

MINISTRY OF ECONOMIC AFFAIRS AND COMMUNICATIONS

***NATIONAL MARKET SURVEILLANCE
PROGRAMME***

2015

ESTONIA

On 9 July 2008 the European Parliament and the Council adopted Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (referred to below as 'Regulation 765/2008').

Article 18(5) of Regulation 765/2008 states that: 'Member States shall establish, implement and periodically update their market surveillance programmes. Member States shall draw up either a general market surveillance programme or sector specific programmes, covering the sectors in which they conduct market surveillance, communicate those programmes to the other Member States and the Commission and make them available to the public, by way of electronic communication and, where appropriate, by other means. The first such communication shall be effected by 1 January 2010.'

This document has been drawn up to meet the obligation laid down in Article 18(5).

The document was drawn up by the Ministry of Economic Affairs and Communications in cooperation with the Consumer Protection Board, the Technical Surveillance Authority, the Maritime Administration, the Health Board, the Labour Inspectorate, the Environmental Inspectorate and the Agricultural Board.

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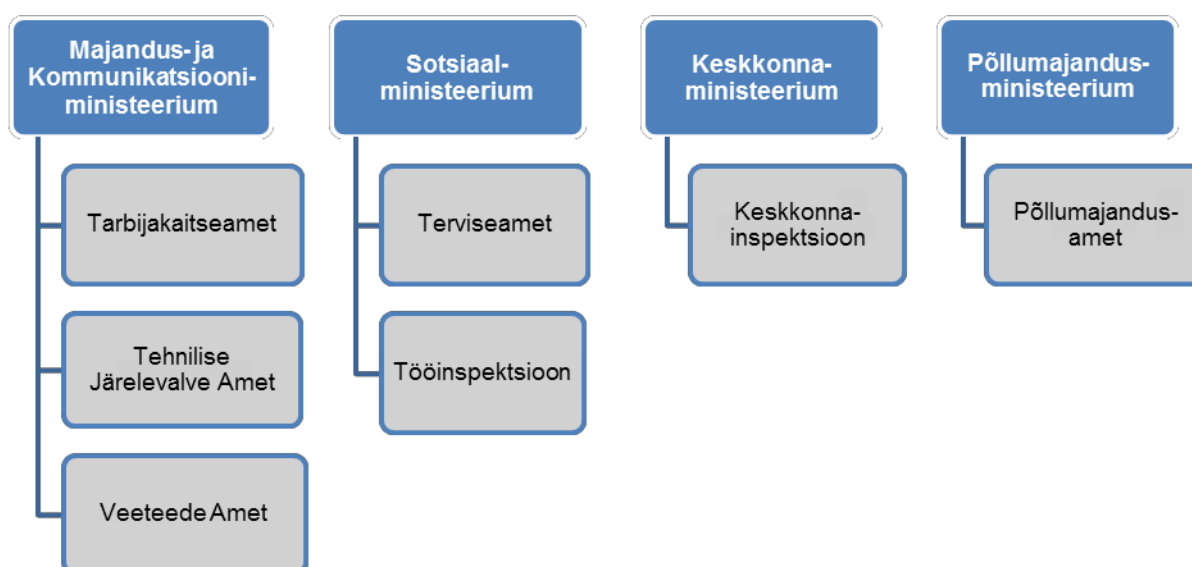
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1 General market surveillance organisation and infrastructure

1.1 Identification and responsibilities of national market surveillance authorities

The principles of market surveillance in relation to the marketing of products are set out in [Regulation \(EC\) No 765/2008](#) and the [Product Conformity Act](#).¹ Market surveillance authorities and the allocation of functions of the authorities are established by law, to which cooperation agreements between the authorities themselves are added. Surveillance is carried out on a sectoral basis in Estonia. The market surveillance of products is carried out by 7 authorities in Estonia: the Consumer Protection Board, the Health Board, the Technical Surveillance Authority, the Labour Inspectorate, the Maritime Administration, the Environmental Inspectorate and the Agricultural Board.

Market surveillance authorities by the areas of government of ministries are the following:



Ministry of Economic Affairs and Communications	Ministry of Social Affairs	Ministry of the Environment	Ministry of Agriculture
Consumer Protection Board	Health Board	Environmental Inspectorate	Agricultural Board
Technical Surveillance Authority	Labour Inspectorate		
Maritime Authority			

Consumer Protection Board

The [Consumer Protection Board](#) is a government authority within the area of government of the Ministry of Economic Affairs and Communications. It has management functions, conducts state surveillance on the consumer market and exercises the enforcement powers of

¹ Market surveillance is a type of state supervision and is also subject to the Administrative Procedure Act, the Law Enforcement Act, etc.

the state on the bases and to the extent laid down by law.

The mission of the Consumer Protection Board is to harness the law and awareness in order to protect consumers' interests. The main functions of the Consumer Protection Board are:

- to conduct market surveillance on the consumer market to ensure that the goods and services sold are safe and to protect consumers' economic interests by strengthening their position on the market;
- to advise consumers and raise their awareness by organising training and drawing up and distributing information material;
- to resolve consumer complaints with the involvement of the various parties and ensuring the impartiality of the procedure.

The bases for the operations and competence of the Consumer Protection Board are Section 17 of the [Consumer Protection Act](#), the Statutes of the Consumer Protection Board, and the surveillance obligations and rights of a body conducting extra-judicial proceedings, as laid down in the relevant Acts.

The aim of the market surveillance conducted by the Consumer Protection Board is a well-functioning consumer market where safe goods and services are sold to consumers for their intended use, where there is healthy competition and where economic operators take account in their operations of consumers' lawful economic interests.

The main function of the Market Surveillance Department of the Consumer Protection Board is to conduct surveillance and checks of goods and services sold on consumer markets in respect of the requirements arising from the legislation regulating the field of consumer protection, to review and assess from the consumer's perspective the terms and conditions of standard contracts concluded with consumers, to advise consumers and economic operators, to make proposals for legislation to be adopted or amended, to participate in cooperation at both the national and international level, etc.

The Department is divided into four divisions: the Trade Division, the Finance and Communications Division, the Tourism and Advertising Division and the Consumer Service Division. In addition to the head of department and the 4 heads of the divisions, there are 11 senior inspectors, 25 lawyers, 7 experts and 1 senior specialist working in the Department.

In the most general terms, the surveillance carried out by the Consumer Protection Board is targeted at the products and services sold on the consumer market, both their safety and their conformity to contract terms and conditions (quality), the information provided about the goods and services, including information about the price, and advertising and marketing measures in general. In addition to carrying out surveillance to verify compliance with the requirements laid down in the Consumer Protection Act, the Product Conformity Act, the [Trading Act](#) and the [Law of Obligations Act](#), the Consumer Protection Board also monitors compliance with the requirements laid down in the [Tourism Act](#), the [Metrology Act](#), the [Tobacco Act](#), the [Packaging Act](#), etc.

The Consumer Protection Board is also the Estonian contact point and competent authority for the RAPEX rapid alert system for dangerous goods.

The compliance of goods and services, including their safety, is the responsibility of the Trade Division of the Market Surveillance Department. The personnel of the Trade Division is the following:

- Head of Division — 1
- Senior Expert — 1
- Lawyers — 5

- Experts — 5
- Senior Inspectors — 9

The 2015 budget of the Consumer Protection Board is about EUR 1.79 m. The estimated annual expenditure on wages per employee of the Trade Division is about EUR 18 500. The planned testing costs for 2015 are EUR 20 000 (1.1 % of the budget).

Technical Surveillance Authority

The [Technical Surveillance Authority](#) is a government authority within the area of government of the Ministry of Economic Affairs and Communications. It has management functions, conducts state surveillance and exercises the enforcement powers of the state on the bases and to the extent laid down by law.

The Technical Surveillance Authority carries out market surveillance primarily to verify compliance with the requirements laid down for the following products and equipment:

- construction products;
- radio equipment and telecommunications terminal equipment;
- electrical equipment;
- appliances burning gaseous fuels;
- machinery;
- measuring instruments;
- pressure equipment, aerosol dispensers;
- lifts, cableways;
- explosives for civil uses, pyrotechnics.

The Technical Surveillance Authority also carries out market surveillance in respect of compliance with the following requirements:

- hazardous substance content in electrical and electronic equipment;
- noise emissions for outdoor equipment;
- equipment and protective systems intended for use in potentially explosive atmospheres;
- eco-design of energy-related products;
- energy labelling of equipment.

Maritime Administration

The [Maritime Administration](#) is a government authority within the area of government of the Ministry of Economic Affairs and Communications. It has management functions, conducts state surveillance and exercises the enforcement powers of the state on the bases and to the extent laid down by law.

The Maritime Administration has the rights and responsibilities of a market surveillance authority in respect of products under the Product Conformity Act and the [Maritime Safety Act](#):

- recreational craft;
- partly completed recreational craft;
- components.

The objective of the market surveillance executed by the Maritime administration is to ensure that the recreational craft put into use are compliant with the relevant safety, health, environmental and consumer protection requirements as well as to ensure the protection of the internal market.

Health Board

The [Health Board](#) is a government authority within the area of government of the Ministry of Social Affairs. It has management functions, conducts state surveillance and exercises the enforcement powers of the state on the bases and to the extent laid down by law.

The objective of the Health Board's operations is to implement public health policy aimed at promoting and improving a healthy living and learning environment and focusing on high-quality health protection and healthcare services in the fields of healthcare, health protection, chemical safety and medical devices.

The main function of the Board is to perform, within the scope of its legal functions, a management function and carry state supervision to verify the fulfilment of the requirements of the legal acts that regulate the areas of activity of the Board and to exercise the enforcement powers of the state where these requirements are violated.

The areas of activity of the Board are the following: healthcare; monitoring and epidemic control of infectious diseases; environmental health; chemical safety; and medical device safety.

The Health Board is the competent authority in the following sectors:

- chemical safety;
- biocides;
- cosmetics;
- medical device safety.

The main tasks of the Chemical Safety Department are to fulfil the functions of the competent authority in the sector of chemicals, including biocides and detergents, and cosmetics, to organise activities related to product safety and to plan and coordinate appropriate state surveillance.

The main tasks of the Medical Devices Department are to restrict or suspend the distribution or use of non-compliant medical devices; to maintain a database of medical devices, parties that place medical devices on the market, and risk events; to process risk events; to resolve disputes related to the classification of medical devices; to specify products; to analyse information collected about medical devices; and to assess the safety of medical devices.

The main tasks of the Surveillance Department are to coordinate and perform surveillance in all areas of activity of the Health Board. The Surveillance Department exercises state supervision in the sectors of chemical safety, biocides, cosmetics and medical devices.

The structure of the Health Board includes the Central Laboratory (comprised of the Laboratory of Communicable Diseases, the Laboratory of Chemistry and the Laboratory of Physics), the Tartu Laboratory and the Kohtla-Järve Laboratory. The core functions of the laboratories are bacteriological, virological, chemical and physical testing.

The number of employees in the Health Board, including the number of specialists directly involved in market surveillance and the number of inspectors, is provided in Table 1. The Health Board has 4 employees working in the medical devices sector, including 2 surveillance inspectors, and 9 employees in the chemicals and product safety sector, including 5 surveillance inspectors.

Table 1. Human resources	(2014)
Number of specialists directly involved in market surveillance in the medical devices sector	2

Number of inspectors of market surveillance of medical devices	2
Number of specialists directly involved in market surveillance in the chemicals and product safety sector	4
Number of inspectors of market surveillance of chemicals and product safety	5
Total	13

The budget of the Health Board was EUR 4 122 687.00 in 2015. The estimated annual expenditure on wages per inspector is about EUR 16 596.86. The Health Board plans to spend EUR 25 525.00 (0.62 % of the budget of the Board) on laboratory tests in the chemicals and product safety sector in 2015.

Labour Inspectorate

The [Labour Inspectorate](#) is a government authority within the area of government of the Ministry of Social Affairs. It conducts state surveillance and exercises the enforcement powers of the state on the bases and to the extent laid down by law.

The main functions of the Labour Inspectorate are the implementation of working environment policy; state supervision of the fulfilment in the working environment of the requirements of legal acts providing for occupational health and safety and labour relations; informing the public, employees and employers of hazards in the working environment; and the resolution of individual labour disputes in an extra-judicial labour dispute resolution body.

The Labour Inspectorate conducts market surveillance to verify that the safety and protective properties of personal protective equipment used in the workplace are ensured in the production and sale of the equipment.

The objective of surveillance is to prevent personal protective equipment that does not meet the requirements from being placed on the market and put into use. The basis for conducting surveillance is the Product Conformity Act and Minister for Social Affairs [Regulation No 64](#) of 29 September 2010 concerning safety requirements for personal protective equipment and the procedure for verifying conformity.

Environmental Inspectorate

The [Environmental Inspectorate](#) is a government authority within the area of government of the Ministry of the Environment. It coordinates and conducts surveillance relating to the use of the natural environment and natural resources, exercising the enforcement powers of the state in the cases laid down by law.

The main legal acts regulating environmental surveillance are the [Environmental Supervision Act](#) and [Law Enforcement Act](#). Legal provisions regarding the environment are laid down in the specific Acts covering each particular field, such as the [Waste Act](#), the [Ambient Air Protection Act](#) and the [Chemicals Act](#).

The Environmental Inspectorate conducts market surveillance regarding dangerous substances in problem products (batteries, motor vehicles and motor vehicle parts, electrical and electronic equipment and parts) and labelling of tyres.

Agricultural Board

The [Agricultural Board](#) is a government authority within the area of government of the Ministry of Agriculture. It has management functions, and it conducts state surveillance and

exercises the enforcement powers of the state on the bases and to the extent laid down by law in the fields of land improvement, plant protection, plant health, plant variety rights, seeds and plant propagating material, organic agriculture, fertilisers and horticultural products.

Under Section 2(6) of the [Fertilisers Act](#), the Agricultural Board is the competent authority for the purposes of Article 27 of [Regulation \(EC\) No 2003/2003](#) relating to fertilisers. The above legal acts set out the fundamental principles for regulating the fertilisers sector; they apply to fertilisers designated as ‘EC fertilisers’ and to the handling of such fertilisers. The market surveillance of fertilisers with the ‘EC fertilisers’ marking is carried out in accordance with Regulation 765/2008.

1.2 Coordination and cooperation mechanisms between national market surveillance authorities

A **Market Surveillance Council** has been formed under the Ministry of Economic Affairs and Communications to promote cooperation and the exchange of information between the authorities involved in market surveillance. The Council is composed of the representatives of all the authorities engaged in market surveillance, including the Tax and Customs Board, and the ministries of the respective areas of government. Some of the tasks of the Council are to make proposals regarding the strategic objectives for market surveillance, the development of activity priorities and the promotion of cooperation between the market surveillance authorities and the Tax and Customs Board.

Cooperation between the market surveillance authorities is based on cooperation agreements and other agreements as well as the efforts of the Market Surveillance Council.

The **Health Board** and the **Consumer Protection Board** have concluded a cooperation agreement to improve the results of controlling products on the internal market and to implement Regulation 765/2008. The cooperation agreement specifies the tasks, rights and obligations and provides the contact lists of responsible officials and the procedures for information exchange of both bodies. Information is exchanged on an ongoing basis all year round, and solutions to problems arising during inspections are discussed in meetings in order to improve cooperation, if necessary.

Furthermore, an expert working group for borderline products has been set up under the **Health Board**; the working group is composed of the representatives of various authorities (**the State Agency of Medicines, the Veterinary and Food Board, the Agricultural Board and the Consumer Protection Board**). The operation of the working group is organised according to the ‘rules of procedure for the expert working group for borderline products’. Agreements on the specifying of products are reached by email or by organising meetings if necessary. In 2014 (the first 10 months), a consensus was reached with regard to the identification of 41 products.

The **Agricultural Board** cooperates with the **Agricultural Research Centre**, which as an approved laboratory under Section 34(2) of the Fertilisers Act and Article 30 of Regulation (EC) No 2003/2003 conducts laboratory studies required for surveillance. The **Agricultural Board** also cooperates with the **Consumer Protection Board** and the latter is involved at the level of retail sale in ensuring control on the basis of the Consumer Protection Act.

