

Review and assessment of the functioning of market surveillance activities pursuant to Article 18(6) of Regulation (EC) No 765/2008 - 2010-2013

Ireland

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.

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Scope of the report

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

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

Overview of general market surveillance activities

A. Review of general market surveillance activities

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

[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.

Organisation of Market Surveillance:

In Ireland responsibility for Community harmonisation legislation is dispersed across various Government Departments and State Agencies. There is no central body responsible for market surveillance and no single piece of overarching market surveillance legislation. Responsibility for Community harmonisation legislation is allocated to Government Departments according to competence. Market surveillance responsibilities are conferred on authorities through primary legislation in the case of chemicals and secondary legislation implementing Community harmonisation legislation for the other sectors.

Market surveillance authorities undertake risk based and reactive market surveillance and participate in specific priority projects.

The Department of Jobs, Enterprise and Innovation has coordinated Ireland's notifications under Regulation (EC) No. 765/2008.

Budget

There is no specific budget for market surveillance activities as Market Surveillance Authorities are part of larger organisations. Any budget would come from a total amount given to these organisations. The figures below are to taken as approximate.

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

		2010	2011	2012	2013
1.1	Budget available to market surveillance authorities in nominal terms ¹ (€)	4.8m	4.8m	4.9m	4.8m
1.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	N/A	N/A	N/A	N/A
2	Staff available to market surveillance authorities (full-time equivalent units)	41.74FTE	39.59FTE	42.13FTE	41.6FTE
3	Number of inspectors available to market surveillance authorities (full-time equivalent units)	29.99FTE	28.84FTE	112.88FTE	109.1FTE

B. Assessment of the functioning of market surveillance activities

The assessment from Market Surveillance Authorities in Ireland is as follows:

Department of Justice (MSA for 2007/23/EC and 93/15/EEC)

Inspectors are primarily explosives inspectors responsible for the enforcement of explosives legislation and not market surveillance inspectors per se. No other staff are allocated for the purposes of market surveillance. Any market surveillance activity is a sub set of the overall enforcement activities for explosives under explosives legislation. Some enforcement activities reported here are taken under explosives legislation and not market surveillance legislation. In addition not all pyrotechnics placed on the market are CE marked due to the transitional provisions contained in the Directive 2007/23/EU.

National Standards Authority of Ireland (NSAI)(MSA for 2004/22/EC, 2009/23/EC and 2007/45/EC)

The role of market surveillance is incorporated into the activities of the Legal Metrology Service which is already charged with inspection of measuring instruments in trade use. Market surveillance activities are performed within existing operations budget.

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.

Health Products Regulatory Authority (HPRA)(MSA for 93/42/EEC, 98/79/EC, 90/385/EEC and Regulation 1223/2009)

The Joint Plan of Immediate Actions

The most significant factor influencing the medical device sector over the last number of years is the Commission's Joint Plan of Immediate Actions.

As a result of issues identified by the Poly Implant Prothese (PIP) Breast Implants and DePuy ASR/Metal on Metal (MOM) hip crises, the European Commission in early 2012 took a series of initiatives which included:

- a stress test of the then draft proposals to revise the medical devices legislation to assess its ability to manage such issues;
- mandating specific reviews of the scientific and safety aspects to be conducted by the SCENIHR;
- publication of the 'Joint Plan for Immediate Actions' to strengthen and restore confidence in the regulatory system for medical devices.

The Joint Plan for Immediate Actions recognised the need to further develop and strengthen the existing regulatory system in advance of the broader revision of the legislation which is ongoing. Focussing on measures to strengthen oversight of notified bodies, to increase market surveillance activities for devices, and increase inter-authority collaboration and information exchange, the purpose of the joint plan was to enhance the existing regulatory framework. These objects were set out as a series of short and medium term actions for Member States, Competent Authorities and the European Commission.

The implementation of the joint-plan is now nearing completion across Europe. Overall it has been a highly successful programme resulting in significant action and development of the regulatory regime since its publication.

In relation to notified bodies, this plan has led to:

- The introduction of a voluntary joint assessment scheme for the designation and oversight of notified bodies. The assessments involve an independent review by the European Commission assisted by appropriate experts selected from member states. The purpose of the review is to assess the competency and performance of national designating authorities

such as the HPRA, and to ensure they are applying designation criteria in a harmonised way. To date 20 joint assessments have been conducted in 2013 across Europe. The programme continues to have a positive tangible impact on the oversight and functioning of notified bodies across Europe.

- New and enhanced legislative requirements for notified bodies and the authorities responsible for their oversight. These include more specific definition of operational requirements for notified bodies and mandatory joint assessments to be conducted on an on-going basis. In addition the European Commission has published its recommendation for notified bodies which provides guidance to notified bodies on best practices relating to their assessment and monitoring activities
- A requirement for notified bodies to conduct unannounced inspections of the manufacturing facilities for which they are responsible. The positive impacts of these inspections have been evident throughout the EU.
- A requirement for notified bodies to update their contracts with manufacturers to ensure proactive communication of important vigilance/safety information. This requirement has yield positive benefits in terms of increased proactive communication throughout the European network.

In relation to market surveillance, cooperation between authorities, and communication, this plan has led to:

- the establishment of a forum, led by the European Commission for regular exchange and sharing of information on emerging safety issues. The forum has been operational since July 2012 and has been successful in further developing collaboration and achieving collective resolution on key issues.
- A review of the scope of current market surveillance activities on medical devices conducted by member states. This has provided a platform from which a coordinated approach to surveillance can be developed, allowing for enhanced cooperation and targeted proactive market surveillance, including joint activities.
- A detailed review of the European regulatory authority structures to promote cooperation, communication and work-sharing. This will not only enhance cooperation and communication between authorities but also seek to increase the management and

transparency of the system.

- An increase in the number of reports received by the HPRA from healthcare professionals on medical devices issues. This was another initiative for authorities to promote as part of the joint plan.
- Dialogue with clinical societies and professional bodies on medical devices has become common-place at European level. This allows for key input and advice from expert clinicians and device users.
- Increased discussion on the use of registers for medical devices is underway at European level. The European Commission's PARENT (cross-border PATient REgistries iNiTiative) initiative is seeking to ensure that such registers are appropriately established and have datasets which can be compared and analysed cumulatively.

It is anticipated that the European Commission has indicated its intention to build on the principles of the existing joint plan, and is shortly expected to make an additional formal proposal with details of further actions to develop the regulatory system over the timeframe of 2014 to 2015.

The HPRA has been strongly committed to the joint plan from the time of its introduction and has contributed significantly at both national and European levels to ensure realisation of its objectives.

Additional specific national concerns

The HPRA will work to optimise and develop the regulatory activities conducted for medical devices at national and European level. This will include ongoing provision of dedicated support to developments at European level.

While the joint plan and issues outlined above have positively contributed to the functioning of the market surveillance system, there remains a number of specific concerns that affect consistent application of market surveillance requirements for medical devices. While many of these will in time be addressed through the on-going revision of the medical device legislation, there are a number a number of pressing concerns, some of which we believe can be addressed through further interim measures as follows:

1. The HPRA's powers in relation to manufacturers are detailed in the Medical Devices Directives. The position is somewhat different in relation to distributors. In Irish legislation, the HPRA currently does not have any legislative powers over medical device distribution /

distributors apart from the provisions as set out in the New Approach legislation. The key concern in this area is medical device management, storage and traceability throughout the distribution chain particularly when a field safety corrective action is being conducted. The HPRA works to inform distributors of the need for effective communication and to ensure effective communication of safety related issues and actions. To address this gap it is proposed to develop legislation and corresponding guidance in this area, which will provide information for manufacturers in relation to requirements and expectations of distributors. It is expected that legislative powers will be afforded to the HPRA to request distributors to conduct appropriate follow up on the market and be required to undergo an audit of their quality systems.

2. Traceability of medical devices can also create difficulties when investigating issues such as non-compliant and counterfeit medical devices. The selling and distribution of medical devices over the internet through online web-shops can also lead to difficulties in enforcing compliance due to issues with traceability. The proposals for the implementation of unique device identifiers (UDI) for medical devices will assist some of the market surveillance activities by improving traceability and deterring the practice of counterfeiting medical devices. The HPRA is actively involved in developing the framework for the UDI system.
3. A considerable hindrance to effectively applying a harmonised market surveillance approach and action is where different Member States take differing positions on the qualification and classification of products as medical devices.
4. Another difficulty is that issuing alerts regarding hazards are not covered under national legislation but are provided for in the 'New Approach' legislation.

Finally, in the event that a serious issue arises (such as PIP) and an action is taken under medical devices legislation, the penalties are minor when the potentially serious nature of the offence is considered. Article 26(4)(A) of SI 252 of 1994 provides that a *“person guilty of an offence under these Regulations shall be liable, on summary conviction, to imprisonment for a period not exceeding six months or to a fine not exceeding £1,000 or to both such imprisonment and fine”*.

