

Translation from Finnish

Legally binding only in Finnish and Swedish

Ministry of Economic Affairs and Employment, Finland

Act on the Market Surveillance of Certain Products

(1137/2016)

By decision of Parliament, the following is enacted:

Chapter 1

General provisions

Section 1

Scope of application

This Act applies to the market surveillance of products falling within the scope of application of the Lift Safety Act (1134/2016), Measuring Instruments Act (707/2011), Act on the Conformity of Pyrotechnic Articles (180/2015), Act on the Conformity of Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (1139/2016), Pressure Equipment Act (1144/2016), Electrical Safety Act (1135/2016) and Act on the Conformity of Explosives, unless otherwise provided in the said Acts.

Furthermore, this Act applies to measures taken by surveillance authorities referred to in Articles 27–29 of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, hereinafter the New Legislative Framework (NLF) Regulation, concerning products falling within the scope of application of the Acts specified in subsection 1, unless otherwise provided in the said Acts.

Section 2

Definitions

For the purposes of this Act:

1) *making available on the market* means any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

2) *notified body* means a body designated by a Member State of the European Union and notified to the European Commission that has the right to perform conformity assessments;

3) *market surveillance* means the activities referred to in Article 2(17) of the NLF Regulation and carried out by public authorities to ensure the conformity of products;

4) *withdrawal* means any measure aimed at preventing a product in the supply chain from being made available on the market;

5) *placing on the market* means the first making available of a product on the Union market;

6) *recall* means any measure aimed at returning a product from the market and from end users or bringing it into conformity;

7) *product presenting a risk* means a product having the potential to affect adversely the health and safety of persons in general, and public security as well other public interests to a degree which goes beyond that considered reasonable and acceptable under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;

8) *risk assessment* means the identification of effects as well as the estimation and evaluation of risks;

9) *economic operator* means economic operators referred to in the Acts specified in section 1, subsection 1;

10) *external border control* means controls of products entering the European Union market carried out by Finnish Customs in situations referred to in Articles 27–29 of the NLF Regulation;

11) *non-conforming product* means a product which is not in conformity with the requirements laid down for it in the Acts specified in section 1, subsection 1;

12) *serious risk* means a situation posing a risk requiring rapid intervention and follow-up, including cases where the effects are not immediate.

Chapter 2

Organisation of surveillance

Section 3

Supreme oversight of surveillance

The supreme oversight of surveillance relating to compliance with the provisions of this Act rests with the Ministry of Economic Affairs and Employment.

Section 4

Surveillance authorities

The Finnish Safety and Chemicals Agency is the market surveillance authority referred to in this Act.

Finnish Customs acts as the authority responsible for the external border controls referred to in Articles 27–29 of the NLF Regulation and supervises compliance with export prohibitions referred to in section 23 and destruction orders referred to in section 25 at the external border.

Section 5

Cooperation procedure in the surveillance of products imported into the Union market

Provisions on the cooperation procedure of the market surveillance authority and Finnish Customs and time limits for the surveillance of products imported into the Union market are laid down in Articles 27–29 of the NLF Regulation and below in this Act.

Section 6

Performance of tasks and order of priority

The market surveillance authority shall perform its tasks in a manner that is effective and as appropriate as possible on the basis of risk assessment. If circumstances so require, tasks shall be prioritised.

Section 7

Surveillance plan

The market surveillance authority shall draw up a surveillance plan for the market surveillance of products falling within the scope of application of the Acts specified in section 1, subsection 1. The provisions of Article 18(5) of the NLF Regulation shall be taken into account in the surveillance plan.

Chapter 3

Surveillance measures

Section 8

Public authorities' right to receive information from economic operators

The market surveillance authority and Finnish Customs have the right to receive from economic operators the information necessary for surveillance. The right to information also applies to such information necessary for surveillance that, as information on a private business or professional activity, on the economic status or state of health of a private person or otherwise, shall while in the possession of a public authority, be kept secret under the Act on the Openness of Government Activities (621/1999).

Section 9

Right to perform checks

For the purpose of surveillance, the market surveillance authority and Finnish Customs have the right to access all premises in which activities referred to in the Acts specified in section 1, subsection 1 are carried out or in which information relevant to surveillance is stored, and to perform checks necessary for surveillance. Checks shall not, however, be extended to premises used for residential purposes of a permanent nature. Checks shall take place in compliance with the provisions of section 39 of the Administrative Procedure Act (434/2003).

Separate provisions regarding the market surveillance authority's right to extend a check to premises used for residential purposes of a permanent nature are, if necessary, issued by the Acts specified in section 1, subsection 1.

Section 10

Right to obtain products for examination

The market surveillance authority and Finnish Customs have the right to obtain products for examination where this is required for the monitoring of product conformity. The provisions of this section concerning products also apply to samples taken of products and parts thereof.

The market surveillance authority shall, where so requested by an economic operator, reimburse for a product referred to in subsection 1 at current price, unless the product is found to be non-conforming. Where Finnish Customs levies a charge for the taking of a sample for examination as separately provided, no payment for samples need, however, be made by the market surveillance authority.

