

***NATIONAL MARKET SURVEILLANCE
PROGRAMME***

2016

Luxembourg

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1. GENERAL MARKET SURVEILLANCE ORGANISATION AND INFRASTRUCTURE

In Luxembourg, several ministerial departments and public authorities are involved in market surveillance, in particular:

- Commissariat aux Affaires Maritimes (Maritime Affairs Authority),
- Institut Luxembourgeois de la Normalisation, de l'Accréditation, de la Sécurité et qualité des produits et services (ILNAS, Luxembourg Institute for Standardisation, Accreditation, and the Safety and Quality of Products and Services) - Market Surveillance Department,
- Ministère de l'Economie (Ministry of Economic Affairs),
- Ministère de la Santé (Ministry of Health) - Department of Health,
- Ministère de la Santé (Ministry of Health) - Pharmacy and Medicines Division,
- Ministère du Développement durable et des Infrastructures (Ministry of Sustainable Development and Infrastructure) - Environment Department,
- Ministère du Développement durable et des Infrastructures (Ministry of Sustainable Development and Infrastructure) - Department of Transport.

The roles of the market surveillance authorities in Luxembourg are presented on ILNAS's [Quality Portal](http://www.portail-qualite.public.lu/fr/securite-sante/surveillance-marche/index.html)¹.

1.1. Identification and responsibilities of national market surveillance authorities

ILNAS is a public body attached to the Ministry of Economic Affairs.

The ILNAS (Establishment) Act of 20 May 2008 made fundamental changes in the area of market surveillance in Luxembourg, bringing together several competences under a single body, ILNAS. This Act was repealed in 2014 and replaced by the [ILNAS \(Reorganisation\) Act of 4 July 2014](http://www.legilux.public.lu/leg/a/archives/2014/0135/a135.pdf#page=2)². Market surveillance, for which ILNAS is responsible, is carried out by the market surveillance department.

ILNAS's market surveillance department has, since June 2015, been certified in accordance with ISO 9001:2008 for its quality management system.

ILNAS's market surveillance department comprises:

- 11 officials who carry out market surveillance relating to the 25 areas of legislation specified in the ILNAS (Reorganisation) Act of 4 July 2014, as amended, and
- 3 officials who perform technical testing in the test laboratory of ILNAS's market surveillance department. These technical tests involve physical, electrical and mechanical testing under the following directives:

¹ Quality Portal: <http://www.portail-qualite.public.lu/fr/securite-sante/surveillance-marche/index.html>

² <http://www.legilux.public.lu/leg/a/archives/2014/0135/a135.pdf#page=2>

- Low Voltage Directive,
- Electromagnetic Compatibility Directive,
- Radio Equipment Directive,
- Toy Safety Directive.

The test laboratory does not offer services to the private sector. It is accredited in accordance with EN ISO/IEC 17025 for its 'Low Voltage' work.

1.2. Mechanisms for coordination and cooperation between national market surveillance authorities

In Luxembourg, national coordination falls within the remit of ILNAS's market surveillance department and involves:

- informing the European Commission of the national market surveillance programmes of the various competent authorities,
- being the point of contact between the competent national authorities for market surveillance and the European Commission,
- being the national point of contact for the European Union's rapid alert system, RAPEX, as well as of the general information support system, ICSMS.

A national committee has been set up to facilitate the national coordination of market surveillance. The committee meets about twice a year and is made up of representatives from the ministerial departments and public authorities listed in section 1 (General market surveillance organisation and infrastructure).

1.3. Cooperation between national market surveillance authorities and customs

ILNAS cooperates very closely with the customs authorities. This cooperation is key to the effective supervision of the placing on the market of products imported from third countries and thus helps to prevent dangerous and non-compliant products from entering, and freely circulating within, national territory and the European Union. To these ends, ILNAS and the customs authorities signed a cooperation agreement in 1998. This agreement was revised and updated in 2011.

