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# Product Conformity Act<sup>1</sup>

Passed 20.05.2010  
RT I 2010, 31, 157  
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Amended by the following acts

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| 20.05.2010 | RT I 2010, 31, 158    | 01.01.2011, will 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   |
| 19.02.2014 | RT I, 13.03.2014, 4   | 01.07.2014, in part 23.03.2014   |
| 23.04.2014 | RT I, 10.05.2014, 1   | 20.05.2014   |
| 05.06.2014 | RT I, 29.06.2014, 1   | 01.07.2014   |
| 19.06.2014 | RT I, 12.07.2014, 1   | 01.01.2015   |
| 19.06.2014 | RT I, 29.06.2014, 109 | 01.07.2014, the ministers' official titles have been replaced on the basis of subsection 107 <sup>3</sup> (4) of the Government of the Republic Act.   |
| 18.02.2015 | RT I, 23.03.2015, 3   | 01.07.2015   |
| 09.12.2015 | RT I, 31.12.2015, 1   | 01.03.2016   |
| 04.05.2016 | RT I, 17.05.2016, 1   | 13.06.2016   |
| 16.06.2016 | RT I, 01.07.2016, 12  | 11.07.2016   |

## 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 supervision;
- 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 will 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 supervision 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 will 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.

(8) The General Part of the Economic Activities Code Act applies to the commencement, carrying out and termination of the economic activities of an undertaking regulated by this Act, taking account of the specifics arising from this Act.

[RT I, 29.06.2014, 1 – entry into force 01.07.2014]

## § 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 supervision 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 will 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 a person specified in clause 2 (1) 1) of the Consumer Protection Act;

[RT I, 31.12.2015, 1 – entry into force 01.03.2016]

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, a minister authorised by it and the minister responsible for the field may, by a regulation, establish requirements for a product and a procedure for attestation of the conformity with these requirements and designate a market supervision authority who exercises market supervision over the fulfilment of these requirements.

[RT I, 17.05.2016, 1 – entry into force 13.06.2016]

(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 are 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 responsible for the field 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 will 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 will 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 will 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 supervision authority takes 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 do 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 supervision 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 ensures safety during the display.

## **§ 10. Product Contact Point**

(1) The Product Contact Point contributes to the free movement of products in the European Economic Area by sharing information. Via the Product Contact Point, economic operators receive information about the technical regulations applicable to products in accordance with Regulations (EC) No 764/2008 and (EU) No 305/2011. [RT I, 23.03.2015, 3 – entry into force 01.07.2015]

(2) The Ministry of Economic Affairs and Communications ensures the performance of the functions of Product Contract Points specified in Regulations (EC) No 764/2008 and (EU) No 305/2011. [RT I, 23.03.2015, 3 – entry into force 01.07.2015]

(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.

## **§ 10<sup>1</sup>. Technical assessment body**

(1) The minister responsible for the field grants the right to act as an Estonian technical assessment body to a person who complies with the requirements provided for in Regulation (EU) No 305/2011 of the European Parliament and of the Council. The scope of the right to act as an Estonian technical assessment body is provided for in a public law contract concluded between the person and the minister responsible for the field.

(2) A person who wishes to act as an Estonian technical assessment body submits to the minister responsible for the field an application where the person certifies that it is able to perform the duties provided for in Regulation (EU) No 305/2011 of the European Parliament and of the Council.

(3) Upon receipt of an application specified in subsection (2) of this section, the minister responsible for the field will by a directive establish a committee for assessment of the compliance of the person with the requirements. [RT I, 23.03.2015, 3 – entry into force 01.07.2015]

# **Division 2 General Obligations of Economic Operators**

## **§ 11. Obligations of manufacturers**

(1) Manufacturers 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 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 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 is undertaken by the manufacturer on a voluntary basis or at the request of the market supervision authority.

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

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

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

#### **§ 12. Obligations of distributors**

(1) Distributors act with due care to ensure the conformity of products with requirements. Distributors must 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, 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 supervision 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 will immediately inform the market supervision authority that exercises supervision over the relevant product group.

(2) In the event of serious risk, the manufacturer, importer or distributor will forward the following to the market supervision 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 supervision authority.

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

(4) Economic operators cooperate with the market supervision 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 supervision authority an economic operator will inform the market supervision 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 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 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 will draw up an EC declaration of conformity provided for in § 19 of this Act and affix the conformity marking.

(3) Manufacturers 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 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 are taken into account.

(5) Manufacturers 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 will be provided on the packaging or in a document accompanying the product.

(6) Manufacturers 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 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 must 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 will 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 allows 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 regulatory authority during the term specified in subsection 14 (3) of this Act;
- 2) further to a request from the market supervision authority, provide the authority with all the information and documentation necessary to demonstrate the conformity of a product;
- 3) cooperate with the market supervision authority, 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 may only place compliant products on the market.