In October 2010, The Health Products Regulatory Authority (HPRA), formerly the Irish Medicines Board (IMB) assumed the role of competent authority for **cosmetic** products from the Department of Health in Ireland. Market surveillance activities since October 2010, involve a cooperative system of surveillance between the HPRA and the Health Services Executive which comprises of regionally

based environmental health officers and three Public Analyst's Laboratories for the analysis of physico-chemical parameters and microbiological analysis of cosmetic products. For the years 2010-2013 the number of cosmetic products sampled for analysis were: 539 (2010); 656 (2011); 544 (2012); 342 (for Q3&4 of 2013).

HPRA also has a Memorandum of Understanding in place with Revenue Customs authorities for the exchange of information on cosmetic product imports at border controls.

The 2014-2015 plan for cosmetics surveillance activities is included in the public narrative document on the EU Commission's website at the following link:

<http://ec.europa.eu/DocsRoom/documents/4431/attachments/3/translations/en/renditions/pdf>

Regulation (EC) No 1223/2009 on cosmetic products was adopted in 2009 and came into force in July 2013. A number of key provisions came into effect with the adoption of the regulation – specifically the publication of a harmonised standard in the Official Journal in the area of cosmetic Good Manufacturing Practice; new vigilance reporting requirements (reporting of Serious Undesirable Effects (SUEs); a central notification process to a European Commission database (Cosmetic Product Notification Portal, CPNP) as well as guidelines on cosmetic product safety reports (CPSRs) and product information file documentation. Prior to 2013, there was no mandatory requirement to meet the European Cosmetic GMP guidelines (IS EN 22716:2007) nor were there vigilance reporting requirements. Once the Cosmetic Regulation came into force in July 2013, GMP inspections commenced and the recording and monitoring of investigations into SUEs were enabled. For the years 2010 – July 2013, there was a lack of harmonisation across Europe as to the implementation of the Cosmetics Directive 76/768/EEC and in 2013 this improved with the implementation of Regulation 1223/2009 on cosmetic products.

Common findings of non-compliance continue to be found in the following areas:

- No Responsible Person designated particularly in the case of import
- Poor application of GMP requirements
- Lack of systems at the level of distribution in order to meet traceability requirements
- Importation of non-compliant product from third countries containing prohibited substances (e.g. tooth whitening products and skin lightening products)

- CPSR not carried out in accordance with the Annex I guidelines in Regulation (EC) No 1223/2009
- Internet purchasing of non-compliant products

Challenges continue to exist for authorities in terms of in-market control obligations where resource is an ongoing issue as well as the difficulties with monitoring internet sales.

Health and Safety Authority (HSA)(MSA for 2010/35/EU, 2006/42/EC, 1995/16/EC, 1994/9/EC and Regulation 648/2004)

The Health and Safety Authority is both an occupational safety and market surveillance authority and consequently there are some market surveillance actions that occur in the framework of occupational safety inspections that are not separately recorded. The resources of the Authority have been reduced in recent years due to restrictions on public spending which impacts on the Authority's ability to engage in market surveillance. The absence of independent test laboratories in Ireland means that there is less inclination to send products for testing for logistical and cost reasons. There is no state supported system for the reporting and recording of accidents that occur outside the workplace.

National Consumer Agency (NCA)(MSA for 2009/48/EC, 89/686/EEC, 2009/142/EC, 2006/95/EC and 2001/95/EC)

The National Consumer Agency is currently operating under significant budgetary and staffing constraints. However, resources devoted to the product safety function have remained relatively stable over the period with 7 – 8 staff in the Product Safety Unit. The unit has a wide remit and any Market surveillance is conducted on a risk basis and usually in the context of PROSAFE Joint Actions. However focused and risk based market surveillance projects have also been conducted on a number of occasions.

Market surveillance activities in specific sectors

Sector 1 Medical Devices (Health Products Regulatory Authority)

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	474 incident reports received, of which 407 occurred in Ireland, 97 of which received from users	611 incident reports received, of which 549 occurred in Ireland, 117 of which received from users	1051 incident reports received, of which 967 occurred in Ireland, 258 of which received from users	954 incident reports received, of which 882 occurred in Ireland, 96 of which received from users
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections ² (total number)	43	52	42	53
3.1	number of reactive inspections ³	2	7	1	10
3.2	number of self-initiated inspections ⁴	39	27	14	3
3.3	number of inspections prompted by the customs ⁵	2	18	27	40
4	Number of inspections based				

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' inspections 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.

	on:				
4.1	tests performed in laboratories	0	0	0	0
4.2	physical checks of products ⁶	2	18	27	40
5	Number of inspections resulting in:				
5.1	finding of non-compliance ⁷	43	52	42	53
5.2	corrective actions taken by economic operators ("voluntary measures") ⁸	43	52	42	53
5.3	restrictive measures ⁹ taken by market surveillance authorities .	0*	0*	0*	0*
5.4	application of sanctions/penalties		0*	0*	0*
6	Number of inspections where other Member States were invited to collaborate	0	1	0	1

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

The HPRA proactively informs the general public of its activities in relation to medical devices through:-

1. Brochures aimed at the public – since 2009 the HPRA has published a suite of medical device brochures, they include;
 - Buying medical devices on line

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.

- Buying medical devices for personal use
- Medical devices in the home
- Implantable medical devices
- Safety tips for contact lens wearers
- Safety tips for blood glucose meters
- Automated external defibrillators
- Selling Medical devices in Ireland

Further details are available on HPRA website- the HPRA website has a patient and public section; users can access safety related information and report issues and concerns relating to medical devices. Safety issues can be reported by post, e-mail, phone or online.

<http://www.hpra.ie/homepage/stakeholders/patients-and-public>

2. Website – the HPRA recently launched a new website. This website contains safety and regulatory information for patients and public, health professionals and industry.
3. Information Days – the HPRA has hosted 2 full information days for relevant stakeholders and has presented at over 40 events and conferences over the 4 year period, ensuring updates are provided on safety and regulatory issues to industry and health professionals.
4. Exhibitions - the HPRA has for a number of years been an exhibitor at the Young Scientist Exhibition (first and second level scientific competition) which has resulted in significant public engagement with over 10,000 visitors to the HPRA stand each year.
5. Safety Notices- the HPRA issue safety communications on a regular basis. Over the past 4 years the HPRA have published 17, 34, 19 and 16 safety notices in relation to medical issues. These have been mainly targeted at health professionals, however some of the HPRA safety notices are issued to the general public for display in pharmacies, diabetes clinics etc.
6. Newsletter – the HPRA publishes 3 newsletters annually covering all aspects of medical device regulation including market surveillance. These are targeted at all stakeholders including industry, users, researchers etc
7. HPRA media coverage – since 2010 there has been a total of 17 proactive consumer engagements through the media and the HPRA responded to 217 press queries specifically in relation to medical devices.

The HPRA has and continues to conduct communication surveys to determine the level of awareness among the general public of the HPRA's role and to determine the best means of public communication. In 2013 we conducted a survey of health professionals to inform our safety communications to Health care professionals and as a result have further developed our communication strategy resulting in more communications on safety issues.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ¹⁰ (€)	€1.4m	€1.4m	€1.4m	€1.4m
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)	15.75	15.75	16.75	17.25
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	1.25	1.5	1.5	1.5

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

As of July 2014 there are approximately 388 general medical device (class I, custom-made, system and procedure pack manufacturers/authorised representatives) and Irish-based IVD manufacturers/authorised representatives registered with the HPRA. As there is no requirement to register all CE marked medical devices being placed on the Irish market with the HPRA we do not have data regarding the number of different medical devices on the market in Ireland. With the advent of the proposed legislation for distributors and the development of a corresponding database of distributors and devices, this data should be more readily available.

As a result of the Joint Plan of Immediate Actions, there has been an increasing trend in reports to the HPRA since 2012; the total number of incident reports in 2013 was 954, of which 882 occurred in Ireland, 96 were reported by users.

Indeed feedback from the incident reports resulted in the increase in the number of reactive inspections (10) in 2013. There was a corresponding decrease in time available for self initiated inspections. Mainly due to the demand on resource for reactive inspections and the participation of the HPRA in the voluntary joint assessment activities.

There was also an increase in the number of inspections prompted by the customs to 40 in 2013; this may reflect the increasing tendency to purchase medical devices over the internet where devices are

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.

sourced often outside of Europe.

Consistently over the last 4 years in all inspections conducted, non-compliances were found and these were corrected voluntarily in discussion with the economic operator.

We recognise that in order to meet increasing challenges and requirements, particularly following the Joint Plan of Immediate Actions in 2012, it is necessary to continue to review and improve our approach to market surveillance.

