment containing certain fluorinated greenhouse gases

subsidiary companies of international holding companies. However, a previous study for DG ENTR on the air conditioning sector citing Eurovent data[146] estimated that East Asia (particularly Japan and Korea), have a dominant market share with 60% and 13% respectively. These data estimates were checked, for instance with JRAIA (The Japan Refrigeration and Air conditioning Industry). They estimated that Japanese manufacturers share of the market is in the region of 50-60% in Europe.

The US has a 10% share of production, the EU has only an estimated 7% share, whilst Israel has 6% and China 5%. Notwithstanding the points above regarding international manufacturers setting up manufacturing facilities in the EU, a 2008 market study for the Commission confirmed that the majority of small air conditioners for domestic use are manufactured and assembled outside Europe[147], with the exception of mini-chillers, where Europe has a stronger manufacturing base (although international manufacturers with manufacturing plants in Europe are also present in the market).

Although in absolute terms, Europe's market share is relatively low, European manufacturers have a higher market share in the production of high-end air conditioning systems produced in lower volume, and in specialised market segments. For example, an interviewee from a European manufacturer commented that "while East Asian manufacturers dominate small air-conditioning systems for comfort and office cooling, European manufacturers have a higher market share of large-scale industrial cooling systems. Europe also has a significant market share for other types of air conditioners such as precision air conditioning and chillers. For instance, the UK and Germany have a strong market position in respect of precision air conditioning (such as cooling systems for data centres). Although disaggregated data is difficult to obtain, interview feedback found that European manufacturers and the US also have a strong market share in respect of industrial refrigeration. For instance, Italy is strong in the chillers market. It is not possible to provide accurate data on the percentage of firms that are SMEs in the air conditioning industry. As noted above, at 4 digit NACE code level, it is difficult to obtain sufficient disaggregation through Eurostat. Discussions with industry associations confirmed however that at least for smaller air conditioners for domestic use, small comfort coolers and for portable air conditioners, the market is dominated by large firms. A further market study from 2012 (Lot 6, Ecodesign)[148] was only able to identify small numbers of SMEs manufacturing air conditioning systems, chillers and fan coils (not quantified).

Market size

Before providing information on the European air conditioner and air conditioning systems market, we first provide an indication of the size of the market globally.

Market research data was obtained by CSES directly from the industry on the air conditioning market globally in 2013. The data shows the relative importance of different geographic markets in million units and their respective global market share.

146 It should be noted that this data is not publicly available, since it is proprietary.
147 Idem.
148 Sustainable Industrial Policy – Building on the Ecodesign Directive – Energy-Using Product Group Analysis/2 Lot 6: Air-conditioning and ventilation systems, Part 2 Market Study, July 2012

Table 7-37: World market for air conditioning in 2013

Geographic region	No. of units (m. units)	Percentage share
China	41.2	42.0
United States	14.35	14.6
Japan	9.58	9.8
Latin America	6.95	7.1
Europe	6.65	6.8
South East Asia	6.2	6.3
India subcontinent	4.87	5.0
Middle East	4.57	4.7
Africa	2.86	2.9
Oceania	0.91	0.9
Total	**98.14**	100.0

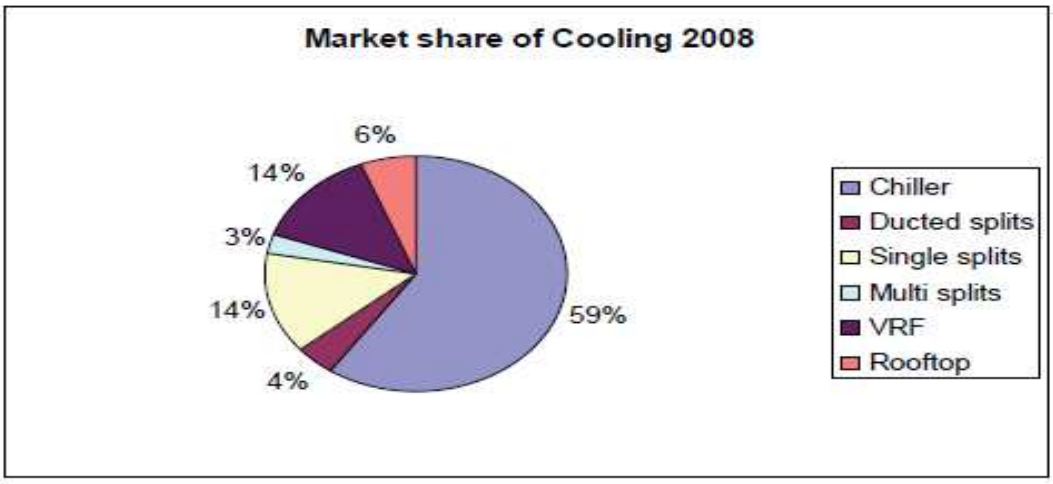
Source: JARN, the "Japan Air Conditioning, heating and refrigeration news" magazine, 25 May 2013

The data shows that 98.1m units were sold globally annually. The data confirms that China is the world's largest air conditioner market, although, as noted earlier, Japan and Korea are the biggest manufacturing companies for air conditioners sold on the European market. The **estimate of 98.1m units sold globally compares with about 6.65m units sold in Europe in 2012**, according to Eurovent figures. As will be demonstrated below, although European manufacturers have a relatively low market share globally in terms of sales volume, they have a higher market share for non-domestic air conditioning systems and for chillers.

A study undertaken for the Commission in 2008[149] noted that Southern European countries accounted for a large share of demand within the EU, reflecting climatic factors as a key demand driver. In the figure below, a breakdown of the market share for different air conditioning systems by type and cooling capacity is provided. The figure shows that chillers with air conditioning in them account for 59% of the market, and other types of air conditioning a much lower proportion. Single splits and VRF splits (ducted splits are not so easy to install in European households since most do not have duct space) each with a 14% share of the market respectively.

149 Preparatory study on the environmental performance of residential room conditioning appliances (airconditioning and ventilation), ECODESIGN Lot 10, July 2008

Figure 7-1: Market Share - Air Conditioning Systems by type and cooling capacity



Source: Sustainable Industrial Policy – Building on the Ecodesign Directive, July 2012 (Note: single splits below 12 kW are excluded from the graph.)

A 2012 study[150] on the impact of the Eco-design Directive provides an assessment of current market size and structure. However, according to the study "Extra EU-27 trade and Intra EU-27 trade are only available in Prodcom at the even more aggregated level of Procom code 28251 Non-domestic cooling and ventilation equipment. The Prodcom data are therefore of limited value for this analysis, being too aggregated"[151].

Prodcom data in respect of different types of air conditioning systems is now provided. The "apparent production" values are derived from the reported figures and do not take into account possible stock levels between production or import and sale). The first category of Prodcom data relates to air conditioning systems, self-contained or split-systems. The data shows that European manufacturing exports account for a small proportion of total sales.

Table 7-38: Window or wall air conditioning systems, self-contained or split-systems, Prodcom category 28251220, Million Euros

Year	2003	2004	2005	2006	2007	2008	2009
Exports	87	96	98	147	173	155	119
Imports	620	1,032	924	944	1,389	1,255	668
Production	1,148	1,343	1,264	1,101	1,396	935	682
Apparent consumption	1,681	2,279	2,089	1,898	2,612	2,034	1,231

Source: Eurostat, Prodcom

150 Sustainable Industrial Policy – Building on the Ecodesign Directive – Energy-Using Product Group Analysis/2 Lot 6: Air-conditioning and ventilation systems, Part 2 Market Study, July 2012

151 The relevant Prodcom categories are: 28251220: Window or wall air conditioning systems, self-contained or split-systems. These products are within the scope of this case when used for comfort cooling and over 12 kW cooling capacity: smaller units are under Prodcom code 28251250: Air conditioning machines with refrigeration unit (excluding those used in motor vehicles, self-contained or split-systems machines). This category includes comfort-conditioning air conditioning chillers and chillers used for other air conditioning applications, and other products, 28251270: Air conditioning machines not containing a refrigeration unit; central station air, handling units; boxes and terminals, constant volume units and fan coil units (including air handling units and terminal units – including fan coil units - but also other component parts of central air conditioning systems).

Prodcom data in respect of air conditioning machines with refrigeration units is now provided. Again, the level of imports considerably exceeds exports.

Table 7-39: Prodcom category 28251250: air conditioning machines with refrigeration unit (excluding those used in motor vehicles, self-contained or split-systems machines), million Euros

	2003	2004	2005	2006	2007	2008	2009
Exports	375	404	422	430	502	631	509
Imports	1,299	1,949	1,594	1,203	1,657	1,384	881
Production	1,607	1,779	1,566	1,699	2,095	2,364	1,651
Apparent consumption	2,532	3,324	2,738	2,473	3,250	3,117	2,023

Source: Eurostat, Prodcom (note – data on exports was not available in earlier years).

Lastly, the third Prodcom category examined was air conditioning machines not containing a refrigeration unit. Here, unlike in the first two areas, European manufacturing is comparatively stronger, with exports considerably exceeding imports.

Table 7-40: Prodcom 28251270: Air conditioning machines not containing a refrigeration unit; central station air handling units; vav boxes and terminals, constant volume units and fan coil units, million Euros

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Exports	188	215	244	270	344	390	328	344	467	459
Imports	167	292	251	254	357	274	207	224	258	200
Production	1,474	1,270	1,253	1,531	1,682	1,777	1,465	1,550	1,676	1,736
Apparent consumption	1,453	1,347	1,260	1,516	1,696	1,661	1,344	1,429	1,466	1,477

Market research data

In the following table, data on the number of units sold annually in the EU based on product sales data from market research are now provided. The Prodcom figures are larger, which reflects the wider scope of Prodcom classifications.

Table 7-41: Comparison of Prodcom and Market Research Data (2009)

Air conditioning products	Market Research (no. of units sold annually in EU)	Prodcom value	Prodcom category
Chillers	85000	2384000	28251250
AHUs for air conditioning and fan coil units	184,000 + 1,140,000 = 1,324,000	1716000	28251270

Source: Market research data and Prodcom, Analysis presented in Sustainable Industrial Policy – Building on the Ecodesign Directive (DG ENTR).

The data presented above from the market research report draws on a number of sources, such as Eurovent sales data for EU27 for 2008 and 2009, market research reports from BSRIA for

six countries (an extrapolation was made for EU27). Although the data is from 2008 and 2009, market research data provides a more accurate picture than Prodcom data since it is disaggregated for air conditioning and fans and for chillers[152].

Key industry trends and challenges

A number of key industry trends were identified through the research. These are, in summary:

- The adverse impact on the market of the global economic and financial crisis, with a significant drop in the numbers of air conditioning units sold in the European Union in 2008, 2009 and 2010, albeit with a recovery in 2011 and 2012.
- Convergence of cooling and heating products and systems.
- The integration of more energy-efficient technologies into air conditioners and cooling systems.

Annual turnover in the sectors under review has declined due to the **global economic and financial crisis**, in particular due to lower levels of construction activity. This has led to reduced demand for new air conditioning systems. However, demand for maintenance and repair services has been relatively steady during this period. Although initiatives to reduce energy consumption at EU and Member State level will help to boost demand for the installation of new, energy-efficient units in future, the number of units sold in the European market has declined overall in the past five years. The number of units has fallen sharply across the EU to 9.2m units in 2007, and further still to only 5m units in 2009. It has recovered somewhat during 2010 and 2011, but declined again to 6.65m units in 2012 (source: Eurovent).

There has been a trend towards **convergence in cooling and heating systems**, with integrated solutions becoming more common. Discussions with two air conditioning associations found that more diverse air conditioning solutions are needed.

A further key driver has been the transition towards the use of **more energy-efficient technologies and parts and components** in air conditioners and cooling systems. This has been driven globally by European legislation on Ecodesign implementing regulations to eliminate the worst-performing products.

Summary of applicable Union harmonisation legislation and standards

A mapping exercise was undertaken to identify applicable IM legislation and standards relevant to the air condition sector. The mapping of Union harmonisation legislation was based on desk research and discussions with individual manufacturers and the information has been verified by industry associations. The main applicable legislation, is in summary:

- Low Voltage Directive (LVD)
- Electromagnetic Compatibility Directive (EMC)

152 The data is based on sales to end-users irrespective of whether they are imported, manufactured within EU27 or assembled from imported components. Import and export is only reported from a national perspective so intra-EU and extra-EU figures cannot be determined from this derived data.

- Machinery Directive (2206/42/EC)
- Implementing Regulation on Ecodesign requirements, Regulation 206/2012 EC for air conditioning equipment below 12 kW.
- Regulation Ecodesign requirements for fans (327/2011 EC)
- Regulation Energy Labelling Air conditioners and comfort fans (626/2011 EC)
- Directive 2002/31/EC energy labelling of household air-conditioners
- Pressure equipment Directive 97/23/EC (PED)
- REACH Regulation (1907/2006 EC)
- RoHS Directive (2011/65/EC)
- Packaging and packaging waste (2004/12/EC)
- Regulation Ecodesign requirements electric motors (640/2009 EC)
- Regulation Ecodesign requirements glandless circulators (641/2009 EC)
- Regulation Ecodesign requirements water pumps (547/2012 EC)
- The Gas Appliances Directive (2009/142/EC) "GAD", which applies to gas-fired air-conditioning units

It should be noted that whereas for electrically-powered air conditioners, among the core applicable legislation is the LVD and the EMC, for gas-fired air-conditioning and/or heat pump appliances, the GAD may provide the main legal framework. The focus in this case however has not been on gas-fired air-conditioning. Since the HVAC sector is very large, we have sought to focus on other types of air–conditioning systems.

A more detailed mapping of the applicable legislation is provided as an annex to this case study. This provides a summary of the main issues addressed through the legislation (e.g. product safety, energy-efficiency), key administrative requirements for manufacturers and examples of relevant standards.

In addition, an overview of applicable environmental legislation affecting air conditioners and air conditioning systems has been mapped out and is provided in annex, since the interaction between Union harmonisation legislation and European environmental legislation has cumulative effects.

Analysis of costs of compliance with Union harmonisation legislation

10 interviews have been carried out as part of this case study, eight with firms, of which six firms provided sufficient quantitative data to be able to quantify the costs of compliance with IM legislation. Through the interviews, a good mix was achieved between firms of different size and market share. Two out of the top five global manufacturers were interviewed, as well as a large European manufacturer of air conditioners and an SME producing chillers. In addition, two interviews with industry associations have been carried out (see Section 8 –

information sources). Comments and data have also been provided by an international industry association (JRAIA - the Japan Refrigeration and Air conditioning Industry). In the following table, basic information about the firms interviewed is summarised:

Table 7-42: Basic information on the firms interviewed

Firm	Product category	Firm size	Annual turnover and sales from product in the EU	Main markets
A	Air conditioners & air conditioning systems	Large	Turnover £600m – 800,000 units	98% of sales in EU28
B	Air conditioners & air conditioning systems	Large	Turnover (UK) €100m >200 units	Europe, the Middle East and Africa
C	Air conditioners & air conditioning systems	Large	NA but production in EU numbers in millions of units	80% of sales in EU28
D	Industrial chillers	Small	100 units	Ca. 100% of sales in EU28
E	Air conditioners & air conditioning systems	Large	500,000 units	33% EU 66% outside EU
F	Air conditioners & air conditioning systems	Large	€520m – 300,000 units	50% sales EU28 50% outside EU (mainly Russia)
G	Air conditioners & air conditioning systems	Large	Turnover £42m - 2,500 precision aircon / 500 chillers	80% UK 20% RoW (EU and Middle East (10%))
H	Air conditioners & air conditioning systems	Large	Turnover €200m No. of units not available	Europe, Asia, USA – evenly split

It should be noted that sufficient data was obtained for SCM purposes from firms A, B, C, E, F and G. Firms D and H were not included in the SCM analysis. In the case of Firm D, this was because although data on human resources involved in compliance and testing was provided, this was an outlier as a % of staff costs compared with the total. In the case of Firm H, no data was available because they currently outsource manufacturing to ODM suppliers so do not have any information about compliance costs including testing.

In this section, a summary of how compliance with Union harmonisation regulations is managed in enterprises in the air conditioners and air conditioning systems sectors is provided. This sets out the main steps required in order to place an air conditioner or air conditioning system on the market and considers the internal business processes necessary. This provides important contextual information for interpreting the costs of complying with Union harmonisation legislation.

Overview as to how compliance is managed by air conditioning manufacturers

As mapped out in Section 3, a number of different pieces of Union harmonisation legislation are applicable to air conditioners. This includes longstanding New Approach directives such as the LVD-D and EMC-D (applicable to all electrical appliances) and more recent legislation adopted in the last decade, such as the Ecodesign requirements (implementing regulations for air conditioners and fan coolers), Energy Labelling requirements and requirements under RoHS and REACH relating to substances used in the manufacture of air conditioners. Additionally, air conditioners are subject to environmental legislation such as the F-Gas Regulation 842/EC/2006[153] and its different implementing regulations and the Energy Performance of Buildings Directive 2010/31/EU (EPBD).