(2) Before placing a product on the market importers 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 ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements.

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

(5) During the term provided for in subsection 14 (3) of this Act, importers keep a copy of the EC declaration of conformity at the disposal of the market supervision authority and ensure that the technical documentation can be made available to the market supervision 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 act with due care in relation to the requirements applicable.

(2) Before making a product available on the market, distributors must 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 will 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 will inform the manufacturer or importer and the market supervision authority that exercises supervision over the product group.

(4) Distributors 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 must 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 will be drawn up for the product. The declaration of conformity must 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 will 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 will demand that the manufacturer take corrective measures and will 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 will demand that the manufacturer take corrective measures and, if necessary, the conformity assessment body will 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 will 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 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 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 the right to operate in Estonia will inform the body specified in subsection 30 (1<sup>1</sup>) of this Act:

[RT I, 17.05.2016, 1 – entry into force 13.06.2016]

- 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) [Repealed – RT I, 17.05.2016, 1 – entry into force 13.06.2016]
- 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 will, 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 will inform the market supervision authority of the suspicion that a product placed on the market or a product put into service is non-conforming.

(4) [Repealed – RT I, 17.05.2016, 1 – entry into force 13.06.2016]

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

(2) The confidentiality requirement will apply if the market supervision 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 will ensure the compliance of the contractor with the requirements of the body. The conformity assessment body is fully liable for the services provided by contractors.

(3) Conformity assessment bodies 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 keep at the disposal of the market supervision authority 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 constitutes a separate and distinct part of the undertaking and does not participate in the design, manufacture, distribution, installation, use or maintenance of the products it assesses. An accredited in-house body must 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 supplies its services exclusively to the undertaking of which it forms a part.

(3) Notification of an accredited in-house body will 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) [Repealed – RT I, 17.05.2016, 1 – entry into force 13.06.2016]

(4) [Repealed – RT I, 17.05.2016, 1 – entry into force 13.06.2016]

#### **§ 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, must 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 must 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 must 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 must not provide respective consultation services. This does 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 will 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;

[RT I 2010, 31, 158 – entered into force 01.01.2011]

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 will 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 applies for an activity license of a conformity assessment body must be accredited by an accreditation body compliant with Regulation (EC) No 765/2008 to carry out the conformity assessment applied for under the activity license.

[RT I, 17.05.2016, 1 – entry into force 13.06.2016]

(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 will submit to the body that granted it the right to operate the report of the follow-up inspection carried out by the accreditation body.

[RT I, 17.05.2016, 1 – entry into force 13.06.2016]

### **§ 29. Submission of documents to obtain activity license**

(1) In addition to the information required in the General Part of the Economic Activities Code Act, an application for an activity license must contain the following data and documents:

1) 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;

2) the conformity assessment procedures the applicant would like to carry out as a conformity assessment body and references to applicable legislation;

3) a certificate certifying accreditation or a copy thereof,

4) a copy of the liability insurance policy.

(2) If a conformity assessment body uses the services of a contractor, the body will 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 will 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) [Repealed – RT I, 29.06.2014, 1 – entry into force 01.07.2014]

(1<sup>1</sup>) The Technical Regulatory Authority grants an activity license. In the field of medical devices, the Health Board grants an activity license.

[RT I, 17.05.2016, 1 – entry into force 13.06.2016]

(1<sup>2</sup>) The authority exercising market supervision in the respective field can be involved in granting an activity license.

[RT I, 17.05.2016, 1 – entry into force 13.06.2016]

(2) Unless otherwise provided by legislation, an activity license will 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) [Repealed – RT I, 29.06.2014, 1 – entry into force 01.07.2014]

(2) The granting of an activity license may be refused if the applicant's right to operate as a conformity assessment body has previously been revoked on the following grounds:

[RT I, 17.05.2016, 1 – entry into force 13.06.2016]

- 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**

[Repealed – RT I, 29.06.2014, 1 – entry into force 01.07.2014]

### **§ 33. Revocation of activity license**

(1) [Repealed – RT I, 29.06.2014, 1 – entry into force 01.07.2014]

(2) [Repealed – RT I, 29.06.2014, 1 – entry into force 01.07.2014]

(3) The revocation of the activity license of a conformity assessment body must 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 will hand its conformity assessment documentation over to the body specified in subsection 30 (1<sup>1</sup>) of this Act. The documentation does not need to be handed over if the activity license of the conformity assessment body is revoked in part.

[RT I, 17.05.2016, 1 – entry into force 13.06.2016]

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

(1) The body that granted an activity license to a conformity assessment body will notify the European Commission and other Member States of granting, suspending or revoking the license. Notification ensures 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 will receive an identification number.

[RT I, 17.05.2016, 1 – entry into force 13.06.2016]

(2) A conformity assessment body may commence operation within the limits of the right to operate specified in the activity license when 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.

