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Product Conformity Act¹

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20.05.2010	RT I 2010, 31, 158	01.01.2011, shall enter into force on the date specified in the decision of the Council of the European Union concerning abrogation of the derogation established with regard to the Republic of Estonia on the basis of Article 140(2) of the Treaty on the Functioning of the European Union, Decision No. 2010/146/EU of the Council of the European Union of 13 July 2010 (OJ L 196, 28.7.2010, pp. 24–26).
06.06.2012	RT I, 28.06.2012, 1	08.07.2012

Chapter 1 GENERAL PROVISIONS

§ 1. Purpose of Act

(1) The purpose of this Act is to ensure product safety and conformity and the free movement of goods.

(2) To achieve the purpose, this Act sets out the following:

- 1) the requirements for ensuring product safety and product conformity attestation (hereinafter conformity assessment) and the grounds of accreditation and market surveillance;
- 2) the principles of evasion of obstacles to the free movement of goods, which may arise from technical regulations and standards, and the grounds of standardisation;
- 3) the establishment of Product Contact Points and the rules of procedure for application of technical regulations with regard to products that fall outside the scope of application of Community harmonisation legislation (hereinafter EU harmonisation legislation) in accordance with Regulation (EC) No. 764/2008 of the European Parliament and of the Council laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No. 3052/95/EC (OJ L 218, 13.8.2008, pp. 21–29) (hereinafter Regulation (EC) No. 764/2008).

§ 2. Application of Act

(1) The requirements established for conformity assessment and conformity-assessment bodies provided for in this Act shall be applied if their application is prescribed by another act, a regulation issued on the basis of an act or EU legislation (hereinafter legislation).

(2) This Act applies to products and their market surveillance insofar as the aspects regulated by this Act have not been regulated by another act. If requirements for a product have been established in another act, this Act shall apply only to the extent of the requirements not regulated by another act.

(3) The requirements provided for in Division 3 of Chapter 2 and in Chapter 3 of this Act apply only if the requirements established for a product arise from EU harmonisation legislation (harmonised area), which is based on the principles provided for in Decision No. 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, pp. 82–128) (hereinafter Decision No. 768/2008/EC). The requirements arising from Division 3 of Chapter 2 and from Chapter 3 do not apply if no EU harmonisation legislation regulates a product (non-harmonised area).

(4) This Act does not apply to the technical regulations or standards of national defence and national security.

(5) In the event of adoption of legislation containing sanitary and phytosanitary measures, the notification requirements provided for in § 43 of this Act apply.

(6) The provisions of the Administrative Procedure Act apply to the administrative procedure provided for in this Act with the specifications provided for in this Act.

(7) The provisions of this Act applicable to the European Union and to the Member States of the European Unions also apply to the Member States of the European Economic Area and to Switzerland and Turkey.

§ 3. Product

(1) For the purposes of this Act, ‘product’ means the thing specified in Article 15(4) of Regulation (EC) No. 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93 (OJ L 218, 13.8.2008, pp. 30–47), which is subject to EU harmonisation legislation.

(2) For the purposes of this Act, ‘product’ also means, among other things, a movable that is intended for consumers or that consumers may use in a presumably reasonable manner even if not intended for them, as well as any product that is made available to consumers in the context of providing a service, that is supplied or made available, whether for consideration or not, in the course of commercial or professional activity, and regardless of whether the product is new, used or reconditioned.

(3) A product supplied as an antique is not considered a ‘product’ for the purposes of this Act.

(4) If a product is placed on the market or made available on the market as a product that needs to be repaired or reconditioned before use, this Act shall not apply to such product if:

- 1) the manufacturer, its authorised representative, the importer or the distributor (hereinafter economic operator) informs the consumer of the need to repair or recondition the product before use;
- 2) the product is not subject to the requirements arising from EU harmonisation legislation.

(5) For the purpose of subsection 5 (8), § 10 and Chapter 5 of this Act, ‘product’ means any product, incl. agricultural and fishery products.

§ 4. Definitions

(1) The definitions used in this Act and legislation established on the basis thereof have the following meaning:

- 1) ‘importer’ means a person located in the European Union who places a product originating from a third country on the market of the Union;
- 2) ‘withdrawal’ means any measure aimed at preventing a product in the supply chain from being made available on the market;
- 3) ‘distributor’ means a person participating in the supply chain, including a trader for the purposes of clause 2 1) of the Trading Act, who places a product on the market, except a manufacturer or importer;
- 4) ‘standard’ means a document drawn up by consensus by a standardisation body for overall and repeated use, which contains technical specifications of the activity or the result thereof. Adherence to a standard is usually voluntary;
- 5) ‘standardisation body’ means a person engaged in drawing up, organising and adopting standards recognised on the national, regional or international level;
- 6) ‘recall’ means any measure aimed at achieving the return of a product that has already been made available to the end user;
- 7) ‘consumer’ means the person specified in clause 2 1) of the Consumer Protection Act;
- 8) ‘technical regulation’ means a technical specification applicable to a product, process or service provided for in legislation. A provision of law that contains the obligation to pay a tax for the purpose of influencing the consumption of a product is also considered a technical regulation. A technical rule for the purposes of Regulation (EC) No. 764/2008 is also considered a technical regulation. The provisions of legislation regulating national social security are not considered technical regulations;
- 9) ‘manufacturer’ means a person who manufactures a product or has a product designed or manufactured, and markets that product under their name or trademark. An importer or distributor who places a product on the market under their name or trademark or who, in a manner that may affect the conformity of the product with the applicable requirements, alters the product that has already been placed on the market, is also considered a manufacturer;
- 10) ‘placing on the market’ means a product first being made available on the European Union market;

- 11) 'making available on the market' means any supply of a product for distribution, consumption or use on the European Union market in the course of commercial activity, whether in return of payment or free of charge;
- 12) 'conformity assessment' means the process of demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;
- 13) 'conformity assessment body' means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;
- 14) 'authorised representative' means a person established within the European Union who has received a written mandate from a manufacturer to act on their behalf in relation to specified tasks.

(2) In addition to the definitions set out in subsection (1) of this section, the definitions used in Regulation (EC) No. 765/2008 are used in this Act.

Chapter 2

REQUIREMENTS FOR PRODUCTS AND OBLIGATIONS OF ECONOMIC OPERATORS

Division 1

Requirements for Products

§ 5. Placing products on market and putting products into service

- (1) A product that is not safe may not be placed on the market or put into service.
- (2) If a requirement established in legislation regarding a product, a product not conforming with the requirement cannot be placed on the market or put into service.
- (3) If a product has been subjected to conformity assessment by legislation, the product cannot be placed on the market or put into service if the procedure for conformity assessment provided for in the legislation has not been followed.
- (4) The Government of the Republic or the minister authorised by it may, by a regulation, establish requirements for a product and a procedure for attestation of the conformity with these requirements and designate a market surveillance authority who carries out market surveillance over the fulfilment of these requirements.
- (5) The requirements established on the basis of this Act may be based on the purpose of ensuring the health and safety of people. The requirements established on the basis of this Act may also be based on another aspect of protection of public interests, including the need to ensure consumer protection, occupational safety, compatibility, interoperability, energy economy or environmental sustainability. The rules arising from Division 1 of Chapter 5 of this Act shall be taken into account upon establishing requirements for products.
- (6) Requirements established for products may also arise from directly applicable legislation of the European Union.
- (7) The Minister of Economic Affairs and Communications may establish more detailed requirements for the purpose of achievement of the goals of the decisions of the European Commission made on the basis of Article 13 of Directive 2001/95/EC of the European Parliament and of the Council on general product safety (OJ L 11, 15.1.2002, pp. 4–17).
- (8) If a requirement that does not arise from EU harmonisation legislation is established for a product by Estonian legislation, a product that does not conform to such requirement may be placed on the market and put into service in Estonia, provided that the product has been lawfully manufactured in a contracting state of the European Economic Area or Switzerland or if it has been lawfully manufactured or placed on the market in a Member State of the European Union or Turkey, provided that protection equal to the protection provided for in Estonian legislation has been ensured with regard to the product.