A cooperation protocol has been concluded between the **Consumer Protection Board** and the **Technical Surveillance Authority**; the protocol defines the responsibilities and activities of the Board and the Authority in areas of overlapping surveillance competence to ensure the protection of the public from non-compliant products and services with maximum efficiency.

Cooperation between the bodies must ensure more coordinated and efficient surveillance and promote the development of a joint surveillance structure in overlapping areas. The areas of competence of the Technical Surveillance Authority and the Consumer Protection Board overlap in the sectors of telecommunications, construction and electrical safety, energy efficiency, pyrotechnics, machinery safety, legal metrology and railway. Given that the authorisations of the Authority and the Board for exercising state supervision in these sectors lack a precise definition on some points, the two bodies have agreed on a division of tasks in the areas where a precise definition of the competences of the bodies is absent.

The **Consumer Protection Board** has a close and effective cooperative relationship based on professional assistance with the **Tax and Customs Board**, the **Road Administration** and the **Police and Border Guard Board**, with which the Board has begun joint actions to organise the used cars sector. The **Consumer Protection Board** has a similar cooperative relationship to control areas of overlap with the **Rescue Board** (fireplaces, pyrotechnics, sky lanterns), the **Environmental Inspectorate** (tyres, waste equipment, etc.) and the **Labour Inspectorate** (personal protective equipment for consumers).

The **Technical Surveillance Authority** cooperates with the **Labour Inspectorate** in accident investigations. The most important cooperation partner for the Technical Surveillance Authority is the **Rescue Board**. The **Technical Surveillance Board** also cooperates with the **Environmental Inspectorate** and the **Estonian Association of Electrical Enterprises** in respect of the hazardous substance content in electrical and electronic equipment. Information is often exchanged during regular information days and the exchange of emails on an ad-hoc basis. Information requests are submitted to receive information, when necessary.

In addition to the above, the **Labour Inspectorate** also cooperates with the Health Board.

1.3 Cooperation between national market surveillance authorities and customs

Consumer Protection Board

In order to implement Regulation 765/2008, the Consumer Protection Board has concluded a cooperation agreement with the Tax and Customs Board to improve the effectiveness of controls to establish the safety of goods. The cooperation agreement specifies the tasks, rights and obligations and provides a contact list of responsible officials and a list of products to be checked for both bodies.

The cooperation agreement is accompanied by a Guide for Customs Checks of Product Safety in Cooperation with Market Surveillance Authorities, which is annexed to the agreement. The guide describes in detail the requirements, procedure and form of information exchange and the methods, processes, proceedings and elements of cooperation. Information is exchanged on an ongoing basis all year round and solutions to problems that arise during inspections are discussed in annual meetings of the surveillance authorities and the Tax and Customs Board in order to improve cooperation where necessary.

The Consumer Protection Board and the Tax and Customs Board exchange information concerning the following goods:

- children's products;
- toys;
- clothing and textile products;
- shoes;
- personal protective equipment for leisure purposes.

The Consumer Protection Board has the right to request information about the importing of goods belonging to the above categories. The requests are based on the codes of the combined nomenclature (CN) of goods. All customs officials have the right to consult the appropriate contact person in the Consumer Protection Board when customs formalities give rise to suspicions about the compliance of a product. The Consumer Protection Board informs the Tax and Customs Board, where necessary, about particular enterprises and CN codes that require more thorough checks before releasing the goods for free circulation.

If customs release for free circulation goods that require more thorough checks or customs formalities give rise to suspicions about the compliance of a product, customs implements control measures according to Regulation 765/2008. The Consumer Protection Board is immediately informed about the implementation of such measures. In the event of goods or cases that require more in depth checks, the objective of the check is separately agreed between the contact persons.

In the Consumer Protection Board, inquiries are made by the officials listed in the cooperation agreement. Information is exchanged according to the 'Guide for Customs Checks of Product Safety in Cooperation with Market Surveillance Authorities' prepared by the Tax and Customs Board. Information is generally exchanged by email. An official of the Tax and Customs Board consults with the contact person at the Consumer Protection Board by telephone or email. Notices of checks written on the form provided in the cooperation agreement are sent to the email address of the contact person of the Tax and Customs Board or the general email address of the Board.

In the first 11 months of 2014, the Tax and Customs Board received 48 notices of checks concerning 49 articles of goods withheld by customs (55 509 units in total).

- In 19 instances, the Consumer Protection Board made a decision to release for free circulation;
- in 27 instances, the Board prohibited the release for free circulation (toys, personal protective equipment);
- in 2 instances, the decision was not within the competence of the Consumer Protection Board (step counters, musical candles);
- in 1 instance, sample products were promised.

Technical Surveillance Authority

Regular inquiries and information exchange occur between the Technical Surveillance Authority and the Tax and Customs Board regarding product groups belonging in risk groups based on a risk analysis.

Health Board

In order to implement Regulation 765/2008, the Health Board concluded a cooperation agreement with the Tax and Customs Board in 2010 to improve the effectiveness of inspections that are designed in order to verify the safety of goods. The cooperation agreement specifies the tasks, rights and obligations, and it provides a contact list of responsible officials and a list of products to be checked for both bodies.

The cooperation agreement is accompanied by the Guide for Customs Checks of Product Safety in Cooperation with Market Surveillance Authorities, which is annexed to the agreement. The guide describes in detail the requirements, procedure and form of information exchange and the methods, processes, proceedings and elements of cooperation. Information is exchanged on an ongoing basis all year round and solutions to problems arising during

inspections are discussed in the annual meetings of the surveillance authorities and the Tax and Customs Board in order to improve cooperation where necessary.

Information about the following goods is exchanged:

- Chemicals;
- Biocides;
- Toys;
- Cosmetics;
- Detergents;
- Medical devices.

The Health Board has the right to request information about the importing of goods related to the categories of chemicals and product safety. The requests are based on the codes of the combined nomenclature (CN) of goods. All customs officials have the right to consult the appropriate contact person in the Health Board when customs formalities give rise to suspicions about the compliance of a product. The Health Board informs the Tax and Customs Board, where necessary, about particular enterprises and CN codes that require more in depth checks before releasing the goods for free circulation.

If customs releases for free circulation goods that require more in depth checks or customs formalities give rise to suspicions about the compliance of a product, customs implements control measures according to Regulation 765/2008. The Health Board is immediately informed about the implementation of such measures. In the event of goods or cases that require more in depth checks, the objective of the check is separately agreed between the contact persons.

In the Health Board, inquiries are made by the officials listed in the cooperation agreement. Information is exchanged according to the ‘Guide for Customs Checks of Product Safety in Cooperation with Market Surveillance Authorities’ prepared by the Tax and Customs Board. Information is generally exchanged by email. An official of the Tax and Customs Board consults with the contact person at the Health Board by telephone or email. Notices of checks written on the form provided in the cooperation agreement are sent to the email address of the contact person of the Health Board or the general email address of the Board.

In 2014 (9 months), the Health Board received:

- 79 notices of checks in the chemicals and product safety sector, concerning 362 articles of goods in total; 44 of these articles of goods have been released for free circulation; 35 articles were non-compliant and were not released for free circulation (55 204 products in total);
- 725 notices of checks in the medical devices sector; 6 were released for free circulation; 14 were non-compliant (and not released for free circulation); and in 1 instance the product did not qualify as a medical device.

Environmental Inspectorate

A cooperation agreement has been concluded between the Environmental Inspectorate and the Tax and Customs Board. According to the cooperation agreement, information exchange is based on risk analysis and aimed at giving an expert assessment of products assigned for customs inspection. There are no agreed procedures for information exchange.

Maritime Administration

The substantive and efficient exchange of information also occurs between the Maritime

Administration and the Tax and Customs Board, as necessary.

Agricultural Board

Cooperation between the Tax and Customs Board and the Agricultural Board is regulated by cooperation agreement No 1.1-2/3 of 15 February 2005. A new cooperation agreement has been drawn up and will be signed soon. Points 19 and 20 of the annex to the cooperation agreement make the following provisions:

19. When releasing goods for free circulation, a customs officer checks on the website of the Agricultural Board whether the fertiliser being imported is in the list of fertilisers entered in the fertilisers register.

20. A customs official does not release for free circulation products that are not in the list referred to in Point 19 and informs the fertilisers sector coordinator at the Agricultural Board (contact information available at <http://www.pma.agri.ee/index.php?id=105&sub=264#3200>) about the facts of the case.

Labour Inspectorate

The Tax and Customs Board also cooperates with the Labour Inspectorate in market surveillance.

1.4 RAPEX rapid information exchange system

The **Consumer Protection Board** is the Estonian contact point and one of the competent authorities for the RAPEX rapid alert system.

Consumer Protection Board, Rahukohtu 2, Tallinn 10130

RAPEX contact person: Milvi Paidra, phone (+372) 620 1712, Milvi.paidra@tarbijakaitseamet.ee

The Consumer Protection Board is responsible for notifying the European Commission about any restrictions to the placing on the market of a product, about measures taken (or intended) and special conditions prescribed by the measures. All market surveillance authorities are required to regularly exchange information with each other about dangerous products identified by them. This information must also be immediately forwarded to the Consumer Protection Board. The Health Board, the Technical Surveillance Authority and the Tax and Customs Board have appointed contact persons for this purpose. Information received from the European Commission is passed through these persons to a competent authority and a response is later received as feedback according to a defined time schedule.

For each notification received, a check is carried out to verify if the dangerous goods described are commercially available or not and the European Commission is notified of the results upon the expiry of an agreed deadline. If dangerous goods have been detected on the market, the sanctions and measures implemented in the given case will also be notified.

The Consumer Protection Board verifies the existence of the dangerous products described in the RAPEX reports on the Estonian market according to its competence and in line with the *guidelines for checking dangerous products based on RAPEX alerts*.

The guidelines require the employees of the Market Surveillance Department of the Consumer Protection Board to regularly examine the alerts and check the commercial availability of dangerous goods (toys, category I and II personal protective equipment, clothing, cosmetics, furniture, childcare products, lighters, lasers, etc.) in the process of conducting market surveillance. In the first 11 months of 2014, the officials of the Consumer

Protection Board checked the availability on the Estonian market of products notified in 1 536 RAPEX notifications on a total 1 202 occasions.

In the first 11 months of 2014, the European Commission notified:

- 1 885 products requiring urgent measures (under Article 12 of Directive 2001/95/EC on general product safety);
- 99 instances of products that did not present a serious risk but with regard to which Member States had taken measures to restrict their placing on the market;
- 142 informative notifications were received through RAPEX.

Alerts were received regarding toys, clothing and shoes, vehicles, electrical goods, childcare products, hobby and recreational goods, lighters, laser pointers, etc.). Of the notified goods, 33 products were found on the Estonian market.

Estonia in turn submitted 15 alerts during the 11 months:

- 11 notifications concerning dangerous toys;
- 2 notifications concerning cosmetics;
- 1 notification concerning a children's high chair;
- 1 notification concerning a wrist watch.

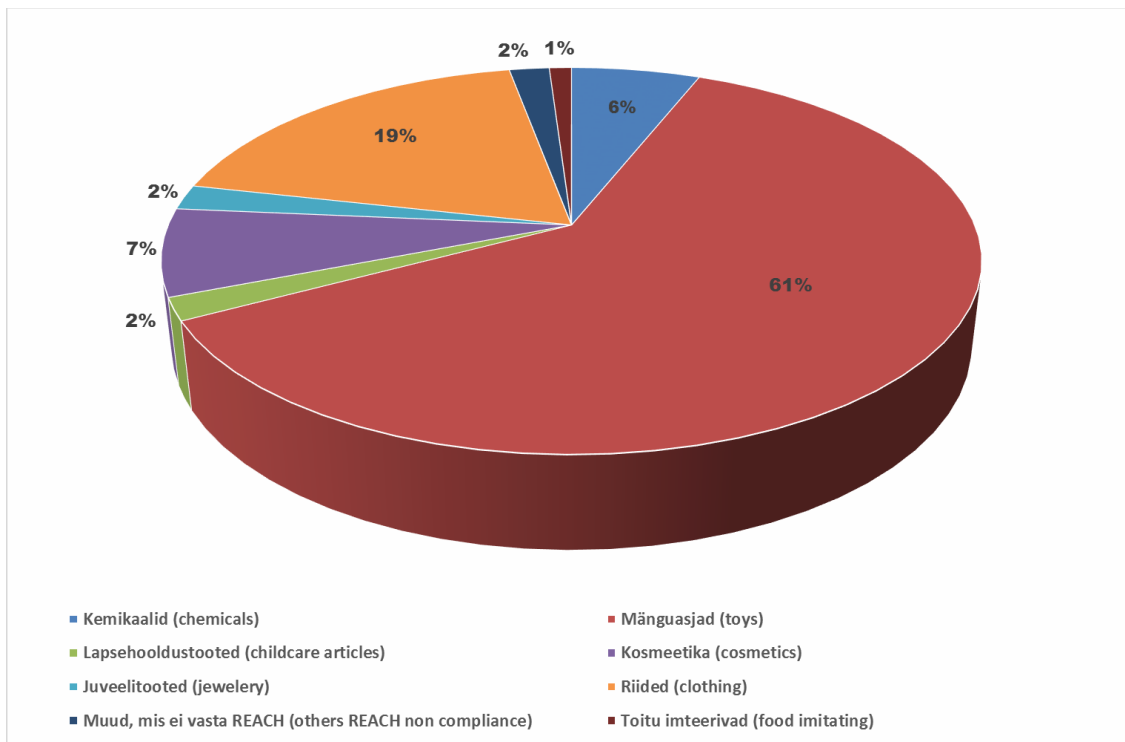
The Health Board discovered 15 and the Consumer Protection Board 5 of the above products. The toys, cosmetics and other products that were notified were declared dangerous by the Health Board and the traders were required by a precept of the Health Board or the Consumer Protection Board, respectively, to withdraw the dangerous products from the market and to inform consumers about the risks of using the products and the possibility of returning them to the point of sale.

The **Health Board** immediately notifies the RAPEX contact point of any dangerous product discovered in the process of market surveillance in accordance with the deadlines laid down in Part IV of Commission Decision of 16 December 2009 on guidelines for the management of the Community Rapid Information System RAPEX established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC. The notifications within the area of competence of the Health Board are sorted based on a notice received from other Member States, and the Health Board surveillance inspectors check the availability of the dangerous products on the Estonian market. The RAPEX contact point is informed about the results and a reaction to the European Commission is prepared.

The RAPEX contact point in the Health Board is the Head of the Chemicals and Product Safety Bureau of the Health Board. Contact details: Marina Karro, Paldiski tee 81, 10617 Tallinn. Email: Marina.Karro@terviseamet.ee; phone: 6 943 530

In the first 9 months of 2014, the Health Board processed 479 notifications received through RAPEX; the notifications were divided by type of product, as follows:

Figure 1. RAPEX notifications processed by the Health Board and product categorisation.



The **Technical Surveillance Authority** uses information from RAPEX, where necessary.

1.5 ICSMS information system

At national level, all market surveillance authorities in Estonia, except the Agricultural Board, have joined the ICSMS system and have access to it with data entry capability. Each market surveillance authority is responsible for data entry into ICSMS within its areas of competence.

The functions of the ICSMS national contact point are fulfilled by the **Ministry of Economic Affairs and Communications** (contact person: Piret Schasmin, piret.schasmin@mkm.ee, +372 625 6391). The ICSMS national administrator (user account administrator) is based at the **Technical Surveillance Authority** (Richard Saarman, Richard.Saarman@tja.ee).

The **Consumer Protection Board** has been using the ICSMS system as an additional source of information regarding possible dangerous products. Additionally, in 2015 the Consumer Protection Board is planning to introduce the use of ICSMS in reporting surveillance activities concerning non-compliant products, in keeping with national agreements among other things. The contact person at the Consumer Protection Board is Trade Division expert Milvi Paidra (Milvi.paidra@tarbijakaitseamet.ee).

The **Technical Surveillance Authority** has the most long-standing experience in using ICSMS (about 10 years). Each department of the Authority is separately responsible for data entry (each within its areas of competence). The Authority primarily uses ICSMS as a means of gathering information.

