

**Template for drafting a national market surveillance programme pursuant to
article 18(5) of Regulation (EC) No 765/2008**

NATIONAL MARKET SURVEILLANCE PROGRAMME

2016

Ireland

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1. GENERAL MARKET SURVEILLANCE ORGANISATION AND INFRASTRUCTURE

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. Please see the organigram in Annex I for details of legislative and market surveillance responsibility for Community harmonisation legislation considered to come within the scope of Regulation (EC) No. 765/2008.

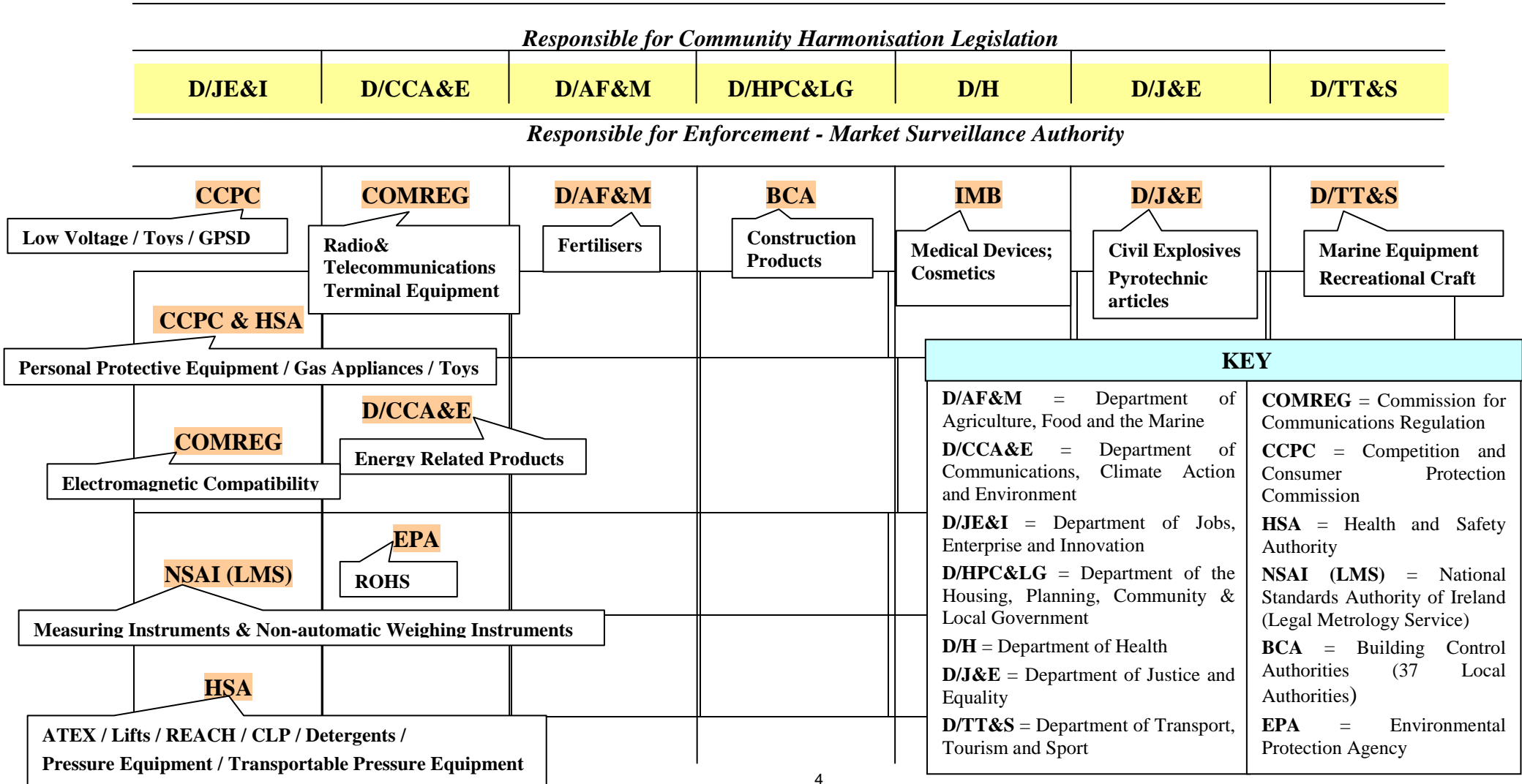
Ireland has a limited manufacturing sector and therefore does not have many notified bodies. It is also not a significant point of first import for imported products. Market surveillance authorities undertake risk based and reactive market surveillance and participate in specific priority projects. Ireland is heavily reliant on other MS's laboratories and test facilities.

Regarding the control of imported products from third countries Ireland's market surveillance authorities, working closely with Revenue's Customs Service, will fulfil obligations under Article 27-29.

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

1.1. Identification and responsibilities of national market surveillance authorities

The responsibilities of the various MSA in Ireland are contained in the diagram below:



1.2. Coordination and cooperation mechanisms between national market surveillance authorities

To fulfil the requirement of Article 18(1) the Department of Jobs, Enterprise and Innovation established a national Market Surveillance Forum (MSF) in May 2009. Represented at the Forum are Government Departments responsible for Community harmonisation legislation, market surveillance authorities, Revenue's Customs Service, and the Irish National Accreditation Board (INAB). The establishment of the Forum has centralised the issue of market surveillance in Ireland, and has been a significant and useful development. It has provided co-ordination of the individual, separate sectors within one platform and allowed for important debate and communication between authorities on common issues. The Department of Jobs, Enterprise and Innovation provides a secretariat role to the Forum and communicates guidance from the Expert Group on the Internal Market for Products (IMP).