Since 2013, ILNAS and the customs authorities have been using a joint electronic database for the exchange of information.

Customs inform ILNAS when, during their regular inspections, they find:

- a product which may not comply with the relevant legislation,
- a product not accompanied by the required administrative documents,

- a product not bearing the required markings,
- a product displaying false or misleading CE marking.

ILNAS then takes on the case, carries out the necessary checks and finally decides whether the product may be imported or not.

1.4. Rapid information exchange system (RAPEX)

ILNAS is Luxembourg's national contact point for the RAPEX system. It is in charge of sending RAPEX notifications to the European Commission.

ILNAS officials also monitor, among economic operators, products that have been the subject of a RAPEX notification. They act as necessary to prohibit the placing on the market of these products on national territory.

1.5. Information and Communication System on Market Surveillance (ICSMS)

ILNAS is also Luxembourg's contact point for the ICSMS. The ICSMS has been presented to the various competent national authorities. Its database contains information, accessible online, on product compliance for the authorities responsible for market surveillance. Most of the information comes from the monitoring activities carried out by the competent authorities.

The main benefits of the ICSMS are that it makes it possible:

- for the authorities responsible for market surveillance to exchange information and files efficiently,
- to avoid multiple analyses of the same product,
- to inform market surveillance authorities of dangerous and non-compliant products,
- to inform consumers of dangerous products.

It should be noted that ILNAS's electronic database is structured in such a way that information can be easily uploaded to the ICSMS. Via the ICSMS, ILNAS thus systematically shares the results of its examinations with the other competent authorities in EU Member States.

1.6. General description of market surveillance activities and relevant procedures

In general, the statutory tasks of each authority with market surveillance responsibilities are set out in the relevant legislation.

With a view to the proper management and performance of its statutory tasks, ILNAS:

- put in place, in 2014, a strategy which has been read and approved by the minister for economic affairs,
- has put in place a document on the functioning of its market surveillance department,
- has established an internal policy for ensuring that the decisions it takes concerning the strategy and functioning of its market surveillance department are appropriate,
- obtained certification, in June 2015, of its quality management system, in accordance with ISO 9001:2008. In this context, various procedures were put in place.

The market surveillance procedures applied by ILNAS are as follows:

- market surveillance by site visits,
- market surveillance following a communication from the customs authorities,
- urgent matters - public advice,
- internal and external laboratory,
- establishment of the National Market Surveillance Programme and of the national activity report,
- implementation of decisions taken,
- RAPEX notifications,
- safeguard clause notifications.

The main objective of ILNAS's market surveillance department is to act preventively. To this end, it raises awareness among economic operators that they should react only in cases of non-compliance. In the course of this work, ILNAS meets - where necessary - with relevant stakeholders (for example, economic operators, associations, federations).

The market surveillance department has factsheets on the legislation in relation to which ILNAS is the competent authority. These [factsheets](#)³ are published on ILNAS's Quality Portal.

Starting in March 2016, the market surveillance department also intends regularly to publish newsletters to inform and raise awareness among economic operators and consumers.

Officials in the market surveillance department check a product's conformity following:

- visits to economic operators' premises (proactive checks),

³ Quality Portal: www.portail-qualite.lu/fr/securite-sante/surveillance-marche/fiches-produits/index.html

- warnings received by an external party (for example, a Member State, a complaint from an economic operator, in the event of an accident, etc.),
- information obtained from the customs authorities.

In cases of non-compliance, officials may apply administrative measures or even take action under criminal law, as set out in the ILNAS (Reorganisation) Act of 4 July 2014, as amended.

When a non-compliant product which poses high risk is identified, ILNAS:

- informs the European Commission by RAPEX notification,
- publishes a [warning](#)⁴ on its Quality Portal,
- informs the Union Luxembourgeoise des Consommateurs (Luxembourg Consumers' Union),
- if necessary, informs the media.

