



**IRELAND**

**Regulation (EC) No. 765/2008**

**National Sector Specific Market Surveillance Programme**

**2014-15**

**February 2014**

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## **Horizontal Summary**

### **Introduction:**

This document is Ireland's National Sector Specific Market Surveillance Programme, covering the years 2014 and 2015, in respect of market surveillance of products that come within the scope of Community harmonisation legislation, as required by Article 18(5) of Regulation (EC) No. 765/2008.

### **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. 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.

### **Co-operation and Co-ordination:**

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 National Consumer Agency (NCA) is a member of PROSAFE and will continue to play an active role in this group.

The NCA 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.

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 will facilitate 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.

**Duration of programme:**

This is a biennial programme, covering 2014 and 2015.

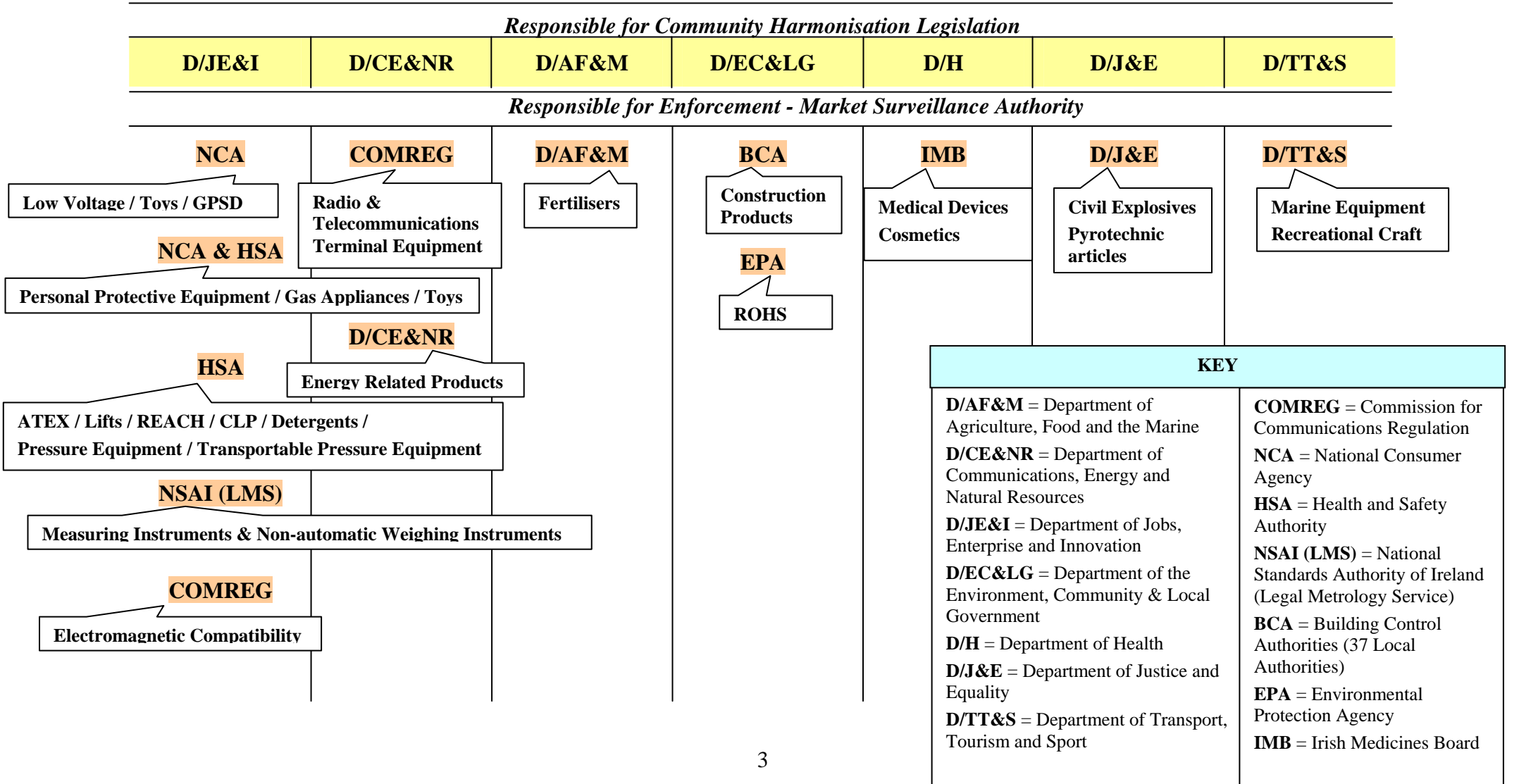
**Horizontal priorities:**

As stated, market surveillance is sectorally organised with no central control. The Market Surveillance Forum has provided a central platform to consider common market surveillance issues. The horizontal priorities for the Forum for 2014 – 15 are:

1. Ensure that Ireland's legislative framework meets the obligations of Regulation No. 765/2008. (Legislation to be made by individual sectors).
2. Promotion of co-operation and co-ordination protocols between the market surveillance authorities and Revenue's Customs Service.
3. To consider participation in cooperation and coordination initiatives with other Member States and third countries.
4. To extend the use of, and consider the number of RAPEX notification points to ensure that the requirements under Article 22 are met.
5. To continue to review Ireland's market surveillance mechanism, though the MSF, in order to ensure that its component parts are in accordance with Regulation 765/2008.
6. Participation, as appropriate, in the CE marking awareness campaign in order to strengthen the EU regulatory system.

## Annex I: Organigram of Market Surveillance Responsibility

Regulation (EC) No. 765/2008



## **Annex II: Sectoral Market Surveillance Programmes**

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## **A. Department of Agriculture, Food and the Marine**

### **Fertiliser Sampling and Labelling Inspections Public Narrative Document**

**Member State:** *Ireland*

**Surveillance Authority:** *Department of Agriculture, Food and the Marine*

**Planning Year:** *2014 -2015*

**Person responsible for the sectoral NMSP:** *Gerry Lohan, Agricultural Inspector*

**Email Address:** [gerry.lohan@agriculture.gov.ie](mailto:gerry.lohan@agriculture.gov.ie)

1. **Objective:** The objective of the plan is to ensure, insofar as is feasible within the existing legal, organisational and resources framework, that an effective market surveillance programme is in place to meet the requirements of Regulation (EC) 2003/2003 and Regulation 463/2013. These Regulations are transposed into Irish law in Statutory Instrument (SI) No. 384 of 2005. (Non-EEC fertilisers are regulated under SI No. 248 of 1978).
2. **Structure and responsibilities:** The market surveillance activities are carried out by the Department's Inspectorate, including authorised officers of the Department of Agriculture, Food and the Marine, supported as appropriate, by scientific experts from other authorities, in particular the State Laboratory which is the official laboratory designated to carry out sample analyses.
3. **Organisation:**
  - a. **Human resources:** The inspectorate/authorised officers are direct employees of the Department of Agriculture, Food and the Marine. The primary statutory responsibilities of this inspectorate include carrying out, on behalf of the Minister, the implementation and enforcement of legislation regarding import, manufacture and storage of fertiliser and lime products and activities relating to the placing of fertiliser products on the market.
  - b. **Technical resources:** The inspectorate and authorised officers receive annual training on sampling and transport of samples to the appropriate testing laboratory.
  - c. **Financial resources:** All activities are performed within the existing Departmental budgets.
4. **General monitoring approach:**
  - a. Planned and routine inspections and sampling are carried out on production and storage sites. Inspections and sampling are carried out on a risk assessment basis, established on results from previous test results, and on a production volume basis.
  - b. Reactive inspections are taken where it is suspected that non-compliant manufacture, import, storage or placing of products on the market occurs.