§ 6. Presumption and assessment of safety

- (1) The safety of a product shall be presumed if the product conforms to:
 - 1) the requirements of the EU harmonisation legislation applicable to the product to the extent of the requirements arising from the legislation, or
 - 2) the health protection and safety requirements of the contracting state of the European Economic Area where the product has been placed on the market, provided that the sphere has not been regulated by EU harmonisation

legislation covering the product or product type and these requirements are in accordance with the Treaty on the Functioning of the European Union.

(2) If a product conforms to the requirements of the harmonised standard specified in subsection 41 (1) of this Act, the safety of the product shall be presumed with regard to the requirements covered by the harmonised standard.

(3) If, under subsections (1) and (2) of this section, the safety of a product cannot be presumed, the safety of the product shall be assessed taking into account the following:

- 1) the standards of the European standardisation bodies adopted by Estonia, which are not harmonised standards;
- 2) original Estonian standards;
- 3) recommendations of the European Commission, which contain guidelines for assessment of product safety;
- 4) the best practices in product safety in the specific industry;
- 5) the state of the art of science and technology;
- 6) the reasoned expectations of consumers regarding safety.

§ 7. Determination of safety

(1) A product is considered to be safe if the product, under normal conditions of use including duration and, where applicable, upon adherence to being put into service, installation and maintenance requirements, does not present any risk to the safety or health of persons or jeopardise the surrounding environment.

(2) In determining whether a product is safe, the market surveillance authority shall take into account, in particular, the following circumstances:

- 1) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, instructions for installation and maintenance;
- 2) the effect on other products, where it is reasonably foreseeable that it will be used with other products;
- 3) the presentation of the product, the labelling, warnings, instructions for use and disposal, and any other information regarding the product;
- 4) the potential risk upon use by certain categories of consumers, in particular children and the elderly.

(3) The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be dangerous.

(4) 'Dangerous product' means any product that does not meet the requirements provided for in subsections (1) to (3) of this section.

(5) 'Serious risk' means any risk arising from a product, including those the effects of which are not immediate, calling for urgent intervention by the market surveillance authority.

§ 8. Dangerous products that appear to be other than they are

(1) It is prohibited to manufacture, place on the market, make available on the market, distribute, import or export dangerous products that appear to be other than they are.

(2) 'Dangerous products that appear to be other than they are' means products that, albeit not being foodstuffs, possess a size or volume, odour, colour, appearance, form, packaging, labelling, such that it is likely that consumers, in particular children, may confuse them with foodstuffs and in consequence place them in their mouths, or suck or ingest them, which might be dangerous and cause physical harm.

§ 9. Display of non-conforming products

A product that does not conform to the requirements or whose conformity has not been assessed may be displayed at trade fairs, exhibitions, demonstrations and other public displays, provided that the product has been equipped with clearly visible and understandable information indicating that the product does not conform to the requirements and it cannot be placed on the market or put into service before it has been brought into compliance with the requirements. The presenter of the product shall ensure safety during the display.

§ 10. Product Contact Point

(1) The Product Contact Point shall contribute to the free movement of products in the European Economic Area by sharing information. Via the Product Contact Point, economic operators shall receive information about the technical regulations applicable to products in accordance with Regulation (EC) No. 764/2008.

(2) The Ministry of Economic Affairs and Communications shall ensure the performance of the functions of Product Contract Points specified in Regulation (EC) No. 764/2008.

(3) The Ministry of Economic Affairs and Communications may share the performance of the functions of the Product Contract Point with another person on the basis of a contract under public law.

Division 2

General Obligations of Economic Operators

§ 11. Obligations of manufacturers

(1) Manufacturers shall provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks.

(2) The presence of warnings does not exempt any manufacturer from compliance with the other requirements laid down in this Act.

(3) Manufacturers shall take measures commensurate with the characteristics of the products they supply, enabling them to:

- 1) be aware of risks these products might pose;
- 2) choose to take appropriate action to avoid these risks such as withdrawal of the products from the market, warning consumers or recall of the products from consumers.

(4) The measures referred to in subsection (3) of this section shall include:

- 1) an indication, by means of the product or its packaging, of the identity or trademark and contact details of the manufacturer, with reference to the type, batch or serial number of the product or another mark, except where not to give such information is justified;
- 2) the carrying out of sample testing of products placed on the market and, if necessary, keeping a register of complaints and keeping distributors informed of such monitoring;
- 3) other relevant measures.

(5) Action such as that referred to in clause (4) 2) of this section shall be undertaken by the manufacturer on a voluntary basis or at the request of the market surveillance authority.

(6) Where other measures laid down in this Act do not suffice to prevent the risk, a product shall be recalled from a consumer if:

- 1) the manufacturer considers it necessary, or
- 2) the market surveillance authority orders the manufacturer to do so.

(7) If the manufacturer is not established in the European Union, the provisions of this section shall apply to the manufacturer's representative. If the manufacturer does not have a representative in the European Union, the provisions of this section shall apply to the importer.

§ 12. Obligations of distributors

(1) Distributors shall act with due care to ensure the conformity of products with requirements. Distributors shall not make any products available on the market:

- 1) that they know, on the basis of the information in their possession and as professionals, are not safe;
- 2) that they know, on the basis of the information in their possession and as professionals, do not comply with the requirements, or
- 3) whose non-conformity with requirements should have been foreseen.

(2) To avoid these risks, distributors shall, among other things:

- 1) within the limits of their respective activities, participate in monitoring the safety of products placed on the market;
- 2) pass on information on product risks to the manufacturer;
- 3) keep the documentation necessary for tracing the origin of products.

§ 13. Informing market surveillance authority

(1) Where an economic operator knows or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market or that they distribute cannot be deemed to be safe on the basis of § 6 of this Act, they shall immediately inform the market surveillance authority that exercises supervision over the relevant product group.

(2) In the event of serious risk, the manufacturer, importer or distributor shall forward the following to the market surveillance authority:

- 1) information that enables the relevant product or batch of products to be clearly identified;
- 2) a full description of the risk arising from the product;
- 3) information that enables the former and later possessors and suppliers of the product to be identified;
- 4) information on the measures the person has taken in order to prevent the risks;
- 5) other information that may be required by the market surveillance authority.

(3) The information and documentation to be submitted in accordance with subsection (2) of this section shall be in a language that the market surveillance authority understands.

(4) Economic operators shall cooperate with the market surveillance authority in order to prevent the risks that may arise from products supplied or delivered to consumers by them.

(5) At the request of the market surveillance authority an economic operator shall inform the market surveillance authority of any and all economic operators to which the economic operator has supplied the product or that have supplied the product to the economic operator.

Division 3

Additional Obligations of Economic Operators in Harmonised Areas

§ 14. Obligations of manufacturers

(1) When placing their products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in the relevant legislation.