Large firms and SMEs manage the process of ensuring regulatory compliance with Union harmonisation legislation in broadly similar ways. In large firms, there are commonly separate divisions dealing with different aspects of regulatory compliance: a regulatory compliance manager or department with overall responsibility for compliance (including following EU legislation-making and standardisation processes and familiarisation with the introduction of new and the revision of existing Union harmonisation regulations and the applicable administrative requirements), a division dealing with research and development and product design, and a division responsible for carrying out conformity assessment procedures through product testing within in-house R&D and/ or testing laboratories.

Large firms are in an advantageous position compared with SMEs however since they can devote staff to the earlier preparatory stages in the development and recasting of Union harmonisation regulations and in the development and revision of harmonised standards in order to anticipate and respond to regulatory developments. SMEs also try to follow and to anticipate regulatory developments.

SMEs also try to follow and to anticipate regulatory developments but they have less resources available to dedicate to this step. The European industry association pointed out that there is anecdotal evidence to suggest that smaller air-conditioning companies are leaving the market because of the complexity /cost of the regulation. It was difficult to verify this assertion since the smaller size segment of air conditioning companies were generally unwilling to take part in the case (although one small chillers firm did participate – and they were managing compliance with Union harmonisation legislation). Five main steps were identified in the process of achieving regulatory compliance for the study and these have been used in order to quantify the current costs of compliance. The steps are:

153 There is currently a proposal for a revised regulation on fluorinated greenhouse gases - COM(2012) 643

- Familiarisation with applicable/relevant obligations
- Introduction of processes or changes to product design and production processes to ensure compliance with substantive obligations
- Conformity assessment procedures and relevant documentation
- Declaration of conformity or other statement of compliance and CE marking
- Other activities related to obligations posed by authorities

Firms interviewed commented that while these five steps broadly reflect the processes involved in achieving regulatory compliance, for large firms, there is in addition a preparatory step that can involve significant time resources, that of "keeping track of EU legislation and standards".

Any differences between firms in their approach to managing compliance are commented on and the extent to which these differences are dependent on firm size and on the number of products/models being produced.

The companies interviewed were asked to assess the proportion of time FTEs spend on each of the five steps of the above process. Each firm provided slightly different information on this aspect as a result of their internal set-up considering factors such as the extent to which they relied on third party testing services, as opposed to carrying out conformity assessment tests in-house.

However, familiarisation with Union harmonisation legislation and the applicable administrative requirements was generally seen as quite time consuming (e.g. firm G mentioned that 30% of time was concentrated on this activity). The introduction of changes to product design and carrying out conformity assessment procedures were also seen as time-intensive (e.g. firm D invests 60% of time in total on these items). However, the production of a declaration of conformity and other activities stemming from regulatory obligations were generally seen as less time consuming (e.g. Firm A spends 20% of time in total in this regard). Staff specialising in regulatory compliance spend more time on familiarisation processes with Union harmonisation legislation and less on the other five steps, whereas for laboratory staff (engineers working in R&D and in testing) the majority of their time is spent on carrying out product testing and on conformity assessment.

Familiarisation with relevant legislation and purchase of standards

Preparatory steps – taking part in EU legislation-making and standardisation processes

Several of the larger air conditioning manufacturers interviewed stated that they invest resources in following EU legislation-making and standardisation processes. The aim is to enable them to shape and influence the development of new and the revision of existing Union harmonisation legislation.

This enables them to anticipate legislative changes so that new regulatory requirements or changes to existing requirements (and forthcoming updates to technical standards) can be incorporated from as early a stage in the product design process as possible. This enables

them to minimise substantive compliance costs by factoring in new requirements from as early a stage in the product design and R&D process as possible.

Large firms interviewed often have dedicated staff specialising in regulatory compliance. They are therefore able to actively contribute to EU legislation-making processes, for example by participating in the work of EU industry associations[154], responding to public consultations, attending workshops with industry representatives in order to establish a consensus industry position on new legislative proposals and taking part in EU standardisation processes.

Taking part in this preparatory step involves time and human resource costs. Several of the large firms interviewed have full-time regulatory compliance teams consisting of between two and four FTEs. A senior manager at a large European manufacturer estimated that *"Contributing to the p*olicy debate regarding Eco-labelling and Ecodesign took several years from the start of the discussions until the adoption of these regulations. Given that both regulations potentially have a significant impact on the air conditioning industry, during the 2 year period leading up to their adoption was the most intensive, and the amount of time spent *on these regulations alone amounted to 0.5 FTE".*

However, there are clear benefits for industry in actively following regulatory development and standards-making processes. This enables large firms to influence policy and legislative-making processes likely to affect them. Industry may not always be happy with the end result, but at least has the opportunity to influence the process. More generally, this facilitates regulatory compliance because large firms are then able to anticipate forthcoming legislative changes and updates to technical standards. This investment in participating directly in EU policy and legislative making processes gives large firms a competitive advantage over their smaller rivals, who typically follow regulatory developments but lack the resource to follow new developments closely.

Familiarisation with applicable legislation and administrative requirements

Familiarisation activities are required to ensure that air conditioning firms are aware of the applicable legislative and administrative requirements. At least in middle and larger sized firms, this step requires input from dedicated regulatory compliance staff who assume responsibility for keeping track of regulatory changes and updates to harmonised technical standards. They are then responsible for briefing different business divisions about new regulatory developments, such as product engineers, product managers and sales teams.

In large firms, such as firm F, there is a division of 2-3 people providing specialist in-house expertise on compliance matters. Another large company, Firm B, mentioned that they employ a full-time regulatory specialist and one of their main tasks is to update product managers, engineers and country sales teams on new legislative developments and how these will affect different product categories. They also provide guidance to colleagues on how new IM legislation and changes to existing regulations should be interpreted. Whist only a small number of full-time regulatory specialists are employed, familiarisation with legislation is an activity that cuts across a number of business functions (e.g. country sales teams and product engineers). Consequently, it was estimated that the total number of FTEs involved in

154 EU industry associations provide an opportunity for industry to feedback their views on the revision of existing EU regulations and on the proposed introduction of new legislation, for instance, through Commission working groups that have been set up on specific directives and regulations e.g. working group on Ecodesign.

familiarisation with the legislation is equivalent to 15 full time staff. However, Firm H tended to use product safety consultants to provide specialist advice and consultancy support to assist them in the familiarisation process with new legislation. It should however be noted that there is an intention to move this function in-house in the near future.

In SMEs, familiarisation requires a significant effort, but there are less dedicated resources available. Firm D, an Italian firm manufacturing chillers employs a full-time manager who specialises in regulatory compliance to keep track of regulatory developments. The person concerned estimated that approximately 50% of their time was spent on familiarisation activities. The owner of the company also spends about 20% of their time on compliance matters (of which about half on familiarisation).

Several interviewees commented that familiarisation with more Union harmonisation directives and regulations introduced in the past five years take up a lot more time than other pieces of legislation. Whereas the legal and administrative requirements for long-established Directives such as the LVD and EMC are well-known to manufacturers and have not changed fundamentally in years , a lot more time is required for compliance specialists to familiarise with the requirements set out in more recent legislation, especially legislation with either environmental, consumer protection or energy-efficiency objectives, such as RoHS and the Ecodesign implementing regulations.

Currently, Ecodesign requirements only apply to small air conditioners under 12 kW and comfort fans under 125W. There is a separate measure that applies to fans of between 125 W and up to 500 kW even if they are included as a component in larger equipment, as detailed in the following sub-section.

Introduction of changes to product design and production processes to ensure compliance with substantive obligations The introduction of new legislative requirements under Union harmonisation legislation may require changes to be made to products either during the R&D and design phase, during the production process and in the case of fans integrated into products, also to products that have already been placed on the market.

The costs of making such changes depend how far in advance air conditioning manufacturers are aware about forthcoming changes and on the length of the product life cycle. The research showed that it is much more costly for manufacturers to make design changes to existing product platforms than it is to incorporate new requirements into new product platforms or those at a very early stage in their development.

An Ecodesign preparatory study noted that the life cycle of air conditioning platforms is typically between 10 and 12 years. The life cycle of an individual air conditioning model is longer than for other types of industrial products[155]. Therefore, the introduction of substantive obligations has a more significant impact on air conditioners.

Since basic air conditioning platforms form the basis on which products are updated through the development of new models and variants, there can be major costs if design modifications have to be made or particular components are withdrawn. Eco-design requirements were regarded as the most administratively burdensome piece of Union harmonisation legislation.

155 In comparison, the lifecycle of a laptops platform in which different model variants are developed is in the region of 2 to 5 years. It is easier to integrate regulatory requirements into the development of new platforms rather than to invest in modifying platforms that have already been developed.

Implementing regulations setting out ecodesign requirements for air conditioners and comfort fans (Regulation EU 206/2012) applied from January 1st 2013 to units of <12KW. Since ecodesign targets the worst-performing products, redesign is necessary only for approximately 20% of existing models.

Even though large air conditioning units and systems have not yet been made subject to ecodesign legislation, the main implication has been that lower-performing fans integrated into larger air conditioning systems and units have had to be replaced or taken off the market for testing, adaptation or permanent removal.

A large European manufacturer of air conditioning systems, Firm G, commented that although they only produce large air conditioning systems over 12 12 kW, they have already been affected by the implementing regulations. *"Ecodesign requirements have meant that* changes have had to be made to replace fans in older products. Sometimes, fans have had to be withdrawn by suppliers because they no longer meet the required performance threshold *for energy efficiency"* . In such cases, the firm has then had to identify alternative energy-efficient fans to incorporate as components into larger products, such as air conditioners used for cooling purposes in data centres.

This in turn requires updating the corresponding technical documentation and DoCs and further testing has had to be carried out. Both Firm F and Firm G confirmed that are indirect impacts as a result of fan products used as components being withdrawn, such as a finished unit having to be retested under the EMC Directive, because the old fan originally included as a component when the product was placed on to the market is no longer compliant and a new type of fan has had to be installed. Firm F commented however that 'it is difficult to quantify such substantive compliance costs' since no data is kept on the total costs incurred across a number of different products due to the replacement of fans.

The comments made confirm the findings from an earlier evaluation of the Ecodesign Directive undertaken by CSES that there are some specific issues in respect of the compatibility of ecodesign requirements for fans when these are integrated into other types of products such as machinery and air conditioning systems and larger air conditioners.

Firm C suggested that since the core product safety directives applicable to air conditioners change infrequently that the introduction of new (and updating of existing) technical standards is a greater administrative burden than the legislation itself. Firms A and B had difficulties in determining the exact number of FTE involved in carrying out conformity assessment procedures under IM legislation internally since a significant proportion of manufacturing takes place in Asia. It was therefore difficult for them to know the exact number of engineers involved, especially since the engineers work on products designed for the global market, which will then be designed and tested to meet dual or multiple regulatory requirements.

There can be difficulties for manufacturers in meeting regulatory requirements, while at the same time addressing end-user and consumer needs. For instance, the aim of increasing energy-efficiency is not always compatible with that of reducing indoor and / or outdoor noise.

Conformity assessment procedures

The Supplier's Declaration of Conformity (SDoC) can be applied by manufacturers for most types of air conditioners. Most manufacturers therefore carry out the majority of product testing in internal laboratories, but may also use an external third-party (on a voluntary basis) to carry out some aspects of testing. The use of a third-party provides a useful external validation that helps to ensure an additional guarantee for the enterprise.

A European industry association indicated that although the SDoC procedure can be applied to the LVD, most manufacturers prefer to use a third party. In addition, some firms also make use of external product safety consultants in order to provide advice and to help project manage the testing and compliance process. For example, Firm H uses 2 consultants who work on a working part-time basis for the company for approximately 3 months a year advising on regulatory compliance linked to testing.

Firm D (an SME with 64 staff) employs 7 FTE that deal with regulatory compliance / conformity assessment, 2 of who deal with following regulatory compliance requirements and 4 of who work in the internal testing department. Whereas the EMC and the LVD were believed to be the least burdensome, Ecodesign, the MD and the PED were regarded as the most costly pieces of legislation. The firm has invested in accreditation for internal production control under the PED in relation to chillers which has limited its reliance on third parties.

Given the relatively low number of units manufactured by the SME, the costs of complying with IM legislation per unit are higher when compared with large companies. This message was reiterated by Eurovent, the air conditioning industry association that SMEs face much higher regulatory costs per unit. In comparison, large air conditioning manufacturers are able to spread the costs of compliance across a large number of units produced and sold in European markets.

In Firm E, 11 FTE are employed as regulatory and conformity assessment specialists, 5 staff work on internal testing and R&D for air conditioning and 4 staff perform similar activities but working for heaters. Firm E suggested that the initial set-up costs for establishing internal testing functions is expensive. This includes for safety tests (€30,000 to €40,000) and performance tests (€30,000 to €40,000) and room and equipment instrumentation (€200,000). Annual costs include calibration services for instrumentation (€20,000) and replacing instrumentation, estimated at between €30,000 and €50,000.

Firm F commented that Ecodesign particularly in relation to fans is the most costly piece of legislation, followed by the EMC and the LVD. The MD was viewed as being less costly. In total, part of the job description of 20 product engineers is to work on compliance-related matters and this equates to about 10-15% of their time e.g. 2-3 FTEs. The firm spends on average €1 million on external testing per annum and this includes carrying out testing in respect of the EMC-D and the LVD-D. In addition, there are one-off costs associated with the purchase of equipment (€50,000) and annual costs for calibrating equipment (this relates to €20,000 for IM regulations).

In the case of the LVD Directive, one of the oldest New Approach Directives, most testing is carried out by an in-house laboratory with a 3rd party technician being present. However, many SMEs do not have such a laboratory facility and therefore have to send samples to a 3rd party for testing. This means that testing costs can be significantly higher, both in absolute

terms and when spread across the total number of units sold. Perhaps surprisingly since the legislation is long-standing and well-embedded, Firm E suggested that the LVD was the most costly IM legislation[156] on the grounds that even if third party testing is not required, there is a need to validate internal test results and to use a notified body to test a random selection of products so as to provide additional reassurance that the product is safe.

In Firm G, conformity assessment procedures cut across the work of two specialised departments that have a combined annual budget of approximately €1.4 million. The development department is composed of 20 electrical and mechanical engineers and CAD designers. The test centre is composed of 6 engineers that evaluate designs and performance functionality. Overall, it is estimated that 3 FTE engineers spend 20 - 25% of their time ensuring that products are compliant. This includes the development of technical reports and product testing. With regard to salaries of staff working on compliance, one engineer has a salary of approximately €60,000 per annum; the costs of annual testing equipment were estimated in the region of €25,000.

Firm G commented that the Machinery Directive and Low Voltage Directives were less costly since the SDoC procedure can be applied. It was noted that some types of industrial air conditioning units must comply with the Pressure Equipment Directive (PED) . Here, complex tests need to be carried out by third parties, or if testing is carried out internally, there is a mandatory requirement that this must be carried out by a third party[157].

Declaration of conformity (DoC) or other statement of compliance and CE marking

Producing a DoC and CE marking was seen as less costly compared with the previous steps described. However, it was recognised that the minor administrative costs involved at the end of the compliance process are only possible once the preceding steps have been completed, which require investment by air conditioning firms.

Firm E stated that producing the DoC is neither problematic nor costly. Firm H stated that producing the DoC itself does not take up a lot of time, since the information contained in the DoC can typically be fitted on to one sheet of A4 paper. Rather, the conformity assessment procedures leading up to the DoC and the development of a technical file are the most time consuming aspect.

Other information obligations and administrative costs

Other administrative requirements under Union harmonisation legislation can however be costly. For instance, the requirement to translate instruction manuals into all EU languages was viewed as costly. Under the LVD Directive, an instruction manual must be supplied in the language where the product is sold. Some interviewees noted that instruction manuals are becoming bigger and more complex, with a requirement to "provide an ever-increasing number of safety warnings to consumers". Firm E suggested that industry would prefer to minimise the amount of text needed on products and to use pictorial symbols or warnings

156 The reason why the LVD can result in high costs is due to the duration of the testing process which can take up to one month in a third party laboratory, even after the manufacturer has carried out testing in-house. The main mechanism chosen by manufacturers to achieve presumption of conformity with the LVD is through harmonised standards. Two standards are applicable for air conditioners: (i) EN 60 335-1 (general standard applying to household and similar electrical appliances) and Part 2 specific additional requirements for each category of appliances standard for safety requirements in household appliances and (ii) EN 60 335-2-40: specific requirements for electrical heat pumps, air-conditioners and dehumidifiers.

157 This includes (PED) final observation of a pressure tests and (EMC) check for radiated and conductive emissions.

rather than written text that needs to be translated. This would help to reduce costs and reduce the length of compliance and other documentation that has to be provided with products.

Another point raised was that the administrative costs of producing energy labelling (as opposed to the testing of products to check their energy efficiency which is a substantive obligation and can be costly) have been kept to a minimum due to the use of pictograms rather than text. Pictograms were viewed as facilitating communication with consumers across the EU's multilingual market, without the need to spend money on translation or on producing lots of paper to accommodate translations into multiple languages.