Regarding EU co-ordination and co-operation, EU Commission ADCO and Expert working groups will continue to be a valuable platform. Ireland intends to continue to attend and contribute to priority groups. The Competition and Consumer Protection Commission (CCPC) is a member of PROSAFE and will continue to play an active role in this group.

The CCPC and the Health and Safety Authority (HSA) cover, between them, the majority of consumer and industrial products. They have a dual market surveillance role for certain Regulations where professional goods migrate to the consumer, such as Personal Protective Equipment, Machinery and Gas Appliances. Informal co-operation and co-ordination mechanisms exist between the Agencies.

1.3. Cooperation between national market surveillance authorities and customs

Revenue's Customs Service is not designated with a market surveillance function because its competence does not extend to expertise in specific sectors of products. It is reliant on the market surveillance authorities and facilitates them through controlling imports based on specific information received. In this regard it has access to documentation relating to imports from third countries and information associated with customs declarations can be profiled in order to target products that are likely to present a risk. It is recognised that co-operation between the market surveillance authorities and Revenue's Customs Service is essential for carrying out appropriate checks on products at the point of import. Revenue's Customs Service circulates EU Product Safety Alerts to all market surveillance authorities in the State and encourages market surveillance authorities to sign data exchange agreements where more in-depth information is needed from the Customs Service.

1.4. Rapid information exchange system - RAPEX

The [Competition and Consumer Protection Commission](#) (CCPC) is the contact point for RAPEX in Ireland and circulates reports at a national level.

1.5. ICSMS information system

For the sectors covered by Irish MSA please see this link: <https://webgate.ec.europa.eu/icsms/public/authoritySearch.jsp?locale=en>. The [Health and Safety Authority](#) is the contact point for ICSMS in Ireland.

1.6. General description of market surveillance activities and relevant procedures

Ireland has a limited manufacturing sector and therefore does not have many notified bodies. It is also not a significant point of first import for imported products. Market surveillance authorities undertake risk based and reactive market surveillance and participate in specific priority projects. Details of sectoral specific activities can be found in the next section.

2. MARKET SURVEILLANCE IN SPECIFIC SECTORS

[This section should provide information on market surveillance activities in relation to specific sectors. The relevant information could be part of the same document or be presented in separate documents, however the numbering of the different sections should remain the same even if they constitute separate documents.

A reference list of sectors to be covered is provided in the annex. Member States are invited to include additional sectors, as appropriate.

2.1. Sector 29 [Fertilisers]

2.1.1. Responsible authority and contact details

Authority: Department of Agriculture, Food and the Marine

Contact: Gerry Lohan

Agricultural Inspector, Department of Agriculture, Food and the Marine,
Feedingstuffs, Fertilisers, Grain and Poultry Division, Administration Building,
Backweston Campus, Celbridge, Co. Kildare, Republic of Ireland

e-mail gerry.lohan@agriculture.gov.ie

Budget: As required

Staff: As required

Laboratories: Access as necessary

2.1.2. Market surveillance procedures and strategy

Controls: Monitor and follow-up as necessary

Penalties: €3,000 fine or up to six months in prison

Co-operation with other Government Departments and Agencies as necessary

Surveillance as per national legislation – SI 248/1978; SI 384/2005

2.1.3. Report from activities carried out under the previous planning period

Monitoring and enforcement is conducted as part of annual fertiliser controls. This consisted of 114 inspections and fertiliser samples tested for nutrient content.

2.2. Sectors 3, 4, 16, 20 and 30 [Toy Safety Directive 209/48/EC, Personal Protective Equipment Directive 89/686/EEC as amended, Appliances Burning Gaseous Fuels Directive 209/142/EC, Low Voltage Directive 206/95/EC - Directive 214/35/EU, General Product Safety Directive 2001/95/EC]

2.2.1. Responsible authority and contact details

Authority: Competition and Consumer Protection Commission

Contact: PO Box 12585, Dublin 1, Ireland

Email: productsafety@ccpc.ie

The Product Safety Unit of the Commission has a staff compliment of 6 Authorised Officers. The Unit's activities are financed from the annual budget allocated to the Commission. The Commission does not have any in-house laboratories or test facilities but can call upon relevant external expertise as required. The Unit keeps up-to-date on best practice at EU level and regularly attends relevant meetings and workshops. It also has direct access to an in-house Legal Advisor.

2.2.2. Market surveillance procedures and strategy

The Unit has the responsibility for market surveillance, Rapex, and investigation and follow-up of product safety complaints and issues.

The Unit actively participates in the National Market Surveillance Forum, which is chaired by the Department of Jobs, Enterprise and Innovation, which meets regularly and works closely with other regulatory bodies in the Country. In particular, it co-operates with the National Customs Authorities where procedures are in place for sharing information and investigates various consignments of goods being imported into the State where product safety concerns or compliancy issues have arisen.

The activities of the Unit are generally reactive where complaints and queries from the public are received directly via the Commission's helpline or from other regulatory authorities and followed up accordingly using a risk assessment based approach. The Unit also responds to notifications received through the Rapex system and follows up with domestic economic operators to ensure that appropriate remedial action is being taken. Market surveillance activity is undertaken as required, in support of this activity.