(2) Before placing their products on the market, manufacturers shall draw up the required technical documentation regarding the products and carry out the conformity assessment procedure applicable or have it carried out. When compliance of a product with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EC declaration of conformity provided for in § 19 of this Act and affix the conformity marking.

(3) Manufacturers shall keep the technical documentation and the EC declaration of conformity for at least ten years after the product has been placed on the market, unless provided otherwise in legislation.

(4) Manufacturers shall ensure that procedures are in place for series manufacturing to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of a product is declared shall be taken into account.

(5) Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing their identification. Where the size or nature of the product does not allow it, the required information shall be provided on the packaging or in a document accompanying the product.

(6) Manufacturers shall indicate their name or trademark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product.

(7) Manufacturers shall ensure that the product is accompanied by instructions and safety information in the official language of a contracting state of the European Economic Area, which can be understood by potential end-users. A product to be made available to consumers on the market shall be accompanied at least by instructions and safety information in Estonian.

(8) Manufacturers who consider or have reason to believe that a product they have placed on the market is not in conformity with the requirements laid down in EU harmonisation legislation shall immediately take the necessary corrective measures to bring that product into conformity, to recall it from consumers or to withdraw the product from the market.

§ 15. Authorised representatives

(1) A manufacturer may, by a written mandate, appoint an authorised representative.

(2) The mandate shall allow the authorised representative to do at least the following:

- 1) to keep the EC declaration of conformity and the technical documentation at the disposal of the surveillance authority during the term specified in subsection 14 (3) of this Act;
- 2) further to a request from the market surveillance authority, provide the authority with all the information and documentation necessary to demonstrate the conformity of a product;
- 3) cooperate with the market surveillance authorities, at their request, on any action taken to eliminate the risks posed by products covered by their mandate.

(3) The functions of authorised representatives do not include the obligations specified in subsection 14 (1) of this Act or drawing up technical documentation.

§ 16. Obligations of importers

(1) Importers shall only place compliant products on the market.

(2) Before placing a product on the market importers shall ensure that:

- 1) the appropriate conformity assessment procedure has been carried out by the manufacturer;

- 2) the manufacturer has drawn up the technical documentation;
- 3) the product bears the required conformity marking or markings;
- 4) the product is accompanied by the required documents;
- 5) the manufacturer has complied with the requirements set out in subsections 14 (5) and (6) of this Act.

(3) Importers shall ensure that, while a product is under their responsibility, storage or transport conditions shall not jeopardise its compliance with the requirements.

(4) Where deemed appropriate with regard to the risks presented by a product, importers shall, to protect the health and safety of consumers, carry out sample testing of marketed products, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of such monitoring.

(5) Importers shall, during the term provided for in subsection 14 (3) of this Act, keep a copy of the EC declaration of conformity at the disposal of the market surveillance authority and ensure that the technical documentation can be made available to the market surveillance authority, upon request.

(6) In addition to the provisions of this section, the requirements provided for in subsections 14 (6) to (8) of this Act apply to importers.

§ 17. Obligations of distributors

(1) When making a product available on the market distributors shall act with due care in relation to the requirements applicable.

(2) Before making a product available on the market distributors shall verify that:

- 1) the product bears the required conformity marking or markings;
- 2) the product is accompanied by the required documents and by instructions and safety information prescribed by legislation;
- 3) the manufacturer has complied with the requirements set out in subsections 14 (5) and (6) of this Act;
- 4) the importer has complied with the requirements set out in subsection 14 (6) of this Act.

(3) Distributors who consider or have reason to believe that a product is not in conformity with the applicable requirements shall make the product available on the market only after the product has been brought into conformity with the requirements. Where the product presents a risk, distributors shall inform the manufacturer or importer and the market surveillance authority that exercises surveillance over the product group.

(4) Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements.

(5) Distributors who consider or have reason to believe that a product they have made available on the market is not in conformity with the applicable requirements arising from EU harmonisation legislation shall make sure that the corrective measures necessary to bring that product into conformity, to withdraw it from the market or recall it from consumers, if appropriate, are taken.

Chapter 3 CONFORMITY ASSESSMENT

Division 1 General Provisions

§ 18. Conformity assessment

(1) The conformity of a product is attested by way of due conformity assessment provided for in legislation applicable to the product.

(2) It may be established in legislation that product conformity assessment must be attested by a state authority, the manufacturer or a conformity assessment body. If legislation imposes the obligation of attestation of the conformity of a product on a state authority, the latter may, for the purpose of identifying the technical requirements, use the services of a competent accredited body that complies with the requirements established for conformity assessment bodies in § 28 of this Act.

(3) It may be established in legislation that upon placing a product on the market or putting a product into service the product must be accompanied by a declaration of conformity or other documents specifying the conformity, installation, maintenance or use of the product.

§ 19. EC declaration of conformity

(1) By an EC declaration of conformity a manufacturer certifies that the requirements established for a product by relevant legislation have been complied with.

(2) If a product is subject to multiple instruments that require a declaration of conformity to be drawn up, one declaration of conformity shall be drawn up for the product. The declaration of conformity shall specify the related EU harmonisation legislation.

(3) The EC declaration of conformity complies with the requirements provided for in the instrument, follows the structure of the same set out in Annex III of Decision No. 768/2008/EC, contains the elements specified in the relevant modules set out in Annex II of the Decision, and it is updated regularly.

§ 20. Conformity marking

(1) If an instrument provides for the obligation to affix a conformity marking, i.e. the CE marking, the manufacturer or their authorised representative shall affix the CE marking to the product that complies with the requirements provided for in the instrument and whose conformity with the requirements has been evaluated and certified pursuant to the established procedure.

(2) CE marking is subject to the general principles provided for in Regulation (EC) No. 765/2008 and the requirements of the instrument providing for the obligation to install the conformity marking.

(3) EU harmonisation legislation may also provide for the obligation to install a conformity marking that differs from the conformity marking referred to in the instrument specified in subsection (2) of this section.

§ 21. Certificate of conformity

(1) A certificate of conformity is a document issued by a conformity assessment body, which certifies that the product or quality system conforms to the requirements established in the certificate.

(2) If a conformity assessment body identifies that a manufacturer has failed to comply with the requirements arising from legislation serving as the basis for the issue of a conformity certificate, the relevant harmonised standard or other technical specifications, the conformity assessment body shall demand that the manufacturer take corrective measures and shall not issue a conformity certificate before the corrective measures have been applied.

(3) If a conformity assessment body identifies after the issue of a certificate that a product no longer complies with the requirements serving as the basis for the issue of the certificate, the conformity assessment body shall demand that the manufacturer take corrective measures and, if necessary, the conformity assessment body shall suspend or revoke the certificate.

(4) If no corrective measures are taken or if they do not have the desired effect, the conformity assessment body shall limit the validity of the certificate or suspend or revoke the certificate.

Division 2 Operating as Conformity Assessment Body

§ 22. General requirements for activities of conformity assessment bodies

(1) Conformity assessment bodies shall perform their functions in a competent, transparent, impartial, independent, non-discriminating and proportionate manner and follow the requirements established for the conformity assessment of specific products.

(2) Conformity assessment bodies shall participate in cooperation between conformity assessment bodies operating in the European Union within the scope of their field of activity.