- c. Intervention inspections to initiate seizure, detention and disposal may be carried out where necessary. These may be supported by Gardai (police) and/or revenue or customs officials where deemed necessary.

## 5. Setting of priorities:

The following factors will be used to set priorities:

- a. **Identification of premises:** Identification and updating of locations involved in manufacture, import, storage, transport and sale of fertilisers is carried out on an ongoing basis. This is achieved through regular contact with industry representative associations.
  - b. **Assessment of premises and sites:**
    - i. Activity relating to manufacture, processing, storage, transport or sale.
    - ii. Knowledge of the legislation pertaining to activities.
    - iii. Compliance with record keeping.
    - iv. Recording and maintaining results of previous inspections.
    - v. Frequency of previous inspections or date of last inspection.
    - vi. Requirement for involvement of other agencies and control authorities.
    - vii. Cost benefit factors of inspections.
    - viii. Resource capacity of inspectorate (time, human and budget resources).
  - c. **Setting priorities**
    - i. Allocation of available resources including time, personnel and budgets.
    - ii. Selection of target premises and sites for inspection.
    - iii. Establishing frequency and target dates for inspection and sampling.
    - iv. Selection of type of inspection and sampling.
6. **Horizontal co-operation:** Other organisations, agencies and regulatory authorities, including those of other Member States may be involved in the programme by providing information or assistance as agreed. Horizontal co-operation has been shown in dealings with the Department of Justice and Equality and the Health and Safety Executive (HSA).
7. **Time period:** The planned inspection programme is run on an annual basis.
8. **Non-compliant products/placing on the market.** Legislation in the form of Statutory Instrument 384 of 2005 transposing Regulation (EC) 2003/2003 and Regulation 463/2013 allows for withdrawal, seizure, detention and in certain cases forfeiture and destruction of non-compliant products. Penalties of up to €3,000 or six months imprisonment, or both, are specified in the legislation.



## **B. Department of Communication, Energy and Natural Resources**

### **Energy Related Products Public Narrative Document**

**Member State:** *Ireland*

**Surveillance Authority:** *Minister for Communications, Energy and Natural Resources*

**Planning Year:** *2014-2015*

**Person responsible for the sectoral NMSP:** *Enda Gallagher, Energy Efficiency and Affordability Division*

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**Telephone:** *+353(01)6783211*

#### **1. Objective**

The objective of this plan is to ensure, insofar as is feasible within existing legal, organisational and infrastructural frameworks, that an effective market surveillance programme is in place to meet the requirements of Regulation 765/2008 as it applies to products regulated under Directives 2010/32/EC (Energy Labelling), 2009/125/EC (Ecodesign) and Regulation 1222/2009 (Tyre Labelling).

#### **2. Structure and responsibilities**

Market surveillance activities in respect of the above legislation is carried out by Energy Efficiency and Affordability Division of the Department of Communications, Energy and Natural Resources, supported as required by experts from the Sustainable Energy Authority of Ireland (SEAI) and other market actors.

#### **3. Organisation**

##### **3.1 Human Resources**

The Energy Efficiency and Affordability Division of the Department of Communications, Energy and Natural Resources is 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, some market surveillance services are outsourced to suitable market actors through public procurement processes.

##### **3.2 Technical Resources**

The technical capacity to test and analyse products in accordance with the requirements of the Energy Labelling and Ecodesign Directives and the Tyre Labelling Regulations does not presently exist in Ireland and is provided by external resources appointed through a public procurement processes.

##### **3.3 Financial Resources**

Market surveillance activities are performed within the Department's existing programme budget, which is subject to national restrictions on Government spending.

## **4. General monitoring approach**

Due to the limited resources available, monitoring and surveillance activities are combined with inspection and testing programmes where possible.

### **4.1. Proactive inspections**

Inspection of retail sites for compliance with the Energy Labelling Directive and Tyre Labelling Regulations with regard to affixing of correct labels on products and the supply of appropriate documentation. Inspections may include announced or unannounced inspections.

### **4.2 Reactive inspections**

Investigation of complaints from the public or affected parties, and information received from customs authorities or other member states' market surveillance authorities.

### **4.3 Product testing**

When suspected of non-compliance, applicable products are tested in accredited laboratories. Where products are tested for compliance with the Ecodesign Directive, and such products are also covered by the Energy Labelling Directive, such testing is considered to satisfy the test requirements of both Directives.

## **5. Setting of Priorities**

The following factors are used to set priorities:

### **5.1 Identification of undertakings supplying relevant products**

Maintenance of a database of sites supplying products covered by the Energy Labelling and Ecodesign Directives and Tyre Labelling Regulation and recording details of inspections, the findings and follow-up actions.

### **5.2 Risk assessment**

Risk factors that will be taken into account in undertaking market surveillance activities will include, but not be limited to:

- Market share.
- Geographic location.
- History of non-compliance.
- Complaints or information supplied by a third party.
- Products which may not have been examined previously.

### **5.3 Setting priorities**

The prioritisation of activities is determined by a combination of:

- Resource capacity (time, human and budget resources).
- Selection of target sites for inspection.
- Selecting frequency and target dates for inspection and/or testing.

## **6. Horizontal Co-operation**

The Department 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. The Department 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).

## **7. Time Period**

The current policy for the market surveillance programme is based on a two-year framework.

## **8. Informing undertakings**

Information on the legislation and obligations of affected parties is disseminated through:

- Publications (leaflets, brochures or other guidance material) to inform suppliers, dealers and the public of the requirements.
- The use of professional and trade associations.
- Training / information sessions.
- A dedicated market surveillance webpage the Departments website.

## **9. Non-compliant products**

Legislation transposing the relevant Directives sets out the enforcement process and allows for withdrawal, seizure, detention and in certain cases forfeiture and destruction of non-compliant products. Penalties and the associated appeals procedures are also specified in the transposing legislation.