Assessment of costs of Union harmonisation legislation for the whole sector

An assessment was undertaken of the compliance costs of Union harmonisation legislation for manufacturers in the air conditioners and air conditioning sector. As noted earlier, one chiller company was also included. Since the wider HVAC sector is very wide, not all categories of firm were interviewed (e.g. heating pumps firms). The aim was to have a narrower focus on air conditioning.

As noted in Section 4, the assessment was carried out on the basis of quantitative information provided by six manufacturers (from the eight interviewed in total). The costs are related to turnover. In the first column, we seek to distinguish between different types of costs. The distinction between one-off and recurrent costs has been taken into account in the analysis, and some costs, such as the costs of purchasing laboratory equipment have been annualised[158].

A summary of the estimated costs of compliance is provided below (it should be noted that the costs presented in the table represent the net costs after a deduction for "Business as Usual" costs has been taken into account).

Table 7-43: Summary of main costs of compliance for air conditioners manufacturing industry

	Unit of measurement	Average cost/ year (total)	Estimated no. of firms	Total costs (annualised)
Compliance with administrative requirements				**€ 17.198.600**
Familiarisation	Manufacturers	€ 64,617	100[159]	€ 6,461,700
Preparation of DoC and technical documentation	Manufacturers	€ 106,169	100	€ 10,616,900
Standards purchase	Manufacturers	€ 1,200	100	€ 120,000
Conformity assessment				**€ 23.524.975**

158 These costs were annualised in order to arrive at comparable annual costs, using a system similar to firms' accounting for depreciation. For some questions, we also asked questions in the SCM questionnaire about how much they spent on testing equipment over a 5 year period, which had to be annualised.

159 Although there is a lack of data on market size and structure at a sufficiently disaggregated level in Prodcom and SBS data, we estimate that there are approximately 20 major manufacturers active in Europe, and perhaps some 80 small and medium sized manufacturers. Even market studies do not provide reliable estimates in this regard so this is a "best estimate".

	Unit of measurement	Average cost/ year (total)	Estimated no. of firms	Total costs (annualised)
(internal)				
Product design	Manufacturers	€ 96,597	100	€ 9,659,650
Testing (internal)	Manufacturers	€ 53,653	100	€ 5.365.325
Testing equipment	Manufacturers	€ 85,000	100	€ 8,500,000
Conformity assessment (external)				**€ 9,360,000**
Consultancy/advisory services (product design)	Manufacturers	€ 18,720	100	€ 1,872,000
3rd party conformity assessment by notified bodies	Manufacturers	€ 74,880[160]	100	€ 7,488,000
Total				**€ 50.083.575**

The key assumptions made in order to arrive at the above annualised calculations are the following. The firms interviewed provided data on the level of human resources involved in compliance, for instance on familiarisation with the legislation and technical standards and on how much time and FTE staff are involved in the preparation and updating of DoCs and technical documentation. With regard to estimated salary costs for staff working on regulatory compliance, there were considerable differences between firms. As explained in Section 4, there were even major variations in staff costs within firms, depending which aspects of compliance were carried out in Europe and Asia. In order to provide a better basis for comparison between firms, we therefore sought information on human resources and applied a standard tariff using Eurostat data on average salaries. The figures used were €30 an hour, which equates to about €50000 year FTE.

Several firms were also able to provide data on the internal and external costs of testing. Where data was missing, imputations had to be made using data from those firms that did provide data. For instance, one of the top 5 global players provided data on their expenditure on third party conformity assessment, whereas the other was unable to, since testing and conformity assessment was carried out in Asia and the data was not available even internally. We therefore used data from those firms that were able to provide estimates and used this as the basis for assumptions about the level of expenditure for other firms (taking into account other data that was provided, such as the volume of sales units produced and sold in the European market, annual turnover and the number of product platforms manufactured annually).

Firms were asked to provide data on the costs of carrying out conformity assessment testing in-house, for instance their annual expenditure on conformity assessment procedures carried out internally(again taking into account the number of product platforms manufactured annually), and the one-off and recurrent costs linked to testing. This includes the one-off

160 There were considerable differences in the estimates of compliance costs for large, medium and small air conditioning manufacturers, reflecting significant differences in the volume of units sold annually in Europe. Standardised parameters were estimated based on the data obtained, taking into account differences between firms of different size thresholds.

purchase of laboratory equipment and the annual (recurrent) costs of calibrating testing equipment. Not all firms were able to provide this data, either because of commercial sensitivity considerations, or because the information was not shared internally by particular divisions carrying out the testing (especially for the larger Asian manufacturers). Nevertheless, sufficient data was obtained to be in a position to make assumptions about the level of costs in a typical firm, depending on its size, sales volume and the number of product platforms manufactured per year.

In quantifying the annualised costs of compliance, we attempted to take into account which compliance costs were one-off and which were recurring. It is important to note that the distinction is often blurred between the two in the case of compliance with Union harmonisation legislation. Examples of one-off costs are the purchase of laboratory and testing equipment, R&D costs, third party conformity assessment costs. Other costs are evidently recurrent, such as the recalibration of testing equipment. However, the picture is more nuanced for other types of compliance costs, which are both one-off and recurring. For example, the cost of the preparation of a DoC and technical documentation is mainly incurred prior to a product being placed on the market. However, in addition to these one-off costs, there are also recurring costs linked to the need to update and maintain a DoC for 10 years post-placement on the market. There is a need to update technical documentation, for instance, to reflect new spare parts and components that are introduced as replacements once a product is already on the market. As regards product design, the costs are mainly one-off, but there could also be recurrent costs if regulatory changes are made and modifications to product design are needed once the product is on the market.

"Business as Usual" (BAU) costs were also taken into account. A number of air conditioning manufacturers stated that a certain proportion (typically 20% to 30%) of product safety testing that they carry out can be considered as BAU since it forms part of internal quality assurance procedures. A number of firms stated that some testing would have been carried out anyway so as to minimise reputational risk even if there is no legal requirement to involve a third party in conformity assessment and the Supplier's Declaration of Conformity (SDoC) can be applied. It was common among manufacturers interviewed to involve a third party in testing for the Low Voltage Directive.

However, there was wide variance in estimates of BAU between firms. A number of firms suggested that approximately 50% of the human resources and cash costs of compliance were BAU, whereas other firms interviewed estimated the proportion to be lower, at 15-25%. An interesting finding was that several manufacturers noted a distinction in BAU depending on the objectives of different pieces of Union harmonisation legislation. A distinction can be drawn between safety requirements, which were seen as an integral part of BAU and those Union harmonisation regulations that related to environmental requirements, which were viewed as imposing additional compliance costs that would not occur in the absence of Union harmonisation regulations. The most commonly cited example in this regard were the eco-design requirements.

Although firms may consider some types of environmental requirements as part of BAU, for instance, as part of their marketing strategy to differentiate products from competitors, the % of BAU costs was much lower. Firm C pointed out that the business as usual case is hypothetical and that it was difficult to provide an accurate quantitative estimate given that without EU regulation, national legislation would apply for safety and environmental requirements. It was suggested that this would create a more complex and fragmented regulatory landscape than is currently the case.

Overall conclusions

This case study focused on air conditioners and air conditioning systems. Since the HVAC industry is very broad, it was not possible to include all categories of air conditioner.

There were difficulties in obtaining reliable data on the air conditioning sector in Europe since Prodcom data was only available at a high level of aggregation. However, global market data shows that the manufacturing of small air conditioners (<12 KwH) and comfort cooling systems is dominated by a small number of global manufacturers, especially from East Asia (the EU has only an estimated 7% share). According to data on the size of the world market for air conditioning in 2013, global production was 98m units in 2013, whereas the size of the European market was about 6.65m units sold in 2012. European manufacturers have a stronger market share in niche markets such as chillers and high-end data cooling systems.

IM legislation applicable to air conditioners and air conditioning systems includes some of the core product safety directives such as the Low Voltage Directive (LVD) and the Electromagnetic Compatibility Directive (EMC). In addition, IM legislation with an environmental focus is applicable, for instance the Ecodesign implementing regulations for small air conditioners and comfort fans <12kwH. From 2015, the extension of ecodesign requirements through Lot 3 Ecodesign Implementing Regulations for larger air conditioners is likely to result in extra administrative costs for industry. These future costs are expected to be quite high compared with well-established IM legislation.

On the basis of information provided by the eight companies interviewed, most of whom were able to provide quantitative information, the costs of compliance with Union harmonisation legislation were estimated at around €50.8 million, equivalent to c.a. 1% of annual turnover. Administrative compliance costs (familiarisation with the legislation and applicable administrative requirements, the preparation of a DoC and technical documentation) were estimated to be approximately €17.2 million. Substantive compliance costs, such as integrating Union harmonisation regulatory requirements into product design and carrying out testing as part of conformity assessment procedures (internally and externally) were estimated at € 23.5 million per year.

The interviews with firms were consistent in pointing to the Ecodesign Directive as one the main current cost drivers of compliance-related activities. It was acknowledged however that the costs of the introduction of new legislation, whilst high in the short-term tend to diminish over time as the legislation becomes better embedded. The need to replace fans integrated into larger air conditioning systems already in the development pipeline or about to be placed on the market was a particular industry concern, since many fans do not meet eco-design requirements.

Sources of information - interviews

References - Sources

- Preparatory study on the environmental performance of residential room conditioning appliances (airco and ventilation), Economic and Market analysis, July 2008.

- Market research data and Prodcom, Analysis presented in Sustainable Industrial Policy – Building on the Ecodesign Directive (DG ENTR).

- A comprehensive overview of applicable legislation in the area of Ecodesign, the Energy Performance of Buildings Directive and the Energy Labelling Directive was produced recently as part of an Ecodesign preparatory study for air conditioning equipment above 12 kW – see www.ecohvac.eu, task 1, page 128-160.

- JARN, the "Japan Air Conditioning, heating and refrigeration news" magazine, 25 May 2013 Prodcom data, 2010.

Interviews

- 1 with a national association in the UK (FITA), and 1 with an EU Industry association (Eurovent).

- 7 interviews with manufacturers of air conditioners, 1 interview with a manufacturer of chillers (6 of the 8 discussions yielded quantitative data.

Annex - Applicable Union harmonisation legislation and standards

This Annex provides information that supplements the summary overview of the applicable Union harmonisation legislation and standards in Section 3 of the case.

A mapping exercise was undertaken to identify applicable Union harmonisation legislation relevant to the air conditioning sector. An overview of relevant legislation and of relevant technical standards is now provided. This draws on desk research and has subsequently been verified by industry associations and enterprises. There are differences in the applicable legislation and technical standards depending on the size of the air conditioning system and its intended purpose (e.g. domestic, industrial, fixed installations vs. portable air conditioners). For example, Ecodesign implementing regulations have only so far been introduced for air conditioning systems <12 kW, although as will be shown in this case study, the withdrawal of non-compliant fan products can also affect manufacturers of larger air conditioning and precision engineering systems which integrate such fans into their products. The PED is only relevant to larger air conditioning systems for industrial use.

Table 7-44: Overview of Union harmonisation legislation and standards applicable to air conditioners and conditioning systems

Name of legislation	Main issue addressed (safety, environment, other)	Administrative requirements for economic operators	Relevant standards
Core legislation			
Low Voltage Directive (LVD)	Health & Safety (electrical)	Testing according to relevant safety standards Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations)	Two applicable standards to achieve presumption of conformity for portable and household air conditioning: Part 1 EN 60335-1 (general standard applying to household and similar electrical appliances) Part 2 EN 60335-2-40 Particular requirements for electrical heat pumps, air-conditioners and dehumidifiers EN 50564:2011 Ecodesign – stand by and off mode:
Electromagnetic Compatibility Directive (EMC)	Electromagnetic compatibility	Testing according to relevant technical standards Development of	

		technical file Declaration of conformity and CE marking	
Machinery Directive (2206/42/EC)	Safety	Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations)	Only applicable to air conditioning systems intended for industrial and/ or commercial use Requirements of the directive for cooling generators of ENTR Lot 6 are covered under the following standards: - EN 12693:2008 Refrigerating systems and heat pumps - Safety and environmental requirements - Positive displacement refrigerant compressors - EN 378-2:2008+A1:2009 Refrigerating systems and heat pumps - Safety and environmental requirements - Part 2: Design, construction, testing, marking and documentation
Gas Appliances Directive (GAD) 2009/142/EC	Specify the safety level required of appliances burning gaseous fuels by specifying design, operating characteristics and inspection procedures.		Two harmonised European standards have been cited in the OJEU under the GAD: (1) EN 12309-1:1999: Gas-fired absorption and adsorption air-conditioning and/or heat pump appliances with a net heat input not exceeding 70 kW - Part 1: Safety; and (2) EN 12309-2:2000: Gas-fired absorption and adsorption air-conditioning and/or heat pump appliances with a net heat input not exceeding 70 kW - Part 2: Rational use of energy[161]
RoHS Directive (2011/65/EC)	Use of hazardous chemicals	Collect compliance statement from suppliers (material	Note: since the 2011 recast Directive, there is an exclusion from RoHS for fixed installed cooling, air

161 It is of particular interest that the latter standard deals with the energy efficiency of gas-fired air-conditioning appliances (the energy efficiency aspect may be subject to one or several of the implementing measures under the EcoDesign Directive).

		declarations) Technical file with supplier declarations and own analysis tests Declaration of conformity to be kept for 10 years	conditioning and refrigerating systems and heating systems designed for non-residential use. CE marking has been applicable since the 2011 RoHS II recast.
Implementing Regulation on Ecodesign requirements[162]: Regulation 206/2012 EU for air conditioning equipment below 12 kW and comfort fans.	Energy consumption/ efficiency	Testing according to harmonised standard Technical file with results of studies and explanations of design choices made and the management system Development of product fiche Declaration of conformity and CE marking Installation instructions and manual	EN 14511:2011 Determination of Full load energy efficiency EN 14825 2011 Determination of part load energy efficiency EN 62301:2005 (CEN) Standby power consumption EN 12102:2008 Sound power level (CEN) Notes: Applies from 1st January 2013. A regulation on Ecodesign requirements for equipment above 12 kW is in preparation.
Regulation Ecodesign requirements for industrial fans (327/2011 EU)	Fan efficiency	Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations	
Regulation Energy Labelling Air conditioners and comfort fans (626/2011 EU)	Energy consumption/ efficiency	Technical file with results of studies and explanations of design choices made and the management system Development of	EN 14511:2011 Determination of Full load energy efficiency EN 14825 2011 Determination of part load

162 A comprehensive overview of applicable legislation in the area of Ecodesign, the Energy Performance of Buildings Directive and the Energy Labelling Directive was produced recently as part of an Ecodesign preparatory study for air conditioning equipment above 12 kW – see www.ecohvac.eu, task 1, page 128-160.

		product fiche Placing of energy label	energy efficiency EN 62301:2005 Standby power consumption (CEN) EN 12102:2008 Sound power level (CEN)
Other legislation			
Pressure equipment Directive 97/23/EC (PED)	Safety of pressurized systems	Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations)	EN 378: 2012 environmental & safety requirements Note: only applies to larger air conditioners
REACH Regulation (1907/2006 EC)	Use of chemicals	Collect statement from suppliers stating that product is in compliance with requirements REACH compliance statement	
Packaging and packaging waste (2004/12/EC)	Packaging	Declaration of Conformity	
Regulation Ecodesign requirements electric motors (640/2009 EC)	Motor efficiency	Development of technical file Declaration of conformity and CE marking Installation instructions and manual for final consumer (with translations	

Regulation Ecodesign requirements glandless circulators (641/2009 EC)	Circulator efficiency (chillers)	Declaration of Conformity CE marking	
Regulation Ecodesign requirements water pumps (547/2012 EU)	Circulator efficiency (chillers)	Declaration of Conformity CE marking	

The European Union's Ecolabel Regulation 66/2010 is a voluntary labelling scheme and can be awarded to products and services that have a lower environmental impact compared with other products in the same group. The label criteria were devised using scientific data on the whole of a product's life cycle, from product development to disposal. There is a link between the voluntary Ecolabel and compliance with Ecodesign regulations in that products bearing the Community eco-label are presumed to comply with the Ecodesign requirements stated in the applicable implementing measures.

Although EU environmental legislation is not formally within study scope, such legislation is particularly important in the air conditioning industry since it forms part of the overall body of EU legislation with which manufacturers must comply. A summary of the main environmental legislation that applies to air conditioners is summarised below:

Table 7-45: Overview of applicable environmental legislation affecting air conditioners and air conditioning systems

Name of legislation	Main issue addressed (safety, environment, other)	Notes and references to relevant standards
F-Gas Regulation (2006/842/EC)	Containment of greenhouse gases	F-gas regulation and its 10 supporting implementing regulations (leakage, certification personnel, labelling, etc.). Note: legislation under revision due to proposal to revise F-gas Regulation, COM(2012) 643 The aim is to reduce the emissions of fluorinates greenhouse gases covered by the Kyoto Protocol.