§ 23. Information obligation of conformity assessment bodies

(1) A conformity assessment body that has obtained an activity license in Estonia shall inform the committee specified in subsection 27 (3) of this Act:

- 1) of refusal to issue a certificate of conformity or limitation, suspension or cancellation of the validity thereof;
- 2) immediately of any circumstance that affects the scope of the right to operate granted under the activity license of the conformity assessment body;
- 3) of the market surveillance authority's requests for information regarding conformity assessment;

4) at the request of the committee, of conformity assessment carried out within the scope of the right to operate granted under the activity license, including of cross-border conformity assessments and contracting.

(2) A conformity assessment body shall, at its own initiative, inform other conformity assessment bodies operating in the same sphere in the contracting states of the European Economic Area of the suspicion that a person may address another conformity assessment body with the request of the conformity assessment of a product or quality system that the conformity assessment body has found to be non-conforming.

(3) Conformity assessment bodies shall inform the market surveillance authority of the suspicion that a product placed on the market or a product put into service is non-conforming.

(4) By February 1 conformity assessment bodies shall annually submit to the Ministry of Economic Affairs and Communications an account of the conformity assessments carried out by them in the previous calendar year in the capacity of a conformity assessment body within the scope of their right to operate granted under the activity license. The information obligation specified in clause 3) of subsection (1) of this section may be fulfilled by submitting a consolidated account.

(5) Conformity assessment bodies shall document their conformity assessment activities and preserve the respective documents for no less than ten years, unless otherwise provided by legislation.

§ 24. Confidentiality

(1) Conformity assessment bodies shall ensure the confidentiality of the information obtained in the course of their activities. This obligation of the employees and mandataries of conformity assessment bodies shall remain in force after termination of a contract made with the conformity assessment body.

(2) The confidentiality requirement shall apply if the market surveillance authority requests information about conformity assessment while performing its tasks.

§ 25. Subsidiaries and subcontractors of conformity assessment bodies

(1) In the course of conformity assessment, conformity assessment bodies may use the services of subsidiaries or subcontractors (hereinafter contractors) with the consent of the person applying for conformity assessment.

(2) If a conformity assessment body uses the services of a contractor in conformity assessment, the body shall ensure the compliance of the contractor with the requirements of the body. The conformity assessment body shall be fully liable for the services provided by contractors.

(3) Conformity assessment bodies shall ensure that the activities of their subsidiaries or contractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

(4) Conformity assessment bodies shall keep at the disposal of the market surveillance authorities the relevant documents concerning the assessment of the qualifications of the contractor and the conformity assessments carried out by them.

§ 26. Accredited in-house conformity assessment bodies

(1) It may be provided by legislation that an accredited in-house body may be used to carry out conformity assessment activities.

(2) An accredited in-house body shall constitute a separate and distinct part of the undertaking and shall not participate in the design, manufacture, distribution, installation, use or maintenance of the products it assesses. An accredited in-house body shall meet the following requirements:

- 1) it has been accredited to carry out a specific conformity assessment;
- 2) the body and its personnel are organisationally identifiable and have reporting methods within the undertaking of which they form a part that ensure their impartiality and demonstrate it to the relevant national accreditation body;
- 3) neither the body nor its personnel are responsible for the design, manufacture, distribution, installation or maintenance of the products they assess nor engage in any activity that might conflict with their independence of judgment or integrity in relation to their assessment activities;
- 4) the body shall supply its services exclusively to the undertaking of which it forms a part.

(3) Notification of an accredited in-house body shall not be given to the Member States or the European Commission.

Division 3

Granting activity licenses to conformity assessment bodies, suspension and revocation of activity licenses

§ 27. Activity license of conformity assessment bodies

(1) In order to operate as a conformity assessment body, an individual or entity (hereinafter person) ought to have an activity license issued by a contracting state of the European Economic Area, and the European Commission and other contracting states of the European Economic Area must be informed of the person.

(2) A body specified in an agreement of mutual recognition made between the European Union and a third country may also operate as a conformity assessment body.

(3) A committee established in the Ministry of Economic Affairs and Communications (hereinafter committee for conformity assessment bodies) shall grant activity licenses to persons established in Estonia, and suspend and revoke them. The affairs of the committee for conformity assessment bodies shall be organised by the Ministry of Economic Affairs and Communications.

(4) The Government of the Republic shall establish the procedure for establishment and the rules of procedure of the committee for conformity assessment bodies and the requirements for the decisions of the committee.

§ 28. Requirements for conformity assessment bodies

(1) A conformity assessment body, including a person who applies for an activity licence of a conformity assessment body, shall comply with the following requirements:

1) the person has been registered in the commercial register, non-profit associations and foundations register or state register of state and local government agencies;

2) the person, including its shareholders and members who hold more than 50 percent of the shares as well as its employees who, based on their position, have a substantial decision-making capacity, has or have an impeccable reputation;

3) the person's activities as a conformity assessment body have been organisationally and in terms of accounting been separated from its other activities;

4) the person is able to act in an independent, professional, impartial and non-discriminating manner;

5) the person has indicated in the submitted application a sufficient number of employees with the required education, training and experience for conformity assessment, who, within the scope of the right to operate specified in the application for the activity license and granted under the activity license, are familiar with the requirements arising from the applicable EU harmonisation legislation and harmonised standards regarding the products that are to be subjected to conformity assessment;

6) the person has the tools that allow for carrying out conformity assessment procedures;

7) the person is technically sufficiently competent to carry out conformity assessment procedures within the scope of the right to operate specified in the application for the activity license and in the activity license;

8) the person and the personnel shall not be the designer, planner, manufacturer, authorised representative of the manufacturer, importer, distributor, supplier, installer, maintainer, owner or user of the products that they assess, not the representative of any of those parties, and their other activities shall not be related to the products to an extent that arouses suspicion in their independence and impartiality, thereby the person or the personnel carrying out conformity assessment shall not provide respective consultation services. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes;

9) the personnel of the conformity assessment body shall be remunerated regardless of the number of conformity assessment procedures and results;

10) at the time of operating as a conformity assessment body the person has valid liability insurance to the extent of a sum insured that ensures the indemnification of possible damage caused to third parties by its activities as a conformity assessment body and that amounts to no less than 64,000 euros;

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11) the person complies with other requirements arising from EU harmonisation legislation applicable to the person's field of activity.

(2) If a person demonstrates their compliance with the criteria laid down in the applicable harmonised standards or parts thereof, the person shall be presumed to comply with the requirements set out in the legislation in so far as the standards cover those requirements.

(3) The conformity assessment body and a person who applied for an activity license of a conformity assessment body shall have to be accredited to carry out the conformity assessment applied for under the activity license.

(4) If a conformity assessment body was accredited by the national accreditation body of another contracting state of the European Economic Area, the conformity assessment body shall submit to the Ministry of Economic Affairs and Communications the report of the follow-up inspection carried out by the accreditation body.

§ 29. Submission of documents to obtain activity license

(1) In order to obtain an activity license or change the scope of the right to operate granted under an activity license, a person (hereinafter applicant) shall submit to the Ministry of Economic Affairs and Communications a written application with the following data and documents:

- 1) the applicant's name, registry code and contact details;
- 2) the name and contact details of the person in charge;
- 3) the number of employees;
- 4) the products or product types with regard to which the applicant wishes to obtain the right to operate for the purpose of conformity assessment and references to applicable legislation;
- 5) the conformity assessment procedures the applicant would like to carry out as a conformity assessment body and references to applicable legislation;
- 6) the original copy of the accreditation certificate or a copy thereof certified by the issuer or a notary public;
- 7) a copy of the liability insurance policy;
- 8) the name, position and contact details of the person who signed the application.