A high-level cross-organisational review has been conducted within the HPRA for the purposes of developing the medical devices activities. Key developmental objectives include optimising the coordination, communication, interface and operational effectiveness of our medical device activities through adopting a life-cycle approach to our regulatory activities and ensure that we continue to improve, optimise and maintain efficiency to add the most value in the services we deliver. The Authority approved a business case in June 2014 to deliver on the review of HPRA Medical Device Strategy & Activities

The high-level objectives of this project which have an impact on Market surveillance have been defined as follows:

1. To reinforce market surveillance of medical devices throughout the device lifecycle.
2. To enhance functioning, oversight and development of notified bodies for medical devices in Ireland and Europe.
3. To increase coordination, communication, cooperation and partnerships with European and international regulatory authorities of health products.
4. To enhance communication & transparency on medical devices at national and European level.
5. To enhance communication and interaction with health professionals and users of medical devices in Ireland and at European level to ensure more engagement with the regulatory system.
6. To enhance the standard of oversight and technical and clinical assessment of medical devices conducted by authorities and notified bodies at national and European level.
7. To enhance coordination, communication and effectiveness of vigilance assessment activities.
8. To increase clarity and consistency on the classification and qualification of medical devices and borderline products at national and European level.
9. To further develop IMB capabilities, resource and expertise in relation to medical devices.

The HPRA strongly believes that optimising resources and funding for medical device competent authority activities is critical for the regulatory system, in particular in ensuring protection of health and to minimise the risks to the safety of patients, users and others in relation to the use of medical devices.

Sector 2 Cosmetics (Health Products Regulatory Authority)

2.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 HPRA interprets this as vigilance Cases	12	25	17	11
2.	Number of substantiated complaints by industry concerning unfair competition HPRA interprets this as quality defects (Compliance Cases)	n/a 31 ^a	n/a 106	n/a 127	n/a 153
3.	Number of inspections ¹¹ (total number)	N/A	N/A	N/A	3 ^b
3.1	number of reactive inspections ¹²	0	0	0	0
3.2	number of self-initiated inspections ¹³	0	0	0	3
3.3	number of inspections prompted by the customs ¹⁴	0	0	0	0
4	Number of inspections based on: HPRA interprets this as number of investigations based on:				
4.1	tests performed in laboratories	18	26	32	8
4.2	physical checks of products ¹⁵	539	656	544	342

¹¹ 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.

¹² 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.

¹³ This concerns 'proactive' inspections 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.

¹⁴ 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.

¹⁵ 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.

5	Number of inspections resulting in: HPRA interprets this as number of investigations resulting in:				
5.1	finding of non-compliance ¹⁶	8	26	13	15
5.2	corrective actions taken by economic operators ("voluntary measures") ¹⁷	16	27	61	57
5.3	restrictive measures ¹⁸ taken by market surveillance authorities .	226 ^c	2058 ^d	1	0
5.4	application of sanctions/penalties	1	0	0	0
6	Number of inspections where other Member States were invited to collaborate	0	0	0	0

Note^a this represents the time period from October – December 2010.

Note^b GMP inspections commenced in 2013 in line with the implementation of Regulation (EC) No 1223/2009 on cosmetic products

Note^{c,d} This represents the total number of units that were subject to restrictive/ preventive measures

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

HPRA hosted one Industry information day for manufacturers and responsible persons in 2010 and one in 2012 aimed at distributors involving participation by market surveillance authorities from HPRA, HSE and the Public Analyst's Laboratories. HPRA also held two meetings a year with industry associations to exchange information on the regulatory requirements and common findings on the market place.

HPRA website contains guidance on the roles and responsibilities of responsible persons and distributors as well as information for retailers and consumers on the requirements of the legislation in terms of compliance and vigilance reporting.

Information on resources (subject to availability)

¹⁶ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

¹⁷ 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.

¹⁸ 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.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ¹⁹ (€)	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)	6.25 FTE from October	6.25 FTE	7.25 FTE	7.25 FTE
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	5 FTE	5 FTE	5 FTE	5.25 FTE

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

An increase in market surveillance activities over the four year period is as a result of the implementation of Regulation (EC) No 1223/2009 on cosmetic products in July 2013. This regulation introduced new requirements in the areas of GMP, vigilance, product notification and product information file compilation.

The number of GMP inspections is expected to increase and a risk based inspection programme has been developed as an output from the inspections in 2013. Identified areas of future focus include importation, traceability in the supply chain, compliance with GMP requirements and root cause determination in the area of vigilance reporting.

Resourcing the area is a key challenge in the current climate.

The cosmetics market in Ireland is one mainly involving distributors and importers with a small manufacturing base. There are less than 10 manufacturing sites where the workforce is greater than 100 personnel in Ireland.

There is no requirement for manufacturers or distributors to register with the Competent Authority and as a result it is difficult to quantify the market size in this regard. Key difficulties exist with identifying the manufacturers of cosmetic products in the absence of a national register and similar

¹⁹ 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.

difficulties exist in terms of identifying the supply chain with respect to cosmetic product imports and distribution.

A platform of European market surveillance authorities has been established at the European Commission which fosters cooperation and exchange of information amongst member states. In addition there is significant technical cooperation with the assistance of the European Directorate for the Quality of Medicines (EDQM) where an Official Cosmetics Control Laboratory Network has been established.

Sector 3 Toys (National Consumer Agency)

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

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

	2010	2011	2012	2013
Toys (Directive 2009/48/EC) related cases investigated	36	36	36	17

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 to detailed statistical analysis of this data at this time.

		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 ²⁰ (total number)		1	3	9
3.1	number of reactive inspections ²¹	n/a	n/a	(see 3.3 below)	(see 3.3 below)
3.2	number of self-initiated inspections ²²	n/a	n/a	n/a	n/a
3.3	number of inspections prompted by the customs ²³		1	3 (not limited to Toys)	9 (not limited to Toys)
4	Number of inspections based on:				

²⁰ 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.

²¹ 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.

²² This concerns 'proactive' inspections 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.

²³ 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.

4.1	tests performed in laboratories	n/a	n/a	n/a	n/a
4.2	physical checks of products ²⁴	0	Representative items from customs consignments were visually and physically checked		
5	Number of inspections resulting in:				
5.1	finding of non-compliance ²⁵	n/a	1 Customs consignment	3 Customs consignments	9 Customs consignments destroyed
5.2	corrective actions taken by economic operators ("voluntary measures") ²⁶	The Agency achieved voluntary corrective actions (where necessary) in majority of cases			
5.3	restrictive measures ²⁷ taken by market surveillance authorities .	n/a	1 Customs consignment destroyed (not limited to Toys)	3 Customs consignments destroyed (not limited to Toys)	9 Customs consignments destroyed (not limited to Toys)
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	None	None	None	None

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

The National Consumer 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

²⁴ 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.

²⁵ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

²⁶ 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.

²⁷ 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.

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 Toys Safety page, Guide to Toy Safety, Toy Safety Tips and links to relevant the Irish legislation containing the transposed legislation.

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, 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 '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 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 ²⁸ (€) 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.	€7.2 million	€6.3 million	€5.2 million	€4.8 million
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 staff (authorised officers) in Product	7 staff (authorised officers) in Product	8 staff (authorised officers) in Product	8 staff (authorised officers) in Product

²⁸ 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.

		Safety Unit with additional authorised Officers available to assist on specific projects if required.	Safety Unit with additional authorised Officers available to assist on specific projects if required.	Safety Unit with additional authorised Officers available to assist on specific projects if required.	Safety Unit with additional authorised Officers available to assist on specific projects if required.
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	7 staff (authorised officers) in Product Safety Unit with additional authorised Officers available to assist on specific projects if required.	7 staff (authorised officers) in Product Safety Unit with additional authorised Officers available to assist on specific projects if required.	8 staff (authorised officers) in Product Safety Unit with additional authorised Officers available to assist on specific projects if required.	8 staff (authorised officers) in Product Safety Unit with additional authorised Officers available to assist on specific projects if required.

3.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.

Sector – 4 - Personal Protective Equipment (National Consumer Agency)

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

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

	2010	2011	2012	2013
Personal Protective Equipment (Directive 89/686/EEC) related cases investigated	8	5	16	3

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 to detailed statistical analysis of this data at this time.

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	8	5	16	3
2.	Number of substantiated complaints by industry concerning unfair competition	-	-	-	-
3.	Number of inspections ²⁹ (total number)	8 (as 1. above)	5 (as 1. above)	16 (as 1. above)	3 (as 1. above)
3.1	number of reactive inspections ³⁰	See 3.3 below	See 3.3 below	See 3.3 below	See 3.3 below
3.2	number of self-initiated inspections ³¹	n/a	n/a	n/a	n/a
3.3	number of inspections prompted by the customs ³²	-	1 (not limited to	3 (not limited to PPE)	9 (not limited to PPE)

²⁹ 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.

³⁰ 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.

³¹ This concerns 'proactive' inspections 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.

³² 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.