Implementing Regulations for the F-Gas Regulation Labelling F gas (1494/2007 EC)	Labelling Certification of technical personnel and companies Leakage	Personnel & company certification is mandatory and concerns personnel who install, maintain or service systems; leak check systems
Energy Performance of Buildings Directive 2010/31/EU (EPBD)	Energy Performance in buildings	Articles 15,16,17,18 deal with the inspection of air conditioning systems, but also the impact of national/ regional calculation methods e.g. SAP in UK, En EV in D, RT 2012 in F There are also a set of related standards developed under CEN TC 113 and CEN TC 228 Energy Performance of Buildings Directive. CEN Standard EN15251 (comfort conditions regarding temperature and humidity).
WEEE Directive (2012/19 EC)	Waste of electrical equipment	The scope is defined in the IA Annex of the WEEE directive (2002/96/EC). Air-conditioning products are dealt with in the IB Annex under 'Large household appliances', as 'Large cooling appliances', 'Air conditioner appliances', 'Other fanning, exhaust ventilation and conditioning equipment'.

3.10.8 Case study 8 – Integrated Circuits

Introduction

The product groups examined in this case study are integrated circuits. This covers a wide variety of products, sub-components and final applications as explained further in section 2, below.

The aim is to analyse the applicable Union harmonisation legislation, assess the costs associated with the implementation of the applicable Union harmonisation legislation, identify areas of overlaps and conflicts between the different parts of the legislation that may lead to problems and costs to industry. This case will also identify and assess the benefits of possible simplifications. The rationale for the selection of these product groups was that:

- Integrated circuits are a fully globalised product group, with important centres of European expertise integrated into the global value chain and which are directly impacted by European legislation
- Integrated Circuits are manufactured in stages, with a number of processes between the first step and the final application in a product. Costs are incurred at each stage of the production process
- Integrated Circuits are perhaps the single most prominent Key Enabling Technology, and are one of the key factors to realise the overall policy objectives of Europe 2020. As such, integrated circuits are the subject of a newly-released European strategy for micro- and nonelectrical components and systems

- Integrated circuits are a key input into a number of additional products and are used primarily by professional users.

This case study is based on desk research and qualitative interviews. In the first phase of the project, structured desk research was carried out in to establish an overview of the integrated circuit industry, identify relevant pieces of legislation and standards, and to identify companies within the industry. An interview with The European Semiconductor Industry Association (ESIA) was then carried out. Thirty-five companies were contacted for interviews. In the end, eight interviews with firms were carried out. The interviews covered one of the largest European-based manufacturers of integrated circuits, another large European manufacturer, one of the largest global manufacturers, based in Asia, and inputs from five smaller 'fabless' manufactures in a variety of applications. A number of companies declined to participate in the study, citing difficulty in assessing costs or, in many cases, confidentiality reasons.

Product definition and description of structure of the sector

According to the standardised language adopted by the International Electrotechnical Commission, a semiconductor is a device whose essential characteristics are due to the flow of charge carriers within a semi-conductor. According to IEC 521-10-03, this includes any microcircuit in which all or some of the circuit elements are inseparably associated and electrically interconnected so that it is considered to be indivisible for the purpose of construction and commerce. This includes a number of applications. The following PRODCOM categories have been used to outline the scope of the product group.

Products within scope
26112240 - Photosensitive semiconductor devices; solar cells, photo-diodes, photo-transistors, etc
26113003 - Multichip integrated circuits: processors and controllers, whether or not combined with memories, converters, logic circuits, amplifiers, clock and timing circuits, or other circuits
26113006 - Electronic integrated circuits (excluding multichip circuits): processors and controllers, whether or not combined with memories, converters, logic circuits, amplifiers, clock and timing circuits, or other circuits
26113023 -Multichip integrated circuits: memories
26113027 - Electronic integrated circuits (excluding multichip circuits): dynamic random–access memories (D RAMs)
26113034 - Electronic integrated circuits (excluding multichip circuits): static random–access memories (S–RAMs), including cache random–access memories (cache–RAMs)
26113054 - Electronic integrated circuits (excluding multichip circuits): UV erasable, programmable, read only memories (EPROMs)
26113065 - Electronic integrated circuits (excluding multichip circuits): electrically erasable, programmable, read only memories (E²PROMs), including flash E²PROMs
26113067 - Electronic integrated circuits (excluding multichip circuits): other memories
26113080 - Electronic integrated circuits: amplifiers

26113091 - Other multichip integrated circuits n.e.c.
26113094 - Other electronic integrated circuits n.e.c.

As is clear by the range of product types, the product category of integrated circuits contains a number of sub-types. In general, integrated circuits are the building blocks of a number of technologies that make up micro- and nano-electronic components and systems. This includes the semiconductors used in all types of digital application used in electronics, automotive, and medical devices. In addition, integrated circuits are moving into an additional range of applications that further complicate the sector. New technologies such as wearable applications are driving breadth of integrated circuits into new product types.

Market size and Industry Structure

The global turnover of the semiconductor sector has been estimated at €230 billion in 2012, while the value of products comprising micro- and nanoelectronic components represents around € 1,600 billion worldwide and has grown by 5% per year since 2000.[163]

The starting point for the size of the European market is the Eurostat PRODCOM database, supplemented by additional market studies. In the PRODCOM database the specific product are covered under the code 261130-XX. Based on data, turnover is in the range of EUR 56.8 billion. Other sources suggest a somewhat smaller industry, with European turnover in 2011 amounting to EUR 30,3 billion.[164] The most comprehensive report outlining the profile of the Integrated Circuits market is the EU Trade in Electronics Sector Fiche, which is cited by the Industry Association as an authoritative source of market information. The Sector Fiche indicates a market size of

Industry Structure

Semiconductor products are multinational composites, and the industry is highly decentralised and diverse. The process of manufacturing can be broken down into discrete steps, with up to 600 sequential operations for each circuit. Final products are based on wafer processing, testing, and assembly, which generally take place in different places, often in different regions across the globe. The value chain is very complex and long, with the industry moving into even greater levels of fragmentation.

Developing newer generations of chips, becoming smaller and more powerful at an exponential rate, requires a high degree of precision in the fabrication process and higher levels of investment. In the 1980s, a new business model emerged to help solve the need for constant investment, called the “foundry” model, comprised of different types of manufactures. Large foundries, called “fabs” are able to increase the volume of their production to a sufficient scope to allow them to update assembly and photolithography systems, and are more commonly located in the Asian Pacific region. The Taiwan Semiconductor Manufacturing Company (TSMC) is the world's largest dedicated independent semiconductor foundry, with its headquarters and main operations located Taiwan. As a corollary industry, the “fabless” semiconductor company model, is comprised of firms

163 European Commission. 2013.
164 Semiconductors: Global Industry Guide. 2012. MarketLine

focused on design, marketing, and sale of circuits while benefitting from lower capital costs while concentrating their research and development resources on the end market.

The industry continues to bifurcate into two types of integrated circuit producers:

- **Integrated Device Manufacturers** (IDM) that design, manufacture and sell their chips. This includes firms in the United States (e.g. Intel), Asia (e.g. Samsung), and in Europe (e.g. STMicroelectronics, NXP, Infineon).

- **Fabless manufacturers** that design components and provide integrated circuit products and services to customers but outsources manufacturing to foundry companies. Fabless manufacturers often source their products from multiple foundries to optimise their supply chain and secure constant access to materials.

- A hybrid '**fab-light**' model has also emerged, which is based on maintaining some high-value manufacturing in-house but outsourcing the rest to a foundry.

The continued migration of production to 'low cost' labour countries combined with the continued high rhythm of technological change has driven companies to focus on core competencies, meaning that European firms are increasingly specialised in one component of the value chain.[165] The emergence of a networked model has allowed for – and subsequently encouraged – a greater degree of specialisation and opportunity for new entrants in highly-innovative areas of design, logistics, services, and computer-supported manufacturing.

This globalisation of the industry has also created a very long and complex supply chain in which European firms increasingly focus on collaboration and industrial partnerships. It is common for companies to rely on supply chains for most subcomponents, with third party testing occurring at various stages along the production phase, depending on the product type, country of origin, and intended final application.

The European industry is driven by a high research-intensity, with the highest R&D intensity of any sector in Europe, at 14.8 percent.[166] Industry clusters are important in the integrated circuits sector, given the high R&D intensity and the need to specialise. The most significant European clusters are located around Grenoble (France), Eindhoven (Netherlands), Dresden (Germany) and Dublin (Ireland), but other European clusters such as Catania in Italy also have global presence. It also appears that the leading clusters will reinforce their position as technology transitions to a new platform based on 450 mm wafers.[167] To sustain these clusters, European-wide supply chains have developed, with additional high-tech clusters in increasingly specialised fields (such as Helsinki and Vienna). Table 7-46 outlines key descriptive data on the European market.

The largest manufacturer is located in Taiwan (TSMC). Within the top 20 producers in terms of worldwide sales, only three are located in Europe: STMicroelectronics, Infineon, and NXP. While European manufacturers do not command a large global share, some producers of integrated circuits have established sites in Europe, including sales, design, and research along with some production as well capacity. In 2011, European production represented less than 10 percent of global production, down from a high of 16 percent only a decade earlier.

165 http://ec.europa.eu/enterprise/newsroom/cf/_getdocument.cfm?doc_id=7382
166 The EU Industrial R&D Investment Scoreboard: http://iri.jrc.ec.europa.eu/scoreboard.html
167 European Strategy for Micro and Nanoelectronic Components and System

Nevertheless, in Europe, micro- and nanoelectronics is responsible for 200,000 direct and more than 1,000,000 indirect jobs. [168]

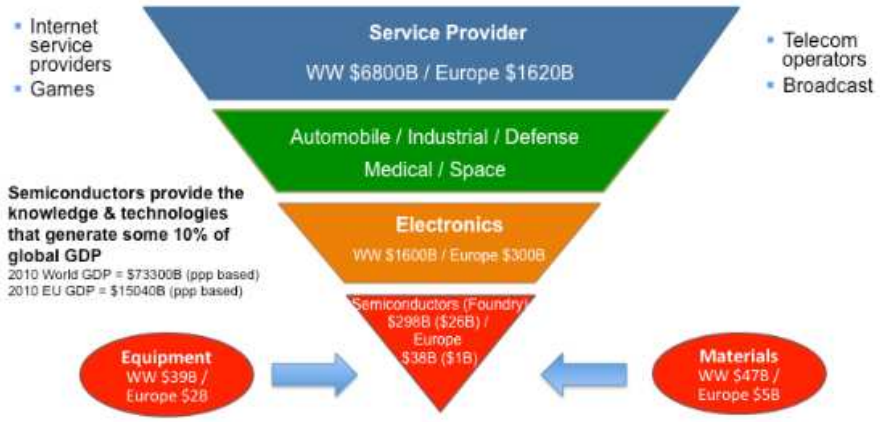
Table 7-46: Data on market size and industry structure

Parameter	Data
EU Market size	Market reports (2011) EUR 30.3 billion
Production volume/value in Europe	PRODCOM – Production Value (2010) – EUR 49.2 billion PRODCOM - Production Quantity: 11.415.218.521 units
Imports	PRODCOM - Value of Imports: 11.174.225.410 units
Exports	PRODCOM - EUR 8.8 billion
Number of enterprises	PRODCOM (2010) 6,984
Total Turnover	PRODCOM - EUR 56.8 billion
Number of employees	ESIA (2012) 200,000 direct employment PRODCOM (2010) 215,000

Source: Eurostat and market reports

The Final Report of the High-level Expert Group on Key Enabling Technologies[169] estimates that the European sector will enjoy a compound annual growth rate of 13 percent over the next years. But the industry data itself does not tell the complete story of the value of the integrated circuits sector to the overall European and global economy. Integrated circuits constitute a Key Enabling Technology (KET) and are valuable for the economic potential, their value-adding and enabling role, as well as their technology and capital intensity in terms of R&D and initiation investment costs.[170] The image below outlines the economic impact of the sector, both in terms of providing a market for suppliers of materials and equipment, moving up into direct employment and the subsequent industries enabled by the presence of software.

Figure 7-2: Value of Enabling Technology



Source: ESIA, 2010

168 http://ec.europa.eu/enterprise/sectors/ict/files/kets/hlg_report_final_en.pdf
169 High-Level Expert Group on Key Enabling Technologies. Final Report. http://ec.europa.eu/enterprise/sectors/ict/files/kets/hlg_report_final_en.pdf
170 High-Level Expert Group on Key Enabling Technologies. Final Report.

Analysis of applicable Union harmonisation legislation and standards

On the basis of desk research and input from firm interviews, we have identified the list of applicable pieces of Internal Market legislation, the basic administrative requirements and the relevant harmonised standards that can be used by manufacturers to meet the essential requirements.

In response to the internal market legislation, a number of **standards** have been developed, as outlined in table 7-47. Integrated circuits are highly technical and subject to broad international standardisation. Extensive standards exist. Given that the range of potential applications and sub-groups is limitless, only the major product-specific regulations have been reviewed. The table is meant to illustrate key standards that are aligned with specific requirements from internal market legislation, and is far from comprehensive.[171]

Standards vary according to the organisation issuing them. A number of standard-setting organisations exist, such as industry-led bodies (JEDEC), as well as the IEC and ISO/CEN. The IEC have been active in developing recent standards for the industry, as it focuses on the electronics industry.

Table 7-47: Summary of Union harmonisation legislation covering Integrated Circuits

Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
RoHS (2011/65/EC)	Use of hazardous chemicals	Collect compliance statement from suppliers (material declarations) Technical file with supplier declarations and own analysis tests Declaration of conformity to be kept for 10 years	EN 50581:2012 IEC62321

171 A search for 'integrated circuits' on the British Standards Institute database resulted in 685 individual standards. http://shop.bsigroup.com/en/SearchResults/?q=integrated%20circuits

Name of legislation	Main issue addressed	Requirements for economic operators	Relevant standards
General product safety Directive	Health & Safety	Provide identification of the product by a product reference Carry out sample testing of products, keep a register of complaints and keeping distributors informed of such monitoring (voluntary) Inform authorities of dangerous products and actions taken to prevent risk Co-operate with the authorities upon request	CENELEC: EN 60950-1:2006/A12:2011
EMC	Electromagnetic compatibility, mostly in the downstream applications of some integrated circuits	Testing according to standards Development of technical file Declaration of conformity and CE marking	IEC 61000 IEC 61967 IEC 62132
Packaging and packaging waste (2004/12/EC)	Packaging	Declaration of Conformity	
REACH	Use of chemicals	Collect statement from suppliers stating that compliance with requirements REACH compliance statement	IEC 62474

The review of the various requirements and the discussions with manufacturers pointed to a few issues in relation to the implementation of the legal framework and the requirements:

- Of the regions that produce integrated circuits, Europe is the most highly-regulated region in the world and plays a key role in the development of global standards. Given the globalised nature of the industry, with highly developed supply chains, undue or particularly burdensome regulation can cause shifts in production location. The initial analysis suggests that most Directives place rather similar obligations on industry; namely, revise the design of some products and then subsequent requirements to test, document, and declare conformity to specific requirements.

- This uniformity in across the sector was pointed out in the interviews with firms as being a positive aspect of the current framework. The industry is in general agreement that the legislation and the surrounding legislative framework are fairly positive. However, specific instances of duplication and inconsistencies have been identified.

- The most specific piece of legislation relating to integrated circuits is the RoHS Directive, which has been in effect since 2006. It was recently updated, known as RoHS2 (2011/65/EU), to address some uncertainties raised by industry and to increase market surveillance. RoHS2 bans new electrical or electronic equipment containing lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl and polybrominated diphenyl ether flame-retardants above specified thresholds and places documentation requirements throughout the supply chain.

- The interviews with firms consistently pointed to the RoHS Directive as the main driver of compliance-related activities. However, the interviews also emphasised that the RoHS-related procedures are part of a larger change to the industry that is now so deeply integrated in to the supply chain that it could not be isolated, even hypothetically.

- RoHS applies to integrated circuits produced in Europe as well as those entering the EU that are manufactured abroad. Due to the global nature of the industry, RoHS has become a de facto global regulation. China recently adopted most of the provisions through 'China RoHS,' which applies to the bulk of manufactured products. The RoHS concept is thus deeply integrated into the global industry and provides a framework for much of the supply chain.

- RoHS provisions are also reinforced and complemented by REACH, Directive No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals. The General Product Safety Directive introduces mandatory requirements concerning the product identification, cooperation with authorities when requested and a voluntary conduct of tests of marketed products, and the keeping of a register of complaints.

Analysis of costs of compliance with Union harmonisation legislation

The information presented in this section is based on the in-depth interviews with eight producers of integrated circuits. The firms range in terms of size and production volume and a located at various points along the production chain.

Given that the integrated circuits industry is completely globalised, turnover has been estimated from the turnover from Europe or from the European subsidiary of global companies. Information has been taken from corporate reports. It should also be noted that

even though turnover is from Europe, the overall activity is fully global, such as R&D taking place in Europe with manufacturing happening in other regions, generally in Asia).