(2) If a conformity assessment body uses the services of a contractor, the body shall also submit information about the contractor and its compliance with the requirements, enclosing a copy of the respective cooperation contract.

(3) If a conformity assessment body wishes to change the scope of the right to operate specified in an existing activity license or to extend the term of validity of the right to operate, the body shall submit in an application the data and documents it has not submitted before or that have change to the extent covered by the previously submitted document.

§ 30. Granting activity license

(1) The committee for conformity assessment bodies shall grant an activity license to an applicant to carry out the conformity assessment procedures laid down in legislation if:

- 1) the applicant complies with the requirements laid down in § 28 of this Act;
- 2) the applicant has submitted an application that complies with the requirements;
- 3) the applicant has no tax arrears;
- 4) no bankruptcy procedure or liquidation procedure has been initiated against the applicant and no wind-up decision has been made with regard to the applicant.

(2) Unless otherwise provided by legislation, an activity license shall be granted for the term of validity of the accreditation certificate or another objective and substantial circumstances serving as the basis for the license.

§ 31. Refusal to grant activity license

(1) The committee for conformity assessment bodies shall refuse to grant an activity license if:

- 1) the applicant does not comply with the requirements arising from legislation;
- 2) the applicant has given false information that is of significant importance upon granting the right to operate;
- 3) the application does not comply with the requirements and the defects have not been eliminated within the term granted for elimination of defects.

(2) The committee for conformity assessment bodies may refuse to issue an activity license if the applicant's right to operate as a conformity assessment body has previously been revoked on the following grounds:

- 1) the conformity assessment body has failed to comply with a precept;
- 2) the conformity assessment body does not allow for exercising state supervision over its activities;
- 3) the conformity assessment body has committed a fundamental breach or repeatedly breached the requirements established for its activities;
- 4) the conformity assessment body continues operating as a conformity assessment body during the term when the validity of its activity license has been suspended.

§ 32. Suspension of validity of activity license

(1) The committee for conformity assessment bodies may suspend the activity license of a conformity assessment body either in part or in full if the body no longer complies with the requirements for operation in the field of activity or if there is reasonable doubt that the body violates the requirements established for conformity assessment bodies.

(2) The validity of an activity license shall be suspended for the term that is reasonably necessary for bringing the conformity assessment body into compliance with the requirements or for the term that is necessary for inspecting the activities of the compliance assessment body.

(3) The committee for conformity assessment bodies shall restore the validity of an activity license if during the term of suspension the committee has received data that attests the compliance of the conformity assessment

body with the requirements or if no violation of the requirements established for the conformity assessment body was identified.

§ 33. Revocation of activity license

(1) The committee for conformity assessment bodies may revoke the activity license of a conformity assessment body either in part or in full if:

- 1) circumstances whereby the conformity assessment body would not have received any activity license or received a partial activity license have emerged;
- 2) the conformity assessment body is not in compliance with the requirements provided for in this Act;
- 3) the conformity assessment body has not eliminated the defects within the term specified in a precept.

(2) The committee for conformity assessment bodies shall revoke the activity license of a person either in part or in full if the person:

- 1) has submitted the respective written application;
- 2) does not allow for exercising state supervision over its activities;
- 3) has committed a fundamental breach or repeatedly breached the requirements established for its activities;
- 4) is liquidated or has been declared bankrupt;
- 5) has given false data which had important significance upon making a decision to grant the activity license to the conformity assessment body;
- 6) continues operating as a conformity assessment body during the term when the validity of its activity license has been suspended;
- 7) during the term of suspension of the activity license, has not submitted to the committee for conformity assessment bodies any data attesting the compliance of the conformity assessment body with the requirements.

(3) The revocation of the activity license of a conformity assessment body shall not influence the validity of the documents issued by the body.

(4) In the event of revoking the activity license of a conformity assessment body, the body shall hand its conformity assessment documentation over to the Ministry of Economic Affairs and Communications. The documentation does not need to be handed over if the activity license of the conformity assessment body is revoked in part. The committee for conformity assessment bodies shall organise handing over the documentation.

§ 34. Notification of activity license and commencement of right to operate

(1) The committee for conformity assessment bodies shall notify the European Commission and other Member States of granting an activity license to a conformity assessment body or suspension or revocation thereof. Notification shall ensure in the Member States of the European Union the recognition of the conformity assessment procedures carried out by the conformity assessment body within the scope of the right to operate granted under the activity license. In the course of notification the conformity assessment body shall receive an identification number.

(2) A conformity assessment body may commence operation to the extent specified in the decision of the committee for conformity assessment bodies if a two-week waiting period has ended and the European Commission or any Member State has not raised any objections to the notification of the conformity assessment body.

(3) If the European Commission or another Member State raises any objections to the notification of granting an activity license to a conformity assessment body, the committee for conformity assessment bodies shall take these into account and renew the procedure for granting an activity license to the conformity assessment body.

§ 35. Publication of information on activity license in register of economic activities

(1) For the purpose of informing the public, the Ministry of Economic Affairs and Communications shall publish decisions on the data on granting activity licenses to conformity assessment bodies or suspension or revocation of the licenses in the register of economic activities as registry entries.

(2) In addition to the information specified in the Register of Economic Activities Act, the following information shall be entered in the register of economic activities regarding a conformity assessment body:

- 1) the products or the product type with regard to which the conformity assessment body has the right to operate, as well as the conformity assessment procedures that the person has the right to carry out as a conformity assessment body;
- 2) information about the decision of the committee for conformity assessment bodies, which granted the person the right to operate, as well as information about the suspension and revocation of such decision;
- 3) information about precepts made to the conformity assessment body;
- 4) the identification number of the conformity assessment body.

(3) A registry entry on the granting of an activity license shall be made immediately after the waiting period specified in subsection 34 (2) of this Act is over and the conformity assessment body's right to operate has entered into force. A registry entry on the suspension or revocation of the activity license shall be made without delay.

Chapter 4 ACCREDITATION

§ 36. Organisation of accreditation

Accreditation shall be organised and carried out in accordance with Chapter II of Regulation (EC) No. 765/2008.

§ 37. Estonian accreditation body

(1) Estonian national accreditation body is a state-founded entity that operates on a not-for-profit basis and the goal of whose statutory activities is the accreditation of conformity assessment bodies.

(2) The person performing the tasks of the Estonian national accreditation body shall be appointed by an order of the Government of the Republic.

(3) The state shall finance the participation of the Estonian national accreditation body in the activities of European and international accreditation cooperation bodies and, if it is agreed on separately, other activities of the accreditation body.

§ 38. Operation as Estonian accreditation body

(1) The Estonian accreditation body shall:

- 1) administer the accreditation system, and accredit, assess and attest the professional competency of measurers;
- 2) organise interlaboratory comparison testing;
- 3) approach all applications for professional competency assessment and accreditation in an impartial manner and in accordance with the principle of equal treatment;
- 4) comply with the requirements established for accreditation bodies in Regulation (EC) No. 765/2008;
- 5) represent Estonia in international accreditation cooperation;
- 6) publish on its website the names of accredited conformity assessment bodies, the scope of accreditation and notices of suspension or revocation of accreditations;
- 7) advise government agencies in accreditation-related matters.