1.7. General framework of cooperation with other Member States and non-Member States

Officials from ILNAS's market surveillance department participate in ADCO (administrative cooperation) meetings in order to exchange information and share good practice with the other EU Member States. They also participate in joint actions run at European level (e.g. PROSAFE joint actions and ADCO joint actions).

1.8. Evaluation of market surveillance actions and reporting

The market surveillance department's quality management system is certified in accordance with ISO 9001:2008. Within this framework, the following actions are carried out:

- the objectives, results and follow-up of activities are presented and audited once a year, along with the management of ILNAS, at the management review,
- the market surveillance department's procedures and administrative documents are regularly reviewed and if necessary amended.

The market surveillance department produces an annual activity report. This report is distributed to the Ministry of Economic Affairs and contains information on the activities carried out in the previous year.

1.9. Horizontal activities planned for the relevant period

The horizontal activities planned for this period are as follows:

⁴ Quality Portal: <http://www.portail-qualite.public.lu/fr/alertes/index.html>

- two market surveillance coordination meetings with the national committee,
- provision of training on the use of the ICSMS and of ILNAS's electronic database,
- bilateral meetings with the national market surveillance authorities in order to work more closely together (for example, by running national joint market surveillance campaigns, exchanging information).

2. MARKET SURVEILLANCE IN SPECIFIC SECTORS

The names and contact details of the authorities responsible for market surveillance in Luxembourg are set out below.

a. Commissariat aux affaires maritimes (Maritime Affairs Authority),

19-21, Boulevard Royal
L-2449 Luxembourg
Tel.: +352 2478 4453
Fax: + 352 299 140
E-mail: cam@cam.etat.lu
Website: <http://www.cam.etat.lu/>

b. ILNAS - Market Surveillance Department

1 Avenue du Swing
L-4367 Belvaux
Tel.: +352 247 74320
Fax: +352 247 94320
E-mail: surveillance@ilnas.etat.lu
Website: www.portail-qualite.public.lu

c. Ministère de l'Economie (Ministry of Economic Affairs)

19-21, boulevard Royal
L-2449 Luxembourg
Tel.: +352 2478 2478
Fax: +352 46 04 48
E-mail: info@eco.public.lu

d. Ministère de la Santé (Ministry of Health) - Department of Health

Allée Marconi - Villa Louvigny
L-2120 Luxembourg
Tel.: +352 247 85500
E-mail: info@ms.public.lu
Website: <http://www.ms.public.lu>

e. Ministère de la Santé (Ministry of Health) - Pharmacy and Medicines Division

Allée Marconi - Villa Louvigny
L-2120 Luxembourg
Tel.: +352 247 85605
E-mail: info@ms.public.lu

Website: <http://www.ms.public.lu>

f. Ministère du Développement durable et des Infrastructures (Ministry of Sustainable Development and Infrastructure) - Environment Department

1, avenue du Rock'n'Roll
L - 4361 Esch-sur-Alzette

Tel.: +352 40 56 56-1

E-mail: infos@aev.etat.lu

Website: <http://www.environnement.public.lu/>

g. Ministère du Développement durable et des Infrastructures (Ministry of Sustainable Development and Infrastructure) - Department of Transport

4, place de l'Europe
L-1499 Luxembourg

Tel.: +352 247 84400

E-mail: info@mt.public.lu

Website: <http://www.mt.public.lu/>

The detailed programme of activities for 2016 is given in a separate Excel file which has been sent to the European Commission.