Proactively, the Unit is an active participant in the European PROSAFE network and partakes in their market surveillance projects and various workshops. It also proposes to strengthen its ongoing co-operation with Customs, which has proved to be quite successful in recent years, through the targeting of specific goods which are known to pose regular safety concerns.

2.2.3. Report from activities carried out under the previous planning period

In the previous period 2014 – 2015 the Commission participated in PROSAFE market surveillance projects relating to carbon monoxide alarms and cords and drawstrings in children's clothing. The results were reported back to PROSAFE and featured in their final reports published for both projects.

During the period (up to Sept 2015), under the Sectors listed above, the Commission with the co-operation of Customs, arranged for the detention and destruction of over 40,000 unsafe consumer products which included a variety of toys, sunglasses, novelty items, electrical chargers and adaptors.

The Commission also investigated approximately 890 complaints received from consumers and other sources and submitted 15 notifications through the Rapex system and reacted to 201 notifications from other member states.

2.3. Sectors 14 and 15 [Pyrotechnics and Explosives for Civil Use]

2.3.1. Responsible authority and contact details

Authority: Explosives Inspectorate, Department of Justice and Equality, 94 St Stephens Green, Dublin 2

Contact: Colm Farrell, Government Inspector of Explosives

Email: cwfarrell@justice.ie

Ph: + 353 1 6028354

Resources: The explosives inspectorate is a part of the Crime 4 Division of the Department of Justice and Equality. The primary statutory responsibilities of this inspectorate include carrying out, on behalf of the Minister, the implementation and enforcement of explosives legislation regarding, import, manufacture, storage and transport of all explosives and pyrotechnics. Inspectors are also appointed under the Carriage of Dangerous Goods legislation responsible for road check enforcement and approval and examination of specialist driver training for the carriage of UN Class 1 goods. The number of inspectors available for market surveillance activities expressed as full-time equivalent units is 0.1. There is no notified body for explosives or pyrotechnic articles in Ireland and so very limited explosive or pyrotechnic testing and evaluation is possible within existing resources. No additional budget is allocated for market surveillance, therefore all activities will have to be performed within the existing Departmental budgets, which are subject to severe national economic restrictions on Government spending.

2.3.2. Market surveillance procedures and strategy

Principles: Due to the limited resources available, it has been decided to take a pragmatic approach to monitoring and surveillance activities and to combine these activities with existing inspection programs where possible. This will include:

Proactive inspections: Including planned and routine inspections of explosive and pyrotechnic articles at places of storage, distribution, transit, sale and use. Inspections will include announced and unannounced inspections

Reactive inspections: Including acting on information received from complaints from the public, persons with specialist knowledge, accidents, customs or police or other market surveillance authorities. Accident investigation may be conducted in conjunction with the Health and Safety Authority who have regulatory responsibility for the use of explosives and pyrotechnics in the workplace.

Precautionary Principle: This approach will be taken, for example if it is suspected that illegal manufacture, import, storage or sales are taking place, or dangerous products are on the market. Intervention inspections, supported by Gardai (police), if necessary, will be made to initiate seizure, detention and destruction where appropriate to prevent danger to the public from arising.

Cooperation: On a national level members of the inspectorate will continue to participate in the Market Surveillance Forum which is organised by the Department of Jobs, Enterprise and Innovation and to cooperate with the other sectoral market surveillance authorities. On an international level members of the inspectorate will

continue to participate in the ADCO on Pyrotechnics and the ADCO on Explosives for civil uses and to cooperate with other national authorities

Strategy: The market surveillance strategy will be determined using the following priorities:

Identification of undertakings: Identification and updating of undertakings and locations involved in manufacture, importation, storage, transport and sale of explosives and pyrotechnics. This will require regular updating from local authorities and other regulatory authorities.

Risk assessment of undertakings and sites: Risk factors include:

- Explosive hazards and degree of risk involved, taking into account explosive quantity and type and location.
- Activity and degree of risk involved , whether manufacture, processing, storage , transport or sale.
- Competence of undertakings including training, experience and qualifications of the managers and personnel of the undertakings.
- Knowledge of the legislation of the undertakings.
- Compliance record of undertakings.
- Results of previous inspections
- Frequency of previous inspections or date of last inspection
- Requirement for involvement of other agencies
- Cost benefit factors of inspections.
- Resource capacity of inspectorate (time, human and budget resources).

Setting priorities

- Allocation of available resources including time, personnel and budgets.
- Selection of target undertakings for inspection
- Selection of type of inspection
- Selecting frequency and target dates for inspection.

2.3.3. Report from activities carried out under the previous planning period

Total inspections include documentary checks carried out on all explosives for civil uses and pyrotechnics prior to the issue of an import licence under explosives legislation. The import licence is not issued unless all the supporting documentation is in order. Consequently the numbers of non-compliant articles, consumer complaints or product related accidents as a result of a defective article is minimal.