Firm	Product / Application	Firm Size	Annual turnover from product (global)	Share of EU market (% of total firm turnover)
A	Fabrication	Large (>1000 employees)	3,900,000,000	33
B	Fabrication	Large (>1000 employees)	17,100,000,000	10
C	Fabrication	Large (>1000 employees)	4,368,000,000	20
D	Fabless - telecommunications	Medium size (250-500)	388,000,000	32
E	Fabless – consumer electronics	Small (<250 employees)	2,400,000,000	10
F	Fabless –touchscreen components	Small (<250 employees)	3,000,000	100
G	Fabless - general	Small (<250 employees)	6,000,000	15
H	Fab-lite - general	Medium size (250-500)	1,800,000,000	66

On the basis of discussion with the integrated circuit producers, IM legislation generates impacts on the following stages of the production process:

- Familiarisation with legislation and the purchase of standards
- Development of alternative designs and the associated testing of materials
- Seeking authorizations and exemptions, if needed, from RoHS and REACH lists of restricted substances
- Documentation of c Documentation of compliance - Testing, technical file and certification
- Monitoring the suppliers in the supply chain for compliance and switching to avoid non-compliance
- Declaration of conformity, CE marking and instruction manual
- Response to market surveillance activities

A number of caveats are necessary.

- It should also be noted that while costs have been suggested at specific points along the path towards compliance with EU Internal Market legislation, specific data on the costs is not available for each step.

- The interviews have produced limited information on the specific impact. One key reason is that, as a result of the dominant use of the foundry model, much of the compliance costs are absorbed throughout the supply chain and not by an individual company. OEM suppliers in third countries are required to adhere to restrictions while also complying with design requirements set out by fabless producers.

- Compliance testing occurs very early in the supply chain and it is not possible to disaggregate compliance costs for the IC firms. In addition, firms have not been able to estimate the amount of resources involved in the design process linked directly to regulatory compliance versus design procedures relate to quality, reliability, or adherence to regulations and standards set out at an international level.

The general process followed by manufacturers to ensure compliance with the IM legislation includes the following closely interlinked steps, and any specific data on costs has been identified and noted.

Familiarisation with relevant legislation and purchase of standards

The introduction of new legislation places costs on firms, including the time and resources used to familiarise themselves with the legislation.

The purchase of standards is one approach to learning about the implications of specific relevant legislation, which generates financial costs. Interviews with firms suggest that no standard 'familiarisation period' can be feasibly created due to the differences in the requirements. Manufacturers, suppliers, distributors, and end producers of consumer products develop administrative systems or databases applicable requirements are organised. Databases are being developed to manage the complexity of keeping track with IM legislation, standards, and amendments.

However, the costs association with each of these features is dependent on the specifics of legislation, of the new provisions, the intended end use of the semiconductor, and of the product portfolio. Therefore, no general average can be derived, according to the interviews. Indeed, the interview respondents suggest that databases and tracking systems are a normal part of working in an industry with a long supply chain and diffuse set of suppliers.

The smaller fabless firm states that they rely on their suppliers as well as their customers to inform them of implications of the various pieces of legislation. Third party testing occurs, but it varies depending on the production chain. In terms of their suppliers, fabless manufacturers tend to create industry partnerships with 'fabs' that produce the raw inputs into the integrated circuits. In general, there are fewer and fewer producers and the fabs are highly involved in the discussions of standards and legislation. On the customer side, the main market for European producers includes some of the most highly-regulated industries, which are careful to conform to legislation. Therefore, according to the interview with a fabless manufacturer, the industry has knowledge of how to comply and this knowledge is shared up and down stream.

Under REACH, the substance of very high concern (SVHC) "candidate list" can be updated annually and functions as a "living list".[172] As soon as a SVHC appears on the "candidate list", suppliers of articles containing the SVHC must forward information on the listed SVHC contained in the article (above a concentration of 0.1%) to recipients. The list is updated every 6 months, and even the larger firms have a very difficult time managing the speed with which the list is updated, though the industry has not produced data to demonstrate the burden. The European Chemical Agency (ECHA) engages in a highly structured public consultation every year, with consultation period of 45 days.[173] However, the participation of industry representatives is highly context- and product-dependent; nevertheless, this period of consultation generates discussion in advance of the introduction of changes, which allows for some familiarisation with the legislation.

According to the interviewees, manufacturers rely on **standards** to meet the essential requirements. Standards vary according to the organisation issuing them. A number of standard-setting organisations exist, such as industry-led bodies (JEDEC), as well as the IEC and ISO. The IEC have been active in developing recent standards.

Two interviews with small fabless producers suggest that smaller companies rely on standards, but that often changes are generally clearly articulated by customers and additional standards are not always purchased. The firm indicated that standards are purchased as needed, with some periods of time requiring the purchase of standards, as well as significant variation depending on the product line. Moreover, industry standards are often translated into customer specifications. Even in the absence of specific standards, producers would need to comply with customer specifications.

New costs have been introduced since the industry has shifted from voluntary industry standards created by JEDEC, which were free, to the IEC standard EN 50581:2012 was made available in 2012 by CENELEC related to **"**Technical documentation for the evaluation of electrical and electronic products with respect to restriction of hazardous substances." This standard must be purchased. The current prices for the identified standards covering a majority of the sector include:

Relevant Standard	**Price (EUR)** [174]
EN 50581:2012	43
IEC62321	252
EN 60950-1:2006/A12:2011	277
IEC 61000	187
IEC 61967	122
IEC 62132	122
IEC 62474	204

172 An updated version of the "candidate list" can be found in the ECHA website: http://echa.europa.eu
173 http://echa.europa.eu/en/web/guest/view-article/-/journal_content/512b7526-9dd6-4872-934e-8c298c89ad99
174 The International Electrotechnical Committee is based in Switzerland and bases its prices on the Swiss Franc (CHF). Conversions use the following rate: CHF/EUR = 0.8147

Given that the range of potential applications and sub-groups is limitless, only the major product-specific regulations have been reviewed (see table above).

Development of alternative designs and the associated testing of materials

Internal market legislation generates two distinct costs on firms in terms of design choices. First, some manufacturers have had to redesign products to comply with restrictions on materials. Second, under the two most applicable internal market directives, RoHS and REACH, companies have an opportunity to petition for an exemption or authorisation from some of the limitation imposed by the legislation. Because two separate lists are created, with separate procedures for exemptions/ authorisation, there is a duplication of effort combined with a high degree of uncertainty about certain substances.

In terms of **redesign**, one important source of compliance costs has been the requirements of the **RoHS** Directive in relation to the use of lead, which is used in a number of components in the manufacture of integrated circuits. The industry is still in the process of phasing out lead. There were significant upfront costs for the conversion to lead-free packaging, and until recently the unique functionality of lead soldering was required for some components and packaging.

Exemptions have been obtained under RoHS to allow for the continued use of some lead in a limited number of applications. Thus, testing for compatibility and replacement programmes has been an ongoing activity for firms. A number of companies outlined a 'conversion roadmap' to demonstrate progress towards converting their product line towards compliance with RoHS.[175]

Large companies initiated compliance programmes in response to European regulations (especially RoHS) relatively early, while many smaller producers did not have the capacity or inclination to develop substitutes and only recently started to address this issue. RoHS compliance presents many product management and design decisions such as whether to bring products into compliance or to make them obsolete, or whether to make use of the currently granted exemptions.[176]

RoHS generated upfront costs of material substitution, given that many types of integrated circuits used lead soldering. While the interviews would not confirm the cost, some studies of the impact of RoHS suggest that the impact equals 1.9% of total turnover,[177] which is generated by the upfront costs of switching to lead-free components. This is roughly in line with a 2008 study which estimated that, generally, the average past and future one-off cost impact of RoHS lies between 1 and 2% of total turnover. However, these studies did not focus exclusively on integrated circuit manufacturers, nor did they document the precise source of costs.

Interviews with firms could not provide further information, though the interview with a large producer suggested that the RoHS compliance programmes are among the most pressing R&D and compliance issues for the industry, especially given the unique functions played by some substances, such as lead.

175 See, for example, the chart created by NXP: http://www.nxp.com/about/corporate-social-responsibility/environment/lead-free-halogen-free/matrix.html#complete

176 ESIA. 2009. Semiconductors: Enabling Sustainable Living in 21st Century Europe.

177 Cited in http://www.nema.org/Policy/Environmental-Stewardship/Documents/081203%20RoHS%20impact%20assessment%20summary.pdf

Seeking authorizations and exemptions

In terms of the authorization and exemption processes, some materials are critically important to the integrated circuits, both in terms of some harmful substances used in the production process while others are found in trace amounts in the final product due to their unique functionality in achieving performance goals for the product. The material development cycle in the semiconductor industry is typically 10-15 years, consisting of fundamental research, hazard and risk evaluation, demonstration and integration with manufacturing equipment (and sometimes the development of new manufacturing equipment or processes), and production. Where chemicals already used in manufacturing need to be replaced, ample time must be provided to develop substitutes for these chemical uses.

The large manufacturers stated in interviews that the requirements often serve as an impediment that is eventually overcome rather than a true barrier. No examples of specific instances could be presented where the use of a key substance could not be substituted or an exemption obtained. A review of company websites outlines the continued use of hazardous or dangerous materials in the production process, even though the substance does not end up in the finished product.

Nevertheless, the exemption and authorisation processes are very costly, according to the interviews, though no fixed amount is available. There are two aspects of the duplication that cause substantive costs. RoSH 2 and REACH apply to some of the same substances in the same products and processes, sometime resulting in duplication of administrative burdens. RoHS 2 provides rules on the restriction of certain hazardous substances in Electrical and Electronic Equipment (EEE), while REACH is a more general act regulating or restricting chemical substances. In terms of specific duplication, in a position paper from March 2013, Orgalime points out[178] that there is some overlap in the Directives. Four substances highlighted under RoHS2 for priority assessment, namely plasticisers BBP, DBP, DEHP and flame retardant HBCDD featured in the REACH Candidate list back in 2008 and are now also included in the list of substances subject to REACH authorisation in Annex XIV.

When seeking exemptions, there are two separate procedures that need to be followed and the two Directives do not recognise each other's lists of banned substances. In some cases, an exemption can be obtained in one list but not in another; in some of these cases, there could be a delay in obtaining the second exemption.

There appears to be inconsistency in the application of RoHS and REACH, especially in terms of valid procedures that are consistent for both Directives. The industry association, ESIA, points out that lists based around the REACH processes that target substances for potential likely action without any upfront risk review on whether or not the risk is managed in how the semiconductor sector uses the substance. This uncertainty creates barriers to product development without a full risk-based assessment taking place.

178 http://www.orgalime.org/sites/default/files/PP_Complementary_REACH_and_RoHS_Mar13.pdf

The overlap and inconsistency cause a duplication of effort and significant uncertainty for the industry, with the greatest effects in product development. So far, the interviews have produced limited information on the specific impact. One key reason is that, as a result of the dominant use of the foundry model, much of the compliance costs are absorbed throughout the supply chain and not by an individual company. OEM suppliers in third countries are required to adhere to restrictions while also complying with design requirements set out by fabless producers.

Compliance testing occurs very early in the supply chain and it is not possible to disaggregate compliance costs for the IC firms. In addition, firms have not been able to estimate the amount of resources involved in the design process linked directly to regulatory compliance versus design procedures relate to quality, reliability, or adherence to regulations and standards set out at an international level.

Documentation of compliance - Testing, technical file and certification

Testing has long been a normal procedure in the integrated circuits industry, either in-house or by specialised testing houses. With the emergence of RoHS and REACH, third party testing houses have emerged to fill the gap in internal capacity of some smaller fabless manufacturers. IDMs have in-house testing capabilities, and increasingly have started to offer testing services to their industry partners to help consolidate some of the processes within the supply chain.

Both RoHS and REACH require the development of a technical file following testing, most often following a specific standard created by the industry. RoHS2 introduces new requirements for companies to maintain technical files. This is a significant difference compared to the first version of the RoHS Directive, which did not prescribe any requirements for manufacturers to maintain compliance documentation.

Under the original RoHS, firms along the supply chain did not have this obligation; the final OEM manufacturer or importer who puts the finished branded equipment on the market in the EU incurred all the costs of managing the supply chain.[179]

As a result of major end users being required to monitor the supply chain, suppliers have long been encouraged through market pressure to maintain technical files, and this has long been a well-established practice in the integrated circuits industry.

However, the practice remained ad hoc and incomplete, according to the large manufacturer interviewed. RoHS2 now puts more of a structured framework in place. Standard EN 50581:2012 was made available in 2012 by CENELEC related to **"**Technical documentation for the evaluation of electrical and electronic products with respect to restriction of hazardous substances"[180] to meet the needs of technical documentation.

179 https://www.bomcheck.net/assets/docs/Guide%20to%20REACH%20Requirements%20for%20component%20suppliers%20and%20equipment%20manufacturers.pdf

180 This European Standard specifies the technical documentation that the manufacturer needs to compile in order to declare compliance with the applicable substance restrictions. The documentation of the manufacturer's management system is outside the scope of this European Standard. http://www.cenelec.eu/dyn/www/f?p=104:110:3448161281810912::::FSP_PROJECT,FSP_LANG_ID:23432,25

Information obligations add an additional administrative cost. An important source of administrative costs is with REACH Regulation. REACH places a legal obligation on all EU suppliers to provide substance declaration information when they supply their outputs (components and sub-assemblies) to the next manufacturer in the supply chain. This could extend to contract manufacturers when they supply equipment to OEM clients, drawing on information which component suppliers are required to disclose to the contract manufacturer. However, the costs vary depending on the unit type and the size of the order.

There are also certain synergies in the databases since many of the requirements are the same and industry standards are able to cover both Directives. A single technical file system can capture information pertaining to both RoHS and REACH. The General Product Safety Directive introduces mandatory requirements concerning the product identification, cooperation with authorities when requested and a voluntary conduct of tests of marketed products, and the keeping of a register of complaints.

Firms provided direct estimates of human resources dedicated to managing the technical files. The resources dedicated to managing these files vary significantly according to firm size and location in the production chain. For example, a small fabless producer (focusing on design and sales) with 25 employees reported that 1 FTE was required to address requests for documentation. A large global producer, with a staff of 24,000, stated that there are approximately 50 FTE dedicated specifically to compliance. In this latter case, approximately half of the staff time is normally dedicated specifically to RoHS. However, the total responsibility for maintaining the files is distributed across a number of additional staff resources, including sales staff, R&D, quality assurance, and management. Another large producer stated that the European-based team has a large legal team, with 42 people and one in-house council that focus on, among other domains, export compliance.

Monitoring the suppliers in the supply chain for compliance and switching to avoid non-compliance

Linked to the certification costs, firms in the downstream stages of the supply chain are required to verify the certification of their suppliers and then pass this information onto their clients. This places significant burdens throughout the supply chain. Although REACH and now ROHS2 place obligations on companies to pass on information, in practice it is the demands of customers that cause companies to collect stringent information, up to the standards of the eventual end-users.

A number of approaches have been adopted to monitor the supply chain. Downstream firms, especially larger firms operating with many suppliers, require relevant supplier to pre-register substances and preparations used in industrial (including engineering) processes and will monitor and support registration by suppliers.

As integrated circuits move from one producer to the subsequent stages of development, the common practice is to use a bill of materials (BOM) to document the materials and substances contained in the circuit. Ideally, suppliers will issue a Full Materials Declaration, which states all of the elements and substances that are contained in an integrated circuit. According to desk research and interviews, this is not consistently practiced. Confidentiality was raised as one potential barrier in obtaining all relevant information. In some cases, re-testing is required where there is a ‘break in the chain’ from one stage to the next. Confidentiality was also cited as one of the impediments to obtaining precise estimates; given that efficient management procedures are part of the value proposition of some companies, details were not forthcoming.

The main concern is the amount of detail that needs to be carried forward along the development process of integrated circuits. One difficulty that was mentioned by a large manufacturer was that there are potentially dozens of suppliers in any single component, and that it is often a problem if one of the intermediary suppliers has not kept adequate records. Often, the level of detail of a company's record system is actually a selling point in terms of the appeal of using a specific supplier.

Some companies are encouraging smaller suppliers to pre-register their Bills of Materials on private platforms that offer industry-wide databases to manage certification and declarations of compliance. BOMCheck is the most developed platform.[181] Under this system, suppliers can create a vendor account and the purchasers can apply for a subscription that allows for verification of records. For the BOMCheck system, the subscription fee for suppliers is an annual fee of EUR 300. [182] More than one million RoHS and REACH Materials Declarations from over 3,100 suppliers have been uploaded to the system, as of June 2013.[183]

Declaration of conformity, CE marking and instruction manual

Based on a review of the websites of a wide sample of the industry, it appears that the standard practice is to post Declarations of Conformity on the company webpage. This does not appear to be particularly burdensome, and the interviews suggest that this is a common practice that is recognised by firms in the sector. Indeed, the introduction of REACH and RoSH2 could potentially redistribute costs across the supply chain rather than place all costs on the single point at which the final product is placed on the market, meaning that costs are transferred rather than altered.

Manufacturers within the EU must obtain a declaration of ROHS compliance for all the parts, components, and materials that they are using, while importers need to obtain a declaration of compliance from their suppliers.

The set-up costs do, however, include the time to carry out the conformity assessment and check that standard documentation has been obtained. Some of the larger downstream companies facilitate this process on behalf of suppliers, and it ensures a smoother process for identifying required documentation. Based on the interviews with firms, the CE Marking is recognised as a normal cost of doing business and is not seen as unduly burdensome.