## **C. Legal Metrology Service, NSAI**

### **Measuring Instruments (Directive 2004/22/EC and 2009/23/EC)**

#### **Public Narrative Document**

**Member State:** *Ireland*

**Surveillance Authority:** *Legal Metrology Service (LMS), NSAI*

**Planning Year:** *2014 - 2015*

**Person responsible for the sectoral NMSP:** *Paul Turner, LMS, NSAI*

**E Mail Address:** [paul.turner@nsai.ie](mailto:paul.turner@nsai.ie)

1. **Objective:** The market surveillance plan has been developed to ensure effective compliance with the requirements of Directive 2004/22/EC on measuring instruments and Directive 2009/23/EC on non-automatic weighing instruments.
2. **Structure and responsibilities:** The Legal Metrology Service, NSAI has been charged with the responsibility for market surveillance through national regulation. Investigative powers have been given to authorised officers who report to the Director of Legal Metrology who has powers to withdraw, recall and dispose of non-compliant instruments and prosecute non-compliant operators.
3. **Organisation:**
  - a. **Human Resources:** 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.
  - b. **Technical Resources:** those needed for physical testing at the operational level are available to the Legal Metrology Service and it is not envisaged that in-depth type approval tests which are normally conducted under laboratory conditions will be undertaken.
  - c. **Financial Resources:** market surveillance activities will be performed within existing operations budget which is unlikely to be increased in the current financial and economic climate.
4. **Approach:** Proactive inspections are routine in the operation of the Legal Metrology Service to ensure measuring instrument in trade use comply with legal requirements. These checks will be used to identify location and compliance of individual measuring instruments being put into use on the market. Reactive investigations will be carried out where complaints are raised by third parties in relation to any product covered by the Directives. For each Directive specific product categories have been selected for a targeted proactive action each year based on current knowledge of products covered by the Directives. The targeted actions will involve investigations moving back through the distribution chain to the manufacturer.

5. **Priority setting:** Information will be gathered through routine inspections to identify the market operators responsible for making instruments available on the market. A risk based inspection strategy will be used to identify the products of greatest risk.
6. **Horizontal Co-operation:** The plan will take account of initiatives and actions to be undertaken by other metrology services co-ordinated by WELMEC (organisation of European Legal Metrology Authorities) and if necessary the plan can be reviewed to take account of any joint actions.
7. **Time Period:** it is intended that the programme will operate on an annual basis at which time it will be reviewed and updated unless agreement is reached with other authorities on joint actions as mentioned in point 6 above, which if it occurs will result in a review of the programme, most likely in the proactive targeted actions.
8. **Information dissemination:** information on the programme will be disseminated through meetings with suppliers and trader group representatives and publicised through media interviews, website etc.
9. **Non-compliant products:** The risk addressed in metrological legislation in trade use is metrological integrity which if breached will generally result in fiscal detriment. National metrology legislation allows for non-compliant products to be withdrawn, recalled and disposed of, if necessary. Where breaches are identified prosecutions may also be taken against the liable economic operators.

## **D. Department of Justice and Equality**

### **Explosives and Pyrotechnic Articles Public Narrative Document**

**Member State:** *Ireland*

**Surveillance Authority:** *Minister for Justice and Equality*

**Planning Year:** *2014 - 2015*

**Person responsible for the sectoral NMSP:** *JK Coates, Senior Government Inspector of Explosives*

**E Mail Address:** [jcoates@justice.ie](mailto:jcoates@justice.ie)

- 1. Objective:** The objective of the plan 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 Regulation 765/2008, insofar as may apply to explosives for civil uses regulated under Directive 93/15/EEC, and pyrotechnic articles regulated under Directive 2007/23/EC (and as recast as Directive 2013/29 EU).
- 2. Structure and responsibilities:** The bulk of market surveillance activities shall be carried out by the explosives inspectorate of the Department of Justice and Equality, supported, as appropriate, by inspectors from other agencies or authorities.
- 3. Organisation:**
  - a. Human Resources:** The explosives inspectorate is a part of the Crime 4 Division of the Department of Justice, Equality and Law Reform. 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. 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.
  - b. Technical Resources:** There is no notified body for explosives or pyrotechnic articles in Ireland. Very limited explosive testing and evaluation is possible within existing resources.
  - c. Financial 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.
- 4. General monitoring approach:** 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:

- a. Proactive inspections: Including planned and routine inspections of sites where explosives are imported, manufactured, stored, sold, or transported. Inspections will include announced and unannounced inspections.
- b. Reactive inspections: Including acting on information received from complaints from the public, 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 in the workplace.
- c. 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.

**5. Setting of Priorities:** The following factors will be used to set priorities;

- a. 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.
- b. Risk assessment of undertakings and sites: Risk factors include:
  - i. Explosive hazards and degree of risk involved, taking into account explosive quantity and type and location.
  - ii. Activity and degree of risk involved, whether manufacture, processing, storage, transport or sale.
  - iii. Competence of undertakings including training, experience and qualifications of the managers and personnel of the undertakings.
  - iv. Knowledge of the legislation of the undertakings.
  - v. Compliance record of undertakings.
  - vi. Results of previous inspections.
  - vii. Frequency of previous inspections or date of last inspection.
  - viii. Requirement for involvement of other agencies.
  - ix. Cost benefit factors of inspections.
  - x. Resource capacity of inspectorate (time, human and budget resources).
- c. Setting priorities
  - i. Allocation of available resources including time, personnel and budgets.
  - ii. Selection of target undertakings for inspection.
  - iii. Selection of type of inspection.
  - iv. Selecting frequency and target dates for inspection.

- 6. Horizontal Co-operation:** Other organisations, agencies and regulatory authorities and agencies, including those of other Member States may be involved in the programme by providing information or assistance as agreed. Discussion on MOU will take place with Customs & Revenue, and other relevant regulatory authorities.
- 7. Time Period:** The planned inspection programme will generally run on an annual basis for high and medium priority targets, but may involve a two year program for low priority targets.
- 8. Informing undertakings:** The explosives inspectorate already carry out active liaison, advice, safety alerts, guidance and consultation with the main undertakings involved in the explosives industry. Meetings are held with particular interest groups (manufacturers, professional operators, mining groups, transport drivers, importers etc.). Technical and legal advice and guidance on explosives legislation is exchanged by meetings, E mail, website notices etc. Health and Safety information is provided to the public and professionals by the Health and Safety authority and general consumer information is provided by the National Consumer Agency.
- 9. Unsafe and un-compliant products:** Explosives legislation transposing the relevant Directives, allows for withdrawal, seizure, detention and in certain cases forfeiture and destruction of the unsafe or un-compliant products. Penalties and associated appeals procedures are also specified in the explosives legislation.