(2) If, as a result of inspection of a conformity assessment body that obtained an activity license on the basis of this Act, the body is required to take corrective measures, the accreditation body shall submit a summary of the results of inspection to the Ministry of Economic Affairs and Communications after taking the measures. The accreditation body shall also immediately inform the Ministry of Economic Affairs and Communications of the suspension or revocation of the accreditation of such bodies, of complaints filed against their activities and of measures taken to resolve these.

Chapter 5 TECHNICAL REGULATIONS AND STANDARDS

Division 1 General Provisions

§ 39. Technical regulations

(1) Legislation containing technical regulations shall be drafted in accordance with international law binding upon Estonia, standards adopted by international or European standardisation bodies or the technical specifications set out in their final drafts. Deviation from the technical specifications set out in standards of their final drafts shall be permitted if taking these into account without any exceptions would be inefficient due to climatic or geographic conditions or technical problems or unfitting for achievement of the desired objectives.

(2) Legislation containing technical regulations shall establish uniform requirements for products manufactured in and imported to Estonia and for services provided.

(3) A reasonable interval shall be allowed between the publication and entry into force of legislation containing technical regulations so manufacturers can bring their products or the method of manufacturing into compliance with the regulations. The requirement of a reasonable interval shall not apply in cases where the rapid entry into force of a technical regulation is necessary for the purpose of protecting human health or safety, protecting the environment or guaranteeing national security.

§ 40. Estonian standards

(1) Estonian standards are standards adopted by Estonian standardisation bodies. The abbreviation for Estonian standards is 'EVS.'

(2) An Estonian standard is deemed adopted when a notice concerning its adoption is published in the official publication of the Estonian standardisation body.

(3) The Estonian national standardisation body shall ensure the availability of standards to the public as of the publication date of the notice provided for in subsection (2) of this section.

(4) An Estonian standard may be:

- 1) a transposed standard of an international or European standardisation body;
- 2) a transposed original standard of another state;
- 3) an original Estonian standard.

(5) An original Estonian standard shall be adopted and made accessible at least in Estonian.

(6) In the event of transposition of a standard of an international or European standardisation body or an original standard of another state, the transposed standard does not have to be in Estonian. The Estonian standardisation body shall make the transposed standard available in at least one of the official languages of the standardisation body that drew up the standard. Different language versions of the transposed standard shall be equal.

§ 41. Usage of harmonised standards

(1) If a notice (reference) on a harmonised standard has been published in the Official Journal of the European Union and the standard has been adopted as the standard of at least one Member State of the European Union and unless legislation provides otherwise, it shall be presumed that products or services conforming with the standard also conform to technical regulations to the extent of the requirements covered by the standard.

(2) If a notice (reference) published on a harmonised standard in the Official Journal of the European Union has been repealed, products or services shall not be deemed to comply with the relevant technical regulations in the event the standard is adhered to.

(3) If an additional notice (reference) has been published on a harmonised standard in the Official Journal of the European Union, the conformity of products or services with the relevant technical regulations shall, in the event of adherence to the standard, be presumed on the terms and conditions set out in the notice.

§ 42. Reference to standard in technical regulation

(1) When taking the requirements of a standard into account in a technical regulation, only the significant requirements or objectives shall be laid down and, where necessary, a reference to the standard shall be made. A standard may be referred to directly or in general in a technical regulation.

(2) A reference to a standard is direct if it contains the designation of the standard, which is a combination of the abbreviation of the standardisation body that adopted or drew up the standard and the number of the standard. A direct reference shall be given with or without a date. In the event of a reference with a date, the standard shall be adhered to as of the date and, in the event of a standard without a date, the standard shall be adhered to as amended.

(3) A reference to a standard is general if reference is made to standards adopted by a standardisation body or to standards identified otherwise and the reference does not contain the designation of the standard.

(4) Recommended reference shall be preferred when referring to a standard in a technical regulation. A reference to a standard is deemed recommended if adherence to the referred standard is not compulsory and other solutions can be applied in order to implement the requirements laid down in legislation. Where a reference to a standard is set out in a technical regulation, compliance with the relevant requirements laid down in legislation shall be presumed upon adherence to the referred standard with regard to the requirements covered by the standard.

§ 43. Notification

(1) The European Commission and contracting states of the European Economic Area shall be notified of legislation that is being drafted and that has been adopted, which contains a technical regulation concerning the product or affecting the marketing of the product, including a sanitary or phytosanitary measure.

(2) There is no need to notify of draft legislation that follows the obligations arising from EU harmonised legislation and international agreements, as a result of which a common technical regulation will be adopted in the European Union.

(3) The drafter of legislation subject to notification shall submit the draft legislation to the authority coordinating notification. The draft legislation shall be submitted for notification at such stage of the proceedings where it is still possible to amend the draft legislation.

(4) The procedure for notification shall be established and the authority coordinating notification shall be appointed by a regulation of the Government of the Republic.

Division 2

Organisation of Standardisation

§ 44. Estonian standardisation body

(1) The Estonian standardisation body is a state-founded non-profit association that represents its members and the purpose of the activities of which, as specified in the articles of association, is to draw up and publish standards and represent Estonia in international standardisation. The interests of the state in the Estonian standardisation body shall be represented by a government agency as a member.

(2) The person performing the tasks of the Estonian standardisation body shall be appointed by an order of the Government of the Republic.

(3) The state shall finance the participation of the Estonian standardisation body in the activities of European and international standardisation bodies and, if it is agreed on separately, other activities of the standardisation body.

§ 45. Obligations of Estonian standardisation body

(1) The Estonian standardisation body shall:

- 1) fulfil standardisation obligations assumed by international agreements and delegated by the state, including the Estonian national standardisation scheme (hereinafter standardisation scheme);
- 2) participate in the work of the international and European standardisation bodies where it is a member;
- 3) draw up standards programmes, participate in the preparation of the standardisation scheme and publish information about these on its website;
- 4) publish in the official publication made available on its website information on drafted Estonian standards as of making them available for an opinion poll or commenting and information on adopted, repealed or harmonised standard-transposing Estonian standards as of their adoption or repeal or the receipt or loss of the status of a harmonised standard;
- 5) inform foreign states, associations of states and international standardisation bodies of drafted or adopted standards and standards programmes;
- 6) use the EVS trademark and ensure that it is not misused.

(2) The Estonian standardisation body shall ensure the availability of Estonian standards in Estonia and the possibility to access them free of charge at least at the address of its seat. Upon making standards available, the Estonian standardisation organisation shall ensure the protection of copyright on standards and publish the terms and conditions of protection of copyright.

(3) The Estonian standardisation body may charge a fee for dissemination of standards. The fee shall be cost-based and ensure the availability of the standardisation service at the required level in Estonia and the availability of funds required for the development of the standardisation body.

(4) The Estonian standardisation body performs the tasks of an information centre of the World Trade Organization (hereinafter WTO). The tasks of the information centre arise from Article 10 of the WTO Agreement on Technical Barriers to Trade, Annex B of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, and other legislation and international agreements that lay down the coordination of the exchange of information pertaining to standards.

§ 46. Standardisation committee

(1) The tasks of the standardisation committee include drafting the standardisation scheme, submission thereof to the Minister of Economic Affairs and Communications for approval, and performance of other related tasks.

(2) The procedure for the formation of and the rules of procedure of the committee shall be established by a regulation of the Government of the Republic.

§ 47. Standardisation scheme

(1) The standardisation scheme is a document that comprises a list of standards drawing up or the transposition of which into Estonian standards is deemed essential by government agencies.