2.1. Medical devices

Competent authority: Ministry of Health - Department of Health

2.2. Cosmetic products

Competent authority: Ministry of Health - Pharmacy and Medicines Division

2.3. Toys

Competent authority: ILNAS - Market Surveillance Department

2.4. Personal protective equipment

Competent authority: ILNAS - Market Surveillance Department

2.5. Construction products

Competent authority: ILNAS - Market Surveillance Department

2.6. Aerosol dispensers

Competent authority: ILNAS - Market Surveillance Department

2.7. Simple pressure vessels and pressure equipment

Competent authority: ILNAS - Market Surveillance Department

2.8. Transportable pressure equipment

Competent authority: ILNAS - Market Surveillance Department

2.9. Machinery

Competent authority: ILNAS - Market Surveillance Department

2.10. Lifts

Competent authority: ILNAS - Market Surveillance Department

2.11. Cableway installations

Competent authority: ILNAS - Market Surveillance Department

2.12. Noise emission by equipment for use outdoors

Competent authority: Ministry of Sustainable Development and Infrastructure - Environment Department

2.13. Equipment and protective systems intended for use in potentially explosive atmospheres

Competent authority: ILNAS - Market Surveillance Department

2.14. Pyrotechnic articles

Competent authority: ILNAS - Market Surveillance Department

2.15. Explosives for civil uses

Competent authority: ILNAS - Market Surveillance Department

2.16. Appliances burning gaseous fuels

Competent authority: ILNAS - Market Surveillance Department

2.17. Measuring instruments, non-automatic weighing instruments, prepackaged products and units of measurement

Competent authority: ILNAS - Market Surveillance Department

2.18. Electrical equipment under the EMC Directive

Competent authority: ILNAS - Market Surveillance Department

2.19. Radio and telecommunications equipment under the RTTE/RED Directive

Competent authority: ILNAS - Market Surveillance Department

2.20. Electrical equipment and appliances under the Low Voltage Directive

Competent authority: ILNAS - Market Surveillance Department

2.21. Electrical and electronic equipment under the RoHS, WEEE and Batteries Directives

Competent authority: Ministry of Sustainable Development and Infrastructure - Environment Department

2.22. Chemicals under the REACH regulation and the regulation on classification and labelling

Competent authority: Ministry of Sustainable Development and Infrastructure - Environment Department

2.23. Eco-design and energy consumption labelling; efficiency requirements for hot-water boilers fired with liquid or gaseous fuels

Competent authorities: Ministry of Economic Affairs and ILNAS - Market Surveillance Department

2.24. Labelling of tyres

Competent authority: ILNAS - Market Surveillance Department

2.25. Recreational craft

Competent authority: Maritime Affairs Authority

2.26. Marine equipment

Competent authority: Maritime Affairs Authority

2.27. Motor vehicles and tractors

Competent authority: Ministry of Sustainable Development and Infrastructure - Department of Transport

2.28. Non-road mobile machinery

Competent authority: Ministry of Sustainable Development and Infrastructure - Environment Department

2.29. Fertilisers

Competent authority: Ministry of Sustainable Development and Infrastructure - Environment Department

2.30. Other consumer products under the General Product Safety Directive

Competent authority: ILNAS - Market Surveillance Department

2.31. **Biocides**

Competent authority: Ministry of Sustainable Development and Infrastructure - Environment Department

2.32. **Labelling of textiles and footwear**

Competent authority: ILNAS and Ministry of Economic Affairs

2.33. **Crystal glass**

Competent authority: Ministry of Economic Affairs

2.34. **Packaging and packaging waste**

Competent authority: Ministry of Sustainable Development and Infrastructure - Environment Department

2.35. **Medicinal products for human use**

Competent authority: Ministry of Health - Pharmacy and Medicines Division

2.36. **Interoperability of the rail system**

Competent authority: Ministry of Sustainable Development and Infrastructure - Department of Transport

2.37. **Drug precursors**

Competent authority: Ministry of Health - Pharmacy and Medicines Division

2.38. **Export and import of hazardous chemicals**

Competent authority: Ministry of Sustainable Development and Infrastructure - Environment Department