## **E. Department of Transport, Tourism and Sport**

### **Maritime Sector: Recreational Craft Products**

#### **Public Narrative Document**

**Member State:** *Ireland*

**Surveillance Authority:** *Minister for Transport, Tourism and Sport*

**Planning Year:** *2014 – 2015*

**Person responsible for the sectoral NMSP:** *Michael Klyne, Marine Surveyor,  
Irish Maritime Administration -Marine Survey Office, Department of Transport,  
Tourism and Sport*

**E Mail Address:** *michaelklyne@transport.ie*

1. **Objective:** The objective of the plan 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 Regulation 765/2008, insofar as may apply to recreational craft products regulated under Directive 94/25/EC (as amended).
2. **Structure and responsibilities:** The Marine Survey Office of the Irish Maritime Administration (IMA) shall carry out market surveillance activities in respect of marine equipment and recreational craft, supported, as appropriate, by other agencies and authorities.
3. **Organisation:**
  - (a) **Human Resources:** The Marine Survey Office (MSO) is a line division of the IMA. The MSO deals with the inspection, survey, certification and licensing of vessels and vessels radio equipment; the examination and certification of seafarers competencies; enforcement of standards by way of audits on organisations and facilities and prosecutions for breaches of regulations.
  - (b) **Technical Resources:** There is no notified body for recreational craft products in Ireland at present.
  - (c) **Financial Resources:** All activities will have to be performed within the existing Departmental budgets, which are subject to national economic restrictions on Government spending.

**4. 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 or information on RAPEX, etc.

Accident investigation may be conducted in co-operation with other agencies including, for example; An Garda Síochána, the Marine Casualty Investigation Board and the Health and Safety.

Follow up inspections and investigations will be undertaken where appropriate.

- (c) Precautionary Principle: This approach will be taken if it is suspected that dangerous recreational craft products are likely to be placed on the market. 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.

**5. 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, RSG and CIRCA;
- iii. Information collected on the compliance record of operators and importers;

- 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.
6. **Horizontal Co-operation:** Other organisations, agencies and regulatory authorities, including those of other Member States (through use of RAPEX, 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 National Consumer Agency, 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.

7. **Time Period:** The planned inspection programme will run on a two-year basis commencing in the period January to June 2014.
8. **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](http://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.

9. **Unsafe and non-compliant products.**
- (a) Recreational Craft national legislation, transposing the relevant Directive, already allows the Minister for Transport, Tourism and Sport to prohibit, restrict or require the withdrawal of unsafe or non-compliant recreational craft products. Offences, Penalties and associated appeals procedures are also specified in this legislation; the European Communities (Recreational Craft) Amendment Regulations

2004 (SI No. 422 of 2004) provides for a fine of up to €3,000 for a person convicted in court of contravening any of the regulations.

Directive 2013/53/EU of the EP and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC, was published in the Official Journal of the EU on 28<sup>th</sup> December 2013. It entered into force on 17 January 2014 and will become applicable on 18 January 2016. The revised Directive takes account of the requirements of Regulation (EC) No. 765/2008 regarding market surveillance.

## **F. Building Control Authorities**

### **Construction Products**

#### **Public Narrative Document**

**Member State:** *Ireland*

**Surveillance Authority:** *37 local Building Control Authorities (i.e. local authorities)*

**Planning Year:** *2014-2015*

**Person responsible for the sectoral NMSP:** *Paris Beausang Department of the Environment, Community and Local Government*

**Email Address:** [paris.beausang@environ.ie](mailto:paris.beausang@environ.ie)

#### **1. Objective:**

The objective of the plan is to ensure, insofar as is feasible within the existing legal, organisational and infrastructural framework, that an effective market surveillance programme is in place to meet the requirements of Regulation (EU) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/9, insofar as it may apply to construction products regulated under Regulation (EU) No. 305/2011 of the European Parliament and of the Council laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (known as the Construction Products Regulation).

#### **2. Structure and responsibilities:**

Market surveillance activities in relation to construction products regulated under Regulation (EU) No. 305/2011 are carried out by building control authorities in accordance with the specific provisions of the European Union (Construction Products) Regulations 2013 (S.I. No. 225 of 2013) and the broader overarching requirements of Chapter III of Regulation (EU) No. 765/2008 and Chapter VIII of Regulation (EU) No. 305/2011. Building control authorities form an integral part of the local government system and generally operate as discrete units within each local authority. There are a total of 37 local building control authorities (i.e. located within 29 County Councils, 5 City Councils and a further 3 Borough/Town Councils).

#### **3. Organisation:**

##### **a. Human Resources:**

Authorised officers have been appointed within each of the 37 local building control authorities to enforce the statutory requirements set out under the European Union (Construction Products) Regulations 2013 and Regulation (EU) No. 305/2011. Building control authorities also have primary responsibility for the enforcement of the Building Regulations 1997 - 2013, the Building Control Regulations 1997 – 2013 as well as for parts of the European Union (Energy Performance of Buildings) Regulations 2012.

##### **b. Technical Resources:**

Building control authorities do not have the technical resources in-house to test construction products which may be non-compliant with the

requirements of the Regulation (EU) No. 305/2011. Typically, the testing and evaluation of construction products, where considered necessary, will be outsourced to accredited bodies providing such services.

**c. Financial Resources:**

All enforcement activity will have to be performed within existing local authority budgets, which are likely to remain subject to national restrictions on Government spending. However, where a construction product is sent for testing by a building control authority and that product is found to be non-compliant with the requirements of Regulation (EU) No. 305/2011, the regulations provide that the building control authority may seek to recover the costs of that test from the relevant economic operator as simple contract debt from any court of competent jurisdiction. Similarly, where an economic operator has been convicted on indictment for an offence under the regulatory regime, a building control authority may seek a forfeiture order to seize and destroy the construction products concerned; the costs associated with the destruction or disposal of the products may be recovered by the building control authority from the relevant economic operator as simple contract debt from any court of competent jurisdiction.

**4. General monitoring approach:**

Under the regulations, building control authorities have powers to obtain access to premises to examine, test or inspect products, request documentation regarding the performance of a product, take samples of the product, request the Minister for the Environment, Community and Local Government to prohibit or restrict the use of a product and prosecute offences.

Given the limited resources available and their application over 37 separate local building control authorities, enforcement action relating to Regulation (EU) No. 305/2011 will generally be carried out on a reactive basis. Typically, market surveillance activity will be triggered on foot of acting on information received from complaints (e.g. from the public, public bodies, contractors, designers, customs, police or other market surveillance authorities etc).

Any construction products identified as non-compliant will be subject to the specific provisions of the European Union (Construction Products) Regulations 2013 and the broader overarching requirements of Chapter III of Regulation (EU) No. 765/2008 and Chapter VIII of Regulation (EU) No. 305/2011.