Where a product is non-conforming and the non-conformity is significant, the market surveillance authority may oblige the economic operator to reimburse the costs arising from the acquisition, testing and examination of the product. The reimbursement is directly distrainable. Provisions on its collection are laid down in the Act on the Enforcement of Taxes and Public Payments (706/2007).

Section 11

Right to receive information from other public authorities and to use samples taken by others

Notwithstanding secrecy provisions and other restrictions on access to information, the market surveillance authority and Finnish Customs have the right to disclose information necessary for surveillance to each other and to receive it from other surveillance authorities.

Notwithstanding secrecy provisions and other restrictions on access to information, the market surveillance authority and Finnish Customs have the right to use samples or products acquired by one another for examinations required for surveillance.

Section 12

Right to receive information from a notified body

Notwithstanding secrecy provisions, the market surveillance authority has the right to receive the necessary information for surveillance from a notified body.

Section 13

Right to disclose information that is to be kept secret

Notwithstanding secrecy provisions, the market surveillance authority may disclose information it has obtained during surveillance about the economic status of a private person or corporation, a business or professional secret or the personal circumstances of a private person to:

- 1) a prosecutor for the consideration of charges and the police and other pre-trial investigation authorities for the prevention or investigation of an offence;
- 2) a rescue authority as well as an occupational safety and health, environmental protection, consumer protection and police authority or another market surveillance authority performing control of product legislation where the disclosure of information is necessary for the performance of the authority's tasks or where these are performing control provided by law;
- 3) a competent foreign authority and international institution for the implementation of an obligation based on a legal act of the European Union or international agreement that is binding on Finland.

Section 14

Use of external experts

The market surveillance authority has the right to use the assistance of external experts in the examination, testing and assessment of product conformity.

External experts may, in an assisting role to the market surveillance authority, participate in checks performed under this Act.

External experts shall have the expertise and competence required by the tasks.

Provisions on criminal liability as a public official apply to an external expert where he or she performs tasks referred to in this section. Provisions on liability for damages are laid down in the Tort Liability Act (412/1974).

Section 15

Executive assistance by the police

The police is obliged to provide executive assistance to the market surveillance authority for the control of compliance with and for the enforcement of this Act and the Acts specified in section 1, subsection 1.

Provisions on executive assistance by the police are laid down in the Police Act (872/2011).

Section 16

Product conformity

A product is regarded as being in conformity if it meets the requirements laid down for the product in the Acts specified in section 1, subsection 1.

Even where a product meets the requirements laid down in the Acts specified in section 1, subsection 1, the market surveillance authority may impose an order or prohibition referred to in sections 17–22 where it transpires that the product nevertheless presents a serious risk to human health, safety, the environment, property or any other public interest referred to in the Acts specified in section 1, subsection 1.

Section 17

Order for action

The market surveillance authority may in the manner determined by it and within a reasonable period of time specified by it order an economic operator to take corrective action to bring a product or documentation relating to a product or information relating to a product into conformity where:

1) the product or documentation or information relating to the product is not in conformity or not submitted to the market surveillance on request; or

2) the product is under normal and reasonably foreseeable conditions of use liable to present a risk to human health, safety, the environment, property or any other public interest referred to in the Acts specified in section 1, subsection 1.

Section 18

Prohibition

The market surveillance authority may prohibit an economic operator from manufacturing, placing on the market, making available on the market or otherwise releasing a product where:

1) the economic operator regardless of an order referred to in section 17 fails to take corrective action or an order referred to in section 17 cannot be regarded as sufficient;

2) the product or documentation or information relating to the product is not in conformity or not submitted to the market surveillance authority on request and the deficiencies are material; or

3) the product or documentation or information relating to the product is not in conformity and the product is under normal and reasonably foreseeable conditions of use liable to present a risk to human health, safety, the environment, property or any other public interest referred to in the Acts specified in section 1, subsection 1.

In addition to a prohibition referred to in subsection 1, the market surveillance authority may order an economic operator to withdraw the product and impose an order for other actions necessary to restrict the making available on the market of the product.

Section 19

Recall

The market surveillance authority may order an economic operator to retrieve from the market and from end users a product that presents a risk to human health, safety, the environment, property or any other public interest referred to in the Acts specified in section 1, subsection 1 and to replace it with an equivalent or like product that is in conformity or to rescind the transaction

where an order referred to in section 17 or a prohibition or order referred to in section 18 is not sufficient.

Where an order referred to in section 17 or a prohibition or order referred to in section 18 is not sufficient and where the non-conformity continues regardless of the order or prohibition, an order referred to in subsection 1 may also be imposed where documentation or information relating to a product is not in conformity or not submitted on request to the market surveillance authority and the deficiencies are material.

Where regarded sufficient to prevent a risk presented by a product referred to in subsection 1, the market surveillance authority may instead of the retrieval of the product from the possession of an end user order the economic operator to repair the product or have it repaired so that the risk caused by a defect or omission in its structure or composition or by false, misleading or insufficient information provided about it is eliminated.