			PPE)		
4	Number of inspections based on:				
4.1	tests performed in laboratories	n/a	n/a	n/a	n/a
4.2	physical checks of products ³³	n/a	Representative items from customs consignments were visually and physically checked		
5	Number of inspections resulting in:				
5.1	finding of non-compliance ³⁴	n/a	1 Customs consignment	3 Customs consignment & RSA high Vis vests	9 Customs consignment
5.2	corrective actions taken by economic operators ("voluntary measures") ³⁵	n/a	n/a	n/a	n/a
5.3	restrictive measures ³⁶ taken by market surveillance authorities.	n/a	1 Customs consignment not limited to PPE	3 Customs consignments destroyed (not limited to PPE) and RSA High-vis vests -recalled from consumers and destroyed by manufacturer	9 Customs consignments destroyed (not limited to PPE)
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	None	None	None	None

³³ 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.

³⁴ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

³⁵ 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.

³⁶ 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 communication activities carried out in the 2010-2013 period (optional)

The National Consumer 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, RAPEX weekly summary reports, Product Safety recalls, Press Releases and links to relevant the Irish legislation containing the transposed legislation.
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, 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..

Information on resources (subject to availability)

NCA information / budget data not available on a sectoral basis.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ³⁷ (€)				
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)				

³⁷ 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.

4.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 in 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

National Consumer Agency has prepared and submitted to the Commission the National Sector Specific Market Surveillance Programme 2010 -2011 and the National Sector Specific Market Surveillance Programme 2012 – 2013.

2010 – Market Surveillance of Swimming Armbands - the Agency carried out a market surveillance of Swimming Armbands to determine compliance with the relevant standard and the Personal Protective Equipment Directive. Six Authorised Officers visited 34 outlets and purchased 49 sets of armbands for subsequent examination. A variety of technical issues became apparent and were taken up by the Agency at EU level with a view to seeking a uniform approach by member states.

2012 – Market Surveillance of Hurling Helmets - In 2012 the Agency carried out an investigation into the safety of hurling helmets to ensure that they complied with the requirements of the Personal Protective Equipment (PPE) Directive which involved engagement with all the major manufacturers and suppliers of hurling helmets in Ireland and also with the Gaelic Athletic Association authorities. The Agency investigation concluded that all sizes and models of helmets sold by the companies did comply with the relevant safety requirements. However during the investigation it came to the Agency's attention that in some cases faceguards were being "customised" either directly by players or on their behalf, by removing some of the protective bars in order to improve the field of vision and the Agency communicated with the relevant manufacturers and suppliers of these faceguards to ensure that all hurling helmet components complied with the requirements of the PPE Directive and had the CE mark, which attests that it conforms to the PPE Directive.

In early 2012 the Agency was informed by the Road Safety Authority (RSA) of a safety issue with high visibility vests which they had distributed free of charge to consumers in Ireland. The vests were independently tested on behalf of the RSA and failed to meet the minimum retro-reflective requirements of the relevant standards. At that time, the RSA had distributed in excess of 200,000 vests, with a further 150,000 remaining in stock. Following a comprehensive investigation, which included consultation with the European Commission, independent experts and other market surveillance authorities in Europe, the Agency concluded that the vests did not comply with the basic health and safety requirements of the PPE directive. In the circumstances, the supplier company voluntarily agreed to destroy 150,000 vests in stock. In addition, the Chinese manufacturer informed the Agency that it had changed its supplier of retro-reflective tape, that it has undertaken to make significant changes to its production process and commissioned an independent audit of the company and a replacement programme for the vests already distributed was implemented in 2013.

Sector 4 - Personal Protective Equipment (Health & Safety Authority)

4.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	0	0	0	0
3.	Number of inspections ³⁸ (total number)			21	
3.1	number of reactive inspections ³⁹				
3.2	number of self-initiated inspections ⁴⁰			21	
3.3	number of inspections prompted by the customs ⁴¹			0	
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products ⁴²			21	
5	Number of inspections resulting in:				
5.1	finding of non-compliance ⁴³			4	

³⁸ 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.

³⁹ 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.

⁴⁰ This concerns 'proactive' inspections 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.

⁴¹ 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.

⁴² 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.

5.2	corrective actions taken by economic operators (“voluntary measures”) ⁴⁴				
5.3	restrictive measures ⁴⁵ taken by market surveillance authorities .			4	
5.4	application of sanctions/penalties			0	
6	Number of inspections where other Member States were invited to collaborate				

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

Guidance on PPE on HSA website including reference to CE marking.

In 2013 Ireland launched a RAPEX alert on a brand of lifejacket following a voluntary recall by the manufacturer.

Information on resources (subject to availability) – No information available as there is not a separate budget allocation for the different Directives.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ⁴⁶ (€)				
7.2	Budget available to market surveillance authorities in relative terms (%age of total				

⁴³ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

⁴⁴ 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.

⁴⁵ 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.

⁴⁶ 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.

	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)				

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

The priority for the HSA during this period has been to ensure the provision and use of PPE at the workplace.

The priority for the HSA during this period has been to ensure the provision and use of PPE at the workplace.

There is concern over supply of “nuisance” dust masks which are not CE marked and could be worn in the mistaken belief about level of protection provided. Ireland has raised this issue at the PPE ADCO Committee.

Sector 7 - Pressure Equipment Directive (Health & Safety Authority)

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

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

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints				
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections ⁴⁷ (total number)		1		
3.1	number of reactive inspections ⁴⁸		1		
3.2	number of self-initiated inspections ⁴⁹				
3.3	number of inspections prompted by the customs ⁵⁰				
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products ⁵¹		1		
5	Number of inspections resulting in:				
5.1	finding of non-compliance ⁵²				

⁴⁷ 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.

⁴⁸ 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.

⁴⁹ This concerns 'proactive' inspections 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.

⁵⁰ 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.

⁵¹ 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.

5.2	corrective actions taken by economic operators (“voluntary measures”) ⁵³				
5.3	restrictive measures ⁵⁴ 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)

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Information on resources (subject to availability) - No information available as there is not a separate budget allocation for the different Directives.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ⁵⁵ (€)				
7.2	Budget available to market surveillance authorities in relative terms (%age of total				

⁵² This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

⁵³ 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.

⁵⁴ 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.

⁵⁵ 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.

	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)				

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

The HSA actively follows up reports from competent persons concerning in-service inspection of pressure equipment where serious defects have been found. This activity is not addressed in this report.

Sector 8 - Transportable Pressure Equipment (Health & Safety Authority)

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

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

		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 ⁵⁶ (total number)				
3.1	number of reactive inspections ⁵⁷				
3.2	number of self-initiated inspections ⁵⁸				
3.3	number of inspections prompted by the customs ⁵⁹				
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products ⁶⁰				
5	Number of inspections resulting in:				

⁵⁶ 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.

⁵⁷ 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.

⁵⁸ This concerns 'proactive' inspections 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.

⁵⁹ 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.

⁶⁰ 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.

5.1	finding of non-compliance ⁶¹				
5.2	corrective actions taken by economic operators (“voluntary measures”) ⁶²				
5.3	restrictive measures ⁶³ 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)

Information on the legal requirements has been placed on the HSA web site – www.hsa.ie/.

Information on resources (subject to availability) - No information available as there is not a separate budget allocation for the different Directives.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ⁶⁴ (€)				
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)				
8	Staff available to market surveillance				

⁶¹ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

⁶² 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.

⁶³ 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.

⁶⁴ 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.

	authorities (full-time equivalent units)				
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)				

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

No Market Surveillance activities carried out in relation to TPED.

Sector 9 Machinery (Health & Safety Authority)

9.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	1			6
2.	Number of substantiated complaints by industry concerning unfair competition	1		1	
3.	Number of inspections ⁶⁵ (total number)	11	56	83	59
3.1	number of reactive inspections ⁶⁶	4	3	9	8
3.2	number of self-initiated inspections ⁶⁷	7	53	74	51
3.3	number of inspections prompted by the customs ⁶⁸	3			1
4	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	0	0
4.2	physical checks of products ⁶⁹	11	56	83	59
5	Number of inspections resulting in:				
5.1	finding of non-compliance ⁷⁰	11	34	23	4

⁶⁵ 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.

⁶⁶ 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.

⁶⁷ This concerns 'proactive' inspections 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.

⁶⁸ 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.

⁶⁹ 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.

⁷⁰ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

5.2	corrective actions taken by economic operators (“voluntary measures”) ⁷¹	7	32	18	3
5.3	restrictive measures ⁷² taken by market surveillance authorities .	4	2	5	1
5.4	application of sanctions/penalties		1		
6	Number of inspections where other Member States were invited to collaborate	1		1	

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

A link to the RAPEX website was provided on the “Safety Alert” section of the HSA web home page.

Under “Topics” on the HSA homepage, the section on “Machinery” references the Machinery Directive and provides a link to the Commission website on the Machinery Directive.

In 2012 a guidance note on the purchase of new machinery was uploaded.

A number of safety alerts related to machinery have been issued over this period.

Information on resources (subject to availability) No information available as there is not a separate budget allocation for the different Directives.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ⁷³ (€)				
7.2	Budget available to market surveillance				

⁷¹ 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.