(2) The standardisation scheme shall be drawn up once a year. The Minister of Economic Affairs and Communications shall approve the standardisation scheme for the coming year by December 31.

§ 48. Drawing up Estonian standards and financing Estonian standardisation body

(1) The costs of drawing up an Estonian standard shall be covered by interested persons.

(2) The drawing up of an Estonian standard commissioned by a state agency or on the basis of the standardisation scheme shall be financed by the state through the budget of the appropriate ministry.

(3) The costs of providing information services for which the Estonian standardisation body is commissioned by the state, including the expenses of the information centre and library of the Estonian standardisation body, the costs of administration of the website, compilation and publication of the official publication, and the membership fees and costs of participation in the work of international and European standardisation bodies shall be covered from the state budget. Such costs shall be specified in the budget of the area of government of the appropriate ministry.

Chapter 6 MARKET SURVEILLANCE AND SURVEILLANCE OVER CONFORMITY ASSESSMENT BODIES

Division 1 Organisation of Market Surveillance

§ 49. Organisation of market surveillance

(1) In harmonised areas market surveillance of products shall be organised and exercised in accordance with Chapter III of Regulation (EC) No. 756/2008 and this Act and, in non-harmonised areas, in accordance with this Act.

(2) The market surveillance authorities may take the measures specified in Division 2 of this Chapter with regard to products of a harmonised area, which have been made available to consumers on the market, provided that these measures are more specific than the measures laid down in Chapter III of the Regulation (EC) No. 756/2008.

(3) The provisions of Section 3 of Chapter III of Regulation (EC) No. 756/2008 apply to controls of products entering the market of the European Union insofar as it has not been regulated by other legislation.

§ 50. Competence of authorities participating in market surveillance

(1) State surveillance over the fulfilment of the requirements established for products by legislation shall be exercised by market surveillance authorities. For the purposes of this Act, market surveillance authorities include the Consumer Protection Board, the Health Board, the Maritime Administration, the Technical Surveillance Authority, the Agricultural Board, the Environmental Inspectorate and the Labour Inspectorate.

(2) The Consumer Protection Board exercises state surveillance over compliance with the requirements established for products designed for consumers.

(3) The Health Board exercises state surveillance over compliance with the health requirements of products.

(4) The Maritime Administration exercises state surveillance over compliance with the requirements established for watercraft.

(5) The Technical Surveillance Authority exercises state surveillance over compliance with the requirements established for the following products:

- 1) building materials and products;
- 2) electrical equipment;
- 3) appliances;
- 4) gaseous fuels, appliances burning gaseous fuels, fittings of appliances burning gaseous fuels;
- 5) lifts, safety components of lifts, cableways, subsystems and safety components of cableways;
- 6) explosives and pyrotechnical products;
- 7) machinery, replaceable appliances of machinery, protection devices, auxiliary lifting equipment, chains, ropes and belts, removable transmission mechanisms, partially assembled machinery;

- 8) equipment used outdoors, based on the noise requirements established for it;
- 9) equipment, protection systems, components and fittings used in an explosive atmosphere;
- 10) measuring instruments and pre-packages subject to compulsory metrological control;
- 11) compliance of household appliances, heating appliances and devices with energy efficiency, energy-performance labels and ecological design requirements;
- 12) pressure equipment, including pressure vessels, piping systems, safety and auxiliary devices, vessels for dangerous liquids, and aerosol dispensers;
- 13) other products whose surveillance has been placed within its competence by this Act or legislation adopted on the basis of this Act.

(6) The Agricultural Board exercises state surveillance over compliance with the requirements established for fertilisers with the marking 'EU fertiliser.'

(7) The Environmental Inspectorate exercises state surveillance over compliance with the requirements established for products of concern and other products that potentially endanger the environment.

(8) The Labour Inspectorate exercises state surveillance over compliance with the requirements established for personal protective equipment used in a working environment.

(9) The Tax and Customs Board inspects the safety of imported products and their compliance with the requirements, thereby cooperating with the appropriate market surveillance authority.

§ 51. Cooperation and exchange of information between authorities participating in market surveillance

(1) For the purpose of facilitating cooperation and exchange of information between the authorities participating in market surveillance, the Minister of Economic Affairs and Communications shall form a market surveillance council in the Ministry of Economic Affairs and Communications.

(2) The market surveillance council shall consist of representatives of all the authorities participating in market surveillance under this Act and representatives of the ministries of their areas of government.

(3) The task of the market surveillance council is to make proposals:

- 1) for establishment of the strategic goals of market surveillance and product safety;
- 2) for shaping the structure and activity priorities of the market surveillance authorities and for coordinated application for state budget funds;
- 3) for furthering cooperation between the market surveillance authorities and the Tax and Customs Board;
- 4) for furthering the training and international cooperation of surveillance officers;
- 5) in other matters concerning market surveillance.

(4) The composition and rules of procedure of the market surveillance council shall be approved by a directive of the Minister of Economic Affairs and Communications.

(5) At the request of the Ministry of Economic Affairs and Communications market surveillance authorities shall submit information about the implementation of Regulation (EC) No. 764/2008.

§ 52. Market surveillance programmes

(1) Market surveillance authorities shall draw up market surveillance programmes with regard to the products over which they exercise surveillance under Regulation (EC) No. 765/2008, implement the programmes and update the programmes regularly.

(2) Market surveillance authorities shall publish their market surveillance programmes on their websites and communicate them to other Member States and the European Commission via the information system specified in Article 23 of Regulation (EC) No. 765/2008.

§ 53. Review and assessment of surveillance operations

(1) Market surveillance authorities shall regularly review the surveillance operations carried out on the basis of their market surveillance programmes, assess these and draw up reports on surveillance operations.

(2) Market surveillance authorities shall publish their surveillance operations reports on their websites and communicate them to other Member States and the European Commission via the information system specified in Article 23 of Regulation (EC) No. 765/2008.

Division 2

Market Surveillance Measures

§ 54. Market surveillance measures

(1) Market surveillance authorities have the right to check to the required extent the safety and conformity of each product placed on the market before the product has reached the end-consumer as well as in cases where the product has been placed on the market as a conforming and safe product.

(2) For the purpose of performance of their tasks, market surveillance authorities have the right to:

- 1) enter the premises where a product is manufactured, stored or offered for sale;
- 2) check the documents attesting the safety and conformity of the product and make transcripts of the documents;
- 3) use technical equipment for recording the situation;
- 4) for the purpose of assessment of safety and conformity, receive information from any and all persons concerned.

(3) Market surveillance authorities shall exercise their mandate in accordance with the principle of proportionality and facilitate voluntary operations they are entitled to carry out under this Act in order to increase the safety of economic operators' products.

(4) Market surveillance authorities have the right to:

- 1) with regard to a product that may present a risk on certain conditions, demand that it be labelled with clear warnings in Estonian about the risks that the product may cause or establish prior conditions to placing the product on the market, which ensure safety;
- 2) with regard to a product that may present a risk to certain persons, demand that these persons are warned of the risk in a suitable manner and at a suitable time, including by publishing separate warnings;
- 3) with regard to a product that may be dangerous, demand the temporary withdrawal of the product from the market or prohibit the presentation of the product for a period that is necessary for assessment and checking of its safety;
- 4) prohibit the placing of a product on the market and take measures that ensure compliance with the prohibition;
- 5) demand or organise the immediate withdrawal of a dangerous product from the market and warn consumers of the risks of the product;
- 6) demand, coordinate or organise jointly with economic operators the recall of a product from consumers and, where necessary, the destruction of the product. A product shall be recalled from consumers if other measures are insufficient.