		2014
1.	Number of product related accidents / user complaints	0
2.	Number of substantiated complaints by industry concerning unfair competition	0
3.	Number of inspections (total number)	422
3.1	number of reactive inspections	0
3.2	number of self-initiated inspections	422
3.3	number of inspections prompted by the	0

	customs	
4	Number of inspections based on:	
4.1	tests performed in laboratories	0
4.2	physical checks of products	45
5	Number of inspections resulting in:	
5.1	finding of non-compliance	2
5.2	corrective actions taken by economic operators (“voluntary measures”)	0
5.3	restrictive measures taken by market surveillance authorities .	2
5.4	application of sanctions/penalties	0
6	Number of inspections where other Member States were invited to collaborate	0

2.4. Sector 25 [Recreational Craft Products]

2.4.1. Responsible authority and contact details

Authority: The Marine Survey Office of the Irish Maritime Administration, Department of Transport, Tourism and Sport

Email: mso@dtas.ie

Contact: Michael Klyne, Marine Surveyor **Tel:** 00 353 (0) 1 6783462

Email: michaelklyne@dtas.ie

Contact: Greg Houlihan, Ship Surveyor **Tel:** 00 353 (0)1 6783476

Email: greghoulihan@dtas.ie

All activities have to be performed within the existing Departmental budgets, which are subject to national economic restrictions on Government spending.

2.4.2. Market surveillance procedures and strategy

General Monitoring Approach: A pragmatic approach to monitoring and surveillance activities will be taken and it is intended to combine these activities with existing inspection and survey programmes where possible. This will include:

- a) **Proactive Inspections:** Planned market surveillance activity including planned and routine inspections and surveys of recreational craft products- such inspections will include announced and unannounced inspections
- b) **Reactive Inspections:** Including acting on complaints or information received from the public, accident investigation reports, Customs, Coast Guard, other market surveillance authorities, intelligence from the Garda

Síochána, the Marine Casualty Investigation Board and the Health and Safety Authority.

Follow up inspections and investigations will be undertaken where appropriate

- c) **Precautionary Principle:** This approach will be taken if it is suspected that recreational craft products are likely to be placed on the market where the market surveillance authorities of one Member State have sufficient reason to believe that a product covered by Directive 2013.53.EU presents a risk to the health or safety of persons, to property or to the environment. To prevent danger to the public or risk to the environment, inspections, supported by Customs or An Garda Síochána, may be made in order to prohibit, restrict or require the withdrawal of any recreational craft product from the market.

Priorities:

- a) **Approach for Setting Priorities:** Work is continuing in the development of a targeted profiling framework for the market surveillance of recreational craft products. This will be based on Customs and RAPEX notifications,

advice from other market surveillance authorities as well as national intelligence.

b) Risk Evaluation: Levels of risk and prioritisation of inspections will be assessed using the following criteria:

- i. The profiling framework outlined at (a) above;
- ii. Information received from European monitoring and information systems such as RAPEX, ICSMS, RSG and CIRCA;
- iii. Information collected on the compliance record of manufacturers, authorised representatives, importers and distributors.
- iv. Results of previous inspections as well as the frequency and dates of all previous inspections;
- v. Requirement for involvement of other agencies;
- vi. The resources available to the Marine Survey Office, taking account of the cost benefit factors of each individual inspection.

Horizontal Co-operation: Other organisations, agencies and regulatory authorities, including those of other Member States (through use of RAPEX, ICSMS, RSG and CIRCA information systems), may be involved in the operation and development of the market surveillance programme by providing information or assistance as appropriate to the circumstances. These agencies (in Ireland) include; Customs, An Garda Síochána, the Competition and Consumer Protection Commission, the National Standards Authority of Ireland, the Health and Safety Authority and the Marine Casualty Investigation Board.

A Data Exchange Agreement was agreed in April 2012 between the Revenue Commissioners' Customs Service and the Department of Transport, Tourism and Sport - on the control of recreational craft products entering Ireland from third countries. The completion of a formal Memorandum of Understanding on these matters with the Customs Service is under review.

Informing stakeholders: The Marine Survey Office already carries out active liaison, advice, guidance and consultation with the main stakeholders involved in the maritime industry. Information on all aspects of the work of the MSO is made available to the public and stakeholders on the Department of Transport, Tourism and Sport's website: www.dttas.ie.

Marine Notices will be used to keep the Maritime industry and the public informed of the updated market surveillance framework. Marine Notices are issued by the Department to convey information to authorities, organisations and agencies across the maritime sector. Marine Notices are published on the Department of Transport website and this website will remain an important method for dissemination of information on this and other matters.

2.4.3. Report from activities carried out under the previous planning period

We checked that the manufacturer and distributor were undertaking recalls as necessary.

2.5. Sector 21 [RoHS Directive]

2.5.1. Surveillance authority responsible and contact details

Surveillance Authority: Environmental Protection Agency.

Contact Details:

Address: *Headquarters*
P.O. Box 3000
Johnstown Castle Estate
Wexford
Y35 W821
Ireland.

Contact details: Martin Doyle, Scientific Officer, Chemicals Unit

E-mail: m.doyle@epa.ie

Resources Available (estimated):

Resource Type:	Allocation:
Labour	0.15FTE
Financial	~€66,000.00
Other	None

2.5.2. Market surveillance procedures and strategy

Market surveillance activities under the Directive are carried out in accordance with the Agency's RoHS Surveillance Strategy. Such market surveillance activities include:

- Surveillance of products for compliance with product essential requirements. Products targeted are generally associated with a medium to high probability of containing the restricted substances.
- Participation in the RoHS Enforcement Network (RoHS AdCo) special projects.
- Liaison where required with other market surveillance authorities.

Intervention mechanisms range from temporary restrictions on product market access, e.g. pending provision of requested information, to direction for product withdrawal from market and/or recall from end users. Intervention levels are considered on a case-by-case basis and applied taking into account the principle of proportionality with high levels of intervention reserved for contraventions deemed to pose serious risks.