The industry has adopted Design for RoHS compliance guidelines, though this is internal for each company and differs based on the application. The large manufacturer uses this design guideline internally, while the small fabless manufacturer relies on the foundry to check for the compliance of its designs before shipment.

181 See the industry-led initiative, BOMCheck, developed by the European trade association COCIR and coordinated by the environmental consultancy ENVIRON, which sits on co-chairs the IPC 1752A materials declaration standard and serves as EMEA regional coordinator for the IEC 62474 materials declaration standard. https://www.bomcheck.net/

182 See press release: http://www.prnewswire.com/news-releases/bomcheck-celebrates-more-than-1-million-rohs-and-reach-materials-declarations-from-over-3100-suppliers-211932871.html

183 There is no limit to the number of part numbers that the supplier can load into the database or the number of customers that the supplier may have on BOMcheck.

Response to market surveillance activities

RoHS2 includes obligations for all EU Member States to perform systematic market surveillance including "appropriate checks on product compliance on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples". In contrast, RoHS1 did not prescribe any enforcement procedures that Member States were required to implement.

While the documentation requirements for compliance are burdensome, interviews did not yield specific instances of particular burdens with market surveillance beyond what would be expected under typical regulation. Under RoHS, firms have 28 days to provide sufficient documentation of conformity, and there is no suggestion in the available information that this is particularly burdensome.

Both the fabless and the IDM interviewed state that while there are some occasions that surveillance authorities request information, by far the largest burden is on supplying information to client downstream, such as manufactures of electronics, automotive, or other industries. The interview respondents state that given the highly-regulated nature of the end manufacturers (automotive, industrial processes, telecommunications industries), some of which are very tightly regulated in Europe and other countries, there is a high burden on the supply chain to maintain records.

Large firms maintain structured protocols for responding to surveillance requests while the smaller firm relies on an ad hoc approach, rarely exceeding the 1 FTE that has been allocated to maintaining the technical file, reacting when necessary to supply information. Details of the document management system were not shared, though the firm was clear in that a standard approach to managing supplier documentation is sufficient for responding to requests. It was also stressed that requests from clients are normally the key source of inquiries and far outweigh any burden from surveillance agencies.

Business as usual

Some of the costs indicated above should be considered as part of a business as usual scenario, especially those related to information sharing. While the interviews focused on the impact of RoHS and REACH, all interviews stated that quality management would still be part of internal procedures irrespective of the regulatory framework requirements, and the information requirement would remain just as burdensome. The large company stated that in some instances, the Directives and corresponding standards are helping to simplify the information as it moves through the supply chain as common standards are imposed for all companies. Product reliability tests are often conducted by established firms that want to ensure the quality of their products, so information will always need to be shared.

Furthermore, the presence of significant legislation in other countries (e.g. China and Japan) means that important part of the documentation required and the significant costs of maintaining sophisticated databases would likely have been incurred even in the absence of EU legislation.

Estimation of Assessment of costs of Union harmonisation legislation for the whole sector

Disentangling costs is limited, given the lack of information and the diffuse burdens across the supply chain. The complex and very long supply chain creates impacts for manufacturers

far upstream and downstream, though it is difficult to estimate the distribution of the burdens. Moreover, interviews suggest that the impacts of pieces of legislation are highly context-dependent, ultimately differing based on the product portfolio of a company (number and types of products), as well as the location with the supply chain.

On the basis of specific cost information from four of the interviews, we estimated the administrative costs for the main cost elements identified and, on the basis of certain assumptions, to extrapolate to the whole of the EU industry. The interviews did not provide sufficient data to present cost details. The following table presents some information. The average figures from the interviews were upscaled using turnover.

Type of Cost	Estimated annual costs for the whole sector
Internal	€ 7.6 million
Third parties	€ 26 thousand
Testing equipment	€ 10 thousand
Total	**€ 7.6 million**

As is evident, internal compliance costs represent the main cost element for the industry. The interviews suggest that internal processes and activities related to compliance were the highest share of the total costs. Compliance testing is linked to companies' R&D activities. Research and Development costs are inevitably high in the integrated circuits industry, which is a major factor explaining why integrated circuits are the most R&D intensive industry in Europe, according to the European Commission's R&D Scoreboard. Third party testing and testing equipment specifically for compliance with internal market legislation is marginal in terms of the overall R&D budgets. Again, a number of assumptions that have been made related to the costs need to be further examined and discussed with the relevant association.

Overall conclusions

This case study examined the role and costs of Union harmonisation legislation for integrated circuits, the building blocks of a number of technologies that make up micro and nano-electronic components and systems. According to PRODCOM data, the European market for integrated circuits has a total market size of €56.8 billion while other sources suggest that the industry is somewhat smaller industry, around €30 billion. European manufacturers do not command a large global share and European production represented less than 10 percent of total global production in 2011.

The applicable Union harmonisation legislation covers issues related to product safety only indirectly (through the General Product Safety Directive), electromagnetic compatibility (EMC) and focuses more on environmental impacts (REACH and RoHS Directives).

On the basis of information provided by some companies, the administrative costs for the sector were estimated at around €7.6 million. The interviews with firms consistently pointed to the RoHS Directive as being the main driver of compliance-related activities. However, the analysis also emphasised that RoHS-related procedures are part of broader changes within the industry that are now so deeply integrated into the supply chain that the compliance costs specifically linked to internal market legislation cannot be easily isolated.

Sources of information

- Eurostat Structural Business Statistics Database and PRODCOM
- Text of applicable IM legislation and relevant standards
- Policy and strategy documents published by the European Commission or relevant industry associations
- Industry Association: The European Semiconductor Industry Association (ESIA)
- Interviews with eight firms, varying in size, market share, and product applications.

ANNEX 8: 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 system has helped to raise awareness of high-risk products (see section 4.82 below). 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[184]. 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[185].

For example, the impact assessment[186] 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, non-compliance was estimated to be 10- 20%[187.] In other areas (e.g. Gas Appliances, Personal protective equipment) the existing studies indicate non-compliance levels of no more than 5-10%[188] and there are also cases – such as explosives – where, according to the relevant

184 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

185 EC (2012), Commission Staff Working Document, Annexes to the Impact Assessment, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2013:0033(52):FIN:en:PDF

186 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

187 Evaluation of the Ecodesign Directive (2009/125/EC) - Final Report

188 Impact assessment study on the review of the Gas Appliances Directive 2009/142/EC

evaluation study[189], 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 association stated that "the manufacturer is already legally responsible for ensuring regulatory 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 non-compliant 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

189 Evaluation on dg enterprise and industry legislation – Cosmetics and Explosives Directives

the internal market since there could be variations for economic operators in their 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**[190], 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 merge 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

190 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.

the value added of each database".

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 8-1: A systems-based and horizontal approach to market surveillance and regulatory enforcement[191]

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

191 Source: Systeemtoezicht en Horizontaal Toezicht, conceptleidraad voor de Rijksinspecties, Begrippen en randvoorwaarden, December 2012 http://www.inspectieloket.nl/vernieuwing_toezicht/programma_systeemtoezicht/

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 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 9: 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').[192] 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"): http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm. The reports have also been published by Member States[193].

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.

192 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.

193 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

- General organisation: 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[194] and in the Report on the implementation of Regulation (EC) No 765/2008[195].

- Resources: this part indicates the overall resources made available to market surveillance, if mentioned in Member States' reports.

- Own assessment: 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

- Coverage: 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.

- Distribution of resources: 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.

- Own assessment: this part summarises each Member State's own assessment of the functioning of market surveillance sectoral activities in the 2010-2013.

194 See the section "National market surveillance programmes " on the following page: http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm

195 COM(2013)77.

2.1 Belgium

General market surveillance activities

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

Table 9-1: Distribution Market Surveillance Responsibility in Belgium

FPS for Economy, SMEs, Self-employed and Energy	Toys 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 and the Environment	Chemical products 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 Health Products	Pharmaceutical products Medical devices Active implantable medical devices
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.

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

Market surveillance in specific sectors

Coverage: 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.

Distribution of resources: 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

Own assessment: 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

General organisation: 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.

Overall resources: 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[196] (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[197] and the authority employed about 130 FTEs for staff (of which about 110 inspectors).

Own assessment: 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

Coverage: 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.

196 The budget also covers inspections of industrial equipment during use, as well as quality control of liquid fuels.
197 Correspondingly, the share of KZP's resources dedicated to market surveillance went down from 62% to 40%.

Distribution of resources: 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[198] (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).

Own assessment: 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 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

General organisation: 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

198 Directive 94/62/EC.

and appliances, radio equipment and telecommunications terminal equipment, measuring instruments, recreational crafts, as well as timber, batteries and novelty lighters.

Overall resources: 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[199] (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[200], 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 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.

199 The figure excludes the wages of personnel not directly involved in markets surveillance.

200 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.

Market surveillance in specific sectors

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

Distribution of resources: 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.

Own assessment: 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[201]. On the other hand, the report does not provide for a more general assessment of the effectiveness or efficiency of these sector specific activities.

2.4 Denmark

General market surveillance activities

General organisation: 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.

Overall resources: 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[202]). 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.

Own assessment: 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.

201 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.

202 The proportion of staff who are inspectors may be slightly greater, since some authorities have not classified their staff in more detail.

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

Coverage: 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 and some national legislation.

Distribution of resources: 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.

Own assessment: 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

General organisation: 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.

Overall resources: 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.

Own assessment: 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).

Coverage: In general, the German report concerns the sectors covered by the national Product Safety Act which transposed the General Product Safety Directive and 12[203] 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[204] implemented under each area.

Table 9-2: Action areas and corresponding market surveillance campaigns

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

203 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).

204 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).

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 requirements205. By contrast, the proportion of those products that presents a serious risk is only 0.7 % (1032 cases).

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.

Distribution of resources: 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 € 12.1 million to € 11.6 million were available to the market surveillance authorities with a staff allocation of a consistent 85 full-time equivalent units (FTE).

Own assessment: 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

General organisation: Market surveillance is carried out by seven authorities: the Consumer Protection Board, the Health Board, the Technical Surveillance Authority, the Labour

205 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

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.

Overall resources: 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.

Own assessment: 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

Coverage: 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.

Own assessment: 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

General organisation: 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.

Overall resources: 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.

Own assessment: 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

Coverage: Ireland reports on most of the sectors from the reference list (including non-harmonised 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.

Distribution of resources: 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).

Own assessment: 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

General organisation: 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.

Overall resources: 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.

Own assessment: 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

Coverage: The Greek 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, 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.

Distribution of resources: 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.

Own assessment: 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

General organisation: 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.

Overall resources: 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.

Own assessment: 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

Coverage: 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.

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

Own assessment: 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

General organisation: 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[206], either by carrying out checks 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

Overall resources: 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. [207] 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.[208] 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

206 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; 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.

207 Budget including both tests carried out by State laboratory and tests subcontracted to private laboratories.

208 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.

customs budget and staff for market surveillance.

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

Market surveillance in specific sectors

Coverage: 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.

Distribution of resources: 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[209].

Own assessment: 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.

2.11 Croatia

General market surveillance activities

General organisation: 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

209 The percentage mentioned here are very rough and purely indicative estimates.

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.

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

Market surveillance in specific sectors

Coverage: 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);

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

Own assessment: 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

General organisation: 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.

Overall resources: 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[210] - 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.

210 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.

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[211]that carry out documentary checks, and more than 900 inspectors[212]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).

Own assessment: 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

Coverage: 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 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[213].

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

Own assessment: 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.

211 63 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.

212 This figure includes 500 FTEs from Guardia di Finanza, 275 from Chambers of Commerce, 100 Carabinieri NAS.

213 However pyrotechnics and civil explosives also come under the responsibility of the police.

2.13 Cyprus

General market surveillance activities

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

Overall resources: 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.

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

Market surveillance in specific sectors

Coverage: 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.

Own assessment: 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

General organisation: Market surveillance in Latvia is handled by 11 different authorities[214] 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.

Overall resources: 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.
- 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

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

214 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).

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.

Own assessment: 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.

General organisation: 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[215]) 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 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,

215 According to the Lithuanian study that the scope of the Product Safety Law in respect of foodstuff is unclear.

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

General organisation: In Luxembourg there are eight market surveillance authorities[216]. 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.[217] The responsibilities of ILNAS and ITM cover about two-thirds of the sectors mentioned in the reference list.

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

Overall resources: 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.

Own assessment: 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

216 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

217 On 1 August 2014 the responsibility for market surveillance authority in these areas were transferred to ILNAS

exchange of data via a common Intranet (EC.SDM) and regular training on product safety and legal requirements.

Market surveillance in specific sectors

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

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

Own assessment: 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

General organisation: 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.

Overall resources: 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.

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

Market surveillance in specific sectors

Coverage: 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.

Own assessment: 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

General organisation: 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.

Overall resources: 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).

Own assessment: 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.

Own assessment: 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

General organisation: Market surveillance of products is organised between six national market surveillance authorities[218], 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).

Overall resources: 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 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 of EU product legislation. Verispect mentions a budget of 0.2 million EUR for market surveillance of measure instruments and a number of FTEs increasing from 0.3 in 2010 to 1.5 in 2013.

Own assessment: The report states that with Regulation (EC) No 765/2008 the market

218 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).

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

Coverage: 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.

Own assessment: 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

General organisation: 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[219] (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 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.

219 This concerns around 100 district administration authorities across the nine federal provinces.

Overall resources: 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.

Own assessment: 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

Coverage: 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.

Own assessment: 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

General organisation: 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[220].

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).

Overall resources: 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.

Own assessment: 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

Coverage: 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.

Own assessment: 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

General organisation: Pursuant to Regulation (EC) No 765/2008, market surveillance is handled by 8 authorities[221] each with their own sector(s) of responsibility. The report further mentions that external border control is assigned to the Tax and Customs Authority which is not considered a market surveillance authority.

Overall resources: 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

220 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).

221 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).

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.

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

Market surveillance in specific sectors

Coverage: 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-water boilers and motor vehicles and tyres,

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

Own assessment: 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

General organisation: 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.

Overall resources: 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.

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

Market surveillance in specific sectors

Coverage: 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).

Own assessment: 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

General organisation: Market surveillance in Slovenia is handled by 9 different market surveillance authorities[222] 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.

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.

222 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.

Own assessment: 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

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

Distribution of resources: 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).

Own assessment: 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

General organisation: 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[223], is

223 The Ministry's responsibility also encompasses the Main Mining Office, which carries out the state surveillance of the explosives market.

the market surveillance authority for most non-food consumer products.[224]

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[225] (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 pre-packaging.

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[226] 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[227].

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 activities, such as official inspections of foodstuffs.

224 The Trade Inspectorate is the sole surveillance authority only in relation to toys, pyrotechnics, construction products, electrical appliances and equipment under the low voltage directive, gas appliances, and the labelling of products and recreational craft.
225 Together with 36 regional public health authorities.
226 16 inspectors from regional labour inspectorates and 2 employees of the National Inspectorate.
227 This figure is not explicitly provided by the Slovak report, but corresponds to the value of the multiplication of estimated full-equivalent units of staff for market surveillance and expenditure per employee.

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.

Own assessment: 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

Coverage: 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).

Distribution of resources: 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.

Own assessment: 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

General organisation: 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).

Overall resources: 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.

Own assessment: 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

Coverage: 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.

Distribution of resources: 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[228] (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 cross-border cooperation in the sectors of marine equipment and motor vehicles.

2.27 Sweden

General market surveillance activities

General organisation: 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

228 Including checks for hot-water boilers efficiency requirements.

RAPEX.

Overall resources: 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.

Own assessment: 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

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

Distribution of resources: 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).

Own assessment: 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

General organisation: 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.

Overall resources: 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.

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

Market surveillance in specific sectors

Coverage: 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.

Own assessment: 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 Annex 2.

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[229]. The objective is to shed a brighter light on some aspects of market surveillance activities in practice.

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

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, 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[230], 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[231] 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[232]:

- 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[233]; 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

230 Also includes those concerning non-harmonised consumer goods.

231 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.

232 The number of inhabitants is taken here as a very simple (although admittedly very rough) estimate of national market sizes.

233 The figure does not include checks carried out by customs that in France are market surveillance authorities.

(7-11 million inhabitants): Belgium reports 1 270[234] inspections per year on average; Greece reports 28 inspections[235], 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 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[236]; 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[237] 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).

234 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.

235 The Greek report notes these were carried out "at virtually zero cost".

236 Not limited to toys.

237 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.

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[238] for the period 2010-2013 were proactive inspections. However the situation changes from country to country (see Table 9-3 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%), 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%)[239] - recorded a high number of reactions to Rapex notifications - and Ireland (0%).

Table 9-3: Share of self-initiated inspections out of total inspections (percentages)

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.
CY	n.a.
LV	98
LT	n.a.
LU	99
HU	62
MT	54

238 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.

239 As regards Belgium the share is calculated on the figures provided for 2013 only.

NL	n.a.
AT	n.a.
PL	83
PT	50
RO	99
SI	77
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% [240], 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.

Table 9-4: Share of inspections prompted by customs (percentages)

BE	n.a.
BG	26

240 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.