⁷² 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.

⁷³ 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.

	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)				

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

A large number of the inspections relate to a project on powered gates which involved visits to a large number of small businesses.

Small companies manufacturing low cost machinery where design is based on experience rather than calculation find the administrative requirements of the Directive difficult e.g. creation of a technical file.

In 2013 particular attention was paid to lack of manufacturer's identification on PTO guards.

Sector 10 Lifts (Health & Safety Authority)

10.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	0	0	0	0
3.	Number of inspections ⁷⁴ (total number)			57 (see note in 10B.)	
3.1	number of reactive inspections ⁷⁵			57	
3.2	number of self-initiated inspections ⁷⁶				
3.3	number of inspections prompted by the customs ⁷⁷				
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products ⁷⁸			57	
5	Number of inspections resulting in:				
5.1	finding of non-compliance ⁷⁹			20	

⁷⁴ 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.

⁷⁵ 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.

⁷⁶ 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.

⁷⁷ 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.

⁷⁸ 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.

5.2	corrective actions taken by economic operators (“voluntary measures”) ⁸⁰				
5.3	restrictive measures ⁸¹ 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)

The HSA actively follows up reports from competent persons concerning in-service inspection of lifts where serious defects have been found. This activity is not addressed in this report.

Information on resources (subject to availability) No information available as there is not a separate budget allocation for the different Directives

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ⁸² (€)				
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)				
8	Staff available to market surveillance				

⁷⁹ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

⁸⁰ 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.

⁸¹ 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.

⁸² 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.

	authorities (full-time equivalent units)				
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)				

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

In 2012 HSA carried out a project which examined the safety of lifts in use and in service inspection, during which some data became available on Lift Directive compliance. The project follow up focused on owner duties in respect of maintenance and periodic inspection. Project planned for 2014 on installer compliance.

In the environment where construction companies and other businesses including lift installers have failed, access to records for lift installations has been difficult.

Sector 13 Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres (Health & Safety Authority)

13.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	0	0	0	0
3.	Number of inspections ⁸³ (total number)		2		
3.1	number of reactive inspections ⁸⁴		2		
3.2	number of self-initiated inspections ⁸⁵				
3.3	number of inspections prompted by the customs ⁸⁶		0		
4	Number of inspections based on:				
4.1	tests performed in laboratories				
4.2	physical checks of products ⁸⁷		2		

⁸³ 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.

⁸⁴ 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.

⁸⁵ This concerns 'proactive' inspections 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.

⁸⁶ 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.

⁸⁷ 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.

5	Number of inspections resulting in:				
5.1	finding of non-compliance ⁸⁸	0			
5.2	corrective actions taken by economic operators (“voluntary measures”) ⁸⁹				
5.3	restrictive measures ⁹⁰ 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)

Information on the legal requirements has been placed on the HSA web site.

Information on resources (subject to availability) - No information available as there is not a separate budget allocation for the different Directives.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ⁹¹ (€)				

⁸⁸ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

⁸⁹ 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.

⁹⁰ 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.

⁹¹ 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.

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)				

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

No comments.

Sectors 14 and 15 (Department of Justice)

14/15.A. Review of market surveillance activities in the sector

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

****Total inspections includes documentary checks carried out on all explosives for civil uses and pyrotechnics prior to the issue of an import licence under explosives legislation**

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	0	0	0	1
2.	Number of substantiated complaints by industry concerning unfair competition	0	0	0	0
3.	Number of inspections ⁹² (total number)	405	444	470	455
3.1	number of reactive inspections ⁹³	0	0	0	1
3.2	number of self-initiated inspections ⁹⁴	405	444	470	454
3.3	number of inspections prompted by the customs ⁹⁵	0	0	0	0
4	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	0	0
4.2	physical checks of products ⁹⁶	54	59	68	76
5	Number of inspections resulting in:				
5.1	finding of non-compliance ⁹⁷	0	0	1	2

⁹² 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.

⁹³ 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.

⁹⁴ This concerns 'proactive' inspections 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.

⁹⁵ 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.

⁹⁶ 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.

5.2	corrective actions taken by economic operators (“voluntary measures”) ⁹⁸	0	0	1	2
5.3	restrictive measures ⁹⁹ taken by market surveillance authorities .	0	0	1	2
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)

The Inspectorate has produced Guidance on the Legal Obligations of Importers, Distributors and Retailers of Fireworks for Sale, Guidance on the Legal Obligations of Importers, Distributors and Retailers of Airbags and also Guidance for the General Public on Fireworks. These are available on our website

The Department conducts an annual public awareness campaign on the dangers of illegal fireworks and penalties associated with their possession and use. Cost is normally approx €40,000.

Information on resources (subject to availability)

**** No budget, staff or inspectors are specifically allocated for market surveillance. All work in this respect is conducted by the staff and inspectors in the Explosives Inspectorate as part of and in addition to other licensing and inspection functions**

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ¹⁰⁰ (€)**	0	0	0	0

⁹⁷ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

⁹⁸ 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.

⁹⁹ 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.

¹⁰⁰ 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

7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)**	0	0	0	0
8	Staff available to market surveillance authorities (full-time equivalent units)**	0.1	0.1	0.1	0.1
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)**	0.1	0.1	0.1	0.1

14/15.B. Assessment of the functioning of market surveillance activities in the sector

Despite the fact that there is no specific budget or staff allocated to the market surveillance of Pyrotechnics or Explosives for Civil Uses, all products being placed on the market are subject to documentary checks and a representative sample are subjected to further physical checks which ensures compliance with their respective Directives and enforcement action has been taken where non compliances were found.

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 16 Appliances Burning Gaseous Fuels (National Consumer Agency)

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

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

	2010	2011	2012	2013
Appliances Burning Gaseous Fuels (Directive 2009/142/EC) related cases investigated	17	11	16	14

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 to detailed statistical analysis of this data at this time.

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	17	11	16	14
2.	Number of substantiated complaints by industry concerning unfair competition	-	-	-	-
3.	Number of inspections ¹⁰¹ (total number)				
3.1	number of reactive inspections ¹⁰²	n/a	n/a	See 3.3 below	See 3.3 below
3.2	number of self-initiated inspections ¹⁰³	5	n/a	n/a	n/a
3.3	number of inspections prompted by the customs ¹⁰⁴	0	0	0	0)

¹⁰¹ 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.

¹⁰² 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.

¹⁰³ This concerns 'proactive' inspections 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.

4	Number of inspections based on:				
4.1	tests performed in laboratories	5	0	0	0
4.2	physical checks of products ¹⁰⁵	n/a	Representative items from customs consignments were visually and physically checked		
5	Number of inspections resulting in:				
5.1	finding of non-compliance ¹⁰⁶	n/a	n/a	n/a	n/a
5.2	corrective actions taken by economic operators ("voluntary measures") ¹⁰⁷	The Agency achieved voluntary corrective actions (where necessary) in majority of cases.			
5.3	restrictive measures ¹⁰⁸ 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)

The National Consumer 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

¹⁰⁴ 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.

¹⁰⁵ 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.

¹⁰⁶ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

¹⁰⁷ 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.

¹⁰⁸ 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, RAPEX weekly summary reports, Product Safety recalls, Press Releases, Business Zones Guides and links to relevant the Irish legislation containing the transposed legislation. In 2010 there was a very significant amount of communication and co-operation at a corporate level between the NCA and the manufacturers of Beko, Flavel, Leisure & New World cookers to ensure that the recall of the products was communicated to all households in Ireland due to the significant risk of carbon monoxide poisoning by using products which did not undergo the refit.

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, investigation of complaints about unsafe products alerting consumers about unsafe products by posting product recalls and RAPEX notifications and Product Safety Alerts including Beko, Flavel, Leisure and New World Cookers in 2011 and similar product recalls, Gas and electrical appliance safety and Gas safety, electrical appliances in the home Information sheet and extensive and ongoing media campaigns including interviews and press releases in order to educate and raise awareness of the hazard and risk to consumers.

Information on resources (subject to availability)

NCA information / budget data not available on a sectoral basis.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ¹⁰⁹ (€)				
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)				

¹⁰⁹ 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.

16.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 in 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

National Consumer Agency has prepared and submitted to the Commission the National Sector Specific Market Surveillance Programme 2010 -2011 and the National Sector Specific Market Surveillance Programme 2012 – 2013.

2010 - Beko, Flavel, Leisure & New World gas cookers – in November 2008, in response to a fatality due to carbon monoxide poisoning the Agency had been working very closely with the companies to contact all of the purchasers of the affected models of Beko, Flavel, Leisure & New World gas cookers to arrange for a free refit. Approximately 7,686 of these cookers had been sold in Ireland between 2003 and 2007 but there was a low rate of response from purchasers and due to the significant danger of carbon monoxide poisoning involved, in 2010, the manufacturers, with ongoing and continuing support of the Agency, intensified their recall campaign through a variety of media formats and included leaflet drop to all postal addresses in Ireland and in total 75% of the cookers were identified.