At the **Health Board**, ICSMS training events have been organised and accounts for inspectors opened. The ICSMS system has so far been used for notifying of cosmetics with serious undesirable effects and the RAPEX system has been used for entering information on dangerous products. In 2015, the Health Board is planning to fully introduce the use of ICSMS in reporting surveillance activities concerning non-compliant products.

The **Environmental Board** has the user rights to ICSMS. However, the Board currently enters all its inspection data in the national OKAS register, which means that the data are only reported in that register. The contact person at the Environmental Board is Rene Rajasalu (rene.rajasalu@kki.ee).

1.6 General description of market surveillance activities and relevant procedures

Consumer Protection Board

Regular market surveillance activities are based on an annual work plan, which takes into account the existing resources and needs. The work plan is prepared according to the obligations arising from legal acts and the principles of conducting market surveillance, the complaints received by the Board, the results of laboratory tests from previous years, information about cases of intoxication, information about dangerous products received through RAPEX and information about dangerous and non-compliant products published in the ICSMS system, joint projects being planned, the results of previous market surveillance inspections, etc.

The Consumer Protection Board therefore conducts its market surveillance activities based primarily on danger prognoses arrived at as a result of mapping its sectors of competence and the need for checks arising from these results; another basis is the need for checks arising from complaints.

Different methods of market surveillance are applied according to the nature of and need for a check. The inspectors check products organoleptically by visual observation and the mandatory documentation concerning the products; they take products to be tested, assess the

results of laboratory tests, decide on compliance or non-compliance with legal acts; they issue precepts requiring the removal of defects, the bringing into compliance of products and the informing of consumers if necessary, or apply legal sanctions if the precepts are not met. The Consumer Protection Board also cooperates with other market surveillance authorities: the Health Board, the Labour Inspectorate, the Technical Surveillance Authority, the State Agency of Medicines, the Environmental Inspectorate and the Tax and Customs Board.

The Consumer Protection Board informs the population about dangerous products withdrawn from the market on an ongoing basis through the website or through the Facebook account of the Board. Appropriate press releases and articles are prepared as necessary.

The Board regularly organises training days for businesses under the trademark 'Suunanäitaja' and, where necessary, also round tables and seminars for businesses and umbrella organisations to address particular shortcomings in surveillance.

The Product Conformity Act provides for penalties for misdemeanour (administrative penalties). The market surveillance authorities can also exercise administrative coercion (precepts, penalty payments and substitutive enforcement), which qualifies as public administration.

Penalties for misdemeanour only include fines. The largest penalty for misdemeanour is a fine of up to EUR 1 200 or EUR 3 200 for a legal person. Penalties are prescribed for violating the conditions of placing a product on the market and making it available on the market, for failure to inform about the dangers of a product and for misuse of a conformity mark.

The following principles are followed in imposing penalties:

- the principle of legality requiring that the activities of each official have a legal basis;
- the principle of publicity requiring that the law enforcement system function as transparently as possible;
- the principle of information requiring that the persons concerned be informed about ongoing proceedings;
- the principle of economy requiring a balance between expenses and result and the optimal use of resources.

Technical Surveillance Authority

The objective of the market surveillance conducted by the Technical Surveillance Authority is to ensure that the products placed on the market comply with requirements that guarantee the protection of the interest of the public at a high level: the health and safety of people, occupational health and safety, consumer and environmental protection and security. Market surveillance must ensure that products covered by Community harmonisation legislation which, when used in accordance with their intended purpose or under conditions that can be reasonably foreseen and when properly installed and maintained, are liable to compromise the health or safety of users or which do not conform in some other manner to the applicable requirements set out in Community harmonisation legislation are withdrawn from the market or their being made available to the public is prohibited or restricted and that the public, the Commission and the other Member States are informed accordingly.

Market surveillance is conducted on the basis of an approved internal prognosis of danger. Danger prognoses are prepared by taking into account the country of origin of the product, its availability/distribution, accidents that have occurred, technical defects discovered, the target group and other factors of importance from a surveillance point of view.

Surveillance operations include visual checks that the products are technically safe and

complete, that the required documentation exists (the declaration of conformity and installation guides, user manuals and maintenance instructions in Estonian) and that the labelling (including warning texts in Estonian) meets requirements. Tests to ascertain conformity to the requirements are commissioned from an approved laboratory where necessary. Products that do not meet requirements are not allowed to be released onto the market before their compliance has been verified. Any non-compliant products on the market are withdrawn from the market.

The complaints received are entered in the GoPro information system and processed according to the requirements laid down by law. Complaints can be submitted both electronically and on paper.

The circumstances of an accident are determined by initiating an appropriate investigation procedure. Information is collected by carrying out an on-the-spot inspection and questioning witnesses. National information systems (the map server of the Land Board, the commercial register, etc.) are also used for acquiring information. Internal cooperation is used where necessary to investigate accidents that cover different sectors. There is also information exchange with other authorities such as the Police Board and the Labour Inspectorate. Accidents are investigated in close cooperation with the alarm centre of the Rescue Board, which provides information about accidents. The Technical Surveillance Authority initiates, where necessary, an investigation procedure based on the information received from the alarm centre.

Dangerous products are notified on the website of the Authority, in local media (newspapers, television, radio, the Internet) and using special information campaigns (informative brochures, hoardings, etc. as well as mass media).

A penalty payment of up to EUR 9 000 can be imposed under an administrative proceeding. A misdemeanour procedure allows legal and natural persons to be penalised within the boundaries set out in special laws. The Technical Surveillance Authority is not authorised to carry out criminal proceedings. The monetary penalty rate is EUR 50 to 32 000.

Stakeholders are involved by organising regular information days, special meetings and consultations and administering the ohutus.ee information portal.

Health Board

A market surveillance authority may apply the special state supervision measures specified in Sections 30, 31, 32, 49, 50, 51 and 52 of the Law Enforcement Act in order to exercise state supervision provided for by law on the basis of and pursuant to the procedure established by the Act.

Regular market surveillance activities are based on an annual work plan, which takes into account the existing resources and needs. The work plan is prepared according to the obligations arising from legal acts and the principles of conducting market surveillance, the complaints received by the Board, the results of laboratory tests from previous years, information about cases of intoxication, information about dangerous products received through RAPEX and information about dangerous and non-compliant products published in the ICSMS system, joint projects being planned, the results of previous market surveillance inspections, etc.

Different methods of market surveillance are applied according to the nature of and need for a check. The inspectors check products organoleptically by visual observation and the mandatory documentation concerning the products; they take products to be tested, assess the results of laboratory tests, decide on compliance or non-compliance with legal acts; they issue

precepts requiring the removal of defects, the bringing into compliance of products and the informing of consumers if necessary, or apply legal sanctions if the precepts are not met. The Board prepares press releases about its surveillance and other activities and published articles in the media to warn consumers about buying, using or keeping dangerous products. The Board also cooperates with other market surveillance authorities: the Consumer Protection Board, the Labour Inspectorate, the State Agency of Medicines, the Environmental Inspectorate and the Tax and Customs Board.

The Health Board informs the population about dangerous products withdrawn from the market on the website of the Board at least once per quarter; from the website the information moves on into the media. Information on dangerous products withdrawn from the market is available on the information page at: <http://www.terviseamet.ee/kemikaaliohutus/toodetoohutus/turult-korvaldatud-ohtlikud-toodete.html>

Each year, the Health Board organises various information days and seminars engaging all interest groups. Representatives of different state authorities as well as those of domestic and foreign enterprises participate in the information days.

The Product Conformity Act provides for penalties for misdemeanour (administrative penalties). The market surveillance authorities can also exercise administrative coercion (precepts, penalty payments and substitutive enforcement), which qualifies as public administration.

Penalties for misdemeanour only include fines. The largest penalty for misdemeanour is a fine of up to EUR 1 200 or EUR 3 200 for a legal person. Penalties are prescribed for violating the conditions of placing a product on the market and making it available on the market, for failure to inform about the dangers of a product and for misuse of a conformity mark.

A monetary penalty for a criminal offence is up to 30 times 500 daily rates. The daily rate of monetary penalty is calculated by the court according to the average daily income of the convicted offender. The court may lower the daily rate due to exceptional circumstances or increase it based on the standard of living of the convicted offender. The calculated daily rate may be no less than the minimum daily rate. The minimum daily rate is EUR 3.20. The court may impose a monetary penalty of EUR 3 200 to 16 000 on a legal person.

A misdemeanour procedure is carried out according to the general part of the Penal Code and the Code of Misdemeanour Procedure. A criminal procedure led by the Prosecutor's office is applied to offences specified in Section 409 of the Penal Code. Penalties are imposed by a court.

Environmental Inspectorate

Checks are carried out according to a work plan approved by the Director General of the Inspectorate. Risk analysis is used in the preparation of the work plan but it is integrated with that of producer liability. Information is acquired by using the surveillance information of other states in the RoHS Enforcement Network. Goods seized in custom checks and provided by the Tax and Customs Board are also checked. No complaint procedure has previously been laid down as no direct complaints are received in this sector. There is no need to develop or implement measures for withdrawing prohibited goods from the market, because no non-compliant products have been discovered to date.

Complaints can be submitted to the Inspectorate by emailing at valve@kki.ee or calling 1313. The phone line works 24/7. The inspectorate is required to check within 14 days whether the reported incident shows elements of misdemeanour and to reply to the complainant within 30 days. All complaints are registered in the OKAS document management system.

The Inspectorate is authorised to initiate a misdemeanour procedure under the Waste Act and impose a fine of up to EUR 32 000 on an enterprise. The Inspectorate is also authorised to confiscate prohibited products under a misdemeanour procedure. The subsequent handling of such products is the responsibility of the county governor.

Maritime Administration

The main activity of the Administration is the verification of compliance of recreational craft imported to and produced in Estonia. The persons who produce recreational craft in Estonia must hold an activity licence in the relevant sector.

The main surveillance measure is the verification of the conformity of documents according to the following principles:

- verification is carried out at points of sale, premises of producers and boat fairs, using random checks;
- the compliance of products is verified using technical documentation if non-compliance is suspected;
- the document (certificate) is discussed with the issuer of the document (notified body); the Member State is notified through the CIRCABC system in the event of counterfeiting;
- in the case of a low-risk non-compliance, at first a precept is issued requiring the product to be brought into compliance;
- in the case of a non-compliance posing a significant risk, Article 7 of Directive 94/25/EC is followed;
- an ex-ante inspection of the product and documentation is carried out after the precept has been met (in both cases).

Inflatable boats and used motorboats imported from a third state are the most problematic product groups in the recreational craft sector. Products are checked according to Regulation 765/2008 in cooperation with the Tax and Customs Board.

A written precept with a warning of a penalty payment has proven effective when a non-compliance is discovered.

Labour Inspectorate

Surveillance to verify the compliance of personal protective equipment is generally carried out at the premises (shops) of the importer or distributor of the equipment. The compliance of the marking of the personal protective equipment produced or sold to wholesale and retail customers is verified, the product documentation presented is checked and the product compliance is visually assessed in the course of surveillance. Tests to ascertain conformity to the requirements are commissioned if necessary. If a danger product is discovered in the course of surveillance, its withdrawal from the market is demanded or requirements presented that would ensure the safety of the protective equipment being sold. In addition to precepts, penalty payments are applied where necessary. All surveillance results are entered in the information system of the Inspectorate (the ITI system). Information about the PPEs withdrawn from the market as a result of surveillance is published in the ICSMS database.

The scope and volume of market surveillance to be carried out is set out in the annual plan of the Inspectorate. The annual plan is based on the results of risk assessment and information gathered previously (the results of the surveillance activities of the last 3 years) and on an ongoing basis (complaints/tips received), and it takes into account existing resources. One of the inputs for the assessment of the need for surveillance are the results of checks of the working environment, in the course of which the compliance with safety requirements of

PPEs used by employees is verified and the appropriateness of the protective properties of the PPEs for the environment where they are used is assessed.

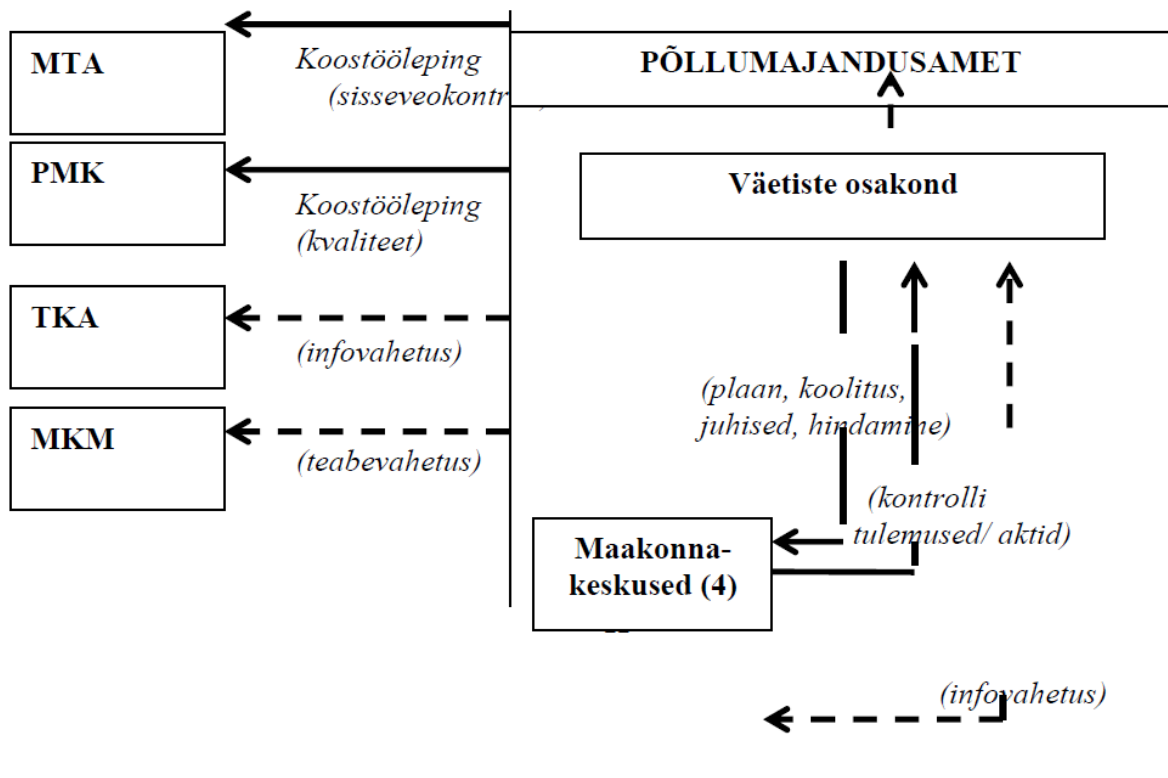
Agricultural Board

The main functions of the Fertilisers Department of the Agricultural Board are the following:

- ✓ organisation of surveillance of fertilisers and marketing thereof;
- ✓ maintaining the national fertiliser register;
- ✓ definition of the risks planning of surveillance in the sector;
- ✓ ensuring that inspectors are provided work instructions in carrying out inspection activities;
- ✓ organisation of lifelong learning and in-service training of inspectors and assessment of the carrying out of inspection activities;
- ✓ preparation of documents guidance notes on organisation of work;
- ✓ assessment of the compliance and effectiveness of surveillance carried out and planning of measures to improve the control system;
- ✓ participation in the work of the Market Surveillance Council.

The Department registers fertilisers and handlers of fertilisers and carries out other official activities provided for by law; it also carries out state surveillance in the sector. The surveillance covers control over the marketing-orientated production, packaging, marking, transporting to Estonia and marketing of fertilisers as well as the taking of samples to determine the quality and verify the compliance of fertilisers. Official control activities in the course of surveillance are generally carried by the inspectors of the Harju, Pärnu, Tartu and Lääne-Viru centres.

The work instructions for inspectors are provided in the inspection handbook for the fertilisers sector (last updated on 14 May 2013). An overview of the control system of the fertilisers sector is provided in Figure 2.



Tax and Customs Board	Cooperation agreement (control of import)	Agricultural Board	
Agricultural Research Centre	Cooperation agreement (quality)	Fertilisers Department	
Consumer Protection Board	(information exchange)		
Ministry of Economic Affairs and Communications	(information exchange)		
		(plan, training, instructions, evaluation)	
			(inspection results/reports)
		County centres (4)	
			(information exchange)

Figure 2. Control system of the fertilisers sector.