**5. Setting of Priorities:**

The following factors will be used to set priorities: -

**a. Identification of products:**

This will be dependant on market intelligence and will derive primarily from acting on complaints from the public or other affected parties as well as from information received from customs and/or other market surveillance authorities (both EU and national).

**b. Risk assessment of products:**

Risk factors include:

- i. end-use of the construction product, i.e. the safety implications of products while in use;
- ii. extent of use of the construction product;
- iii. construction products known to contain certain materials not in compliance with Regulation (EU) No. 305/2011 / European Union (Construction Products) Regulations 2013 / relevant harmonised standard(s);
- iv. compliance record of relevant manufacturers, importers, distributors and retailers;
- v. results of previous inspections / investigations (where relevant);
- vi. frequency of previous inspections / investigations or date of last inspection / investigation (where relevant);
- vii. requirement for the involvement of other market surveillance authorities and agencies as appropriate;
- viii. cost benefit factors of inspections / investigations; and
- ix. resource capacity of Building Control Authorities (time, human and budget resources).

**c. Setting priorities:**

Factors may include:

- i. allocation of available resources including time, personnel and budgets;
- ii. selection of target manufacturers, importers, distributors and retailers for inspection / investigation;
- iii. selection of type of inspection / investigation; and
- iv. selecting frequency and target dates for inspection.

**6. Horizontal Co-operation:**

Other organisations, agencies and regulatory authorities, including those of other Member States may be involved in the plan by providing information or assistance as agreed.

**7. Informing undertakings:**

Building control authorities will continue to carry out active liaison, advice, guidance and consultation with the principal stakeholders involved in the construction sector.

**8. Unsafe and un-compliant products:**

Enforcement powers are set out in the European Union (Construction Products) Regulations 2013 and in the broader overarching provisions set out in Chapter III of Regulation (EU) No. 765/2008 and Chapter VIII of Regulation (EU) No. 305/2011, and will be used when required. Under the regulatory regime: -

- i. the use of a construction product may be subject to special conditions;
- ii. a construction product may be prohibited from being placed on the market,
- iii. if already placed on the market, the use of the construction product may be withdrawn or recalled from the market.

## G. Commission for Communications Regulation

### **R&TTE and EMC Directives Public Narrative Document**

**Member State:** *Ireland*

**Surveillance Authority:** *Commission for Communications Regulation (ComReg)*

**Planning Year:** *2014 - 2015*

**Person responsible for the sectoral NMSP:** *Michael Callan, Compliance Engineer with responsibility for Market Surveillance*

**E Mail Address:** [michael.callan@comreg.ie](mailto:michael.callan@comreg.ie)

- 1. Objective:** The objective of this plan is to ensure that an effective market surveillance program is in place to meet the requirements of Regulation 765/2008 as it applies to equipment regulated under Directive 2004/108/EC and apparatus regulated under Directive 1999/5/EC.
- 2. Structure and responsibilities:** The Commission for Communications Regulation in Ireland (ComReg) shall carry out market surveillance activities in respect of electronic equipment; radio equipment; and telecommunications terminal equipment supported, as appropriate, by other agencies and authorities.
- 3. Organisation**
  - a. Human Resources**

The Commission for Communications Regulation (ComReg) is the statutory body responsible for regulating the telecommunications and postal sectors in Ireland. ComReg is responsible for enforcing the R&TTE Directive (Directive 1999/5/EC) and the EMC Directive (Directive 2004/108/EC). The market surveillance activities for both of these Directives are carried out by the spectrum compliance team, which currently consists of 10 members. The spectrum compliance team has other responsibilities and a limited amount of the teams resources are dedicated to market surveillance.
  - b. Technical Resources**

ComReg has relevant expertise in-house from a technical and legal required for the assessment and testing of products. ComReg also has a wide range of test equipment available in order to complete pre-compliance testing. Notified bodies, within Ireland and external to Ireland, can be called upon for independent testing where necessary.
  - c. Financial Resources**

All market surveillance activities are financed from the annual budget allocated by ComReg which are subject to national economic restrictions on Government spending.



#### 4. General Monitoring Approach

ComReg operate a risk based approach to the enforcement of the EMC and R&TTE Directives. We estimate the severity and the probability of products based on data (where available); frequencies; expertise and experience; interference complaints; and market factors. Priority is given to products that are a threat to safety of life; causes interference to emergency services; air traffic control; and maritime traffic control, etc. Market surveillance activities in ComReg include:

- a. **Proactive market surveillance** – planned and routine market surveillance takes place annually within ComReg. Where appropriate we coordinate with Revenue’s Customs Service. We also participate in pan EU market surveillance campaigns for problem areas in relation to the EMC and R&TTE Directives. Reports are published on circa regarding the outcome of the pan EU market surveillance campaigns. ComReg also conducts Desktop Market Surveillance on pre-determined targeted products.
- b. **Reactive market surveillance** – involves investigating complaints received by the spectrum compliance team and the consumer team in ComReg.
- c. **Sampling** – products are sampled based on risk and a small number of products are taken from the market at random for compliance checks.
- d. **Admin and Technical Tests** – When assessing the compliance of products we complete admin checks and pre-compliance technical tests.

#### 5. Horizontal Co-operation

- a. ComReg co-operates at a horizontal level across Europe with industry; industry groups; the European Commission; other member states; standards bodies; consumer bodies; and notified bodies groups, such as the R&TTE CA. ComReg participates in various meeting groups such as Administrative Co-operation (ADCO) EMC; EMC Working Party (WP); ADCO R&TTE; and Telecommunications Conformity Assessment and Market Surveillance Committee (TCAM).
- b. Within Ireland ComReg co-operates at the national market surveillance forum. ComReg works with Revenue’s Customs Service, the Department of Jobs, Enterprise and Innovation (DJEI); the Department of Communications, Energy and Natural Resources (DCENR); the Irish National Accreditation Board (INAB) and others.

**6. Time period:** The market surveillance program within ComReg runs on an annual basis. The pan EU market surveillance campaigns can run on a bi-annual basis depending on the duration and scope of the campaign.

**7. Informing undertakings:** ComReg has built and maintains relationships with key stakeholders within industry; within the European Commission; European Council; in Ireland; and with the other EU member states. At TCAM and the

EMC WP ComReg and other EU member states; industry groups; standardisation groups; notified bodies; and consumer representatives discuss key issues. The outcomes and decisions at these meeting are shared with all stakeholders.

**8. Unsafe and non-compliant products**

Unsafe and non-compliant products are removed from the market using the powers conferred to ComReg by S.I No. 240 of 2001 (Radio Equipment and Telecommunications Terminal Equipment) Regulations; and S.I. No. 109 of 2007 (Electromagnetic Compatibility) Regulations. Voluntary recalls are preferable, however, legal action is taken and regulatory directions are issued if necessary.