2010 – At the end of 2009 a number of complaint were received by the NCA about gas leaks associated with the use of Jumbo Bottle Gas Regulators and the NCA commenced a significant body of preparation work in order to conduct market surveillance of these products in 2010. However, following consultation with the National gas technical committee and independent testing of the products (which determined that the fault was not a general problem per se but rather batch related), it was not considered necessary to proceed with further market surveillance activity.

Sector 17 Measuring instruments, Non-automatic weighing instruments (National Standards Association of Ireland)

17.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 ¹¹⁰ (total number)	11749	13882	14853	16114
3.1	number of reactive inspections ¹¹¹	0	0	0	0
3.2	number of self-initiated inspections ¹¹²	2871	3655	1815	9934
3.3	number of inspections prompted by the customs ¹¹³	0	0	0	0
4	Number of inspections based on:				
4.1	tests performed in	0	0	0	0

¹¹⁰ 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.

¹¹¹ 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.

¹¹² This concerns 'proactive' inspections 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.

¹¹³ 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.

	laboratories				
4.2	physical checks of products ¹¹⁴	2871	3655	1815	9934
5	Number of inspections resulting in:				
5.1	finding of non-compliance ¹¹⁵	Not distinguishable	Not distinguishable	Not distinguishable	Not distinguishable
5.2	corrective actions taken by economic operators ("voluntary measures") ¹¹⁶	0	0	0	0
5.3	restrictive measures ¹¹⁷ taken by market surveillance authorities .	0	0	0	0
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)

<p>Inspectors creating awareness during inspection activity</p> <p>Information Brochures</p> <p>Website</p>

¹¹⁴ 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.

¹¹⁵ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

¹¹⁶ 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.

¹¹⁷ 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.

Market Surveillance Meetings
Inspector Training
Contact with market operators

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ¹¹⁸ (€)				
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)				

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

No comments to add.

¹¹⁸ 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 20 Electrical Appliances and equipment under LVD (National Consumer Agency)

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

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

	2010	2011	2012	2013
Electrical Appliances and Equipment under LVD (Directive 2006/95/EC) related cases investigated	78	95	80	129

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 to detailed statistical analysis of this data at this time.

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	78	95	80	129
2.	Number of substantiated complaints by industry concerning unfair competition	-	-	-	-
3.	Number of inspections ¹¹⁹ (total number)		1	3	9
3.1	number of reactive inspections ¹²⁰	n/a	(See3.3 below)	(See3.3 below)	(See3.3 below)
3.2	number of self-initiated inspections ¹²¹	n/a	n/a	n/a	n/a
3.3	number of inspections prompted by the customs ¹²²	n/a	n/a	n/a	n/a

¹¹⁹ 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.

¹²⁰ 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.

¹²¹ This concerns 'proactive' inspections 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.

¹²² 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	n/a	n/a	n/a	n/a
4.2	physical checks of products ¹²³	n/a	Representative items from customs consignments were visually and physically checked		
5	Number of inspections resulting in:				
5.1	finding of non-compliance ¹²⁴	n/a	1 Customs consignment	3 Customs consignment	9 Customs consignment
5.2	corrective actions taken by economic operators ("voluntary measures") ¹²⁵	The Agency achieved voluntary corrective actions (where necessary) in majority of cases.			
5.3	restrictive measures ¹²⁶ taken by market surveillance authorities .	n/a	1 Customs consignment destroyed (not limited to LVD)	3 Customs consignment destroyed (not limited to LVD)	9 Customs consignment destroyed (not limited to LVD)
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)

The National Consumer 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

¹²³ 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.

¹²⁴ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

¹²⁵ 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.

¹²⁶ 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 including Toy safety and magnetic toys, RAPEX weekly summary reports, Product Safety recalls, Press Releases, Business Zones Guides including Toys Safety page, Guide to Toy Safety, Toy Safety Tips and links to relevant the Irish legislation containing the transposed legislation.

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, 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 detailed Product Safety Alerts for products including Bosch & Hotpoint/ Indesit dishwashers in 2013 and similar product recalls, Gas and electrical appliance safety and Gas safety, electrical appliances in the home Information sheet and a general guide for electric blanket safety for consumers.

Information on resources (subject to availability)

NCA information / budget data not available on a sectoral basis.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ¹²⁷ (€)				
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)				

20.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 in to enforce consumer law and promote consumer rights with responsibility for market surveillance in

¹²⁷ 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.

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

National Consumer Agency has prepared and submitted to the Commission the National Sector Specific Market Surveillance Programme 2010 -2011 and the National Sector Specific Market Surveillance Programme 2012 – 2013.

2010 - Between 2001 and 2008, approximately 690 GeminoX Ebs Immersion Water Cylinders had been placed on the market and five fires were attributed to these units. The operator had difficulties in locating the products and after a significant engagement and detailed communication consultation with the Agency, GeminoX initiated a further intensive media campaign to trace the remaining units with 320 (approx. 46%) identified and refitted by the end of 2010. The Agency continued to provide ongoing advice and support to GeminoX throughout 2011 and further media campaigns were carried out over the course of 2011 resulting the identification and refitting of 60% of the 680 units.

In 2005, Grasslin had issued a voluntary recall of 38,000 QE7 electric water heater timers and 11,000 units (approx. 29%) had been identified and replaced. However, in 2010 there was a fire in a house in Limerick in 2010 which was attributed to one of these units, so the Agency continued to work closely with Grasslin to provide advice and support to enable the company to raise the awareness of consumers of the risks associated with the product and advice to stop using it immediately and to contact the company for the necessary replacements / repairs at no cost to the consumers. This work continued through 2011 and Grasslin carried out further communication campaigns supported by the Agency. By the end of 2011 over 27,000 (approx. 71%) units had been identified and replaced.

Early in 2013, the Agency investigated an issue concerning Bosch dishwashers following a fire in a Dublin house and a potential fire risk from certain models of Bosch, Neff and Siemens branded dishwashers. Following further detailed and prolonged investigation, The Agency secured the agreement of Bosch Home Appliances (BSH) to extend a voluntary repair action programme to Ireland which had been in place in the UK since 2011. During the investigation, the Agency became aware that a similar problem affected dishwashers sold under the Hotpoint brand (DWF Series) between 1999 and 2003. Over 13,600 of these dishwashers had been sold in Ireland. Following discussions with the Hotpoint parent company, Indesit Ltd, a similar repair programme was initiated for the Irish market. Approximately 29,000 BSH machines and 13,600 Hotpoint / Indesit had been sold in Ireland and a further 3,900 dishwashers from Hotpoint were also identified. There has been significant and ongoing communication and support provided by the Agency to the companies and this is still on going there are still a significant number of the dishwashers unidentified and incidents are still being reported to the Agency.

Sector 21 Electrical and electronic equipment under RoHS, WEEE and batteries – 2011/65/EU and 2006/66/EC (Environmental Protection Agency)

21.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 ¹²⁸ (total number)	49	49	40	17
3.1	number of reactive inspections ¹²⁹	0	0	0	1
3.2	number of self-initiated inspections ¹³⁰	49	49	40	16
3.3	number of inspections prompted by the customs ¹³¹	0	0	0	0
4	Number of inspections based on:				
4.1	tests performed in laboratories	49	49	40	16
4.2	physical checks of products ¹³²	0	0	0	

¹²⁸ 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.

¹²⁹ 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.

¹³⁰ This concerns 'proactive' inspections 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.

¹³¹ 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.

¹³² 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.

5	Number of inspections resulting in:				
5.1	finding of non-compliance ¹³³	5	6	5	0
5.2	corrective actions taken by economic operators (“voluntary measures”) ¹³⁴	5	6	2	0
5.3	restrictive measures ¹³⁵ taken by market surveillance authorities .	0	0	0	0
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)

The EPA works continually with industry to promote compliance including attending relevant conferences and maintaining a dedicated webpage on the organisation’s website. Particular attention has recently focused on some medical device manufacturers relating to the introduction of the RoHS Directive requirements for this sector during 2014.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ¹³⁶ (€)	37,703	36,885	64,458	37,960

¹³³ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

¹³⁴ 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.

¹³⁵ 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.

¹³⁶ 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.

7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	0.0000696	0.0000697	0.0001242	0.0000741
8	Staff available to market surveillance authorities (full-time equivalent units)	0.25	0.10	0.23	0.20
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	0.25	0.10	0.23	0.20

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

In relation to both product sectors, the EPA has not determined the market size or activity levels relating to the sectors concerned so it is not possible to provide statistical data on the relative percentage of products placed on the market within the State which are inspected. The targeting of samples is on a risk basis – the products associated with the greatest probability of non-compliance being allocated the greater resources. The risk assessment is based on experiences gained in previous surveillance campaigns and intelligence obtained from the RoHS Enforcement Network (RoHS AdCo). The EPA works closely with the RoHS AdCo, including participating in special surveillance programmes, in order to maximise the use of limited available resources.