The Agency has committed to participate in the 2016 RoHS Enforcement Network.

2.5.3. Market surveillance activities carried out under the previous planning period

The Agency did not conduct any proactive market surveillance campaign during 2015 due to lack of provision of timely adequate resources. Surveillance activities were limited to follow up investigations in relation to 2 RAPEX notifications relating to contraventions of the RoHS Directive (with none of the products observed to have been made available within the State) and provision of assistance with/taking responsibility for 3 investigations initiated by other MS market surveillance authorities with one ongoing at time of responding to this request.

2.6. Sector 21 [WEEE Directive]

2.6.1. Surveillance authority responsible and contact details

Authority: Environmental Protection Agency

Contact Details:

Address: Headquarters
P.O. Box 3000
Johnstown Castle Estate
Wexford
Y35 W821
Ireland.

Contact details: Michael Owens, Inspector, Producer Responsibility Unit

E-mail: m.owens@epa.ie

Resources Available (estimated):

Resource Type:	Allocation:
Labour	0.5FTE
Financial (excluding Agency labour costs)	~€164,000.00
Other	None

2.6.2. Market surveillance procedures and strategy

All inspections and audits are carried out in accordance with a range of standard operating procedures and utilise standard protocols and checklists. Reports on inspection or audit findings are issued to each organisation that is inspected or audited. Complaints are not a significant portion of annual work and are handled on a case-by-case basis as they arise. Significant transgressors are, and have been successfully, prosecuted. Penalties for non-compliance are set in the relevant regulations and are considered to be significant (e.g. €5,000 per convicted offence in some cases).

Co-operation with other regulatory authorities is carried out on a case-by-case basis as required (e.g. enforcement effort co-ordinated with the national Police force in relation to theft of WEEE or the National Transfrontier Shipment Office on illegal export of WEEE).

Annual enforcement effort for market surveillance generally targets (i) registered EEE/battery producers (ii) the EEE/battery retail sector (i.e. distributors of EEE and batteries) (iii) distance sellers (e.g. web-based selling) and (iv) actors outside the system (e.g. non-registered producers). The effort comprises inspections and/or more detailed

audits. An annual enforcement plan is developed early in the year which sets out the priorities and objectives (e.g. numbers of inspections/audits) for the year ahead. In terms of prioritisation for surveillance consideration is given to environmental risk (e.g. volume of product placed on the market), compliance history and intelligence gathering (e.g. tip offs). The EPA utilises externally contracted resources to do most of the actual inspections and audits.

A considerable effort is also expended on assessing WEEE and waste battery management plans and reports which are submitted by self-complying EEE and battery producers.

2.6.3. Market surveillance activities carried out under the previous planning period

A summary of results for the enforcement activities is set out in the table below:

Enforcement activity	Target organisation	Outcome	Comment
Audits	Self-complying EEE Producers	60 audits carried out.	There are approximately 600 self-complying EEE producers nationally.
Audits	Self-complying battery Producers	2 audits will be carried out before end of year	There are only 4 self-complying battery producers nationally.
Inspections	EEE and battery Distributors	100 Inspections	This figure comprises 80 initial inspections and 20 re-inspections based on findings of initial inspections.
Inspections	Distance sellers	80	Inspections of 80 websites selling EEE and/or batteries into Ireland.
EEE Waste management plans and reports	Self-complying EEE Producers	207 plans and 607 reports assessed in 2015	
Battery Waste management plans and reports	Self-complying battery Producers	4 plans and 4 reports assessed in 2015	

2.7. Sector 22A [REACH Regulation – Prevention of Environmental Pollution]

2.7.1. Surveillance authority responsible and contact details

Authority: Environmental Protection Agency

Contact Details:

Address: Headquarters
P.O. Box 3000
Johnstown Castle Estate
Wexford
Y35 W821
Ireland.

Contact details: Martin Doyle, Scientific Officer, Chemicals Unit

E-mail: m.doyle@epa.ie

Resources Available (estimated):

Resource Type:	Allocation:
Labour	0.2FTE
Financial	~€52,000.00
Other	None

2.7.2. Market surveillance procedures and strategy

The Agency is responsible for surveillance of requirements under REACH, contravention of which would be deemed to pose environmental risks. Market surveillance activities are carried out in accordance with the Agency's REACH Implementation Strategy. Regarding monitoring compliance with the placing on the market of substances listed under Annex XVII of the REACH Regulation, preparations and articles targeted for investigation are chosen largely on a non-compliance risk assessment basis with products assessed to pose potential non-compliances associated with medium to high level environmental risks prioritised. Such market surveillance activities include:

- Surveillance of use of restricted substances in articles and mixtures listed in Annex XVII of the REACH Regulation deemed to pose environmental risks.
- Monitoring industry compliance with authorisation requirements for substances listed in Annex XIV of the REACH Regulation.

- Follow-up investigations of RAPEX notifications relating to contraventions of the REACH Regulation which are deemed to pose environmental risks.
- Liaison where required with the Irish Health and Safety Authority, the lead competent authority for the REACH Regulation within the State.

Intervention mechanisms range from temporary restrictions on product access to market, e.g. pending provision of information by operator following request by Agency, to direction for product withdrawal from market and/or recall from end users. Intervention levels are considered on a case-by-case basis and applied taking into account the principle of proportionality with high levels of intervention reserved for contraventions deemed to pose serious environmental risks.