Risks and control priorities

The types and volumes of fertilisers marketed or produced by an enterprise as well as the functioning and effectiveness of the control system applied in the previous work period are taken into account in risk assessment, in setting control priorities and in carrying out control activities. Previous violations are also taken into account and the frequency of inspections is increased in enterprises with a higher risk level, if necessary. Detonable ammonium nitrate fertilisers of high nitrogen content make up a separate risk group.

By placing a large quantity of non-compliant fertiliser on the market, a wholesaler may cause economic damage to agricultural producers and a threat to the environment. The same kind of damage may be caused by a discrepancy between the content shown on a product label and its actual active substance content, which is among the most frequently identified violations.

A manufacturing enterprise must have a production process in place, as a result of which only compliant fertilisers are marketed. A producer must check product compliance regularly. The own checks system described above ensures the stable quality and compliance of the fertilisers produced, which in turn reduces fertiliser quality-related risks to the end consumer.

Risk level 3 — handlers of ammonium nitrate fertilisers of high nitrogen content; large wholesalers importing fertilisers from third countries to Estonia; producers of lime (ash).

Risk level 2 — handlers and producers of fertilisers with the 'EC FERTILISER' marking.
Risk level 1 — retailers of small quantities of fertiliser placed on the market in compliance with requirements.

Control priorities:

marketing of ammonium nitrate fertilisers of high nitrogen content;

- lime;
- correspondence of fertiliser composition to package labelling;
- compliance of fertiliser composition to applicable requirements;
- existence of a registry entry or 'EC FERTILISER' marking on the fertiliser;
- performance of producer own check obligations, preservation of required data and implementation of measures to prevent a non-compliant fertiliser from being placed on

the market.

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

Consumer Protection Board

The Consumer Protection Board actively participates in the activities of the ICPEN (International Consumer and Enforcement Network) and PROSAFE (Product Safety Enforcement Forum of Europe) international cooperation networks.

A representative of the Board is also a member of the GPSD (General Product Safety Directive) Committee and participates in the work of the CSN (Consumer Safety Network) cooperation network.

The Board is the Estonian contact point and one of the competent authorities for the RAPEX rapid alert system.

The Board is also the Estonian contact point for [Regulation \(EC\) No 2006/2004](#) or the Regulation on consumer protection cooperation and the competent authority in respect of most of the Directives covered by the Regulation.

The consumer protection boards of the Baltic States hold regular meetings (once a year). The cooperation is based on consumer protection cooperation agreements signed between the Estonian, Latvian and Lithuanian consumer protection boards. The annual meetings discuss currently important consumer protection-related questions that are shared by all participants and shared cross-border cases; an overview of the most important events and activities of the preceding period is given and possibilities for more effective cooperation are sought. The meetings usually divide into two blocks, one of which mainly discusses topics related to the economic interests of consumers, consumer contracts, advertisement and trading methods and the other which focuses more on market surveillance and product/service safety.

International cooperation in 2014

I In 2014, the Consumer Protection Board participated in the JA2012 surveillance cooperation project organised by PROSAFE and financed by the European Commission in respect of the following product groups:

- cords and drawstrings on children's clothing
- childcare products
- nanomaterials in cosmetics

II An official of the Board participated as the Estonian representative in the work of the 'Safety of products sold in e-commerce' sub-working group of the CSN.

III Officials of the Board have also participated in exchange of officials programmes financed by the European Commission; this year, they visited the market surveillance authorities in the UK to exchange experiences under the programme. Italian colleagues have visited the Board under the same programme.

International cooperation in 2015 — plans

Participation in the following cooperation projects:

- toys sub-working group of PROSAFE and the EU cooperation project (JA2013);
- ECHA — project for child-resistant fastenings of chemicals;
- OECD — e-commerce surveillance project (product safety);
- OECD information campaign on detergent gel capsules that are dangerous for

- children;
- cooperation project of the market surveillance authorities and customs of the Baltic States.

Sectoral cooperation mechanisms created for information exchange and cooperation are also described under sectoral cooperation.

Technical Surveillance Authority

The Technical Surveillance Authority cooperates with the surveillance authorities of all Member States if necessary. The Board also participates in sectoral working groups of the European Commission (ADCO); a regular meeting of the market surveillance authorities of the Baltic States is held once a year. Direct contacts for information exchange have been established with the market surveillance authorities of Finland and Sweden.

Health Board

International cooperation between Member States is being developed, including participation in joint project projects through the ECHA Forum, PEMSAC (*Platform of European Market Surveillance Authorities for Cosmetics*) and CLEEN (*Chemicals Legislation European Enforcement Network*) networks.

Information on dangerous products is exchanged through the RAPEX (*Rapid Alert System for non-food dangerous products*) and ICSMS (*The Internet-Supported Information and Communication System*) systems. Information on cosmetics placed on the market is available through the CPNP (*Cosmetic Products Notification Portal*) portal, which is continually used for surveillance purposes.

Environmental Inspectorate

The Inspectorate cooperates with other Member States through the RohS Enforcement Network and under 1222/2009 ADCO (regular meetings are held 1 and 2 times a year, respectively).

Maritime Administration

The Administration participates in a working group of the advisory committee on the Recreational Craft Directive (RCD ADCO) along with other Member States. Random joint checks of products in the sector are organised at boat fairs with colleagues from neighbouring countries (Finland in 2008, Latvia in 2009, Finland in 2011, Tallinn in 2012). Information on recreational craft market surveillance is exchanged with other Member States through the CIRCABC system. Separate annual meetings with the market surveillance representatives in the recreational craft sector of all three Baltic States have been held since 2012.

1.8 Evaluation of market surveillance actions and reporting

Consumer Protection Board: The Consumer Protection Board prepares a half year report, an 11 month report and a yearbook on the results of its work. The latter is published in full on the website of the Board. The reports and the yearbook describe both the activities in the work plan and outside it and provide assessments of the functioning of the various sectors as well as the changing of the situation compared to the previous reporting period. The main surveillance indicator is the extent of execution of the work plan.

Technical Surveillance Authority: Market surveillance statistics are gathered, analysed and forwarded to the Ministry of Economic Affairs and Communications (and the relevant report prepared) once a year. The information provided in the report of surveillance results serves as

a basis for the planning of future surveillance. The Authority published the surveillance results on its website and in its yearbook.

Health Board: Surveillance results are made available on the [Health Board website](#) annually. The surveillance indicator is the extent of execution of the work plan and the success rate of ad hoc studies.

Maritime Administration: Market surveillance measures and reports have been evaluated through the reports of the market surveillance programme.

Environmental Inspectorate: Measures are evaluated by the Environmental Protection Department of the Inspectorate; the Department is required to perform quality control of the work of the environmental inspectors.

Labour Inspectorate: The results of market surveillance are analysed twice a year and the surveillance results are published on the website of the Inspectorate as well as in an annual overview of the working environment.

Agricultural Board: At the beginning of each year, the report on the execution of the surveillance plan (available at <http://www.pma.agri.ee/download.php?getfile2=5233>) is prepared. Much attention is focused on the assessment of inspectors as well as activities.²

1.9 Horizontal activities planned for 2015

No reforms of the structure or organisation of market surveillance are planned for 2015 nor are there any other planned cross-sectoral activities to change or develop the functioning of market surveillance.

² The assessment of the effectiveness of work is organised by the head of the department that is responsible for the sector. The assessment covers the following: evaluation of knowledge acquired after the completion training; assessment of control activities at least once every three years and in the two first years of work of a new inspector by observing the inspector perform control activities on the spot; organisation of a re-check at the same enterprise immediately after inspection; written tests, resolution of sample cases, etc.

2 Market surveillance in specific sectors

2.1 Medical devices

2.1.1 *Responsible authority and contact details*

Health Board, Medical Devices Department, Põllu 1a, 50303 Tartu, Eesti e-mail: mso@terviseamet.ee, www.terviseamet.ee

Tagne Ratassepp — Head, phone: +372 744 7409, email: tagne.ratassepp@terviseamet.ee

Kristina Kübar — Chief specialist, phone: +372 744 7400, email: kristina.kubar@terviseamet.ee

The organisation and execution of surveillance in the medical devices sector is carried out by 2 chief specialists and 2 surveillance inspectors (in terms of a full-time equivalent) at the Health Board. The budget and expenditure on wages of the Health Board are provided in point 1.1.

Pursuant to the [Medical Devices Act](#), other legislation enacted on the basis of it and EU legislation, the Health Board carries out surveillance of the following:

- medical devices placed on the market (market surveillance);
- fulfilment of the requirements laid down for notified bodies and producers in the Act and the legislation enacted on the basis thereof;
- notification and investigation of risk events;
- organisation of clinical trials;
- in the event of a dispute over the categorisation of a medical device between producer and notified body;
- fulfilment of requirements laid down for health care providers regarding the profession use of a medical device.

2.1.2 *Market surveillance procedures and strategy*

The Medical Device Department is the leading, coordinating and advisory unit of the Health Board in the medical devices sector. The activities of the Department are directly related to current developments in the world and Europe in particular and amount to the organisation of medical devices-related market surveillance. The Department carries out surveillance of the fulfilment of the requirements laid down in the Medical Devices Act and sub-acts thereof. The Department aims to ensure that only safe and effective medical devices are represented on the European market thereby providing better protection of the health of the people of Estonia. Inspection-based surveillance and the processing of medical devices-related complaints is carried out by the Surveillance Department of the Health Board.

The Board has recently received a large number of complaints concerning glucometers for measuring the quantitative level of blood sugar in fresh capillary whole blood (including the markings of reactive strips). In 2015, emphasis is therefore placed on verifying the compliance of in vitro glucometers made available on the Estonian market. The objective of the market surveillance programme is to verify that the glucometers made available on the Estonian market and the reactive strips thereof comply with the applicable requirements. To this end, an overview of the devices on the Estonian market (devices that have been made available) must be acquired; samples obtained (from distributors for a reasonable price or for free); the existence of harmonised standards and requirements therein studied; cooperation partners among laboratories sought and devices tested according to the requirements laid down in the standard; and the resulting information assessed according to the relevant

requirements of Directive 98/79/EC on in vitro diagnostic medical devices. The programme may continue into the first half of 2016, as the volume of work is large and third parties have to be involved.

2.1.3 Report from activities carried out under the previous planning period

The 2014 medical devices market surveillance programme focused on verifying the existence of clinical evaluations of medical devices produced in Estonia or made available on the European market through Estonia and the compliance of the evaluations with applicable requirements.

The surveillance programme revealed that many products did not have a clinical evaluation although a clinical evaluation must be provided for all products placed on the market and put into service as medical devices (Section 16(1)(2) of the Medical Devices Act). Based on this information, all parties concerned were sent information and instructions on clinical evaluation and provision thereof. We required evaluations to be provided by the end of 2014. Producers and authorised representatives have been called upon to provide feedback and suggest amendments in order to improve the clinical evaluation instructions. The cooperative effort will hopefully lead to all the medical devices produced in Estonia having been provided with a clinical evaluation under the 2014 market surveillance programme. The inspection of producers and technical documentation, including the verification of the existence and assessment of the volume of a clinical evaluation, is also planned in cooperation with the Surveillance Department of the Health Board. As a result of the 2014 market surveillance programme, medical devices produced in Estonia or first made available on the EU market through Estonia should have a compliant clinical evaluation by the end of 2015. The producers and authorised representatives located in Estonia are familiar with the nature of a clinical evaluation and the methods for providing a clinical evaluation.

The specific surveillance activities of the Health Board in the medical devices sector are provided in Table 2. The Tax and Customs Board submitted notices about 25 medical devices, 14 of which were not allowed into circulation.

Table 2. Surveillance results in the medical devices sector (Directives 93/42/EEC, 98/79/EC and 90/385/EEC) for 9 months in 2014	
Total number of checks	67
Number of notices issued by the Tax and Customs Board	25
Total number of products checked	627
Total number of enterprises checked	67
Number of products tested	0
Number of non-compliant products	13
Number of products presenting a serious risk	-
Number of memoranda issued	24
Number of precepts issued	5
Number and total amount of penalty payments implemented	0
Number of substitutive enforcements implemented	0
Number of misdemeanour procedures	0
Fines imposed as a result of misdemeanour procedures	0
Number of articles/products withdrawn from the market	13

Number of products recalled from consumers	N/A
Number of voluntary measures taken by entrepreneurs	-

2.2 Cosmetics

2.2.1 Responsible authority and contact details

According to the Public Health Act and the competences of market surveillance authorities laid down in the cooperation agreement, the surveillance of cosmetic products is carried out by the **Health Board** and the **Consumer Protection Board**. The Health Board carries out inspections at the premises of responsible persons (producers/importers) and verifies the compliance of wholesale cosmetics. The Consumer Protection Board exercises surveillance of retail and verifies the compliance of labelling at service enterprises selling cosmetics to consumers.

Health Board, Paldiski tee 81, 10617 Tallinn, Eesti, email: kesk@terviseamet.ee
www.terviseamet.ee

Contact person: Natali Promet — Chief Specialist, phone: +372 6943533, email: natali.promet@terviseamet.ee

Consumer Protection Board, Rahukohtu 2, 10130 Tallinn, Estonia, email: info@tarbijakaitseamet.ee, www.tarbijakaitseamet.ee

Contact person: Jana Baljutis-Kütt — Chief Expert of Surveillance and Coordination, phone: +372 6201711, email: jana.baljutis-kytt@tarbijakaitseamet.ee

Health Board

The scope of the competence of the Health Board in the cosmetics sector is published on the website of the European Commission at: http://ec.europa.eu/consumers/safety/cosmetics/cooperation_and_trade/eu_level/docs/national_authorities_contacts-cosmetics_en.pdf

In the 2015 budget, EUR 12 624.20 is allocated for the testing of cosmetics. Tests are carried out by the Tartu Laboratory of the Health Board; information is available at <http://www.terviseamet.ee/en/laboratories/tartu-laboratory.html>

<http://www.terviseamet.ee/laborid/tartu-labor/analusid-ja-hinnad/kosmeetikatoodete-analusiid.html>

The organisation and execution of surveillance in the cosmetics sector is carried out by 1 chief specialist and 2 surveillance inspectors (in terms of a full-time equivalent) at the Health Board. The budget and expenditure on wages of the Health Board are provided in point 1.1.

Consumer Protection Board

The organisation and execution of surveillance in the cosmetics sector is carried out by 1 expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of 1.5 positions) at the Consumer Protection Board. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.2.2 Market surveillance procedures and strategy

Health Board

In the course of surveillance, the Board checks the implementation of requirements laid down in [Regulation \(EC\) No 1223/2009](#) of the European Parliament and of the Council on cosmetic products and [Commission Regulation \(EU\) No 655/2013](#), which lays down common criteria for the justification of claims used in relation to cosmetic products. Among other things, the

fulfilment of the obligation to notify of cosmetic products in the CPNP system, the meeting of the requirements for product files, including the existence of a safety report, fulfilment of the obligation to notify of a serious undesirable effect and the compliance of products with the applicable requirements for labelling and components, including the requirements on preservative, colourant and other restricted substance content are checked. Cosmetic products are laboratory tested if necessary, taking into account the possibilities and resources of laboratories.

Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products provides a basis for a unified approach in the European Community to notifying serious undesirable effects resulting from the use of cosmetic products. Data about a serious undesirable effect and an undesirable effect are part of a report on a cosmetic product. In the event of serious undesirable effects, the responsible person and distributors will notify without delay of the effect and any corrective measures taken to the competent authority of the Member State where the serious undesirable effect occurred. A web-based form for notifying of a serious undesirable effect resulting from the use of a cosmetic product is provided on the website of the Health Board at: <http://www.terviseamet.ee/kemikaaliohutus/toodete-ohutus/kosmeetikatoodete-tsm.html>

In 2014 (9 months), one case of a serious undesirable effect was handled and notified through the ICSMS system; the dangerous product was withdrawn and notified through the RAPEX system. The Health Board notified the Tax and Customs Board of the dangerous product and the importing of the product was banned on two subsequent occasions after laboratory tests.