CZ	n.a.
DK	10
DE	n.a.
EE	n.a.
IE	100
EL	0
ES	n.a.
HR	38
IT	n.a.
CY	n.a.
LV	19
LT	n.a.
LU	25
HU	1
MT	0
NL	n.a.
AT	n.a.
PL	19
PT	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 non-compliance was on average 44% in the EU[241]. 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 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.

4.6 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.[242]

Table 9-5 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%.

Table 9-5: Follow up to inspections: percentage of cases of non-compliance where measures and/or penalties were applied

241 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.

242 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.

BE	n.a.
BG	37
CZ	37
DK	68
DE	n.a.
EE	100
IE	100
EL	52
ES	n.a.
FR	29
HR	n.a.
IT	n.a.
CY	46
LV	86
LT	n.a.
LU	71
HU	98
MT	52
NL	n.a.
AT	n.a.
PL	n.a.
PT	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.

4.7 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.

4.8 On budget and staff

Only 10 Member States indicated budget[243] 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;

243 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.

- 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.

In addition Ireland and Slovenia report the figures of 5.875.000 € and 5.633.460 € 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).

4.9 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 9-6: 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 9-7: 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.

		SECTOR 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)		SECTOR 2 - Cosmetics		SECTOR 3 - Toys		SECTOR 4 - Personal Protective Equipment		SECTOR 5 - Construction 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				
IT	60.80	125.00	2.06	1385.25	22.79			35.25	0.58		
CY	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
MT	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
PT	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
SL	2.06	16.50	8.00	1921.5[244]	931.47	1,756.50[245]	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

[244] Figures include also all beauty care services inspections.

[245] Figures include also inspetions in kindergartens.

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				

		SECTOR 6 - Aerosol dispensers		**SECTOR 7 - Simple pressure vessels and Pressure Equipment**		**SECTOR 8 - Transportable pressure equipment**		**SECTOR 9 - Machinery**		**SECTOR 10 - Lifts**	
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							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		
CY	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
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
MT	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
PT	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		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	
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
CY	0.85					0.25	0.30	32.75	38.67	55.50	65.52
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
MT	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
PT	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
SE	9.75			8.00	0.82	1.50	0.15	3.50	0.36		
UK	64.88										

		SECTOR 16 - Appliances burning gaseous fuels		SECTOR 17 - Measuring instruments, Non-automatic weighing instruments (NAWI) 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	
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
CY	0.85	9.33	11.02			117.75	139.02	16.00	18.89	121.25	143.15
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
MT	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
PT	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
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										

		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	
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				
CY	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
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		
MT	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
PT	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 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	
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			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
CY	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
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
MT	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		
PT	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 9-8: Statistics on inspections based on tests performed in laboratories 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.

		SECTOR 1 - Medical devices (including in vitro diagnostic medical devices and active implantable medical devices)		SECTOR 2 - Cosmetics		SECTOR 3 - Toys		SECTOR 4 - Personal Protective Equipment		SECTOR 5 - Construction Products	
Member State	**Population (million)**	**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**	**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**
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
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		
CY	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
MT	0.43										
NL	16.90										
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
PT	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 6 - Aerosol dispensers		SECTOR 7 - Simple pressure vessels and Pressure Equipment		SECTOR 8 - Transportable pressure equipment		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**	**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**	**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										
CY	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
MT	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
PT	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		
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		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	
Member State	**Population (million)**	**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**	**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**
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										
IT	60.80							0.00	0.00	0.00	0.00
CY	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
MT	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
PT	10.37	0.00	0.00	0.75	0.07			2.50	0.24	2.50	0.24
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 - 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	
Member State	**Population (million)**	**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**	**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**
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										
IT	60.80			1.75	0.03			120.50	1.98	28.25	0.46
CY	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
MT	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
PT	10.37	0.00	0.00	1.00	0.10	2.25	0.22	131.25	12.65	1.50	0.14
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 - 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	
Member State	**Population (million)**	**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**	**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**
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										
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		
MT	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
PT	10.37	0.00	0.00								
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 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	
Member State	**Population (million)**	**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**	**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**
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
CY	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
MT	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		
PT	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		
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 9-9: 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 (€)	€ 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 (€)	€ 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 (€)	€ 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 (€)	€ 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 9-10: 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
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 accompanied by any **additional (quantitative or qualitative) 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**, Member 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 Member State's exclusive assessment of its own activities. For this reason, the template does not suggest a specific format. However the assessment should be based on the information provided in Section A, as well on information provided in the National Market Surveillance Programmes for the 2010-2013 period.

1

Contents

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]

3

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[1] (€)				
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				

[1] The budget figure should cover all financial resources which are assigned by public authorities to market surveillance 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)				

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]

5

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

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[2] (total number)				
3.1	number of reactive inspections[3]				
3.2	number of self-initiated inspections[4]				
3.3	number of inspections prompted by the customs[5]				

[2] 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.

[3] 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.

[4] 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.

[5] 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.

4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products[6]				
5	Number of inspections resulting in:				
5.1	finding of non-compliance[7]				
5.2	corrective actions taken by economic operators ("voluntary measures")[8]				
5.3	restrictive measures[9] 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]

[6] 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.

[7] This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

[8] 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.

[9] 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 [10] (€)				
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]

[10] 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 sectors

Product sectors	Relevant legislation[11] [12]	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)[13]	Regulation 648/2004 Directive 2004/42/EC	

[11] 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.

[12] 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.

[13] This section focuses on chemicals other than those falling 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	
24. Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	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	
30. Other consumer products under GPSD (optional)	Directive 2001/95/EC	
31. .... (Additional sectors – please specify)		

11

7. SECTORS COVERED BY MEMBER STATES REPORTS

Product sectors	Relevant legislation	Included in the report? (Y/N)																											
		BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	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	N	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
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

Product sectors	Relevant legislation	Included in the report? (Y/N)																											
		BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SI	SK	FI	SE	UK
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
13. Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	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
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

Product sectors	Relevant legislation	Included in the report? (Y/N)																												
		BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SI	SK	FI	SE	UK
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 telecommunications 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
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	N	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

Product sectors	Relevant legislation	Included in the report? (Y/N)																											
		BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SI	SK	FI	SE	UK
24. Efficiency requirements for hot-water boilers fired with liquid or gaseous fuels	Directive 1992/42/EEC	Y	N	Y	N	-	N	Y	Y	N	N	N	N	N	Y	-	N	Y	N	N	N	N	N	Y	N	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
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	N	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.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)	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

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[246]	4	3	5	5
2.	Number of substantiated complaints by industry concerning unfair competition	1	1		
3.	Number of inspections (total number)[247]	138	133	91	90
3.1	number of reactive inspections[248]	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[249]	133	81	81	81
5	Number of inspections resulting in:				

246 Data available from the Environmental Protection Agency only.
247 The table covers the number of products and not the number of inspections. The number is based on an average.
248 A significant proportion took place as the result of complaints from consumers, possibly as the result of accidents.
249 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
5.1	finding of non-compliance	30	20	44	24
5.2	corrective actions taken by economic operators ("voluntary measures")	8	16	13	11
5.3	restrictive measures taken by market surveillance authorities[250]	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: http://www.sik.dk/Global/Publikationer/Foldere/10-gode-raadtil-haandtering-og-indkoeb-af-legetoej

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_legetoej_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

250 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.

purely because it has a warning symbol indicating that it is 'not suitable for children aged 0-3'.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)	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

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/Sikkerheden-vedmagnetlegetoej-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

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

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[251]	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[252]	49	57	47	15
Number of products presenting a serious risk	10	13	13	17

Measures applied[253]	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[254]	21	10	6	7
Number of products recalled from consumers[255]	2	19	Data not available	Data not available
Number of voluntary measures taken by economic operators[256]	6	8	6	7

251 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.

252 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%.

253 For the Consumer Protection Board, only the number of memos is available.

254 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.

255 The data from 2010–2011 consist of data of the Consumer Protection Board. The Health Board has no data available.

256 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.

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

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

Information on enforcement activities carried out in the 2010-2013 period[257]

		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				
3.	Number of inspections (total number)		1	3	9

257 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
3.1	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	0		258	
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")	259			
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

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

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

1. Agency corporate-focused website – http://corporate.nca.ie/eng/. 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. 2. General consumer-focused website at http://www.consumerhelp.ie/ with information on the role of the Agency as Ireland's market surveillance authority for safety of products covered by the EU Directives, enforcement of product safety legislation,

258 Representative items from customs consignments were visually and physically checked.
259 The Agency achieved voluntary corrective actions (where necessary) in majority of cases.

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.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)[260]	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)[261]	7	7	8	8
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)[262]	7	7	8	8

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.

260 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.

261 Number of authorised officers in Product Safety Unit with additional authorised Officers available to assist on specific projects if required.

262 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[263]	10	6	6	4
5.4	application of sanctions/penalties[264]	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

263 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).

264 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 (€)[265]				
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)[266]				
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

265 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).

266 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 (€)[267]	2000000	1620000	1300000	1320000

267 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[268]

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)				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

268 Data only between 1 July 2013 – 31 December 2013

		2010	2011	2012	2013
5.3	restrictive measures taken by market surveillance authorities				60
5.4	application of sanctions/penalties				40
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

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 complaints	205 (A) 13 (C)	229 (A) 13 (C)	96 (A) 11 (C)	275 (A) 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:				

		2010	2011	2012	2013
4.1	tests performed in laboratories		415		
4.2	physical checks of products				
5	Number of inspections resulting in:				
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				

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

No information

Information on resources (subject to availability)

No distinguishable information provided: combination of sector 3 and 30

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)	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

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)	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

		2010	2011	2012	2013
5.3	restrictive measures taken by market surveillance authorities	1	7	18	22
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.

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

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.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)	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

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:	Sampling and reviews together			
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:
https://www.verbrauchergesundheit.gv.at/lebensmittel/lebensmittelkontrolle/LMSicherheit.html

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

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.	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[269]	95	113	129	243
4	Number of inspections based on: [270]				
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")[271]	486	1082	1047	1016
5.3	restrictive measures taken by market surveillance authorities[272]	77	80	70	45
5.4	application of sanctions/penalties[273]	24	34	17	23
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

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

269 The number of opinions issued at the request of the customs authorities is given.
270 Estimate data. In case of some authorities the number of products is given.
271 The number of operations is given.
272 The number of measures applied is given.
273 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[274] 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.

274 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

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)	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

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

Slovenia

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.

		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 [275]	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.

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

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.

275 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.

The meetings were organized by the Regional Chamber of Craft; we introduced legislation on the safety of toys.

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_vprasanja

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 http://www.zi.gov.si/si/delovna_podrocja/varnost_igrac (and links) contains all the information on the safety of toys aimed at economic operators and consumers.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)[276]	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)[277]	135	133	134	129
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)[278]	112	110	110	109

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.

276 Overall authority budget.
277 Number of employees instead of full-time equivalent units
278 Total number of inspector instead of full-time equivalent units

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.

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

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

		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

		2010	2011	2012	2013
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)

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.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)	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

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

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

		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
3.	Number of inspections (total number)	1507 792 (T) 715 (C)	1351 698 (T) 653 (C)	1739 906 (T) 833 (C)	808 81 (T) 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 26 (T) 680 (C)	636 29 (T) 607 (C)	777 28 (T) 749 (C)	808 41 (T) 672 (C)
4.2	physical checks of products	36 1 (T) 35 (C)	47 1 (T) 46 (C)	 84 (C)	60 5 (T) 55 (C)
5	Number of inspections resulting in:				
5.1	finding of non-compliance	229 29 (T) 200 (C)	190 10 (T) 180 (C)	203 26 (T) 177 (C)	189 25 (T) 164 (C)
5.2	corrective actions taken by economic operators ("voluntary measures")	28 (T)	8 (T)	25 (T)	18 (T)

		2010	2011	2012	2013
5.3	restrictive measures taken by market surveillance authorities	160 1 (T) 159 (C)	138 2 (T) 136 (C)	73 1 (T) 72 (C)	109 7 (T) 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

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

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.

Information on resources (subject to availability)

		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)

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

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

		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

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

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 e-mail 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.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms (€)	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

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	

		2010	2011	2012	2013
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	
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 10: ORGANISATION OF MARKET SURVEILLANCE OUTSIDE THE EU

1. AUSTRALIA

Principal website: www.productsafety.gov.au

Legislative framework

The legislative framework in Australia is established in the Competition and Consumer Act 2010 (CCA), which incorporates the Australian Consumer Law (ACL) at Schedule 2. This legislation gives the Commonwealth Minister the power to set standards, impose interim and permanent bans and order compulsory recalls. It also establishes two notification requirements (for recalls and serious injuries, illnesses and deaths), a consumer guarantees regime which includes a requirement that goods be of acceptable quality including being safe; and a product liability regime (giving consumers a right of action for losses where goods are not safe). State and territory ministers have the power to create short interim bans and compel suppliers to recall goods. The CCA is administered by the Australian Competition and Consumer Commission (ACCC), jointly with state and territory consumer agencies.

Web reference: www.austlii.edu.au/au/legis/cth/consol_act/caca2010265

How are the rules for product requirements set?

Where there are safety concerns about consumer goods a mandatory standard can be imposed. Mandatory standards are regulations made by the Commonwealth Minister who is advised by the ACCC. Mandatory standards often draw on Australian voluntary standards or may draw from international standards. Australian Standards are not legal requirements in Australia unless they are 'called up' through regulations. In addition some Australian bans prohibit goods that do not meet certain requirements (rather than prohibiting sale completely)—see below.

Web reference: www.productsafety.gov.au/mandatorystandards

How are goods prohibited from sale for safety reasons?

Unsafe goods can be prohibited from sale in Australia through the imposition of a ban. Bans can be interim (lasting 60–120 days) or permanent. Permanent bans are imposed by the Commonwealth Minister on advice from the ACCC. Commonwealth, state and territory ministers are able to impose interim bans.

Web reference: www.productsafety.gov.au/bans

Are there notification requirements?

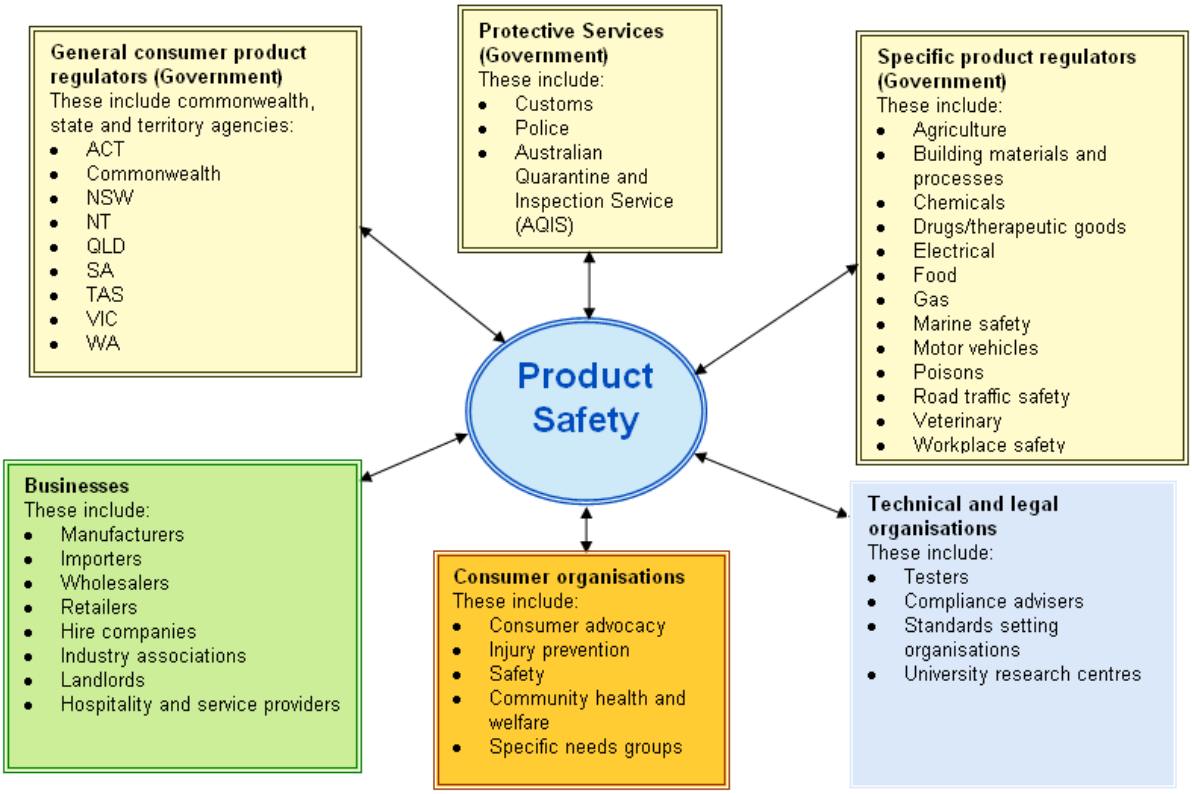
There are two mandatory notification requirements in Australia. Suppliers are required to notify the Commonwealth Minister of a recall within two days of initiating the recall. Suppliers are also required to notify the Commonwealth Minister within two days of becoming aware of a serious illness, injury or death caused by the use of a product they sell. Both notifications can be made via online forms on ACCC websites.