## **H. Environmental Protection Agency**

### **Restriction on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) Public Narrative Document**

**Member State:** *Ireland*

**Surveillance Authority:** *Environmental Protection Agency*

**Planning Year:** *2014 - 2015*

**Person responsible for the sectoral NMSP:** *Philip Nugent Waste Policy and Resource Efficiency Unit, DECLG*

**Email Address:** [Philip.Nugent@environ.ie](mailto:Philip.Nugent@environ.ie)

1. **Objective:** The objective of the plan is to ensure, insofar as is feasible within the existing legal, organisational and infrastructural framework, that an effective market surveillance programme is in place to meet the requirements of Regulation 765/2008, insofar as it may apply to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).
2. **Structure and responsibilities:** The market surveillance activities are carried out by the Chemicals Unit of the Environment Protection Agency (EPA) the competent authority for the enforcement of the RoHS Directive under the European Union (Restriction of Certain Hazardous Substances in Electrical and Electronic Equipment) Regulations 2012, S.I. No. 513 of 2012.
3. **Organisation:**
  - a. **Human Resources:** The Core Prevention Team within the Chemicals Unit of the EPA is tasked with the enforcement of RoHS requirements. A strategy is being implemented including information provision, investigation of complaints, and consideration of producer reported breaches, technical file evaluations and, where deemed necessary, sampling/testing of products placed on the market. There are extensive product recall powers provided for under S.I. 513 of 2012. Information on guidance is available at [www.rohs.ie](http://www.rohs.ie)
  - b. **Technical Resources:** Product technical file evaluations and testing of products is carried out by suitably approved third party laboratories.
  - c. **Financial Resources:** All activities will have to be performed within the existing EPA budget, which is subject to national economic restrictions on Government spending.
4. **General monitoring approach:** The EPA operates a risk based approach to the enforcement of environmental legislation. This approach makes the best use of available resources by focusing on products that pose the highest environmental risk. The EPA currently carries out product technical file examinations and where deemed necessary contracts out analysis of materials

and/or components. Inspections are carried out on a proactive and reactive basis. In the 2012/13 period 25 products were tested the majority compliant. Any products identified as being non-compliant are the subject of ongoing enforcement actions with relevant economic operators. In most cases non-complaint products are removed voluntarily from the market.

The Unit is in the process of formalising arrangements with Customs for the purpose of closer cooperation with surveillance activities and a Memorandum of Understanding and Information Exchange Agreement are being prepared between the EPA and the Customs Authorities to cover a range of product related enforcement activities, e.g. RoHS, POPs, RAPEX notifications are followed up when received.

- 5. Setting of Priorities:** The following factors will be used to set priorities;
- a. Identification of undertakings: This is based on market intelligence and the knowledge of the inspection team. Additionally, certain products or product ranges are jointly chosen and inspected by members of the RoHS Enforcement Network, the RoHS Administration for Cooperation, on an biannual basis.
  - b. Risk assessment of undertakings: Risk factors include:
    - i. Products associated with a high probability of containing the specified restriction substances
    - ii. High volume products
    - iii. Short lifecycle products
    - iv. Consumer products unlikely to be recycled
    - v. Compliance record of undertakings.
    - vi. Results of previous inspections
    - vii. Frequency of previous inspections or date of last inspection
    - viii. Requirement for involvement of other agencies
    - ix. Cost benefit factors of inspections.
    - x. Resource capacity of EPA (human and financial resources).
  - c. Setting priorities
    - i. Allocation of available resources including time, personnel and budgets.
    - ii. Selection of target undertakings for inspection
    - iii. Selection of type of inspection – technical file evaluation or compliance testing
    - iv. Selecting frequency and target dates for inspection.
- 6. Horizontal Co-operation:** Other organisations, agencies and regulatory authorities, including those of other Member States may be involved in the programme by providing information or assistance as required. The EPA is an active member of the RoHS Enforcement Network and liaises with other members of the Network in enforcement activities. During the period of the enforcement plan, the EPA intends migrating product inspection details to the

Commission's Information and Communication System for Market Surveillance (ICSMS).

7. **Time Period:** The inspection programme runs on an annual basis.
8. **Informing undertakings:** The EPA conducts active liaison, advice, guidance and consultation with the main stakeholders. Meetings are held with particular interest groups (manufacturers, retailers, importers etc.). Technical advice and guidance is provided on the EPA website and by notices etc. Health and Safety information is provided to the public and professionals by the Health and Safety Authority and general consumer information is provided by the National Consumer Agency.
9. **Unsafe and un-compliant products:** Products are removed from the market using the powers of S.I. 513 of 2012 and if necessary legal action may taken. Thus far, only one direction has been made by the EPA for product withdrawal from the market and the recall of the product from the customer.

## I. Health and Safety Authority

**Machinery, PPE, ATEX, Lifts, Gas Appliances, PED, TPED, REACH, CLP, Detergents**

### **Public Narrative Document**

**Member State:** *Ireland*

**Surveillance Authority:** Health and Safety Authority (HSA)

**Planning Year:** 2014-15

**Person responsible for the sectoral NMSP:** John Colreavy; Blaithin Tarpey (TPED) and Yvonne Mullooly for chemical related matters.

**Email Address:** [john\\_colreavy@hsa.ie](mailto:john_colreavy@hsa.ie); [blaithin\\_tarpey@hsa.ie](mailto:blaithin_tarpey@hsa.ie); [yvonne\\_mullooly@hsa.ie](mailto:yvonne_mullooly@hsa.ie)

#### **1. Objective:**

The objective of the plan 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 Regulation 765/2008, insofar as may apply to:

Machinery Directive	John Colreavy
Personal Protective Equipment (PPE) Directive	John Colreavy
Equipment for use in Explosive Atmospheres (ATEX)	John Colreavy
Lift Directive	John Colreavy
Gas Appliance Directive (GAD)	John Colreavy
Pressure Equipment Directive (PED)	John Colreavy
Transportable Pressure Equipment (TPED)	Blaithin Tarpey
REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals)	Yvonne Mullooly
CLP (classification, labelling and packaging of chemicals)	Yvonne Mullooly
Detergents Regulation	Yvonne Mullooly

#### **2. Market Surveillance Authority:**

##### **a. Structure and responsibilities:**

Market surveillance activities will be carried out by the Health and Safety Authority (HSA), supported, as appropriate, by inspectors from other agencies or authorities.

The primary statutory responsibilities of the Health and Safety Authority under the Safety, Health and Welfare at Work Act 2005 and the Chemicals Act 2008 are to promote, encourage and foster the prevention of personal injury, occupational ill health, dangerous occurrences at work and the safe and suitable use of Chemicals. In addition the Authority has a legislative remit to

make adequate arrangements for the enforcement of the relevant statutory provisions.