In 2015, the Health Board will be involved in the following priority activities in the cosmetics sector in accordance with the 2014/2015 PEMSAC Work Programme:

- determining the existence of cosmetic products with serious undesirable effects on the market, the withdrawal of such products from the market and notification through the RAPEX and ICSMS;
- implementation of Article 23 of Regulation 765/2008 through the introduction of ICSMS;
- verification of cosmetic product claims on the basis of Regulation (EU) No 655/2013 for the purpose of submitting a report to the Commission;
- handling of cases of serious undesirable effect and checking of good manufacturing practices in the production of cosmetics;
- continued cooperation with the Consumer Protection Board and Tax and Customs Board according to the cooperation agreements.

The Tartu Laboratory of the Health Board is planning to extend its existing preservative identification capability (benzyl alcohol, 2-phenoxyethanol, 1-phenoxy-2-propanol, methylparaben, ethylparaben, propylparaben, isopropylparaben, butylparaben, isobutylparaben, benzylparaben) to the following substances: benzoic acid, sorbic acid and salicylic acid and their salts, as well as methylisothiazolinone, methylchloroisothiazolinone/Methylisothiazolinone, 3-iodo-2-propynyl butylcarbamate (IPBC).

Consumer Protection Board

In the course of surveillance, the Board checks the compliance of products with the requirements laid down in Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products and Commission Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products. Cosmetic products are checked in a laboratory if necessary, taking into account the

possibilities and resources of the Consumer Protection Board. The surveillance of e-shops selling cosmetic products is also performed.

The most prioritised activities in the cosmetic products sector in 2015 are the following:

- inspection of the labelling and Estonian-language information on cosmetic products;
- checking for publication of misleading and false information on cosmetic products;
- organisation of workshops on labelling of cosmetic products for problematic enterprises;
- continued cooperation with the Health Board according to the cooperation agreement.

Considering the positive test results in recent years, the Consumer Protection Board is not planning to test cosmetic products in 2015. A test will only be carried out, where necessary, if a complaint or other signal is received.

2.2.3 Report from activities carried out under the previous planning period

Health Board

The specific surveillance activities carried out by the Health Board in the cosmetics sector are provided in Table 3. There are a total of 218 objects, of which 8 were checked. The total number of checks is 92. A total of 15 producers, 18 importers and 47 distributors were checked. In the course of market surveillance, 1 032 cosmetic products were inspected, 201 of which were produced in Estonia. Laboratory testing was performed on 131 cosmetic products, 3 of which were non-compliant. The non-compliant products had been imported and failed to comply with requirements concerning chemical properties. A total of 24 memoranda and 3 precepts were issued in the cosmetics sector. Three (3) dangerous cosmetic products were notified through RAPEX (a total of 4 727 products were withdrawn from the market).

Table 3. Surveillance results in the cosmetics sector (Regulations (EC) No 1223/2009 and (EU) No 655/2013) for 9 months in 2014

Total number of checks	92
Number of notices issued by the Tax and Customs Board	34
Total number of products checked	1032
Number of products tested	131
Number of non-compliant products	93
Number of products presenting a serious risk	4
Number of memoranda issued	24
Number of precepts issued	3
Number and total amount of penalty payments implemented	0
Number of substitutive enforcements implemented	0
Number of misdemeanour procedures	0
Fines imposed as a result of misdemeanour procedures	0
Number of articles/products withdrawn from the market	3/4727
Number of products recalled from consumers	N/A
Voluntary measures taken by entrepreneurs	4

Consumer Protection Board

The specific surveillance activities performed by the Consumer Protection Board in the cosmetic sector by 1 December 2014 are provided in the table below. A total of 190 checks were carried out, 44.7% of which identified various violations. The most frequent violations concerned non-compliant labelling, the publication of unit prices and price information and

misleading information about cosmetic products. A total of 10 cosmetic products were tested, 1 of which did not comply with the requirements regarding Estonian-language labelling. The products were tested for formaldehyde content. The Board also participated in the Member States' joint programme 'Nanomaterials in cosmetic products' under PROSAFE. In the course of the joint project, the compliance of cosmetic products with the requirements concerning nanomaterials laid down in Article 16 of Regulation (EC) No 1223/2009 was verified. A total of 165 products were checked and 6 of these sent for testing. The inspection visits showed that only 4 of the products checked had been supplied with information (the word 'nano' after the component) indicating the use of nanomaterials. All other products lacked this information, although the lists of components showed the use of nanomaterials in the products. It is recommended that the size of nanomaterial particles be measured in the products taken for testing. The results have not been submitted to the Board to date.

Table 4. Surveillance results in the cosmetics sector (Regulation (EC) No 1223/2009 and Regulation (EU) No 655/2013) for 11 months in 2014

Total number of checks	190
Percentage of violations identified in checks	44.7%
Number of products tested	10
Number of non-compliant products	1
Number of products presenting a serious risk	0
Number of memoranda issued	1
Number of notices of administrative proceedings issued	13
Number of precepts issued	0
Number of misdemeanour procedures	0
Amount of fines imposed as a result of misdemeanour procedures	0
Number of complaints from consumers	20
Number of inquiries from consumers/entrepreneurs	80
Number of consultations over the consumer information line	139

2.3 Toys

2.3.1 Responsible authority and contact details

The surveillance of toys is carried out by the **Health Board** and the **Consumer Protection Board**. Pursuant to the Product Conformity Act and the competences of the surveillance authorities laid down in the cooperation agreement, the Health Board carries out the surveillance of the compliance of toys at manufacturing enterprises, importers and wholesale warehouses, while the Consumer Protection Board carries out the surveillance of retailing.

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Health Board

In 2015, EUR 6 953.00 of the budget of the Board is allocated for the testing of toys. The mechanical, physical and chemical properties of toys are determined at the Chemistry Laboratory and the Physics Laboratory of the Health Board. The organisation and execution of surveillance in the toys sector is carried out by 1 chief specialist (in terms of a full-time equivalent) and 1 surveillance inspector (in terms of a full-time equivalent of 0.5 positions) at the Health Board. The budget and expenditure on wages of the Health Board are provided in point 1.1.

Consumer Protection Board

The organisation and execution of surveillance in the toys sector is carried out by 1 expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of a 2 positions) at the Consumer Protection Board. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.3.2 Market surveillance procedures and strategy

Health Board

The plans for the coming year concerning the safety of toys are made based on the content of complaints received and surveillance results. RAPEX notifications and surveillance results of other Member States are also taken into account in planning. In 2015, the Board plans to continue the ad hoc study of the phthalate content in toys and childcare products and controls of the health security of babies' dummies and childcare products. The Board also plans to verify the compliance of the mechanical and physical properties and the sound pressure level of toys and to determine the lead, cadmium and chromium content of finger and face colourants and make-up products.

Consumer Protection Board

In the course of surveillance, the compliance of toys with the requirements set out in Minister of Economic Affairs and Communications Regulation No 57 of 3 September 2010 'Safety

Requirements for Toys and Procedure for Conformity Attestation of Toys' adopted in accordance with Section 5(4) of the Product Conformity Act is checked. Additionally, laboratory tests are performed according to the Board's danger prognosis, while taking into account the possibilities and resources of the Board. The surveillance of toys sold in e-shops is also carried out.

The most prioritised activities in the toys sector in 2015 are the following:

- Inspection of the labelling and Estonian-language information on toys — the focus is on the labelling of toys for children under 3 years of age, activity toys and toy weapons.
- Testing of toys for phthalate content, element migration and mechanical/physical properties (toys for children under 3). If necessary, testing based on signals from consumers, information received through RAPEX or the media.
- Participation in the PROSAFE JA2014 (toys) product safety programme.

2.3.3 Report from activities carried out under the previous planning period

Health Board

The specific surveillance activities carried out by the Health Board in the toys sector are provided in Table 5. There are a total of 41 examples in the safety of toys sector, 25 of which were checked. The total number of checks is 25. The number of objects checked in the course of monitoring (RAPEX notification, media, other information) is 23, including 1 producer, 5 importers and 15 distributors. In the course of market surveillance, 249 toys were inspected, 8 of which were produced in Estonia. Laboratory testing was performed on 32 toys, 4 of which were non-compliant. The non-compliant products had been imported and failed to comply with requirements concerning chemical properties. In 2014, 4 proposals were issued in the safety of toys sector.

Four (4) notifications concerning dangerous toys were reported in the RAPEX system. Of these, 3 articles of toys were deemed dangerous due to mechanical and physical properties and 1 due to chemical properties. A total of 276 toys were withdrawn.

There are a total of 14 objects in the babies' dummies sector, 9 of which were checked in 2014. The number of objects checked in the course of monitoring (RAPEX notification, media, other information) is 7, including 2 importers and 5 distributors. A total of 61 childcare products were checked in the course of market surveillance, of which 7 imported products were non-compliant.

Table 5. Surveillance results in the toys sector (Directives 2009/48/EC and 2001/95/EC and Regulation (EC) 1907/2006) for 9 months in 2014

Total number of checks	25
Number of notices issued by the Tax and Customs Board	0
Total number of products checked	249
Total number of enterprises checked	25
Number of products tested	32
Number of non-compliant products	3
Number of products presenting a serious risk	4
Number of memoranda issued	4
Number of precepts issued	0
Number and total amount of penalty payments implemented	0

Number of substitutive enforcements implemented	0
Number of misdemeanour procedures	0
Fines imposed as a result of misdemeanour procedures	0
Number of articles/products withdrawn from the market	4/276
Number of products recalled from consumers	N/A
Voluntary measures taken by entrepreneurs	4

Consumer Protection Board

The specific surveillance activities performed by the Consumer Protection Board in the toys sector by 1 December 2014 are provided in Table 6. A total of 302 checks were carried out, 61.9% of which identified various violations. The main violations were the non-compliance of labelling, the absence of a manual in Estonian and the sale of toys without a CE marking. A total of 32 toys were tested, 6 of which were shown to be dangerous (5 due to the phthalate content and 1 due to the sound pressure level). In 2014, the microbiology (in bubble solutions), sound pressure levels, small particle separation and phthalate content in toys were tested. The products that were shown to be dangerous have been withdrawn from the market as a result of the activities of the Board and the dangerous toys have been notified to other Member States through RAPEX. The Board issued press releases on the dangerous products and informed consumers on its Facebook page.

Table 6. Surveillance results in the toys sector for 11 months in 2014	
Total number of checks	302
Percentage of violations identified in checks	61.9%
Number of products tested	32
Number of non-compliant products	1
Number of products presenting a serious risk	6
Number of memoranda issued	10
Number of notices of administrative proceedings issued	12
Number of precepts issued	1
Number of misdemeanour procedures (in force)	6
Amount of fines imposed as a result of misdemeanour procedures	EUR 550
Number of complaints from consumers	57
Number of inquiries from consumers/entrepreneurs	94

2.4 Chemical substances under the REACH and CLP Regulations

2.4.1 Responsible authority and contact details

The Health Board is an authority coordinating surveillance of the fulfilment of the requirements of [Regulation \(EC\) No 1907/2006](#) (the REACH Regulation) and [Regulation \(EC\) No 1272/2008](#) (the CLP Regulation) in Estonia. State supervision of compliance with the requirements of the REACH and CLP Regulations regarding substances and mixtures and products containing them is carried out by the following market surveillance authorities in accordance with their competences:

- The Consumer Protection Board — surveillance of the fulfilment of the requirements applicable to the labelling and packaging of substances and mixtures under the REACH and CLP Regulations in retailing and the fulfilment of the restrictions applicable to the marketing and use of substances, mixtures and products under Annex XVII of the REACH Regulation in retailing.
- The Health Board — surveillance of the fulfilment of the requirements applicable to substances, mixtures and products under the REACH and CLP Regulations by the producers and importers thereof.
- The Labour Inspectorate — surveillance of the fulfilment of the requirements applicable to downstream users of substances and mixtures and requirements applicable to substances, mixtures and products under the REACH and CLP Regulations by downstream users.
- The Environmental Inspectorate — surveillance of the fulfilment of the registration and authorisation requirements applicable to substances, the provisions of the safety data sheets and the exposure scenarios described in the sheets as well as the meeting of restrictions related to health hazards, as provided for in the REACH Regulation; and the fulfilment of the labelling and packaging requirements and other relevant requirements on the treatment of chemicals hazardous to the environment under the CLP Regulation regarding the objects of surveillance within the area of competence of the Inspectorate.

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Health Board: The organisation and execution of surveillance in the chemicals sector is carried out by 1 chief specialist and 1 surveillance inspector (in terms of a full-time equivalent) at the Health Board. The budget and expenditure on wages of the Health Board are provided in point 1.1.

Consumer Protection Board: The organisation and execution of surveillance in the toys sector is carried out by 1 expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of 1 position) at the Consumer Protection Board. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.4.2 *Market surveillance procedures and strategy*

Health Board

The Board actively participates in the work of the ECHA Forum in order to improve the effectiveness of ECHA surveillance activities. The ECHA Forum coordinates the activities of the network of Member State authorities responsible for the enforcement of the REACH Regulation in order to facilitate the effective functioning of the system established with the REACH Regulation and to ensure good cooperation in enforcement, coordination and information exchange between Member States, the ECHA and the Commission.

In 2015, the focus will be on checking the fulfilment of the obligations of producers, importers and downstream users, including the registration of substances and quality of safety data sheets. Special attention will be paid to checking certain substances subject to authorisation. In order to gather information and gain experience in the enforcement of authorisation-related obligations, the Board cooperates with 16 Member States (AT, BE, BG, DK, DE, EL, FI, FR, HU, IE, IT, NL, PL, ES, SE, UK) under an authorisation project of the ECHA Forum. The target substances are MDA and musk xylene (the authorisation deadline is 21 August 2014).

Attention is focused on checking the fulfilment of the requirements on the labelling and packaging of mixtures in connection with the transition period in the application of the requirements of the CLP Regulation. As of 1 June 2015, mixtures must be classified, labelled and packaged according to the CLP Regulation. The relabelling and repackaging according to the CLP Regulation of mixtures classified, labelled and packaged according to Directive 1999/45/EC and placed on the market before 1 June 2015 will not be required until 1 June 2017. Under the 2015 pilot project of the ECHA Forum, focus will be placed on checking child-resistant fastenings, an activity performed by the Health Board and the Consumer Protection Board. The object of inspection is packaging containing a substance or mixture specified in section 3.1.1 of Annex II to the CLP Regulation. Article 35(2) of the CLP Regulation states that '[w]here the packaging contains a substance or mixture which meets the requirements in section 3.1.1 of Annex II it shall have a child-resistant fastening in accordance with sections 3.1.2, 3.1.3 and 3.1.4.2 of Annex II'.

Ad hoc studies are planned within the scope of the restrictions of Annex XVII to the REACH Regulation: phthalate content in children's products, dimethyl fumarate content in products and chromium VI content in leather products.

Chemical laboratory tests will be conducted by the Chemistry Laboratory of the Health Board, which meets the requirements of EVS-EN ISO/IEC 17025:2006 as a testing laboratory in the areas of water, air, materials and foodstuffs testing.

Consumer Protection Board

In the course of surveillance, the compliance of products with the requirements of the REACH and CLP Regulations is verified. Special attention is paid to the labelling of the products.

Under the 2015 pilot project of the ECHA Forum, focus will be placed on checking child-resistant fastenings, an activity performed by the Health Board and the Consumer Protection Board. The object of inspection is packaging (child-resistant fastening) containing a substance or mixture specified in section 3.1.1 of Annex II to the CLP Regulation.

During this period, some chemical products under the REACH and CLP Regulations have been tested at the laboratories of the Health Board. Considering the small number of negative

test results in recent years, the Consumer Protection Board is not planning to test chemicals in 2015. A test will only be carried out where necessary if a complaint or other signal is received.

2.4.3 Report from activities carried out under the previous planning period

The specific surveillance activities by the **Health Board** under the REACH and CLP Regulations in a 9-month period in 2014 are provided in Table 7. The total number of objects was 90, of which 43 were checked. The total number of checks is 60. The number of chemicals checked is 222, 56 of which were produced in Estonia. Laboratory testing was performed on 22 products, 1 of which was non-compliant. The non-compliant product was withdrawn from the market and the measures taken were notified to other Member States through RAPEX. A total of 15 memoranda were issued.