Sector 22 Chemicals (Detergents, Paints, Persistent organic pollutants) – 2004/42/CE and Regulation (EC) No 850/2004 (Environmental Protection Agency)

22.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 ¹³⁷ (total number)	203	1	46	40
3.1	number of reactive inspections ¹³⁸	0	1	0	20
3.2	number of self-initiated inspections ¹³⁹	203	0	46	20
3.3	number of inspections prompted by the customs ¹⁴⁰	0	0	0	0
4	Number of inspections based on:				
4.1	tests performed in laboratories	27	0	26	6
4.2	physical checks of products ¹⁴¹	176	1	20	20

¹³⁷ 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.

¹³⁸ 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.

¹³⁹ This concerns 'proactive' inspections 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.

¹⁴⁰ 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.

¹⁴¹ 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.

5	Number of inspections resulting in:				
5.1	finding of non-compliance ¹⁴²	24	0	0	0
5.2	corrective actions taken by economic operators (“voluntary measures”) ¹⁴³	0	0	0	0
5.3	restrictive measures ¹⁴⁴ taken by market surveillance authorities .	0	0	0	0
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)

The EPA works continually with the relevant economic operators to promote compliance. Operators are provided with guidance relating to the requirements of the legislation as part of the inspection process. Guidance is also provided on dedicated sections of the organisation’s website.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ¹⁴⁵ (€)	44,279.00	8,763.00	23,579.00	€25,554.00
7.2	Budget available to market surveillance authorities in relative terms (%age of total	0.0000817	0.0000166	0.0000454	0.0000499

¹⁴² This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

¹⁴³ 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.

¹⁴⁴ 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.

¹⁴⁵ 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.

	national budget)				
8	Staff available to market surveillance authorities (full-time equivalent units)	0.14	0.14	0.05	0.05
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	0.14	0.14	0.05	0.05

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

The EPA has not determined the market size or activity levels relating to the sectors concerned so it is not possible to provide statistical data on the relative percentage of products placed on the market within the State which are inspected.

During the 2010 market surveillance campaign serious issues regarding the enforceability of the Paints Directive emerged (see [2010 report](#) on the implementation of Directive 2004/42/CE). As none of the issues raised appear to have been resolved at the time of submission of this questionnaire, the EPA has refrained from committing substantial market surveillance resources into this particular product sector. The EPA continues to work with the relevant industries, paint supplier and vehicle refinishing operators, to promote the use of compliant products.

The work carried out to date by the EPA regarding POPs has largely related to the newly added POPs to the Stockholm Convention. The EPA has carried out studies on samples of metal shredder residue, bulky wastes, WEEE and some sludges to determine the levels, if any, of certain POPs contained in these materials. These projects have provided additional input into the overall EC study on the consequences of the addition of the new POPs. Additionally, some of the work has provided a better understanding of emissions of some POPs to the environment.

Sector 22 Chemicals (Detergents, Paints, Persistent organic pollutants) (Health and Safety Authority)

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

Note that this section focuses on chemicals other than those falling under REACH and CLP Regulations since they are already the subject of specific reports available to the public. The following link provides details on the IE national market surveillance in relation REACH and CLP up to 2010 - http://ec.europa.eu/environment/chemicals/reach/pdf/art_117/MSREACHRptg5%20IE.pdf

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 ¹⁴⁶ (total number)	3	0	36	13
3.1	number of reactive inspections ¹⁴⁷				
3.2	number of self-initiated inspections ¹⁴⁸	3	0	36	13
3.3	number of inspections prompted by the customs ¹⁴⁹	0	0	0	0
4	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	0	0

¹⁴⁶ 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.

¹⁴⁷ 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.

¹⁴⁸ This concerns 'proactive' inspections 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.

¹⁴⁹ 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.

4.2	physical checks of products ¹⁵⁰	3	0	36	13
5	Number of inspections resulting in:				
5.1	finding of non-compliance ¹⁵¹		N/A	7	3
5.2	corrective actions taken by economic operators ("voluntary measures") ¹⁵²			7	3
5.3	restrictive measures ¹⁵³ taken by market surveillance authorities .	0	0	0	0
5.4	application of sanctions/penalties	0	0	0	0
6	Number of inspections where other Member States were invited to collaborate				

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

Information dissemination on website.

Information on resources (subject to availability)- No information available as there is not a separate budget allocation for the different Directives

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ¹⁵⁴ (€)				

¹⁵⁰ 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.

¹⁵¹ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

¹⁵² 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.

¹⁵³ 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.

¹⁵⁴ 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

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)				

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

No Comments.

these authorities not related to the enforcement of product legislation laws should be excluded from the calculation.

Sector 23 Ecodesign & Labelling (Also includes information on sectors 24 and 27 (part) as per Annex 1) (Department of Communications, Energy and Natural Resources)

23.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 ¹⁵⁵ (total number)				
3.1	number of reactive inspections ¹⁵⁶	0	0	0	0
3.2	number of self-initiated inspections ¹⁵⁷	0	0	27	38
3.3	number of inspections prompted by the customs ¹⁵⁸	0	0	0	0
4	Number of inspections based on:				
4.1	tests performed in laboratories	0	0	0	0
4.2	physical checks of products ¹⁵⁹	0	0	27	38
5	Number of inspections resulting in:				
5.1	finding of non-compliance ¹⁶⁰	0	0	27	38

¹⁵⁵ 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.

¹⁵⁶ 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.

¹⁵⁷ This concerns 'proactive' inspections 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.

¹⁵⁸ 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.

¹⁵⁹ 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.

		2010	2011	2012	2013
5.2	corrective actions taken by economic operators (“voluntary measures”) ¹⁶¹	0	0	27	36*
5.3	restrictive measures ¹⁶² taken by market surveillance authorities .	0	0	0	0
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

* Two operators ceased trading before corrective actions could be taken

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

DCENR acknowledge that communication / awareness campaigns are essential in assisting economic operators in achieving compliance. Information on the legislation and obligations of affected parties is disseminated in the form of:

- Production of publications such as leaflets, brochures or other guidance material to inform suppliers, dealers and the public of the requirements of the legislation
- Engagement with professional and trade associations.
- In advance of a formal inspection, businesses receive a training / information session to advise them of their obligations and to assist them in achieving compliance.
- A dedicated contact point (including a Freephone number) is provided where stakeholders can direct queries and receive information and assistance.
- One-to-one meetings are available on request by an economic operator
- Our website (www.dcenr.gov.ie/marketsurveillance) is regularly updated to include the most up-to-date information including a list of ‘Frequently-asked-Questions’ to address the common queries being received.

¹⁶⁰ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

¹⁶¹ 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.

¹⁶² 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 ¹⁶³ (€)	150,000	150,000	150,000	150,000
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)	0%	0%	0%	0%
8	Staff available to market surveillance authorities (full-time equivalent units)	0	0	1	1
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	0	0	4	4

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

The Energy Efficiency and Affordability Division within DCENR are responsible for all aspects of implementation of the Energy Labelling Directive and the Tyre Labelling Regulation in Ireland and for market surveillance aspects of the Ecodesign Directive. Due to lack of in-house resources and expertise, most market surveillance services are outsourced to suitable market actors through public procurement processes.

DCENR have acknowledged through our annual market surveillance submissions to DG Energy that we were not in a position to carry out market surveillance for the above legislation pre-2012. Significant work has been undertaken since then to design a market surveillance programme that is both comprehensive and consistent in application. It is our strong view that we have overcome significant legislative and administrative obstacles and have succeeded in setting up the framework for a successful market surveillance regime.

Since 2012, bi-annual market surveillance plans have been in place and have been published in Ireland's biennial national market surveillance programmes as required under Regulation (EC) No. 765/2008. The objective of these plans are to ensure, insofar as is feasible within existing legal, organisational and infrastructural frameworks, that an effective regime is in place to meet our market surveillance obligations.

Due to limited resources available, monitoring activities are combined where possible. DCENR's general approach includes both proactive and reactive activities:

¹⁶³ 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.

- Proactive inspections: Inspection of retail sites for compliance with the Energy Labelling and Ecodesign Directives and Tyre Labelling Regulations with regard to affixing of correct labels and markings on products and the supply of appropriate documentation. A risk-based approach is adopted which takes account of factors such as market share, geographic location and history of non-compliance.
- Reactive Inspections: Investigation of complaints from the public or other affected parties and from information received from Customs authorities or other Market Surveillance Authorities.

The 2012 / 2013 Inspection Programme comprised 65 electrical retailers representing approximately 20% of the Irish electrical retail market and covered the visual inspection of over 14,000 products. The results of the campaign were mixed with 92% of products inspected found to be compliant with Ecodesign requirements and 44% of products found to be complaint with Energy Labelling requirements.

The 2014 / 2015 Inspection Programme is underway and will result in an additional 100 premises being inspected each year. The scope of this programme has been expanded to cover tyre labelling with approximately one quarter of activities being focused in this area.