Section 20

Supplementary regulations to prohibitions and orders

An economic operator shall provide the market surveillance authority within the reasonable period of time specified by the authority an account of how the authority's order or prohibition referred to in sections 17–19 or 21–25 has been implemented.

The market surveillance authority may order the economic operator to ensure that the actions required due to the authority's order or prohibition referred to in subsection 1 are also implemented concerning those products that the operator has placed on the market or made available on the market in other European Union Member States or in the European Economic Area.

Section 21

Temporary prohibition

The market surveillance authority may impose a prohibition referred to in section 18, subsection 1 on a temporary basis for the duration of the investigation of the matter where it is evident that the product may be non-conforming or that the product is under normal and reasonably foreseeable

conditions of use liable to present a risk to human health, safety, the environment, property or any other public interest referred to in the Acts specified in section 1, subsection 1.

The temporary prohibition remains in force until the market surveillance authority finally resolves the matter. The market surveillance authority shall resolve the matter urgently.

Section 22

Order to provide information

Where the market surveillance authority has imposed an order or prohibition referred to in sections 17–21 or 23–25 or the product or its use presents a risk to human health, safety, the environment, property or any other public interest referred to in the Acts specified in section 1, subsection 1, the market surveillance authority may oblige the economic operator to provide information about the matter within the period of time and in the manner specified by the authority. Furthermore, the market surveillance authority may, to ensure the safety of users, oblige the economic operator to provide end users with the necessary information and instructions.

The market surveillance authority may, at the economic operator's expense, provide information about matters referred to in subsection 1 where the operator has not complied with an order to provide information imposed by the authority or where owing to the urgency of the matter the provision of information is necessary due to a risk presented to human health or safety.

Section 23

Export prohibition

Where a product is non-conforming and presents a serious risk to human health or safety, the market surveillance authority may prohibit the export or transit through Finland of the product.

The market surveillance authority may also impose the prohibition referred to in subsection 1 on a temporary basis for the duration of the investigation of the matter where it is evident that the product may pose an immediate hazard to human health or safety and the hazard cannot be otherwise prevented. The temporary prohibition remains in force until the market surveillance authority finally resolves the matter. The market surveillance authority shall resolve the matter urgently.

Section 24

Having actions carried out

Where it is evident that a product is non-conforming and presents a serious risk to human health or safety and the risk cannot be otherwise eliminated and the operator fails to take the actions required by the authority, the market surveillance authority has the right to have the actions necessary for the elimination of the hazard carried out at the economic operator's expense.

Section 25

Destruction order

Where the orders and prohibitions referred to in sections 17–23 cannot be regarded as sufficient, the market surveillance authority may order a product in the possession of an economic operator or Finnish Customs and a product returned to the economic operator under section 19 to be destroyed or, where this is not regarded as appropriate, issue an order on the procedure otherwise to be taken concerning the product.

Section 26

The market surveillance authority's communication to a notified body

The market surveillance authority shall communicate to the relevant notified body any measures targeted at an economic operator concerning a non-conforming product.

Chapter 4

Miscellaneous provisions

Section 27

Notifying the European Commission

The market surveillance authority shall without delay notify the European Commission and the other Member States of the European Union and the European Economic Area of a decision it has made under sections 16–19 where the market surveillance authority considers that the non-conformity of the product is not restricted to the national territory of Finland. In other respects, the provisions of European Union legislation harmonising the conditions for the marketing of products on safeguard clause and safeguard procedures apply to national measures.

In addition, the provisions on the authorities' obligation to notify the European Commission laid down in the Act on Notifying the European Commission of Information Relating to the Market Surveillance of Certain Products Presenting a Risk (1197/2009) shall be taken into account.

Section 28

Notice of a conditional fine and notice of enforced compliance

The market surveillance authority may enforce a prohibition or order that it has imposed under this Act by issuing a notice of a conditional fine or a notice that an action that has been left unperformed will be carried out at the defaulter's expense.

Section 29

Appeal

Pursuant to the provisions of the Administrative Judicial Procedure Act (586/1996), an appeal against a decision referred to in this Act may be filed with the Administrative Court. An Administrative Court decision may be appealed against only if a leave to appeal is granted by the Supreme Administrative Court.

Decisions on the imposition of and an order to pay a conditional fine and on the imposition and enforcement of a notice of enforced compliance are, however, subject to appeal as laid down in the Act on Conditional Fines (1113/1990).

Notwithstanding appeal, the market surveillance authority's decision shall be complied with, unless otherwise ordered by the appeal authority.

Section 30

Criteria for charges payable to Finnish Customs and collection of charges

The provisions laid down under the Act on Criteria for Charges Payable to the State (150/1992) apply to chargeable performances under public law of Finnish Customs.

Section 31

Entry into force

This Act enters into force on 1 January 2017.

The Act also applies to products placed on the market prior to the entry into force of this Act and permitted to be present on the market at the time of the entry into force of the Acts specified in section 1, subsection 1.

The provisions in force at the time of the entry into force of this Act apply to the consideration of matters pending at that time.