The Agency has committed to participate in the REACH REF4 project during 2016. The Agency intends to monitor plastic products for cadmium content.

2.7.3. Market surveillance activities carried out under the previous planning period

During late 2015, the Agency commenced its REACH-Persistent Organic Pollutants market surveillance campaign targeting products, primarily household items, associated with a medium to high probability of containing the restricted substances under the relevant pieces of legislation. Results of the monitoring campaign were not available at the time of responding to this request.

The Agency conducted follow up investigations in relation to 8 RAPEX notifications relating to contraventions of the REACH Regulation deemed to pose an environmental risk. The investigations involved the inspections of economic operator premises associated with the importation and/or distribution of the products or product types under investigation. None of the non-compliant products were observed to have been made available within the State.

2.8. Sector 22B [ODS & F-Gas Regulations]

2.8.1. Surveillance authority responsible and contact details

Authority: Environmental Protection Agency

Contact Details:

Address: Regional Inspectorate
McCumiskey House
Richview
Clonskeagh Road
Dublin 14
D14 YR62
Ireland.

Contact details: Marc Kierans, Inspector, F-Gas/ODS Enforcement

E-mail: m.kierans@epa.ie

Resources Available (estimated):

Resource Type:	Allocation:
Labour	1.5FTE
Financial	€170,000.00
Other	None

2.8.2. Market surveillance procedures and strategy

The objective of the program is to ensure, insofar as is feasible within the existing legal, organisational and infrastructural framework, that an effective market surveillance program is in place to meet the requirements of ODS Regulation (Regulation (EC) No. 1005/2009 and F-gas Regulations (Regulation (EC) No 517/2014).

The market surveillance activities conducted by the Environmental Protection Agency in its role as Competent Authority in Ireland are primarily sector specific in nature and include the following activities:

1. Desk top and on-site inspections and audits of end users, contractors and suppliers of the gases using a risk and sector based approach.

2. Work with relevant stakeholders and provision of guidance to assist sectors in achieving compliance.
3. Work with Customs on monitoring for illegal trade
4. Work with the Commission on the licencing requirements for the import/export of critical use ODS and this includes products and equipment containing or relying on controlled substances such as aircraft with halon fire extinguishers installed.
5. Reporting on 4 above to the Commission.

2.8.3. Market surveillance activities carried out under the previous planning period

In 2015 there were a total of 92 site and 68 desktop inspections. In addition 9 sector specific guidance notes were issued.

Additionally the Agency conducted follow up investigations in relation to 1 RAPEX notification relating to a contravention of Regulation (EU) No 517/2014. The investigations involved the inspections of economic operator premises associated with the importation and/or distribution of the products or product type under investigation. The non-compliant product was not observed to have been made available within the State.

2.9. Sector 22B [Paints Directive]

2.9.1. Surveillance authority responsible and contact details

Authority: Environmental Protection Agency

Contact Details:

Address: Headquarters
P.O. Box 3000
Johnstown Castle Estate
Wexford
Y35 W821
Ireland.

Contact details: Martin Doyle, Scientific Officer, Chemicals Unit

E-mail: m.doyle@epa.ie

Resources Available (estimated):

Resource Type:	Allocation:
Labour	<0.1FTE
Financial	<€8,000.00
Other	None

2.9.2. Market surveillance procedures and strategy

Following difficulties encountered during the 2010 Enforcement Campaign (see [2010 Enforcement Report](#)) and lack of apparent resolution of these issues, the Agency market surveillance activities are largely curtailed to enforceable aspects of the Directive, namely product labelling inspections. Additionally, the Agency, as the lead competent authority for the Directive within the State, provides guidance and advice to Local Authorities when required.

All commercial vehicle refinishing installations must register with the Local Authority in whose functional area the installation is located. Successful registration is dependent of obtaining a compliant report regarding operational procedures by an inspection contractor approved (competent) by the Agency). One of the requirements for granting a compliant report is the exclusive use of vehicle refinishing products compliant with maximum VOC content requirements in ready to use form set out in Annex II Part B of the Directive taking account exemptions under Article 3(3) of the Directive. Under the enacting Regulations – European Union (Paints, Varnishes, Vehicle Refinishing Products and Activities) Regulations 2012 (Statutory Instrument Number 564 of 2012) – where a vehicle refinishing operator is supplied with a product not in compliance with the

relevant VOC content limit, he/she must immediately on becoming aware of the contravention inform the relevant Local Authority and take appropriate action to ensure the protection of human health and the environment.

The revision enforcement training for Local Authorities mentioned in Section 2.5.3, the pilot of which commenced 2015, is likely to be further developed to full-scale training for delivery/completion during 2016.

2.9.3. Market surveillance activities carried out under the previous planning period

During late 2015 the Agency commenced its Paints Market Surveillance Campaign. The campaign is focussing on product labelling inspections and in particular those products listed under Annex I Section 1 of the Directive. Results of the campaign were not available at the time of responding to this request.

Additionally the Agency has initiated conduction of another refresher pilot training schedule for Local Authority inspectors for enforcement of the Directive's requirements in relation to the distribution and use of vehicle refinishing products.

2.10. Sector 22B [Persistent Organic Pollutants Regulation]

2.10.1. Surveillance authority responsible and contact details

Authority: Environmental Protection Agency.