Verification of non-compliance through testing plays an important part in the process of removing non-compliant products from the market. However, due to the fact that Ireland does not have a large indigenous electrical or white good industry and the lack of any national accredited test laboratories, the testing of products will always prove challenging. A number of risk-based testing campaigns will be completed over the period 2014 - 2015, the number and type of products to be tested being dependent on budgetary allocations

Very ambitious work plans have been set by the Commission for both ecodesign and energy labelling and this might prove difficult for market surveillance authorities to keep pace with due to the considerable expertise and resources that will be required to carry out effective market surveillance, which many MSAs do not have (access to). This issue has been identified in the ECOFYS Report on the Evaluation of the Energy Labelling and Ecodesign Directives which was published in June.

DCENR is a participant in the national Market Surveillance Forum established by the Department of Jobs, Enterprise and Innovation (DJEI) to fulfil Ireland's requirements under Article 18(1) of Regulation (EC) No. 765/2008. The Forum brings together market surveillance authorities from the various Ministries and State Agencies, as well as the Revenue Commissioner's Customs Services and the Irish National Accreditation Board. DCENR also attend the Administrative Cooperation Groups (ADCOs) on Ecodesign, Energy Labelling and Tyre Labelling and are currently participating in a joint-European Ecodesign compliance project (ECOPLIANT).

Sector 29 Fertilisers (Department of Agriculture, Food and the Marine)

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

(All inspections are pre-planned but unannounced)

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 ¹⁶⁴ (total number)	207	55	111	93
3.1	number of reactive inspections ¹⁶⁵	0	0	0	0
3.2	number of self-initiated inspections ¹⁶⁶	N/A	N/A	N/A	N/A
3.3	number of inspections prompted by the customs ¹⁶⁷				
4	Number of inspections based on:				
4.1	tests performed in laboratories	207	55	111	93
4.2	physical checks of products ¹⁶⁸	207	55	111	93
5	Number of inspections resulting in:				

¹⁶⁴ 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.

¹⁶⁵ 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.

¹⁶⁶ This concerns 'proactive' inspections 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.

¹⁶⁷ 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.

¹⁶⁸ 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.

5.1	finding of non-compliance ¹⁶⁹	23	14	32	25
5.2	corrective actions taken by economic operators (“voluntary measures”) ¹⁷⁰	23	14	32	25
5.3	restrictive measures ¹⁷¹ taken by market surveillance authorities .	0	0	0	0
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)

No Comments.

Information on resources (subject to availability)

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ¹⁷² (€)	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)	2	2	2	2

¹⁶⁹ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

¹⁷⁰ 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.

¹⁷¹ 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.

¹⁷² 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.

9	Number of inspectors available to market surveillance authorities (full-time equivalent units)	1.5	1.5	1.5	1.5
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29.B. Assessment of the functioning of market surveillance activities in the sector

No Comments.

Sector – 30 - Other consumer product under GPSD (Directive 2001/95/EC) (National Consumer Agency)

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

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

	2010	2011	2012	2013
Other Consumer Products under GPSD (Directive 2001/95/EC) related cases investigated	279	270	294	324

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 does not have sufficient resources available to devote to detailed statistical analysis of this data at this time.

		2010	2011	2012	2013
1.	Number of product related accidents / user complaints	279	270	294	324
2.	Number of substantiated complaints by industry concerning unfair competition	-	-	-	-
3.	Number of inspections ¹⁷³ (total number)		1	3	3
3.1	number of reactive inspections ¹⁷⁴	n/a	n/a	n/a	n/a
3.2	number of self-initiated inspections ¹⁷⁵	n/a	n/a	n/a	n/a
3.3	number of inspections prompted by the customs ¹⁷⁶	0	1	3 (not limited to GPSD)	9 (Not limited to GPSD)

¹⁷³ 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.

¹⁷⁴ 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.

¹⁷⁵ This concerns 'proactive' inspections 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.

¹⁷⁶ 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	0	0	0	4
4.2	physical checks of products ¹⁷⁷	n/a	Representative items from customs consignments were visually and physically checked		
5	Number of inspections resulting in:				
5.1	finding of non-compliance ¹⁷⁸	n/a	1 Customs consignment	3 Customs consignment	9 Customs consignment
5.2	corrective actions taken by economic operators ("voluntary measures") ¹⁷⁹	The Agency achieved voluntary corrective actions (where necessary) in majority of cases.			
5.3	restrictive measures ¹⁸⁰ taken by market surveillance authorities .	n/a	1 Customs consignment destroyed – not limited to GPSD	3 Customs consignment destroyed – not limited to GPSD	9 Customs consignment destroyed – not limited to GPSD
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	None	None	None	None

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

The National Consumer 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

¹⁷⁷ 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.

¹⁷⁸ This refers to any noncompliance (formal or substantial, minor as well as serious) of a product with legislation.

¹⁷⁹ 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.

¹⁸⁰ 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 including Toy safety and magnetic toys, RAPEX weekly summary reports, Product Safety recalls, Press Releases, Business Zones Guides and links to relevant the Irish legislation containing the transposed legislation.

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, 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.

In 2010, a significant Market Surveillance programme was conducted by the Agency in relation to Window Blinds and cords safety and included contacting and advising individual manufacturers and retailers and a media information campaign for the general public. The Agency hosted an information seminar for manufacturers, importers, retailers, installers, engineers, representatives of users and other interested bodies and designed and launched an information video on the consumer focused website at <http://www.consumerhelp.ie/>. The Agency has continued to participate in ongoing media initiatives to raise consumer awareness of the hazards associated with window blind cords including presse releases, interviews on radio and television and the development and launch of an online video and information is also provided regarding how window blind cords can be made safer.

Specific notices posted on the consumer focused website <http://www.consumerhelp.ie/> in relation to Dimethylfumerate (DMF) ,Novelty cigarette lighters and an Amber teething accessories information sheet which was developed and made available to coincide with the recall of amber teething products with a related press release.

Information on resources (subject to availability)

NCA information / budget data not available on a sectoral basis.

		2010	2011	2012	2013
7.1	Budget available to market surveillance authorities in nominal terms ¹⁸¹ (€)				
7.2	Budget available to market surveillance authorities in relative terms (%age of total national budget)				
8	Staff available to market surveillance				

¹⁸¹ 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.

	authorities (full-time equivalent units)				
9	Number of inspectors available to market surveillance authorities (full-time equivalent units)				

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

In 2010, Market Surveillance was conducted in relation to Window Blinds cords and included manufacturers and retailers and an information campaign for the general public and included an information seminar hosted by the NCA for manufacturers, importers, retailers, installers, engineers, representatives of users and other interested bodies. A

2011 – A consignment of 200 Novelty cigarette lighters was suspended at the border by Customs and following an investigation by the NCA and the items were destroyed.

2013 – 9 consignments were suspended at the border by Customs and following investigations by the NCA, 2 of the consignments which did not comply with the GPSD s were destroyed.

Also in 2013, a Market Surveillance project in to Amber Teething and similar accessories, intended for use by children under 36 months, commenced. A number of sample products were sent to an independent UK test house and test results indicated that the products failed due to the risk of choking, inhalation or strangulation for infants under 36 months. In total, four online traders were identified and their products were tested independently and recalled with the agreement of the traders. This project is still on-going as the Agency becomes aware of additional retailers.

Annex 1: Reference list of sectors

Product sectors	Relevant legislation ^{182 183}	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	Y
2. Cosmetics	Regulation 1223/2009	Y
3. Toys	Directive 2009/48/EC	Y
4. Personal protective equipment	Directive 89/686/EEC	Y
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	Y
8. Transportable pressure equipment	Directive 2010/35/EU	Y
9. Machinery	Directive 2006/42/EC	Y
10. Lifts	Directive 1995/16/EC	Y
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	Y
14. Pyrotechnics	Directive 2007/23/EC	Y
15. Explosives for civil uses	Directive 93/15/EEC	Y
16. Appliances burning gaseous fuels	Directive 2009/142/EC	Y
17. Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	Directives 2004/22/EC, 2009/23/EC and 2007/45/EC	Y
18. Radio and telecom 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	Y
21. Electrical and electronic equipment under RoHS, WEEE and batteries	Directives 2011/65/EU, 2002/96/EC and 2006/66/EC	Y
22. Chemicals (Detergents, Paints, Persistent	Regulation 648/2004	Y

¹⁸² 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.

¹⁸³ 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.

organic pollutants) ¹⁸⁴	Directive 2004/42/EC Regulation 850/2004	
23. Ecodesign and Energy labelling	Directives 2009/125/EC and 2010/30/EU	Y
24. Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	Directive 1992/42/EEC	Y
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	Y
28. Non-road mobile machinery	Directive 97/68/EC	
29. Fertilisers	Regulation 2003/2003	Y
30. Other consumer products under GPSD (optional)	Directive 2001/95/EC	Y
31. (Additional sectors – please specify)		

¹⁸⁴ 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.