**b. Resources:**

Market Surveillance inspections will be carried out by inspectors engaged in the enforcement of occupational health and safety legislation and chemical legislation.

**c. Technical Resources:**

All inspectors are qualified to third level in a scientific discipline. The Authority does not operate any testing facility and very limited testing and evaluation is possible within existing resources.

**d. Financial Resources:**

Activities will have to be performed within the existing budgets, which are subject to national economic restrictions on Government spending.

**3. General monitoring approach:**

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 programmes where possible. Most market surveillance activities will be in the form of reactive inspections acting upon information from accidents, complaints from the public, referrals from customs or other market surveillance authorities and alerts. Various powers are available to the Authority if it is suspected that the required corrective action will not take place.

**4. Setting of Priorities:**

The priority of inspections will be determined by factors such as:

- severity of the hazard or level of risk
- experience of the HSA with the product in question.
- concerns about the product or economic operator.
- accidents or dangerous occurrences
- complaints
- results of occupational safety related inspections
- requests for information
- safety alerts

**5. Horizontal Co-operation:**

Other organisations, agencies and regulatory authorities and agencies, including those of other Member States may be involved in the programme by providing information or assistance as agreed. The Authority has a data sharing agreement with the Irish Customs Authority. The HSA works closely with the National Consumer Agency in respect of products for which both organizations have an enforcement role. The Authority participates in the interdepartmental inter agency market surveillance forum which operates under the auspices of the Department of Jobs, Enterprise and Innovation.

#### **6. Time Period:**

The current policy for the market surveillance programme is based on a two year timeframe.

#### **7. Informing undertakings:**

The Health and Safety Authority already carries out inspections of workplaces, provides advice and takes enforcement action where necessary. The Authority has both a formal and informal consultation process for the production of Codes of Practice, Guidance and information sheets. In addition the Authority has advisory committees for several high risk sectors made up of the relevant stake holders. There are also sectoral partnerships in place. The Authority will inform undertakings through these channels and through other liaison structures currently in place along with its website, and newsletter.

#### **8. Unsafe and un-compliant products:**

Product safety legislation transposing the relevant Directives, allows for withdrawal, seizure, detention and in certain cases forfeiture and destruction of the unsafe or noncompliant products. Penalties and associated appeals procedures are also specified in the legislation.



**J. Irish Medicines Board**  
**Cosmetics**  
**Public Narrative Document**

**Member State:** *Ireland*  
**Surveillance Authority:** *Irish Medicines Board*  
**Planning Year:** *2014-2015*  
**Person responsible for the sectoral NMSP:** *Nicola Hickie, Cosmetics Product Coordinator*  
**E Mail Address:** *cosmetics@imb.ie*

**1. Objective:**

The objective of the plan 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 Regulation 765/2008, insofar as may apply to cosmetics regulated under Regulation (EC) No 1223/2009 (as amended) and SI 440 of 2013, European Union (Cosmetic Products) Regulations 2013.

**2. Structure and responsibilities:**

The Competent Authority for cosmetic products in Ireland is the Irish Medicines Board (IMB). The IMB works in conjunction with the Health Service Executive (HSE) in monitoring the compliance of cosmetic products on the Irish market.

Responsibilities include:

- Ensuring the operation of an effective and broad reaching market surveillance programme in conjunction with the HSE.
- Surveying the market and carrying out sampling and analysis of cosmetic products
- The communication and monitoring of investigations into Serious Undesirable Effects.
- The assessment and investigation of RAPEX Alerts relating to cosmetic products
- Investigation of reported safety concerns.
- Inspection of manufacturers to ISO/EN 22716 on cosmetic Good Manufacturing Practices
- Inspection of distributors to ensure compliance with Regulation (EC) No 1223/2009
- Participation in international activities, including relevant EU working groups.
- Generation of Certificates of Free Sale.

**3. Organisation:**

**a. Human Resources:**

The Competent Authority for cosmetic products in Ireland is the Irish Medicines Board (IMB). Market surveillance and enforcement activities are also carried out by the Environmental Health Service of the HSE. Analysis is carried out by the Public Analysts' Laboratories in Cork, Dublin and Galway.

**b. Technical Resources:**

Analytical testing of cosmetics samples is carried out by the Public Analyst's Laboratories. Desk review of product information files and other supporting information is conducted by the IMB.

**c. Financial Resources:**

It is likely that all activities will have to be performed within the existing Departmental budgets, which are subject to national economic restrictions on Government spending.

**4. General monitoring approach:**

A risk based approach to monitoring and surveillance activities has been adopted and includes:

**a. Proactive inspections:**

Including planned and routine inspections of cosmetic products at sites where cosmetics are manufactured, stored and/or sold.

**b. Reactive inspections:**

Including acting on information received from RAPEX alerts, SUE reports, complaints from the public and/or Healthcare Professionals, accidents, customs or police or other market surveillance authorities.

**c. 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 and/or counterfeit products are on the market.

**5. Setting of Priorities:**

During different periods over the course of the year, priority will be given to concentrating on specific hazards that are common to specific products.

**a. Identification of products:**

This is dependant on information received through market surveillance activities and trends observed for the Irish market.

**b. Risk assessment of products:**

Risk factors include:

- i. Intended use of products and the resultant safety implications
- ii. Intended consumer
- iii. Site of application of the product
- iv. Compliance record of products or operators
- v. Products known or suspected to contain certain materials not in compliance with the regulations.

**c. Setting priorities:**

- i. Allocation of available resources including time, personnel and budgets.

**6. Horizontal Co-operation:**

Other organisations, agencies and regulatory authorities and agencies, including those of other Member States may be involved in the programme by providing information or assistance as agreed.

**7. Time Period:**

The planned market surveillance programme will generally run on an annual basis for high and medium priority targets.

**8. Informing undertakings:**

The IMB and HSE conduct active liaison, guidance and consultation with the main stakeholders. Meetings are held with particular interest groups (industry associations, manufacturers, distributors etc.). Information is also provided to the public and healthcare professionals through the provision of guidance information, newsletters and guidance documents on the IMB website.

**9. Unsafe and non-compliant products.**

Where possible the IMB and HSE seek voluntary cooperation from the Responsible Person, manufacturer, importer, distributor and/or retailer in relation to corrective actions or market actions. Products presenting a risk are removed from the market using the powers under Regulation 1223/2009 and the implementing SI 440 of 2013, European Union (Cosmetic Products) Regulations 2013.