Contact Details:

Address: Headquarters
P.O. Box 3000
Johnstown Castle Estate
Wexford
Y35 W821
Ireland.

Contact details: Martin Doyle, Scientific Officer, Chemicals Unit

E-mail: m.doyle@epa.ie

Resources Available (estimated):

Resource Type:	Allocation:
Labour	0.7FTE
Financial	€56,000.00
Other	None

2.10.2. Market surveillance procedures and strategy

The Agency is the lead competent authority for Regulation (EC) No 850/2004 within the State. The Agency is responsible for surveillance of general product compliance with respect to placement on the market, use and production of substances listed in Annex I of the Regulation (excluding food, cosmetic, plant protection products, biocidal and medicine/veterinary products). Market surveillance activities in relation to cosmetic, medicinal and veterinary products respectively are within the remit of The Health Products Regulatory Authority. The Pesticide Registration and Control Division of the Department of Agriculture, Food and the Marine is responsible for monitoring compliance with respect to the placement on the market and use of plant protection products and biocides.

Regarding market surveillance conducted by the Agency, products are targeted for inspection associated with medium to high probabilities of containing the restricted substances with resulting potential contraventions deemed to pose medium to high risk levels. Agency market surveillance activities include:

- Surveillance of use of substances listed in Annex I of the Regulation in preparations, mixtures and articles.
- Follow-up investigations of RAPEX notifications relating to contraventions of the Regulation.
- Liaison, where required, with other public authorities responsible for other market surveillance activities not under the Agency's remit.

Intervention mechanisms range from prohibitions on product market access to prosecution where deemed appropriate. Intervention levels are considered on a case-by-case basis and applied taking into account the principle of proportionality with high levels of intervention reserved for contraventions deemed to pose serious risks.

During 2016 the Agency will largely focus on the further implementation of the National Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants and so the Agency intends to limit largely market surveillance activities to reactive investigations. However, depending on availability of resources, it is hoped to expand Agency surveillance activities regarding the REACH REF4 project to include monitoring for certain persistent organic pollutants.

2.10.3. Market surveillance activities carried out under the previous planning period

During late 2015, the Agency commenced its REACH-Persistent Organic Pollutants market surveillance campaign targeting products, primarily household items, associated with a medium to high probability of containing the restricted substances under the relevant pieces of legislation. Results of the monitoring campaign were not available at the time of responding to this request.

The Agency conducted follow up investigations in relation to 7 RAPEX notifications relating to contraventions of Regulation (EU) No 1342/2015 deemed to pose an environmental risk. Some of these investigations were ongoing at the time of responding to this request. The investigations involved/involves the inspections of economic operator premises associated with the importation and/or distribution of the products or product types under investigation. Thus far, none of the non-compliant products were observed to have been made available within the State.

2.11. Sector 1 [Medical Devices]

2.11.1. *Surveillance authority responsible and contact details*

Authority: Health Products Regulatory Authority (HPRA)

Contact: Ms Maria Carleton, Medical Devices Technical Assessment Manager and Mr Owen Melia, Scientific Officer, Human Products Authorisation and Registration Department, Health Products Regulatory Authority (HPRA), Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2.

Telephone: +353 1 676 4971

Email: devices@hpra.ie

Resources: The medical devices team in HPRA spans across three internal departments (Human Products Registration and Authorisation, Human Products Monitoring and Compliance). The number of full time equivalent units working across the three departments is currently 29 with competencies covering clinical, engineering and medical/biosciences expertise. Significant cooperation across the three departments is carried out to ensure market surveillance activities associated with medical devices are dealt with appropriately.

HPRA does not operate any internal laboratory test facilities for medical devices analysis, however we have used external laboratories to assess medical devices as part of our sampling and analysis activities.

To date, HPRA funding for medical devices has been predominantly provided by the Department of Health, with a contribution from administrative fees applied in areas such as classification, assessment of clinical investigations, audit of manufacturers and the issuance of medical device export certificates. HPRA is committed to introduce fees at national level to cover the costs associated with all of its medical device activities. Discussion commenced with interested parties during 2014 and in July 2015 a public consultation was launched in relation to introduction of a national model for fees.

2.11.2. *Market surveillance procedures and strategy*

The aim of market surveillance activity is to ensure that medical devices placed on the Irish market do not compromise the health and safety of patients/users or other persons and that the devices placed on the market, or put into service in Ireland are in compliance with the relevant legislation.

The market surveillance activities conducted by HPRA in its role as Competent Authority for medical devices in Ireland are primarily sector specific in nature and include the following activities:

- Implementation of the requirements of the legislation in relation to market surveillance for medical devices, including a risk based approach.

- Implementation of the actions outlined in EU Commission Joint Action plan for medical devices.
- Market surveillance activities concerning Irish based manufacturers and authorised representatives.
- Device specific market surveillance projects involving specific product families.
- Promotion of horizontal co-operation through involvement with the Compliance and Enforcement (COEN) Working Group. The work programme for COEN is approved by the EU Competent Authorities on an annual basis.
- Management of a post-market vigilance systems relating to incidents and field corrective actions.
- Dissemination of safety and regulatory information to key stakeholders.
- Contribution to development of best practice in post market surveillance across EU Member States and works with other EU Competent Authorities to develop harmonisation in approach to post market surveillance.
- Post market surveillance audits of manufacturing sites nationally.
- Audits of the Irish Notified Body for medical devices.
- Participation in the Joint Assessment programme for Notified Bodies under Regulation 920 of 2013.
- Regular meetings with stakeholders to provide updates on their work. Information is also provided to the public and healthcare professionals through the provision of guidance information, newsletters and safety and information notices on the HPRA website.
- Provision of periodic HPRA medical device open days and participation at conferences, public events and academic courses for example to provide updates on market surveillance activities.
- Cooperation between HPRA Enforcement and customs relating to non-compliant medical devices.