Web references: www.productsafety.gov.au/recalls; www.recalls.gov.au

Are there likely to be any changes to regulatory arrangements?

The ACL will be reviewed by 2018. Regulations are frequently developed and reviewed. Information on changes is available on the Product Safety Australia website.

Organisation chart



2. CANADA

Legislative framework

The legislative framework in Canada is established in the Canada Consumer Product Safety Act (CCPSA). The Act sets out general requirements and powers, and contains a provision to make regulations. There are currently over 30 regulations under the CCPSA that outline more specific requirements for certain consumer products and/or hazards. In addition, the Act contains a schedule of prohibited consumer products (Schedule 2).

The CCPSA is administered by Health Canada, specifically the Consumer Product Safety Program. Note that cosmetics, which are subject to the Cosmetic Regulations under the Food and Drugs Act, are also administered by the Program.

Web reference:

http://laws-lois.justice.gc.ca/eng/acts/C-1.68/index.html

http://laws-lois.justice.gc.ca/eng/acts/F-27/index.html

How are the rules for product requirements set?

The CCPSA modernised Canada's product safety system and introduced new tools to prevent or address dangers to human health or safety posed by consumer products. These include powers to order corrective measures or mandatory product recalls, and an administrative

monetary penalties scheme with fines up to CDN$25,000 per day for non-compliance with an order.

The CCPSA contains a general prohibition against the manufacture, import, advertisement or sale of consumer products that are a danger to human health or safety.

It also includes other prohibitions against the manufacture, import, advertisement or sale of consumer products that are prohibited or that do not meet regulatory requirements.

For some consumer products, specific product requirements are set out in regulations. Such regulations may outline specifications or make reference to an existing standard. Standards that are incorporated by reference in regulations are considered to be 'mandatory standards'. In the case where there are no regulations set out for a specific product, suppliers may look to an available health and/or safety standard as part of their due diligence. Suppliers may also look to published guidelines from Health Canada or another relevant organization (e.g. regulators in other jurisdictions, industry associations, etc.).

How are goods prohibited from sale for safety reasons?

Orders for mandatory recall can be made for consumer products where the Minister believes on reasonable grounds that they pose a danger to human health and safety.

This determination of whether a consumer product poses a danger to human health or safety is informed by risk assessments, through inspections, product testing or lab reports, and/or professional judgement from the Consumer Product Safety Program, among other considerations.

While there are a number of enforcement powers in the CCPSA to address dangers to human health and safety (including product specific regulations), the Program usually takes a step-wise approach to enforcement where appropriate, first considering voluntary measures.

Are there notification requirements?

A person who manufactures imports or sells a consumer product for commercial purposes must report incidents to Health Canada. Incidents are defined as any occurrence, defect, characteristic, or incorrect or insufficient labelling that resulted or may reasonably have been expected to result in death, serious injury or serious adverse health effects. Incidents also include recalls or other measures initiated by another jurisdiction for health and safety reasons.

Such incidents must be reported to Health Canada and the manufacturer within two days. A manufacturer (or if the manufacturer carries on business outside Canada, an importer) of a product that is involved with a reportable incident in Canada is also required to submit to Health Canada a more detailed written report. This report must be submitted within ten days after the day on which they became aware of an incident unless Health Canada specifies a different timeframe

Health Canada's website: http://www.hc-sc.gc.ca/cps-spc/legislation/acts-lois/ccpsa-lcspc/indust/guide-reporting-declaration/index-eng.php

Are there likely to be any changes to regulatory arrangements?

Federal government departments and agencies are required to make their forward regulatory plans publicly available on their websites annually; Health Canada's Forward Regulatory Plan provides information on planned and potential regulatory initiatives that Health Canada expects to bring forward over the next two years. It is intended to give consumers, business, other stakeholders and trading partners greater opportunity to inform the development of regulations and to plan for the future. This Plan will be adjusted and updated over time as Health Canada's operating environment also changes over time. A list of Government-wide forward regulatory plans is also available on the Treasury Board of Canada Secretariat's website.

Web reference:

Treasury Board of Canada Secretariat's website: http://www.tbs-sct.gc.ca/rtrap-parfa/plan-eng.asp

Health Canada's website: http://www.hc-sc.gc.ca/ahc-asc/legislation/acts-reg-lois/frp-ppr/2016-2018/index-eng.php

3. JAPAN

Legislative framework

In Japan, Consumer Product Safety Act which is administrated by Ministry of Economy, Trade and Industry (METI) and Consumer Affairs Agency (CAA) gives a framework for collecting and publishing information of product accidents.

METI designates products which are considered to have higher possibilities of causing hazards respectively as positive lists and sets technical requirements on them under Consumer Product Safety Act and other regulation acts including Electrical Appliances and Materials Safety Act, Gas Business Act and Act on the Securing of Safety and the Optimization of Transaction of Liquefied Petroleum Gas (hereafter referred to as "LP Gas Act").

Web references:

Consumer Product Safety Act (Collection and Publication of Product Accident Reports, only in Japanese): http://www.meti.go.jp/product_safety/producer/point/04-1.html

Consumer Product Safety Act (Technical Requirements on Designated Products, only in Japanese):
http://www.meti.go.jp/policy/consumer/seian/shouan/index.htm?PHPSESSID=e7aa1

Electrical Appliances and Materials Safety Act:

http://www.meti.go.jp/english/policy/economy/consumer/pse/index.html

Gas Business Act(Only in Japanese): http://www.meti.go.jp/policy/consumer/seian/gasji/

LP Gas Act(Only in Japanese): http://www.meti.go.jp/policy/consumer/seian/ekiseki/

How are the rules for product requirements set?

Under Consumer Product Safety Act, Electrical Appliances and Materials Safety Act, Gas Business Act and LP Gas Act, METI designates products which are considered to have higher possibilities of causing hazards as positive lists and sets technical requirements respectively on them.

Manufacturers and importers are obliged to confirm their products to be conformable to the technical requirements (as well as to conduct self-inspections) and affix prescribed labels (PS marks) on them as well as certifications of their conformity.

As for "Specified Products" which are considered to have especially higher risks, manufacturers and importers are obliged to undergo conformity assessment tests conducted by conformity assessment bodies registered with the government.

In 2014, as for electrical appliances and materials, METI revised the technical requirements from "specification-based" descriptions where the government defines detailed specifications of dimensions, shapes and materials etc. of every item to "performance-based" descriptions where the government only defines essential safety performances.

The similar revisions will be conducted for City Gas and LP Gas equipment and appliances in early 2016.

How are goods prohibited from sale for safety reasons?

As for Consumer Product Safety Act, under certain conditions including cases where serious product accidents have occurred due to defects in the consumer products or where serious danger has occurred to the lives or bodies of consumers or the occurrence of such danger is considered to be imminent, the competent minister may order manufacturers and importers to recall the consumer products and to otherwise take measures necessary to prevent the occurrence and increase of serious danger to the lives or bodies of consumers.

Additionally, as for Consumer Product Safety Act, Electrical Appliances and Materials Safety Act, Gas Business Act and LP Gas Act, the Minister of Economy, Trade and Industry may order manufacturers and importers to collect the consumer products or to take any other necessary measures to prevent the spreading of the hazards or interference caused by the products. Also, under certain conditions where manufacturers and importers violate technical requirements or other necessary regulations to be preserved, the Minister of Economy, Trade and Industry may prohibit manufacturers and importers from affixing labels (PS marks) to their products, which substantively represents prohibition of sales.

Web reference:

http://www.meti.go.jp/product_safety/producer/system/06.html (only in Japanese)

Are there notification requirements?

Manufacturers and importers of designated products under Consumer product Safety Act, Electrical Appliances and Materials Safety Act, Gas Business Act and LP Gas Act shall notify the Minister of Economy, Trade and Industry of their names and classifications of their products.

Also, under Consumer Product Safety Act, manufacturers and importers of consumer products who are responsible for consumer products distributed in Japan are obliged to report

to the government (Consumer Affairs Agency) within 10 days when they come to know serious product accidents have occurred with their consumer products. When sellers come to know the fact, they are required to notify manufacturers and importers.

Web references:

Notifications of Businesses (only in Japanese):
http://www.meti.go.jp/product_safety/producer/system/02.html

Reports of Serious Product Accidents (only in Japanese):
http://www.meti.go.jp/product_safety/producer/point/04-1.html

4. SOUTH KOREA

Legislative framework

The Framework Act on Product Safety (2013) and the individual acts according to product characteristics such as Quality Control and Safety Management of Industrial Products Act and Electrical Appliances Safety Control Act have the provisions to protect consumers from the risk of consumer products. Each law allows for the ban of products which may cause any danger or harm to consumers and the withdrawal of the products.

Also, the Framework Act on Consumers (2012) stipulates the surveillance by collecting injury data of every consumer goods regardless of types. According to the law, the authorities can propose or order a recall, a withdrawal on the products which don't have the safety standards to satisfy, if necessary to businesses.

Web reference:

www.kca.go.kr/web/img/kca/eng/laws/Framework_Act_on_Consumers.pdf

How are the rules for product requirements set?

The safety standards for consumer safety are established after promulgation and acceptance of opinions in accordance with Administrative Procedures Act.

How are goods prohibited from sale for safety reasons?

If the consumer products pose any danger or harm or do not conform to the safety standards, the goods can be prohibited according to the relevant provisions of the laws.

Moreover, regardless of product characteristics, the Framework Act on Consumers forbids products which are dangerous or are deemed to pose harm to consumers.

Web reference:

www.kca.go.kr/web/img/eng/10_1%20FRAMEWORK%20ACT%20ON%20CONSUMER.doc (see Articles 46 to 50), http://www.smartconsumer.go.kra, www.safetykorea.kr

The website provides information on quality comparisons and recall of all items.

Are there notification requirements?

Framework Act on Product Safety states that if any enterprise has found that there exist any seriously defective goods, it must report the defects to the head of the competent central administrative agency (including electronic report). In that case, the retailer should report about the defect of the products which do not have any standards to conform to the director as well. Other necessary matters which the enterprise is required to report can be determined by the Presidential Decree.

Web reference:

www.kca.go.kr/web/img/eng/10_1%20FRAMEWORK%20ACT%20ON%20CONSUMER.doc (see Article 47), http://www.smartconsumer.go.kra ,http://www.safetykorea.kr

The website provides information on quality comparisons and recall of all items.

Are there likely to be any changes to regulatory arrangements?

None

5. NEW ZEALAND

Legislative framework

Part 3 of the Fair Trading Act 1986 (FTA) provides the Minister of Consumer Affairs with the power to ban products, set standards through regulation and order compulsory recalls. The Consumer Guarantees Act 1993 also provides a civil 'guarantee' that consumer goods are safe. The FTA is administered by the Ministry of Business Innovation and Employment (MBIE) and enforced by New Zealand Customs Services and by the Commerce Commission post importation. These provisions cover all consumer products with the exception of food, gas and electrical products, motor vehicles and cosmetics that are regulated by other agencies under product specific legislation.

Web reference:

http://www.consumeraffairs.govt.nz/for-business/compliance/product-safety/requirements-for-importers-and-retailers

How are the rules for product requirements set?

MBIE draws on consumer complaints, marketplace sampling/testing and data and intelligence sourced from other organisations within New Zealand and overseas. The Minister is able to take action that ranges from interim bans of a product through to permanent regulations. The basis for the majority of these provisions are published standards. The preference is for New Zealand or joint Australia/New Zealand standards, the majority of which directly relate to the equivalent ISO standards.

Web reference:

http://www.consumeraffairs.govt.nz/for-business/compliance/product-safety/requirements-for-importers-and-retailers

How are goods prohibited from sale for safety reasons?

The unsafe goods notice provisions are the most frequent means of banning unsafe products. They provide for an 18 month interim ban after which the ban can be made permanent. The Minister of Consumer Affairs can rescind or amend the unsafe goods notice within that 18 month period.

Web reference:

http://www.consumeraffairs.govt.nz/for-business/compliance/product-safety/requirements-for-importers-and-retailers

Are there notification requirements?

No notification requirements are in force at present (but we see below) but in many cases, voluntary prior contact is made with MBIE by businesses contemplating a recall.

Web reference:

http://www.consumeraffairs.govt.nz/for-business/compliance/product-safety/recalls

Are there likely to be any changes to regulatory arrangements?

The Consumer Law Reform Bill (CLRB) is anticipated to be enacted within the next few months and once implemented will provide additional regulatory options including:

- enabling the Minister to issue product safety policy statements that whilst not compulsory are aimed at being persuasive and seek marketplace correction
- introducing compulsory notification of product recalls to MBIE
- giving additional powers for product safety officials.

http://www.consumeraffairs.govt.nz/legislation-policy/policy-development/consumer-law-reform?searchterm=Consumer+Law+Reform

6. UNITED STATES

Federal Government

- Federal government agencies vary in their methods and authorities for market surveillance of compliance
- Some agencies (e.g. NHTSA, CPSC) spot-check in the market by purchasing products randomly and testing them for compliance. These agencies can also conduct audits of manufacturers, either by inspection or written documentation reviews
- Some agencies (e.g. FDA) have a more European-style pre-market type approval process
- Some agencies (e.g. NHTSA, FDA) have incident reporting requirements
- Federal Trade Commission (FTC) monitors and enforces false advertising claims and

unfair competition claims

- All agencies can assess severe penalties for non-compliance with regulations

State Government

- Mote states have "FTC Acts" that authorize investigations and litigation against product manufacturers for false advertising or "unfair" trade practices

- Some states in the US have separate Consumer Protection Bureaus or Agencies; others enshrine this function within the Attorney General's office

- Some Federal statues (e.g. Consumer Product Safety Act) confer shared authority for safety regulatory enforcement with the State agencies

Industry Competitors

- Lanham Act: Federal law authorizing competitors to sue a company for false advertising.

- It has been used to challenge unsupported advertising claims and other forms of false advertising that are alleged to have harmed the plaintiff

- It does not authorize consumer lawsuits against product manufacturers

- Often a "cease and desist" letter citing the Lanham Act results in market corrections

Citizen suits

- Some US regulatory statutes authorize individual consumer to sue to enforce the regulations (more common in environmental sector). These laws are the exception, not the rule

- Ordinarily, individual consumers have no legal standing to sue to enforce federal safety regulations

Self-regulation

- Some US regulatory statutes provide for self-certification of compliance by product manufacturers

- A variation of this regulatory model is self-certification upon receipt of confirmatory testing from a government-approved third-party laboratory (Children's products regulated by the US CPSC)

- This regulatory model permits a product manufacturer to bring a consumer product to market without needing to await government type approval

Consumer Product Safety

Legislative framework

The Consumer Product Safety Act (CPSA) authorizes the Consumer Product Safety Commission (CPSC) to develop standards and bans and to pursue recalls under certain circumstances. The CPSC also administers the Consumer Product Safety Improvement Act (CPSIA) and a range of Acts that deal with specific products.

Web reference: www.cpsc.gov/en/Regulations-Laws--Standards/Statutes/

How are the rules for product requirements set?

The CPSC can promulgate consumer product safety rules to prevent or reduce an unreasonable risk of injury associated with consumer products. The rule may include requirements for performance, markings, warnings and/or instructions. The Administrative Procedure Act (APA) requires the CPSC to solicit input from the public on proposed regulations and to respond to public comments. The CPSC relies on voluntary standards whenever they eliminate or reduce the risk of injury and compliance with the standard is substantial. Voluntary standards can be referenced on an interim basis while the CPSC develops a final consumer product safety rule.

Rules can establish requirements for third party bodies that assess conformity to consumer product safety standards. The CPSC can also establish mandatory test programs for any product.

Web reference: www.cpsc.gov/en/Regulations-Laws--Standards/Rulemaking/

How are goods prohibited from sale for safety reasons?

The CPSC can make rules that ban the manufacture, importation, sale or advertisement of a consumer product that presents an unreasonable risk of injury and no feasible consumer product safety standard would adequately protect the public on a permanent or interim basis.

Web reference: http://www.cpsc.gov//PageFiles/105435/cpsa.pdf (see sections 8 and 9 of CPSA)

Are there notification requirements?

Suppliers must report to the CPSC within 24 hours if they obtain information that reasonably supports the conclusion that a product:

- fails to comply with a consumer product safety rule or a voluntary consumer product safety standard relied on by the CPSC
- fails to comply with any other rule, regulation, standard, or ban under the CPSA or any other statute enforced by the CPSC
- contains a defect which could create a substantial product hazard or
- creates an unreasonable risk of serious injury or death.

Suppliers must report certain choking incidents to the CPSC within 24 hours. Businesses must also report to the CPSC within 30 days if a product is subject to three successful civil law suits.

Web reference:

http://www.cpsc.gov//Global/Business-and-Manufacturing/Business-Education/RegulatedProductsHandbook.pdf (see chapter 9)

Suppliers may report via phone, e-mail, postal mail or online at:

www.saferproducts.gov/CPSRMSPublic/Incidents/ReportIncident.aspx