ANNEX: PRODUCT SECTOR REFERENCE LIST

Product sectors	Relevant legislation
1. Medical devices (including <i>in vitro</i> diagnostic medical devices and active implantable medical devices)	Directives 93/42/EEC, 98/79/EC and 90/385/EEC
2. Cosmetic products	Regulation (EC) No 1223/2009
3. Toys	Directive 2009/48/EC
4. Personal protective equipment	Directive 89/686/EEC
5. Construction products	Regulation (EU) No 305/2011
6. Aerosol dispensers	Directive 75/324/EEC
7. Simple pressure vessels and pressure equipment	Directives 2009/105/EC and 97/23/EC, Directives 2014/29/EU and 2014/68/EU
8. Transportable pressure equipment	Directive 2010/35/EU
9. Machinery	Directive 2006/42/EC
10. Lifts	Directive 1995/16/EC - Directive 2014/33/EU
11. Cableway installations	Directive 2000/9/EC
12. Noise emission by equipment for use outdoors	Directive 2000/14/EC
13. Equipment and protective systems intended for use in potentially explosive atmospheres	Directive 1994/9/EC - Directive 2014/34/EU
14. Pyrotechnic articles	Directive 2007/23/EC - Directive 2013/29/EU
15. Explosives for civil uses	Directive 93/15/EEC - Directive 2014/28/EU
16. Appliances burning gaseous fuels	Directive 2009/142/EC
17. Measuring instruments, non-automatic weighing instruments, prepackaged products and units of measurement	Directives 2004/22/EC and 2009/23/CE, Directives 2014/32/EU and 2014/31/EU, Directives 2007/45/EC, 75/107/EEC and 76/211/EEC, Directive 80/181/EEC
18. Electrical equipment under the EMC Directive	Directive 2004/108/EC - Directive 2014/30/EU
19. Radio and telecommunications equipment under the RTTE/RED Directive	Directive 1999/5/EC - Directive 2014/53/EU
20. Electrical equipment and appliances under the Low Voltage Directive	Directive 2006/95/EC - Directive 2014/35/EU
21. Electrical and electronic equipment under the RoHS, WEEE and Batteries Directives	Directives 2011/65/EU, 2002/96/EC and 2006/66/EC
22. /A Chemicals under the REACH regulation and the regulation on classification and labelling	Regulations (EC) Nos 1907/2006 and 1272/2008

22. /B Other chemicals (detergents, paints, persistent organic pollutants, fluorinated greenhouse gases, substances that deplete the ozone layer, etc.)	Regulation (EC) No 648/2004, Directive 2004/42/EC, Regulation (EC) No 850/2004, Regulation (EC) No 842/2006 and Regulation (EU) No 517/2014, Regulation (EC) No 1005/2009
23. Eco-design and energy consumption labelling; efficiency requirements for hot-water boilers fired with liquid or gaseous fuels	Directives 2009/125/EC and 2010/30/EU; Directive 1992/42/EEC
24. Labelling of tyres	Regulation (EC) No 1222/2009
25. Recreational craft	Directive 1994/25/EC - Directive 2013/53/EU
26. Marine equipment	Directive 96/98/EC - Directive 2014/90/EU
27. Motor vehicles and tractors	Directive 2002/24/EC - Regulation (EU) No 168/2013, Directive 2007/46/EC, Directive 2003/37/EC - Regulation (EU) No 167/2013
28. Non-road mobile machinery	Directive 97/68/EC
29. Fertilisers	Regulation (EC) No 2003/2003
30. Other consumer products under the General Product Safety Directive (optional)	Directive 2001/95/EC
31. Biocides	Regulation (EU) No 528/2012
32. Labelling of textiles and footwear	Regulation (EC) No 1007/2011 and Directive 94/11/EC
33. Crystal glass	Directive 69/493/EEC
34. Packaging and packaging waste	Directive 94/62/EC
35. Medicinal products for human use	Directive 2001/93/EC [<i>recte</i> 2001/83/EC]
36. Interoperability of the rail system	Directive 2008/57/EC
37. Drug precursors	Regulation (EC) No 1277/2005 Regulation (EC) No 273/2004 Regulation (EC) No 111/2005
38. Export and import of hazardous chemicals	Regulation (EC) No 649/2012