In 2014, the second stage of the third coordinated enforcement project (REF-3/II) was continued. The second stage of the REF-3 project was once again a project to check and enforce the registration requirement applicable to producers, importers and sole representatives under the REACH Regulation. However, in the second stage of the REF-3 project, attention was also focused on importers not subject to the registration obligation under REACH due to the fact that a sole representative has been assigned or it is a case of reimporting (persons subject to the obligation to register become importing downstream users). Additionally, information on the checks of importing downstream users and on enforcement was for the first time stored and collected in the second stage of the REF-3 project.

Table 7. Surveillance results in the chemicals sector (REACH and CLP Regulations) for 9 months in 2014	
Total number of checks	60
Number of notices issued by the Tax and Customs Board	14
Total number of products checked	222
Number of products tested	22
Number of non-compliant products	46
Number of products presenting a serious risk	1
Number of memoranda issued	15
Number of precepts issued	0
Number and total amount of penalty payments implemented	0
Number of substitutive enforcements implemented	0
Number of misdemeanour procedures	0
Fines imposed as a result of misdemeanour procedures	0
Number of articles/products withdrawn from the market	1/1
Number of products recalled from consumers	N/A
Voluntary measures taken by entrepreneurs	1

The specific surveillance activities performed by the **Consumer Protection Board** under the REACH and CLP Regulations by 1 December 2014 are provided in the table below.

A total of 127 checks were carried out, 47.2% of which identified various violations. The violations mainly concerned the absence of compliant labelling or provision of inadequate information, publication of unit prices and price information.

The tests covered 5 super glues, 2 of which were shown to be dangerous. The glues were tested for toluene, chloroform and benzene content and the products deemed dangerous were published in RAPEX.

Table 8. Surveillance results under the REACH and CLP Regulations for 11 months in 2014

Total number of checks	127
Percentage of violations identified in checks	47.2%
Number of products tested	5
Number of non-compliant products	0
Number of products presenting a serious risk	2
Number of memoranda issued	0
Number of notices of administrative proceedings issued	2
Number of precepts issued	0
Number of misdemeanour procedures (in force)	0
Amount of fines imposed as a result of misdemeanour procedures	EUR 0

2.5 Other chemicals (Detergents, Paints, Persistent Organic Pollutants, Fluorinated greenhouse gases, Ozone Depleting Substances, etc.)

2.5.1 Responsible authority and contact details

According to the Chemicals Act and the area of competence of the surveillance authority laid down in the cooperation agreement, the **Consumer Protection Board** carries out surveillance of the fulfilment of the requirements for the retail marketing of detergents. The **Health Board** carries out the surveillance of responsible persons (producers/importers) and wholesale.

Pursuant to the Ambient Air Protection Act, state supervision of the fulfilment of the requirement applicable to paints, varnishes and vehicle refinishing products containing volatile organic compounds is carried out by the Environmental Inspectorate, the Tax and Customs Board, the **Consumer Protection Board** and the **Health Board**. The Consumer Protection Board carries out surveillance of the fulfilment of the requirement applicable to paints, varnishes and vehicle refinishing products containing volatile organic compounds in retailing. The Health Board carries out surveillance of the fulfilment of the requirement applicable to paints, varnishes and vehicle refinishing products containing volatile organic compounds in wholesale.

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Health Board: The organisation and execution of surveillance of detergents and volatile organic compounds in paints, varnishes and vehicle refinishing products is carried out by 1 chief specialist and 1 surveillance inspector (in terms of a full-time equivalent) at the Health Board. The budget and expenditure on wages of the Health Board are provided in point 1.1.

Consumer Protection Board: The organisation and execution of surveillance in the chemicals sector is carried out by 1 expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of 0.5 positions) at the Consumer Protection Board. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.5.2 Market surveillance procedures and strategy

Detergents (Regulation (EC) 648/2004)

Health Board

In 2015, checks will be carried out regularly according to the work plan. The laboratory tests of allergenic odoriferous substances will be continued. According to the Detergents Regulation, allergenic odoriferous substances with a content exceeding 0.01 % of a detergent must be separately indicated on the label. The Health Board follows the requirements of [Regulation \(EC\) No 648/2004](#) of the European Parliament and of the Council in checking detergents. The following points are checked: the biodegradability of surfactants (primary and ultimate) as reported in the test results provided by the producer of a detergent; the submission of an ingredient data sheet compliant with Annex VII C of Regulation (EC) No 648/2004 to the Poison Information Centre; the meeting of restrictions on phosphates and

other phosphorous compounds in household laundry detergents and household dishwasher detergents; and the fulfilment of the general requirements on chemicals arising from the REACH and CLP Regulations (safety data sheets, classification, packaging and labelling, taking into account the specifications regarding labelling in the Detergents Regulation). In the course of surveillance, attention is paid to the possible applicability of legislation on biocides where disinfectants are concerned. Thanks to its participation in the [EuroDeter](#) project (CLEEN; 2011–2013), the Board has developed, in the course of its everyday work under the project, a methodology for carrying out checks.

Consumer Protection Board

The compliance of detergents with Regulation (EC) No 648/2004 is checked according to the work plan, and paying special attention to labelling. The Board has not carried out any tests in the detergents sector. Compliance with requirements is checked in the course of regular surveillance.

Volatile organic compounds in paints, varnishes and vehicle refinishing products (Directive 2004/42/EC)

Health Board

In 2015, checks will be carried out regularly according to the annual plan. Checks of volatile organic compounds in paints, varnishes and vehicle refinishing products mainly focus on checking the labelling. Thanks to the ad hoc study on ‘Volatile organic compounds’ conducted under a Ministry of the Environment project in 2012, a common [surveillance database](#) of volatile organic compounds is now used for entering surveillance results and reporting to the Commission.

Consumer Protection Board

The volatile organic compounds in paints, varnishes and vehicle refinishing products are checked to verify compliance with Regulation No 67 (Permitted limits of volatile organic compounds in paints, varnishes and vehicle refinishing products¹) established on the basis of Section 31(1) of the Ambient Air Protection Act. Checks are carried out as part of regular surveillance and mainly focus on the labelling of products. All inspection results are entered in the common surveillance database developed under the Ministry of the Environment project; the results are reported to the Commission based on the database.

The planned activities for 2015 include regular surveillance of detergents and surveillance of volatile organic compounds in paints, varnishes and vehicle refinishing products where necessary or according to priorities.

2.5.3 Report from activities carried out under the previous planning period

The specific surveillance activities carried out by the **Health Board** in the detergents sector are provided in Table 9. There are a total of 86 objects in the detergents and volatile organic compounds sector, 36 of which were checked in 2014 (9 months). The total number of checks is 47. In the course of market surveillance, 312 products were checked, 113 of which were produced in Estonia. Detergents were laboratory tested for odoriferous substances (19 components). Tests for allergenic odoriferous substances were carried out on 10 samples, all of which were compliant (the same allergenic odoriferous substances were shown on the label). A total of 21 memoranda were issued.

Table 9. Surveillance results in the detergents (Regulation (EC) No 648/2004, Directive 1999/45/EC and Regulation (EC) No 1272/2008), paints, varnishes and vehicle refinishing products sector (Directives 2004/42/EC and 1999/45/EC and Regulation (EC) No 1272/2008) for 9 months in 2014

Total number of checks	47
Number of notices issued by the Tax and Customs Board	2
Total number of products checked	312
Number of products tested	10
Number of non-compliant products	52
Number of products presenting a serious risk	0
Number of memoranda issued	21
Number of precepts issued	0
Number and total amount of penalty payments implemented	0
Number of substitutive enforcements implemented	0
Number of misdemeanour procedures	0
Fines imposed as a result of misdemeanour procedures	0
Number of articles/products withdrawn from the market	0
Number of products recalled from consumers	0
Voluntary measures taken by entrepreneurs	0

Consumer Protection Board

A total of 57 checks had been carried out by 1 December 2014, 22.8% of which identified various violations. The violations mainly concerned the absence of compliant labelling or provision of inadequate information, publication of unit prices. Volatile organic compounds in paints, varnishes and vehicle refinishing products were checked on 10 occasions; no violations were identified. No products were tested in this sector.

2.6 Biocides

2.6.1 *Responsible authority and contact details*

Surveillance of the fulfilment of the requirements applicable to biocides, products containing biocides and the making available on the market of these under the [Biocides Act](#) and the legislation based on it and [Regulation \(EU\) No 528/2012 of the European Parliament and of the Council](#) is carried out by the following authorities:

- **Health Board** — surveillance of the fulfilment of the requirements applicable to the making available of a biocide or a product treated with a biocide by the producer or importer of the biocide and in the wholesale of products; surveillance of the requirements applicable to biocides and the use of biocides by a professional pest control service provider and within the scope of application of the Public Health Act and the Health Care Services Organisation Act;
- **Consumer Protection Board** — surveillance of the fulfilment of the requirements applicable to the making available of a biocide or a product treated with a biocide in retailing.

The more specific details of surveillance in the biocides sector are provided in the cooperation agreements signed between the above authorities (the Health Board and the Consumer Protection Board; the Health Board and the Tax and Customs Board).

Health Board, Paldiski tee 81, 10617 Tallinn, Estonia, email: kesk@terviseamet.ee Contact person: Natali Promet — Chief Specialist, phone: +372 6943533, email: natali.promet@terviseamet.ee

Consumer Protection Board, Rahukohtu 2, 10130 Tallinn, Estonia, email: info@tarbijajakaitseamet.ee, www.tarbijajakaitseamet.ee

Contact person: Jana Baljutis-Kütt — Chief Expert of Surveillance and Coordination, phone: +372 6201711, email: jana.baljutis-kytt@tarbijajakaitseamet.ee

Health Board: The organisation and execution of surveillance of biocides is carried out by 1 chief specialist (in terms of a full-time equivalent) and 1 surveillance inspectors (in terms of a full-time equivalent of 0.5 positions) at the Health Board. The budget and expenditure on wages of the Health Board are provided in point 1.1.

Consumer Protection Board: The organisation and execution of surveillance of the biocides sector is carried out by 1 expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of 0.5 positions) at the Consumer Protection Board. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.6.2 *Market surveillance procedures and strategy*

Health Board

The Health Board works in close cooperation with the competent authority of the biocides sector in carrying out market surveillance. It also cooperates with other surveillance and control authorities on the basis of cooperation agreements.

In the biocides sector, the requirements are laid down in the Biocides Act and Regulation (EU) No 528/2012 of the European Parliament and of the Council, including the existence of a certificate of registration / permit, the use of active substances according to the intended use, the existence of information on poisonings and the general requirement for chemicals under the REACH and CLP Regulations (safety data sheets, classification, packaging and labelling,

taking into account the special requirements for the labelling of biocides laid down in the relevant legislation).

Pest control service providers are checked to verify the existence of a notice of economic activities for pest control, the appropriate profession qualifications of the responsible specialist and documentation of pest control.

In 2015, the Health Board is planning to participate in the Eurobiocides III project of the Chemical Legislation European Enforcement Network. The objective of the project is to check products treated with a biocide at the premises of producers or importers and in wholesale, while at the same time raising awareness about their obligations among the parties active in the supply chain.

Consumer Protection Board

In carrying out surveillance, the Consumer Protection Board cooperates with the Health Board in terms of exchanging information on the basis of the cooperation agreement. In the biocides sector, the labelling of products sold to consumers, the existence of registration numbers and other requirements arising from the Biocides Act and other relevant legislation are checked.

In 2015, the Board is planning to carry out scheduled surveillance activities in the sector and also monitor the sale of biocides in e-commerce.

2.6.3 Report from activities carried out under the previous planning period

The specific surveillance activities carried out by the **Health Board** in the biocides sector are provided in Table 10. There are a total of 62 objects in the biocides sector, 33 of which were checked. The total number of checks is 39. In the course of market surveillance, 119 products were checked, 23 of which were produced in Estonia. A total of 16 memoranda were issued. The Tax and Customs Board issued notices about 11 biocides, 10 of which were not allowed into circulation.

Table 10. Surveillance results in the biocides sector (Regulation (EU) No 528/2012 and Regulation (EC) No 1272/2008) for 9 months in 2014	
Total number of checks	39
Number of notices issued by the Tax and Customs Board	11
Total number of products checked	119
Number of products tested	10
Number of non-compliant products	44
Number of products presenting a serious risk	0
Number of memoranda issued	16
Number of precepts issued	0
Number and total amount of penalty payments implemented	0
Number of substitutive enforcements implemented	0
Number of misdemeanour procedures	0
Fines imposed as a result of misdemeanour procedures	0
Number of articles/products withdrawn from the market	0
Number of products recalled from consumers	0
Voluntary measures taken by entrepreneurs	0

The **Consumer Protection Board** had carried out a total of 22 checks by 1 December 2014, 31.8% of which identified various violations (Table 11). The main violations were the inadequate publication of unit prices and price information and inadequate or non-existent labelling. A notice of the initiation of an administrative proceeding was issued to two enterprises, which were involved in offering prohibited products for sale to consumers in e-commerce.

Table 11. Surveillance results in the biocides sector for 11 months in 2014.	
Total number of checks	22
Percentage of violations identified in checks	31.8 %
Number of products tested	0
Number of non-compliant products	0
Number of products presenting a serious risk	0
Number of memoranda issued	0
Number of notices of administrative proceedings issued	2
Number of precepts issued	0
Number of misdemeanour procedures (in force)	0
Amount of fines imposed as a result of misdemeanour procedures	EUR 0

2.7 Electrical and electronic equipment under the Restriction of Hazardous Substances Directive and Waste Electrical and Electronic Equipment Directive and batteries (problem products)

2.7.1 Responsible authority and contact details

The control of problem products is carried out by the **Environmental Inspectorate**, the **Technical Surveillance Authority** and the **Consumer Protection Board**.

Environmental Inspectorate, Kopli 76, 10416 Tallinn phone: 696 2236 fax: 696 2237 email: valve@kki.ee www.kki.ee

Contact person: Rene Rajasalu, Rene.Rajasalu@kki.ee, +372 53 421 035

Consumer Protection Board, Rahukohtu 2, 10130 Tallinn, Estonia, email: info@tarbijakaitseamet.ee, www.tarbijakaitseamet.ee

Contact person: Jana Baljutis-Kütt — Chief Expert of Surveillance and Coordination, phone: +372 6201711, email: jana.baljutis-kytt@tarbijakaitseamet.ee

Environmental Inspectorate: The exact figures cannot be submitted because the 2015 budget has not been approved yet. The technical equipment available to the Inspectorate includes an XRF device of the Estonian Environmental Research Centre, which allows non-destructive tests to be carried out.

Consumer Protection Board: The organisation and execution of surveillance of products of concern is carried out by 1 expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of 0.25 positions) at the Consumer Protection Board. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.7.2 Market surveillance procedures and strategy

Environmental Inspectorate

The objects and products to be subjected to surveillance in 2015 will be agreed in cooperation with the Ministry of the Environment. The sector to be controlled will be determined on the basis of the information received at the *RoHS Enforcement Network* meeting. The focus will predominantly be on IT equipment and other small electronic equipment (e-cigarettes and the batteries in them). As regards the placing on the market of a prohibited product, the Inspectorate will initiate a proceeding concerning a violation of the Waste Act. The Inspectorate will continue to cooperate with the Tax and Customs Board with regard to the importers of batteries.

In 2015, the Inspectorate is planning to issue a memorandum addressed to importers (the sector will be determined in the first quarter of 2015), reminding them of the requirements for the labelling of electronic equipment arising from the Waste Act.

Consumer Protection Board

In the course of surveillance, toys will be taken for testing from retail stores; the electronic components and batteries in the toys will be tested for metals: lead, mercury, cadmium and hexavalent chromium. The fulfilment of the requirements for the presentation of information to consumers applicable under the Waste Act will also be checked.

The most prioritised activities in the category of products of concern in 2015 are the following:

- Testing of electronic components and batteries in battery-powered toys (products of concern) for metals (lead, mercury, cadmium and hexavalent chromium). Battery-powered toys that cost up to EUR 7.00 will be tested. The total number of tests planned is 10.
- Information provided to consumers on the returning of products of concern is to be checked only where necessary if a complaint or other signal is received.