## Irish Medicines Board

### Medical Devices Public Narrative Document

**Member State:** *Ireland*

**Surveillance Authority:** Irish Medicines Board

**Planning Year:** 2014-15

**Person responsible for the sectoral NMSP:** Maria Carleton, Operations Manager,  
Sinead Carty, Human Products Monitoring

**Email Address:** [maria.carleton@imb.ie](mailto:maria.carleton@imb.ie), [Sinead.carty@imb.ie](mailto:Sinead.carty@imb.ie)

1. **Objective:** The objective of the plan 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 Regulation 765/2008, insofar as may apply to medical devices regulated under Directives 90/385/EEC, 93/42/EEC (as amended) and 98/79/EC.
2. **Structure and responsibilities:** The market surveillance activities shall be carried out by the Human Products Safety Monitoring Department, the Human Products Authorisation and Registration Department and the Compliance Department of the Irish Medicines Board.
3. **General monitoring approach:** 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 the Irish Medicines Board in its role as Competent Authority for medical devices in Ireland are primarily sector specific in nature and include the following activities:

- a. Implementation of the requirements of the legislation in relation to market surveillance for medical devices.
- b. Implementation of the actions outlined in Commissioner Dalli's Joint Action plan.
- c. Device specific market surveillance projects involving specific product families.
- d. Post market surveillance audits of manufacturing sites in Ireland.
- e. Audits of the Irish Notified Body for medical devices.
- f. Participation in the Joint Assessment programme for Notified Bodies under Regulation 920 of 2013.
- g. Audits of manufacturers based in Ireland are also conducted further to requests from other Member States.

4. **Horizontal Co-operation:**

Horizontal co-operation is achieved 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. The European Commission is made aware of the work programme.

The Irish Medicines Board contributes to development of best practice in post market surveillance across EU Member States and works with other EU Competent Authorities to develop harmonization in approach to post market surveillance.

In addition, the Irish Medicines Board actively participates in the Joint Assessment Working Group and Notified Body working group which develops guidance for the surveillance and assessment of Notified Bodies.

5. **Time Period:** The proactive audit programme is updated annually, while the proactive market surveillance projects may commence this year they may run over a longer timeframe.

6. **Informing undertakings.** The Irish Medicines Board holds 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 advisory notices on the IMB website.

Detail of market surveillance projects and device families for audit are made available to the public in our annual reports and also through the newsletter published three times per year. Information on projects may be disseminated through industry links such as Irish Medical Device Association.

It is planned to run an Information Day in 2014 where updates will be given regarding market surveillance activities.

7. **Unsafe and un-compliant products.** Enforcement actions and penalties are outlined in national legislation transposing the relevant Directives in conjunction with the IMB Act 1995 (as amended) and are used when required.

## **K. National Consumer Agency**

### **Public Narrative Document**

**Member State:** *Ireland*

**Surveillance Authority:** *National Consumer Agency*

**Planning Year:** *2014 – 2015*

**Person responsible for the sectoral NMSP:** *John Shine, Director of Commercial Practices, National Consumer Agency.*

**E Mail Address:** [john.shine@nca.ie](mailto:john.shine@nca.ie)

#### **1. Objective :**

The market surveillance plan has been developed to ensure, insofar as it is feasible within existing organisational arrangements and resource constraints, that the National Consumer Agency (NCA) fulfils its role as the competent authority in Ireland for the market surveillance of non-food consumer products under the following European Directives:

- General Product Safety Directive 2001/95/EC
- Low Voltage Directive 73/23/EEC as amended
- Toy Safety Directive 88/378/EEC
- Personal Protective Equipment Directive 89/686/EEC as amended
- Gas Appliances Directive 90/396/EEC.

#### **2. Structure and Responsibilities :**

Market surveillance activity under this plan will be undertaken by authorised officers within the product safety unit of the NCA.

In addition to market surveillance responsibilities, the NCA is also the National contact point for the EU RAPEX system (a rapid alert system facilitating the exchange of information between EU product safety authorities in relation to unsafe consumer products).

#### **3. Organisation :**

##### **a. Human Resources :**

The product safety unit has a staff complement of 7 authorised officers and has responsibility for market surveillance, RAPEX follow-up and investigation of product safety complaints.

##### **b. Technical Resources :**

The unit keeps up to date on best practice at EU level and regularly attends meetings and workshops. The unit can call upon relevant external expertise as required e.g. in the assessment and testing of products. The unit also works closely with other regulatory bodies and participates in the National Market Surveillance Forum. The unit has direct access to an in-house Legal advisor, if required.

**c. Financial Resources :**

All activities are financed from the annual budget allocated to the NCA.

**4. General Monitoring Approach :**

**a. Proactive inspections :**

The NCA is an active participant in the European PROSAFE network (forum for market surveillance authorities). Current PROSAFE projects, involving market surveillance activity, relate to carbon monoxide / smoke alarms and cords / drawstrings on items of clothing.

**b. Reactive inspections :**

The NCA follows up and/or investigates complaints received directly from consumers via our helpline or from other channels (e.g. regulators, customs authorities). The NCA also responds to notifications received through the RAPEX system and follows up, as appropriate, with economic operators. Market surveillance activity is undertaken, as required, in support of this activity.

**5. Setting of Priorities :**

The NCA is actively involved in PROSAFE and participation in joint projects is considered depending on current priorities and available resources. Timeframes for such project activity, including the nature and extent of market surveillance, is agreed at PROSAFE level.

Other market surveillance activity is undertaken on a risk basis, and is informed by information received from various sources and complaints from the public. The NCA also co-operates closely with the Customs authorities and investigates consignments being imported into the State, where product safety concerns have arisen.

**6. Horizontal co-operation :**

The NCA engages with National authorities / regulators as required and is a member of the National Market Surveillance Forum, which is chaired by the Dept. of Jobs, Enterprise & Innovation. The NCA engages bilaterally with the European Commission (DG SANCO) and with the product safety authorities in other EU member states and participates in a variety of EU / PROSAFE fora.

**7. Time Period :**

The current plan is for the 2014 – 2015 period.

**8. Informing Undertakings :**

The NCA is in bilateral contact with economic operators in relation to specific product safety issues. A weekly product safety bulletin is issued to stakeholders. The NCA website ([www.consumerconnect.ie](http://www.consumerconnect.ie)) has a dedicated product safety area, which is updated with product recalls as they arise. Specific media activity / press releases / social media campaigns are undertaken for significant issues.

**9. Unsafe and un-compliant products :**

Economic operators have an obligation to notify the NCA when they become aware that a consumer product is unsafe and to take appropriate remedial measures, which may include removing unsafe products from sale and recalling / refitting product already sold.

The NCA notifies the European Commission and other Member States via the RAPEX system of product safety issues originating in Ireland. Similarly, the NCA follows up with domestic economic operators in relation to RAPEX notifications originating from elsewhere in the EU.

Where unsafe / non-compliant products have been found in the domestic market, the NCA follows up with the relevant economic operators to ensure that appropriate remedial action is being taken. The NCA has the power to direct an operator to remove the product from the market and failure to do so could result in prosecution. However, in the majority of situations, matters are progressed with the co-operation of business and the NCA does not usually have to resort to using its formal powers.