(5) A market surveillance authority has the right to take the measures specified in subsection (4) of this section also if a product complies with § 6 of this Act, but the market surveillance authority has evidence that the product is dangerous.

(6) Market surveillance authorities may prohibit placing products described in subsection 5 (8) of this Act on the Estonian market or demand that these be withdrawn from the market or altered or that additional tests be carried out pursuant to the procedure laid down in Regulation (EC) No. 764/2008. This requirement shall not apply to measures taken on the grounds set out in Article 3 of Regulation (EC) No. 764/2008.

(7) If any offences by a conformity assessment body or other substantial defects are identified in the course of state surveillance, the official or authority exercising state surveillance shall immediately inform the committee for conformity assessment bodies thereof.

(8) In the event of a serious risk the Tax and Customs Board shall, with the approval of the appropriate market surveillance authority, have the right to prohibit making the product available on the market or exporting the product.

(9) Upon taking market surveillance measures, market surveillance authorities shall follow the appropriate rules of procedure arising from EU harmonisation legislation.

§ 55. Publication of information

(1) Market surveillance authorities shall make public the information concerning the risks arising from products and information regarding identification of products, the characteristics of the risk arising from products, and the measures taken.

(2) Market surveillance authorities may obligate economic operators to disclose information about the risks arising from a product. If an economic operator fails to perform the obligation to disclose information within the prescribed term, the market surveillance authority may perform the obligation with the means and pursuant to the procedure provided for in the Substitutive Enforcement and Penalty Payment Act.

(3) Market surveillance authorities do not have the right to disclose the business secrets of economic operators obtained upon implementation of this Act, except for the information concerning the characteristics of a product, whose disclosure is justified by the need to ensure safety.

(4) The Public Information Act, taking into account the exceptions laid down in this Act, shall apply to publication of information.

§ 56. Checking safety and conformity

(1) In the course of market surveillance, market surveillance authorities have the right to:

1) obtain samples of products placed on the market from economic operators free of charge for the purpose of checking their safety or conformity;

2) where necessary, commission an expert assessment in order to identify the safety or conformity of products.

(2) The market surveillance authority shall bear the expenses of the expert assessment. If it is established that the product is not safe or does not conform to the requirements, the economic operator shall pay the documented costs of the expert assessment.

(3) If the conformity of the product obtained for checking is established, the market surveillance authority shall return it to the economic operator. If the product obtained for checking is partly or fully destroyed or becomes unfit for use in the course of the check, the market surveillance authority shall compensate for the damage caused to the economic operator. The sample of the product shall not be returned and the damage shall not be compensated if the dangerousness or non-conformity of the product is identified.

§ 57. Notifying European Commission of restrictions on placing products on market

(1) Where the restrictions listed in subsection 54 (7) of this Act are imposed on placing products on the market, and where a market surveillance authority imposes or intends to impose, due to serious risk arising from a product, any recommended, agreed or mandatory measures with respect to the manufacturers or distributors of the product whereby specific conditions are prescribed for the possible placing on the market or use of the product, the relevant market surveillance authority shall, to the extent that such notification is not required under some other legislation, inform the European Commission of the restrictions.

(2) The reasons for imposing the restrictions shall be specified upon notification. Notice shall also be given of any amendment to or repeal of such restrictions.

(3) If it can be presumed that the effects of the risk arising from a product do not or cannot go beyond the territory of Estonia, notice shall be given only of the restrictions concerned insofar as they involve information likely to be of interest to the Member States of the European Union from the product safety standpoint, and in particular if they are in response to a new risk which has not yet been reported in other notifications.

(4) The procedure for informing the European Commission of restrictions imposed on placing products on the market shall be established by a regulation of the Government of the Republic.

§ 58. Specifics of issuing precepts and maximum penalty payment

(1) Before a precept is issued for the withdrawal from the market of products or recall of products from consumers, or before the performance of a corresponding act, the economic operator shall be given the opportunity to submit objections. No opportunity to submit objections has to be given to the economic operator if the market surveillance authority is obligated to take measures without delay.

(2) If an economic operator is not given the opportunity to submit objections before a precept is issued for the withdrawal from the market of products or recall of products from consumers or before a corresponding act is performed due to the fact that the market surveillance authority had to take measures without delay, the opinion of the economic operator shall be obtained after the precept is issued or the act is performed.

(3) In a precept issued for the withdrawal from the market of products or recall of products from consumers, and upon the performance of corresponding acts, the distributors, users and consumers shall be encouraged to participate in taking the relevant measures.

(4) The filing of a challenge against a precept or act shall not release the economic operator of the obligation to comply with the precept.

(5) In the event of failure to comply with a precept the maximum penalty payment imposed pursuant to the procedure provided for in the Substitutive Enforcement and Penalty Payment Act shall be 10,000 euros.

[RT I 2010, 31, 158 - entry into force 01.01.2011]

Chapter 7

LIABILITY

§ 59. Violation of conditions of placing products and making products available on market

(1) Violation of the conditions of placing a product on the market or making a product available on the market is punishable by a fine of up to 300 fine units.

(2) The same act if committed by a legal entity is punishable by a fine of up to 3,200 euros.
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§ 60. Failure to give notice of risks arising from products

(1) Failure to give notice of risks arising from products already placed on the market is punishable by a fine of up to 200 fine units.

(2) The same act if committed by a legal entity is punishable by a fine of up to 2,000 euros.
[RT I 2010, 31, 158 - entry into force 01.01.2011]

§ 61. Misuse of conformity markings

(1) Misuse of a conformity marking is punishable by a fine of up to 200 fine units.

(2) The same act if committed by a legal entity is punishable by a fine of up to 2,000 euros.
[RT I 2010, 31, 158 - entry into force 01.01.2011]

§ 62. Procedure

(1) The provisions of the General Part of the Penal Code and the Code of Misdemeanour Procedure apply to the misdemeanours provided for in §§ 59–61 of this Act.

(2) The bodies conducting extrajudicial proceedings of the misdemeanours provided for in §§ 59–61 of this Act are, within the limits of their competence, the Consumer Protection Board, the Health Board, the Maritime Administration, the Technical Surveillance Authority, the Agricultural Board, the Environmental Inspectorate and the Labour Inspectorate.

Chapter 8 IMPLEMENTING PROVISION

§ 63. Entry into force of Act

This Act shall enter into force at the time and pursuant to the procedure provided for in the Product Conformity Act Implementation Act.

¹ Directive 2001/95/EC of the European Parliament and of the Council on general product safety (OJ L 11, 15.1.2002, pp. 4–17); 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 (OJ L 192, 11.7.1987, pp. 49–50); Decision No. 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, pp. 82–128); Directive 98/34/EC of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, pp. 37–48), amended by Directive 98/48/EC (OJ L 217, 5.8.1998, pp. 18–26);

Directive 2009/125/EC of the European Parliament and of the Council establishing a framework for the setting of ecodesign requirements for energy-related products (recast) (OJ L 285, 31.10.2009, pp. 10–35); Directive 2010/30/EC of the European Parliament and of the Council on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products (recast) (OJ L 153, 18.06.2010, pp. 1–12).
[RT I, 28.06.2012, 1 - entry into force 08.07.2012]