2.7.3 Report from activities carried out under the previous planning period

Environmental Inspectorate

In 2014, on-the-spot checks were carried out at the premises of 15 producers (importers) whose area of activity is the import and sale of electrical and electronic equipment. Document checks were carried out. As an additional, positive sanction, a memorandum was sent to 34 importers of e-cigarettes to point out the requirements applicable in the sector. A total of 5 products were sent to a laboratory and tested for dangerous substances using XRF. No violations were found.

The **Consumer Protection Board** had carried out a total of 281 checks of products of concern by 1 December 2014; 26.3 % of the checks identified violations. In 2014, the Consumer Protection Board tested 9 battery-powered toys, 5 of which were shown to be non-compliant. The main problem was the lead content in electronic components.

2.8 Personal protective equipment

2.8.1 Responsible authority and contact details

According to the Product Conformity Act, the surveillance of personal protective equipment for professional use is carried out by the **Labour Inspectorate** and the surveillance of non-professional personal protective equipment in retailing by the **Consumer Protection Board**.

Consumer Protection Board, Rahukohtu 2, 10130 Tallinn, Estonia, email:

info@tarbijakaitseamet.ee

www.tarbijakaitseamet.ee

Contact person: Jana Baljutis-Kütt — Chief Expert of Surveillance and Coordination, phone: +372 6201711, email: jana.baljutis-kytt@tarbijakaitseamet.ee

Labour Inspectorate, Gonsiori 29, 10147 Tallinn, Estonia, email: ti@ti.ee, www.ti.ee

Contact person: Apo Oja, Deputy Director General, apo.oja@ti.ee, (+372) 6269402, (+372)56875449.

The organisation and execution of surveillance in the PPEs sector is carried out by 1 expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of 0.75 positions) at the **Consumer Protection Board**. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.8.2 Market surveillance procedures and strategy

Consumer Protection Board

In the course of surveillance, the compliance of PPEs with the requirements set out in Minister of Social Affairs Regulation No 57 of 29 September 2010 ‘Safety Requirements for Personal Protective Equipment and Procedure for Conformity Attestation of Personal Protective Equipment’ adopted in accordance with Section 5(4) of the Product Conformity Act is checked.

The most highly prioritised activities in the personal protective equipment sector in 2015 are the following:

- Checking of the labelling and Estonian-language user manual of personal protective equipment. Attention will be focused on helmets and elbow and knee pads.
- As regards safety reflectors, attention will be focused on the displaying of products similar to safety reflectors close to actual safety reflectors and the use of the term ‘safety reflector’ on products that are not actually safety reflectors. The checks will be performed on a so-called campaign basis during the high season for safety reflector sales.

Labour Inspectorate

Surveillance to verify the compliance of personal protective equipment is generally carried out at the premises (shops) of the importer or distributor of the equipment. The compliance of the marking of the personal protective equipment produced or sold to wholesale and retail customers is verified, the product documentation presented is checked and the product compliance is visually assessed in the course of surveillance.

The scope and volume of market surveillance to be carried out is set out in the annual plan of the Inspectorate. The annual plan is based on the results of risk assessment and information gathered previously (the results of the surveillance activities of the last 3 years) and on an ongoing basis (complaints/tips received) and it takes into account existing resources. One of

the inputs for the assessment of the need for surveillance are the results of checks of the working environment, in the course of which the compliance of PPEs used by employees with safety requirements is verified and the appropriateness of the protective properties of the PPEs for the environment where they are used is assessed.

2.8.3 Report from activities carried out under the previous planning period

Consumer Protection Board

The specific surveillance activities performed by the Consumer Protection Board in the PPEs sector by 1 December 2014 are provided in the table below (Table 12). A total of 98 checks of helmets and protective gear were carried out, 52.0% of which identified various violations. The main violations were the absence of a user manual in Estonian and the absence of appropriate labelling. A total of 153 checks of safety reflectors and reflective vests were carried out, 13.7 % of which identified various violations. The main violations were the absence of a user manual in Estonian and the absence of appropriate labelling (including a conformity mark).

No PPEs were tested in 2014.

Table 12. Surveillance results in the personal protective equipment sector for 11 months in 2014	
Total number of checks	279
Percentage of violations identified in checks	30.1%
Number of products tested	0
Number of non-compliant products	0
Number of products presenting a serious risk	0
Number of memoranda issued	4
Number of notices of administrative proceedings issued	0
Number of precepts issued	0
Number of misdemeanour procedures (in force)	0
Amount of fines imposed as a result of misdemeanour procedures	EUR 0

2.9 Tyre labelling

2.9.1 *Responsible authority and contact details*

Surveillance of the labelling of tyres is carried out by the **Environmental Inspectorate** in cooperation with the Consumer Protection Board.

Environmental Inspectorate, 76 Kopli St, 10416 Tallinn, phone: 696 2236, fax: 696 2237, email: valve@kki.ee www.kki.ee

Contact person: Rene Rajasalu, Rene.Rajasalu@kki.ee, +372 53 421 035

The exact figures cannot be submitted because the 2015 budget of the Environmental Inspectorate has not been approved yet. As a rule, the Environmental Inspectorate does not have the means to check the compliance of tyres with markings. Furthermore, there is no laboratory in Estonia capable of testing tyres for compliance markings (the nearest laboratory is in Finland).

2.9.2 *Market surveillance procedures and strategy*

Importers of tyres are producers for the purposes of the Waste Act. The Waste Act lays down a series of obligations that the producer must meet. Most producers have joined a producer responsibility organisation in order to meet these requirements. The Environmental Inspectorate is required to check the activities of the producer responsibility organisation once a year. The producers who have joined the organisation are also checked as part of the annual check. The Inspectorate also requires the organisation to inform such producers as have joined the organisation about the requirements for the marking of tyres.

In 2015, the Inspectorate is planning to carry out a consumer information campaign explaining the meaning of the markings on tyres and their significance for consumers.

2.9.3 *Report from activities carried out under the previous planning period*

In 2014, the Environmental Inspectorate checked 2 producer responsibility organisations, carrying out the surveillance of 120 importers/distributors of tyres through the organisations. On-the-spot checks were carried out at the points of sale of 10 distributors (including online points of sale), where the markings of tyres were checked. No violations were found.

2.10 Recreational craft

2.10.1 *Responsible authority and contact details*

The state supervision of recreational craft is carried out by the **Maritime Administration**.

Maritime Administration — 9 Lume St, Tallinn 10416, Estonia, eva@vta.ee, www.vta.ee

Contact person: Andres Kõnd, Head of Recreational Craft and Inland Vessels Department, +372 6205750, +372 53447681, andres.kond@vta.ee

2.10.2 *Market surveillance procedures and strategy*

A significant part of the surveillance activities in the recreational craft sector is carried out in the form of so-called advisory surveillance. This mainly concerns persons acting in the sector under an activity licence.

Market surveillance can also be carried out using the water craft registration procedure of the Road Administration, where there is good, constructive cooperation in checking compliance during pre-registration inspections.

2.10.3 *Report from activities carried out under the previous planning period*

Surveillance activities in numbers

- Number of checks of products sold on the Internet: 1;
- Number of notices issued by the Tax and Customs Board 14;
- Total number of products checked: 370. Includes products in the notices of checks as well as products checked during pre-registration checks.
- Number of products tested: 0.

Measures

- Number of memoranda issued: the proposals and observations related to compliance with legislation made by the Maritime Administration have mainly been oral, particularly concerning the products displayed at the Tallinn International Boat Show (Meremess), and the shortcomings have been removed immediately or information added to the effect that the given product is a sample and the products sold have a CE marking;
- Number of precepts issued: 1.

Assessment of surveillance activities: Outstanding positive changes have been made as a result of market surveillance activities. Close cooperation with the relevant structural units of the Tax and Customs Board and the Road Administration has played a significant role. The Maritime Administration is also developing a more constructive cooperative relationship with its Latvian and Lithuanian colleagues in order to ensure a more homogeneous approach in the market surveillance activities of the neighbouring countries.

2.11 Fertilisers

2.11.1 Responsible authority and contact details

State supervision of the fulfilment of the requirements laid down in EU legislation, the Fertilisers Act and the legal acts regarding the handling of fertilisers based on the Fertilisers Act is carried out by the Agricultural Board. The Consumer Protection Board carries out surveillance of the fulfilment of the requirements applicable to the packaging and labelling of fertilisers sold to consumers. State supervision of the requirements for the handling of fertilisers to verify their compliance with customs rules within the meaning of the Customs Act is carried out by the Tax and Customs Board.

Agricultural Board — general contact: phone: (+372) 671 2602, email: pma@pma.agri.ee, Fertilisers Department: Teaduse 2, 75501 Saku, Harju County, fax: 671 2604, vaetis@pma.agri.ee

Contact person: Jan-Roland Raukas — Head of Department, phone: +372 671 2612, email: jan-roland.raukas@pma.agri.ee

Consumer Protection Board, Rahukohtu 2, 10130 Tallinn, Estonia, email: info@tarbijakaitseamet.ee, www.tarbijakaitseamet.ee

Contact person: Jana Baljutis-Kütt — Chief Expert of Surveillance and Coordination, phone: +372 6201711, email: jana.baljutis-kytt@tarbijakaitseamet.ee

An overview of the staff of the **Agricultural Board** is provided in Table 13.

Table 13. Overview of employees			
	Total	Full-time	Part-time
Responsible department	2	1	1
County centres	4		4

Laboratory services are outsourced from the Agricultural Board under a cooperation agreement.

Consumer Protection Board

The organisation and execution of surveillance in the fertilisers sector is carried out by 1 expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of 0.1 position) at the Consumer Protection Board. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.11.2 Market surveillance procedures and strategy

Agricultural Board

The long-term objectives for 2017–2015 in the fertilisers sector are the following:

- the fertilisers offered for sale to consumers correspond to the declared data and are of good quality and safe;
- fair competition is ensured on the market.

Sub-objectives:

- risk-based planning and execution of surveillance; improved effectiveness of the inspection of fertilisers from other Member States;
- control of the marketing and production of organo-mineral fertilisers is initiated;
- control of importers of ammonium nitrate fertilisers of high nitrogen content into

Estonia in cooperation with the Tax and Customs Board;

- fulfilment of the market surveillance obligations arising from Regulation 765/2008;
- information of clients has been ensured; additional material in English has been made available on the website of the Agricultural Board;
- input has been provided for the development of an information system of the sector.

Surveillance of the fulfilment of the requirements arising from the Fertilisers Act and the relevant EU legislation is organised by the Fertilisers Department of the Agricultural Board. The main function of the Department is the organisation and performance of the state supervision of the production and marketing of fertilisers; the taking of decisions required by law; the assessment and analysis of the effectiveness of surveillance; the design and implementation of measures for updating the control system, including

- the processing of registration applications and the taking of decisions required by law;
- the training of inspectors carrying out surveillance in the sector;
- the keeping of the national fertiliser register.

The objective of surveillance is to ensure that the fertilisers that reach consumers:

- are, if used correctly, safe to human and animal life and health as well as to property and the environment;
- meet the requirements for the composition of fertilisers;
- are labelled as required.

The compliance of fertilisers is inspected at the premises of the manufacturer, packager, importer or distributor in accordance with an annual surveillance plan for the sector. The surveillance plan is drawn up on the basis of the registered fertiliser handlers that have notified [the Board] of their operations, the obligations arising from legislation, the results of surveillance conducted in preceding years and a risk assessment. The main surveillance measures are checking that the labelling on the packaging of fertilisers meets the requirements, taking samples of fertilisers and sending them to the Agricultural Research Centre for analysis, assessing laboratory results, and, where necessary, issuing orders to eliminate shortcomings and processing misdemeanours.

The Agricultural Board cooperates with the Tax and Customs Board in inspecting fertilisers to be released for free circulation.

Consumer Protection Board

In the fertilisers sector, the Consumer Protection Board carries out regular surveillance to check the marking of the products sold to consumers. In 2015, surveillance will only be carried out on the basis of inquiries received or in the presence of a direct need, because this is not a high-priority sector for the Board.

2.11.3 Report from activities carried out under the previous planning period

Agricultural Board

In the first 11 months of 2014, the Agricultural Board carried out 22 inspections (including 76 instances involving testing), 6 of which identified violations. A decreasing trend is observable through several years. The main violations were violations of the requirements on composition (the fertiliser does not correspond to the composition shown on the packaging) and the requirements for marking.

Consumer Protection Board

A total of 10 checks had been carried out by 1 December 2014, 30 % of which identified various violations (3 violations). The main violations were the inadequate publication of unit prices and price information and illegible labelling. No products were tested in this sector.

2.12 Pyrotechnics

2.12.1 Responsible authority and contact details

The market surveillance of pyrotechnics is carried out by the **Technical Surveillance Authority** and the **Consumer Protection Board**. The Consumer Protection Board carries out state supervision of the fulfilment of the requirements for the retail sale of pyrotechnics.

Consumer Protection Board, Rahukohtu 2, 10130 Tallinn, Estonia, email: info@tarbijakaitseamet.ee, www.tarbijakaitseamet.ee

Contact person: Jana Baljutis-Kütt — Chief Expert of Surveillance and Coordination, phone: +372 6201711, email: jana.baljutis-kytt@tarbijakaitseamet.ee

Technical Surveillance Authority, Sõle 23A, Tallinn 10614, email: info@tja.ee, www.tja.ee
Contact person: Merike Ring, merike.ring@tja.ee

The organisation and execution of surveillance in the pyrotechnics sector is carried out by 1 expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of 0.5 positions) at the **Consumer Protection Board**. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.12.2 Market surveillance procedures and strategy

In the course of surveillance, the compliance of pyrotechnical products with the Explosive Substances Act is verified. The **Consumer Protection Board** carries out surveillance within its area of competence to check whether products comply with the requirements arising from legal acts, and are supplied with the required information and labelling and a user manual. In the last two years, the Board has also cooperated with the Rescue Board in the form of joint inspections as well as participating in meetings organised by the Technical Surveillance Authority. In 2015, the Board is planning to carry out regular surveillance and continue to cooperate with other authorities.

2.12.3 Report from activities carried out under the previous planning period

The specific surveillance activities performed by the **Consumer Protection Board** in the pyrotechnics sector in 2013 are provided in the table below. Surveillance data for 2014 are not available due to ongoing inspections.

Total number of checks	118
Percentage of violations identified in checks	11%
Number of tested products	0
Number of non-compliant products	0
Number of products presenting a serious risk	0
Number of memoranda issued	5
Number of complaints from consumers	0
Number of inquiries from consumers/entrepreneurs	4
Number of consultations over the consumer information line	49

2.13 Textiles

2.13.1 Responsible authority and contact details

State supervision of the fulfilment of the requirements for the labelling of clothing and textile products established on the basis of the Trading Act is carried out by the Consumer Protection Board. The requirements laid down in Regulation (EU) No 1007/2011 of the European Parliament and of the Council on textile fibre names and related labelling and marking of the fibre composition of textile products (referred to below as the *Textile Regulation*) is applied to the labelling of the fibre composition of textile products.

Consumer Protection Board, Rahukohtu 2, 10130 Tallinn, Estonia, email: info@tarbijakaitseamet.ee, www.tarbijakaitseamet.ee

Contact person: Jana Baljutis-Kütt — Chief Expert of Surveillance and Coordination, phone: +372 6201711, email: jana.baljutis-kytt@tarbijakaitseamet.ee

The organisation and execution of surveillance in the textiles sector is carried out by 1 expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of 0.3 positions) at the Consumer Protection Board. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.13.2 Market surveillance procedures and strategy

In the course of surveillance, the fulfilment of the requirements for the labelling of, or other methods of providing information on, textile clothing and other textile product offered or sold to consumers is checked. With the end of the transition period of the Textile Regulation on 9 November 2014, it is relevant to acquire an overview of the application of the requirements of the Regulation and to verify that the information provided to consumers is accurate and adequate. The surveillance of e-shops selling clothing is also carried out. The supply of unlabelled or irregularly labelled clothing will be reduced and consumers will be provided with relevant information for making an informed purchase as a result of the surveillance activities.