Areas of focus in 2016 include:

- Preparation for the implementation of the new medical device and *in-vitro* diagnostic device legislation.
- Participation in European Joint Action Market surveillance programmes
- Engagement with early innovators in the medical device area, including the e- and m-health areas to identify expertise and guidance needs at national and European level.
- Promote and facilitate UDI through discussions with relevant stakeholders.
- Participation as national experts in a number of Joint Assessments in 2016 and continue to contribute to guidance in this area.
- Further develop our resource and capabilities internally including growing the network of experts and range of expertise that can be accessed.
- Expand sampling and analysis program to verify compliance of devices on the market.
- Further development of HPRA's medical device signal process.

2.11.3. *Market surveillance activities carried out under the previous planning period*

During 2015 HPRA has continued to develop its lifecycle approach to market surveillance focused on protecting the health and safety of those who use medical devices by ensuring that all devices on the Irish market comply with the relevant European Directives. It is expected that the noted increase in market surveillance activity through Member State market surveillance requests and certificate notifications will continue into 2016. Some of the 2015 market surveillance activities included:

- Development of the system and procedure pack guidance.
- Review of food intolerance products available on the Irish market.
- Review of the standalone software on the HPRA register.
- Development and issuance of a Medical Device Information Notice.
- Implementation of a national eAlert system for dissemination of medical device safety information.
- Development of sampling procedures.
- Development of specific test methods for inspection of implants.
- Reviews of clinical data presented as part of clinical evaluations of high risk medical devices.
- The designation renewal of the Irish Notified Body in accordance with the new Regulation (920/2013) on notified bodies.

HPRA continues to develop regulatory activities in line with the European Commission's 2012 joint plan for immediate action and in preparation for the significant revision of the medical device legislation at EU level. Key objectives are to strengthen the regulatory system, foster innovation, optimise internal processes, contribute to co-operation in Europe and internationally, and reinforce HPRA's reputation as a leading and expert regulatory authority for medical devices.

ANNEX: REFERENCE LIST OF PRODUCT SECTORS

Product sectors	Relevant legislation ^{1 2}
1. Medical devices (including In vitro diagnostic medical devices and Active implantable medical devices)	Directives 93/42/EEC, 98/79/EC and 90/385/EEC
2. Cosmetics	Regulation (EC) 1223/2009
3. Toys	Directive 2009/48/EC
4. Personal protective equipment	Directive 89/686/EEC
5. Construction products	Regulation (EU) 305/2011
6. Aerosol dispensers	Directive 75/324/EEC,
7. Simple pressure vessels and Pressure equipment	Directives 2009/105/EC and 97/23/EC
8. Transportable pressure equipment	Directive 2010/35/EU
9. Machinery	Directive 2006/42/EC
10. Lifts	Directive 1995/16/EC
11. Cableways	Directive 2000/9/EC
12. Noise emissions for outdoor equipment	Directive 2000/14/EC
13. Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	Directive 1994/9/EC
14. Pyrotechnics	Directive 2007/23/EC
15. Explosives for civil uses	Directive 93/15/EEC
16. Appliances burning gaseous fuels	Directive 2009/142/EC
17. Measuring instruments, Non-automatic weighing instruments and Pre-packaged products	Directives 2004/22/EC, 2009/23/EC and 2007/45/EC
18. Electrical equipment under EMC	Directive 2004/108/EC
19. Radio and telecom equipment under RTTE	Directive 1999/5/EC
20. Electrical appliances and equipment under LVD	Directive 2006/95/EC
21. Electrical and electronic equipment under RoHS and WEEE and batteries	Directives 2011/65/EU, 2002/96/EC and 2006/66/EC
22./A Chemical substances under REACH and Classification and Labelling Regulations	Regulations (EC) 1907/2006 and 1272/2008/EC
22. /B Other chemicals (Detergents, Paints, Persistent Organic Pollutants,	Regulation (EC) 648/2004, Directive 2004/42/EC, Regulation (EC) 850/2004,

¹ For ease of reference this table indicates established EU legislation. New legislation replacing that listed in the table should be also taken into account for the relevant period in which it is applicable.

² 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.

Fluorinated greenhouse gases, Ozone Depleting Substances, etc.)	Regulation (EC) 842/2006 and Regulation (EU) 517/2014, Regulation (EC) 1005/2009
23. Eco-design and Energy Labelling; Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	Directives 2009/125/EC and 2010/30/EU; Directive 1992/42/EEC
24. Tyre labelling	Regulation (EC) 1222/2009
25. Recreational crafts	Directive 1994/25/EC
26. Marine equipment	Directive 96/98/EC
27. Motor vehicles	Directives 2002/24/EC and 2007/46/EC
28. Non-road mobile machinery	Directive 97/68/EC
29. Fertilisers	Regulation (EC) 2003/2003
30. Other consumer products under GPSD (optional)	Directive 2001/95/EC
31. Biocides	Regulation (EU) 2012/528
32. Textile labelling	Regulation (EC) 1007/2011
33. (Additional sectors – please specify)	