2.13.3 Report from activities carried out under the previous planning period

The specific surveillance activities performed by the Consumer Protection Board regarding the labelling of clothing are provided in the table below. Inspections of the labelling of clothing were carried out on a total of 218 objects; 16.5 % of the inspections identified violations. The Board has also processed complaints and requests for explanation from consumers regarding clothing damaged or inadequately cleaned during dry cleaning due to a misleading or absent care label.

Total number of checks	218
Percentage of violations identified in checks	16.5%
Number of memoranda issued	2
Number of notices of administrative proceedings issued	0
Number of precepts issued	0
Number of misdemeanour procedures (in force)	0
Amount of fines imposed as a result of misdemeanour procedures	EUR 0
Number of complaints from consumers	52

Number of inquiries from consumers/entrepreneurs

93

2.14 Construction products, radio equipment and telecommunications terminal equipment, electrical equipment, appliances burning gaseous fuels, machinery, measuring instruments, non-automatic weighing instruments and pre-packaged products, simple pressure vessels and pressure equipment, transportable pressure equipment, aerosol dispensers, lifts, cableways, explosives for civil uses

2.14.1 Responsible authority and contact details

The **Technical Surveillance Authority** carries out market surveillance primarily in respect of compliance with the requirements laid down for the following products and equipment:

- construction products;
- radio equipment and telecommunications terminal equipment;
- electrical equipment;
- appliances burning gaseous fuels;
- machinery;
- measuring instruments, non-automatic weighing instruments and pre-packaged products;
- simple pressure vessels and pressure equipment, transportable pressure equipment, aerosol dispensers;
- lifts, cableways;
- explosives for civil uses and pyrotechnics.

The Technical Surveillance Authority also carries out market surveillance in respect of compliance with the following requirements:

- hazardous substance content in electrical and electronic equipment;
- noise emissions for outdoor equipment;
- equipment and protective systems intended for use in potentially explosive atmospheres;
- eco-design of energy-related products, energy labelling of equipment.

Technical Surveillance Authority, Sõle 23A, Tallinn 10614, phone: 667 2000, fax: 667 2001, email: info@tja.ee

Contact persons:

Construction products — Sten Luide, sten.luide@tja.ee, 667 2062

Radio equipment and telecommunications terminal equipment — Tanel Vinkel, tanel.vinkel@tja.ee, +372 667 2090

Electrical equipment — Taavi Lentso, taavi.lentso@tja.ee, +372 667 2164, Tanel Vinkel, tanel.vinkel@tja.ee, +372 667 2090

Appliances burning gaseous fuels, simple pressure vessels and pressure equipment, transportable pressure equipment, aerosol dispensers — Andrus Rumm, andrus.rumm@tja.ee, +372 6672195

Machinery — Andrus Rumm, andrus.rumm@tja.ee, +372 6672195; Richard Saarman, richard.saarman@tja.ee, +372 6672175

Measuring instruments, non-automatic weighing instruments and pre-packaged products — Andrus Rumm, andrus.rumm@tja.ee, +372 6672195; Triinu Sillamaa, triinu.sillamaa@tja.ee; +372 6672194

Explosives for civil uses and pyrotechnics — Merike Ring, merike.ring@tja.ee, +372 6672186

In 2015, a total of 10 persons will be carrying out market surveillance. The average monthly wages over four years, excluding performance pay, of eight officials active in market surveillance was EUR 1 042. Average wages including taxes: EUR 1 397. The total operational expenditure, including transferred finances, of the Technical Surveillance Authority in 2013 was EUR 2 415 905.80. There is a fleet of six cars at the disposal of the officials for the purpose of carrying out surveillance.

2.14.2 Market surveillance procedures and strategy

The Technical Surveillance Authority uses precepts and penalty payments in surveillance procedures / administrative procedures and fines in misdemeanour procedures. An important part of a surveillance procedure is the suspension of offering for sale of non-compliant products and the withdrawal of products from the market.

Market surveillance activities are based on an annual work plan, which takes into account the existing resources and needs. The work plan is prepared according to the complaints received by the Authority, the results of laboratory tests from previous years, information about dangerous products received through the RAPEX and ICSMS systems, the results of previous market surveillance inspections, etc.

2.15 Childcare products

2.15.1 Responsible authority and contact details

Pursuant to the Product Conformity Act and the competences of the surveillance authorities laid down in the cooperation agreement, surveillance to verify the safety of childcare products and babies' dummies is carried out by the Health Board (at the premises of importers, in wholesale warehouses and pharmacies) and the Consumer Protection Board (in retailing).

Consumer Protection Board, Rahukohtu 2, 10130 Tallinn, Estonia, email: info@tarbijakaitseamet.ee, www.tarbijakaitseamet.ee

Contact person: Jana Baljutis-Kütt — Chief Expert of Surveillance and Coordination, phone: +372 6201711, email: jana.baljutis-kytt@tarbijakaitseamet.ee

The organisation and execution of surveillance of childcare products is carried out by 1 expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of 0.5 positions) at the Consumer Protection Board. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.15.2 Market surveillance procedures and strategy

In the course of surveillance, the compliance of childcare products with the requirements in the Product Conformity Act is checked.

In 2015, the most prioritised activities in the childcare products sector are the following:

- Verification of the existence of the Estonian-language labelling and user manuals of childcare products and the correspondence of the Estonian-language information to the foreign-language information. In 2015, attention will be focused mainly on buggies and prams, baths, travel cots and baby walkers.

There are no tests planned for 2015 and tests will be carried out only where necessary, including when complaints or other signals are received.

2.15.3 Report from activities carried out under the previous planning period

The specific surveillance activities performed by the Consumer Protection Board in the childcare products sector by 1 December 2014 are provided in the table below. A total of 123 checks were carried out, 46.3% of which identified various violations. The main violations were the absence of a user manual or labelling in Estonian and the non-conformity of the Estonian-language manual to the foreign-language manual.

Under PROSAFE, the Board also participated in sub-project 'Children's high chairs' of the JA2012 joint market surveillance project financed by the European Commission. The compliance of children's high chairs to the EU Regulation and standard EN 14988:2006+A1:2012 'Children's high chairs' was checked under the joint project. Under the project, 4 children's high chairs were taken from the Estonian market for testing. The test results showed 2 high chairs to be dangerous and the other 2 chairs failed to comply with the requirements for labelling.

Table 16. Surveillance results in the childcare products sector for 11 months in 2014

Total number of checks	123
Percentage of violations identified in checks	46.3%
Number of products tested	4

Number of non-compliant products	2
Number of products presenting a serious risk	2
Number of memoranda issued	3
Number of notices of administrative proceedings issued	1
Number of precepts issued	0
Number of misdemeanour procedures (in force)	2
Amount of fines imposed as a result of misdemeanour procedures	EUR 180
Number of complaints from consumers	8
Number of inquiries from consumers/entrepreneurs	19
Number of consultations over the consumer information line	114

2.16 Candles

2.16.1 *Responsible authority and contact details*

State supervision under the Product Conformity Act and the Consumer Protection Act to verify the safety of candles sold or offered to consumers is carried out by the Consumer Protection Board. According to Article 3 of Directive 2001/95/EC of the European Parliament and of the Council on general product safety, producers shall be obliged to place only safe products on the market. A product is presumed to be safe, as far as the risks and risk categories covered by the relevant national standards are concerned, when it conforms to voluntary national standards transposing European standards, the references of which have to be published by the Commission in the Official Journal of the European Union, in accordance with Article 4 of the Directive. The safety requirements for candles are laid down in standards EN 15493:2007 'Candles. Specification for fire safety'; EN 15494:2007 'Candles. Product safety labels'; EN 15426:2007 'Candles. Specification for sooting behaviour'. The Consumer Protection Board checks that candles sold in retailing are provided with safety instructions.

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The organisation and execution of surveillance in the fertilisers sector is carried out by 1 expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of 0.1 positions) at the Consumer Protection Board. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.16.2 *Market surveillance procedures and strategy*

In the course of surveillance, the provision of candles with the necessary information, including information on the purpose of the candle, and safety instructions is checked. The minimal recommended safety instructions are provided in the standard. The safety information must be shown either on the product or on the packaging as text or in pictograms. Warnings in a foreign language must be shown in Estonian. Council Directive 87/357/EEC on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers must be taken into account when offering relevant specially shaped candles. Products that appear to be other than they are may be confused with foodstuffs, especially by children, and placed in the mouth, sucked or ingested, which might be dangerous and cause physical harm.

Providing information and warnings to consumers is very important in this sector, because it helps to avoid causes of fires and accidents.

2.16.3 *Report from activities carried out under the previous planning period*

The Consumer Protection Board had carried out a total of 194 checks in the safety of candles sector by 1 December 2014, 19.6% of which identified various violations. The main violations were the absence of safety instructions, non-compliant labelling, illegible labelling, irregular publication of unit prices and price information and misleading information about cosmetic products.

2.17 Children's clothing (cords, drawstrings)

2.17.1 Responsible authority and contact details

State supervision under the Product Conformity Act and the Consumer Protection Act to verify the safety of children's clothing is carried out by the Consumer Protection Board. According to Article 3 of Directive 2001/95/EC of the European Parliament and of the Council on general product safety, producers shall be obliged to place only safe products on the market. A product is presumed to be safe, as far as the risks and risk categories covered by the relevant national standards are concerned, when it conforms to voluntary national standards transposing European standards, the references of which have to be published by the Commission in the Official Journal of the European Union, in accordance with Article 4 of the Directive. The safety requirements for children's clothing are provided in standard EN 14682:2007 'Safety of children's clothing. Cords and drawstrings on children's clothing'.

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The organisation and execution of surveillance in the safety of children's clothing sector is carried out by 1 expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of 0.75 positions) at the Consumer Protection Board. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.17.2 Market surveillance procedures and strategy

In the course of surveillance, the safety of children's clothing is checked with respect to cords and drawstrings. The object of inspection is clothing for children of up to 7 years of age and up to 134 centimetres in height and clothing for children aged 7 to 14 (boys 134 to 182 centimetres and girls 134 to 176 centimetres in height) fitted with cords or drawstrings. Special attention is paid to clothing for infants. A large number of RAPEX alerts have been received regarding such clothing.

In 2014, the Member States identified and prohibited the sale of 196 clothing items that posed the risk of strangulation and 214 clothing items liable to cause injuries to children.

The results of the preceding period, the experience gained from participation in the international project for the safety of children's clothing and RAPEX alerts are taken into account in carrying out surveillance.

2.17.3 Report from activities carried out under the previous planning period

The surveillance results of the Consumer Protection Board in the children's clothing sector as at 1 December 2014 are provided in the table below. A total of 274 checks were carried out, 46.4% of which identified various violations. The main violations were the following: the most frequent violation in clothing for small children (ages 0 to 7) was the presence of cords or drawstrings in the hood and neck area of clothes (53 %); hoods in clothing for older children and youngsters often had drawstrings of the wrong length (21 %); violations concerning the length of cords and drawstrings in the waist area were identified in 14.6 % of the cases; violations of safety requirements concerning the length of cords and drawstrings in the lower area were identified in 6 % of the cases.

The Consumer Protection Board also participates in the 'Joint Market Surveillance Action on Cords and Drawstrings on Children's Clothing II' (JA2012) cooperation project of the

Member States. A guide for the safety assessment of children's clothing and a methodology for risk assessment were prepared in the course of the joint project.

Table 17. Surveillance results in the children's clothing sector for 11 months in 2014	
Total number of checks	274
Percentage of violations identified in checks	46.4%
Number of memoranda issued	8
Number of notices of administrative proceedings issued	5
Number of precepts issued	2
Number of misdemeanour procedures (in force)	13
Amount of fines imposed as a result of misdemeanour procedures	EUR 1 170

2.18 Lighters

2.18.1 Responsible authority and contact details

In accordance with Article 13 of Directive 2001/95/EC of the European Parliament and of the Council on general product safety, Commission Decision 2006/502/EC has been adopted, requiring Member States to take measures to ensure that only lighters which are child-resistant are placed on the market and to prohibit the placing on the market of novelty lighters.

State supervision of the fulfilment of the safety requirements for lighters applicable under the Product Conformity Act and the requirements for conformity attestation is carried out by the Consumer Protection Board. Under a cooperation agreement, the Consumer Protection Board cooperates with the Tax and Customs Board in the prevention of novelty lighters and lighters without a child-resistance mechanism being placed on the market.

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The organisation and execution of surveillance in the lighters sector is carried out by 1 expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of 0.2 positions) at the Consumer Protection Board. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.18.2 Market surveillance procedures and strategy

In the course of surveillance, the compliance with safety requirements of lighters offered or sold to consumers, the supplying of lighters with safety information and the supplying of luxury and semi-luxury lighters with the necessary documents is checked. If surveillance activities give rise to suspicion, an inspection of documents is carried out and, if necessary, laboratory tests of lighters are ordered to verify compliance with safety requirements and child-resistance.

The results of the preceding period, RAPEX alerts and the experience gained from participation in the international project for the safety of lighters are taken into account in carrying out surveillance.

2.18.3 Report from activities carried out under the previous planning period

The surveillance results of the Consumer Protection Board in the lighters sector as at 1 December 2014 are provided in the table below. A total of 187 checks were carried out, 25.1% of which identified various violations. The violations mainly concerned safety (28.3 %), labelling (8.4 %) and the absence of information in Estonian (40 %). A total of 14 instances of sale of novelty lighters were identified. A measurement of the force needed to operate the lighter was commissioned from Metrosert AS with regard to two lighters in order to verify child-resistance. The measurement results showed that the samples were child-resistant.

Table 18. Surveillance results in the lighters sector for 11 months in 2014

Total number of checks	187
Percentage of violations identified in checks	25.1 %
Number of products tested	2

Number of non-compliant products	0
Number of products presenting a serious risk	0
Number of memoranda issued	0
Number of notices of administrative proceedings issued	1
Number of precepts issued	0
Number of misdemeanour procedures (in force)	8
Amount of fines imposed as a result of misdemeanour procedures	EUR 580

2.19 Used cars

2.19.1 Responsible authority and contact details

Pursuant to the Consumer Protection Act, the Trading Act and the Product Conformity Act, the Consumer Protection Board carries out surveillance to verify compliance with legal requirements.

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The organisation and execution of surveillance in the used cars sector is carried out by 1 leading expert, 1 lawyer and 3 chief surveillance inspectors (in terms of a full-time equivalent of 3 positions) at the Consumer Protection Board. Additional human resources are brought in where necessary. The budget and expenditure on wages of the Consumer Protection Board are provided in point 1.1.

2.19.2 Market surveillance procedures and strategy

In the course of surveillance, the accuracy of the information provided to consumers, the marking of the point of sale, the accuracy of the sale advertisements of passenger cars, misleading trading methods and the fulfilment of other legal requirements is checked. A misdemeanour procedure is initiated if necessary. Various guidance materials for entrepreneurs and consumers have been prepared.

In 2015, the used cars sector is among the most highly prioritised sectors in the work plan of the Board; surveillance activities and other necessary procedures are carried out under the work plan.

2.19.3 Report from activities carried out under the previous planning period

The surveillance results of the Consumer Protection Board in the used cars sector as of 1 December 2014 are provided in the table below.

The scale of the used cars project that started in 2013 increased significantly this year. The Police and Border Guard Board joined the project alongside the three authorities (the Consumer Protection Board, the Road Administration and the Tax and Customs Board) already involved in it. The awareness of both entrepreneurs and consumers was raised as a result of joint inspections and information campaigns. The problems and shortcomings in the used cars sector are the following: car sale advertisements are not accurate; odometer readings are tampered with, which misleads consumers; sellers do not check the background and history of vehicles.

Table 19. Surveillance results in the used cars sector for 11 months in 2014	
Total number of checks	85
Percentage of violations identified in checks	88.2%
Number of memoranda issued	0
Number of notices of administrative proceedings issued	0
Number of precepts issued	0
Number of misdemeanour procedures (in force)	15

Amount of fines imposed as a result of misdemeanour procedures	EUR 1760
Number of complaints from consumers	50
Number of inquiries from consumers/entrepreneurs	123
Number of consultations over the consumer information line	760