[RT I, 17.05.2016, 1 – entry into force 13.06.2016]

(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 body that granted the activity license will take these into account and renew the procedure for granting the activity license to the conformity assessment body.

[RT I, 17.05.2016, 1 – entry into force 13.06.2016]

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

(1) For the purpose of informing the public, the body that granted the activity license will publish data on granting the activity license to the conformity assessment body or suspending or revoking the license in the register of economic activities as a registry entry.

[RT I, 17.05.2016, 1 – entry into force 13.06.2016]

(2) [Repealed – RT I, 29.06.2014, 1 – entry into force 01.07.2014]

(3) A registry entry on the granting of an activity license will 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 will be made without delay.

## **Chapter 4 ACCREDITATION**

### **§ 36. Organisation of accreditation**

Accreditation will 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 will be appointed by an order of the Government of the Republic.

(3) The state finances 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:

- 1) administers the accreditation system, and accredits, assesses and attests the professional competency of measurers;
- 2) organises interlaboratory comparison testing;
- 3) approaches all applications for professional competency assessment and accreditation in an impartial manner and in accordance with the principle of equal treatment;
- 4) complies with the requirements established for accreditation bodies in Regulation (EC) No 765/2008;
- 5) represents Estonia in international accreditation cooperation;
- 6) publishes on its website the names of accredited conformity assessment bodies, the scope of accreditation and notices of suspension or revocation of accreditations;
- 7) advises 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 will submit a summary of the results of inspection to the body specified in subsection 30 (1<sup>1</sup>) of this Act after taking the measures. The accreditation body will also immediately inform the body that granted the activity license of the suspension or revocation of the accreditation, of complaints filed against the activities of the conformity assessment body and of measures taken to resolve these.

[RT I, 17.05.2016, 1 – entry into force 13.06.2016]

### **§ 38<sup>1</sup>. Fee for accreditation and assessment of professional competency of measurer**

(1) The Estonian accreditation body charges a fee for accreditation and assessment of the professional competency of a measurer.

(2) The fee is charged for the following:

- 1) review of an application;
- 2) accreditation, including supervision over an accredited body;
- 3) keeping accreditation and the certificate certifying the professional competence of a measurer valid.

(3) The fee is paid in the manner and by the due date indicated in an invoice issued by the Estonian accreditation body.

(4) If the accredited body has not paid an invoice by the due date, the Estonian accreditation body will suspend the validity of its accreditation until the invoice has been paid. If an invoice has not been paid within six months after the due date specified in the invoice, the Estonian accreditation body will revoke the accreditation. If an invoice is overdue, the Estonian accreditation body has the right to refuse accreditation. This subsection also applies to a measurer who has been declared professionally competent.

[RT I, 01.07.2016, 12 – entry into force 11.07.2016]

### **§ 38<sup>2</sup>. Fee for review of application**

(1) The applicant pays the following fee for having their application reviewed:

- 1) 300 euros for the review of the first accreditation application;
- 2) 200 euros for the review of an application for extending the scope of accreditation;
- 3) 175 euros for reviewing an application for assessment of the professional competency of a measurer.

(2) No fee is charged for an application for extension of the scope of accreditation within the limits of an accredited conformity assessment scheme or a test field.

(3) The fee is not refunded to the applicant if the applicant withdraws the application or if the application is not granted for a reason independent of the Estonian accreditation body.

[RT I, 01.07.2016, 12 – entry into force 11.07.2016]

### **§ 38<sup>3</sup>. Accreditation fee**

(1) The applicant pays a fee for accreditation. The size of the fee depends on the time spent on assessment, the complexity of assessment, the rate of the assessors and the direct expenses related to the assessment.

(2) The rate of the assessor is agreed with the assessor. The Estonian accreditation body introduces the estimated cost of accreditation to a body applying for accreditation or to an accredited body in advance and allows for the expression of an opinion on the fee of the assessor to be involved.

(3) The rate of the hourly fee of the assessor in charge of the assessment (hereinafter *chief assessor*) is up to 20 times the minimum hourly rate established in accordance with subsection 29 (5) of the Employment Contracts Act. The Estonian accreditation body annually establishes the hourly rate of the chief assessor. The provisions of this subsection do not apply to other assessors involved in accreditation.

(4) The direct expenses of accreditation include the assessor's business trip expenses, translation expenses if assessment is not carried out in Estonian, and other expenses related to accreditation. The making of an advance payment to cover direct expenses may be requested.

[RT I, 01.07.2016, 12 – entry into force 11.07.2016]

#### **§ 38<sup>4</sup>. Annual fee for keeping accreditation and certificate valid**

(1) An accredited body and a professionally competent measurer pay an annual fee for keeping accreditation and the certificate of the measurer valid.

(2) The amount of the annual fee depends on the expenses required for the sustainable functioning of the Estonian accreditation body, which are divided between accredited bodies and professionally competent measurers proportionally, taking account of the extent and complexity of the accreditation.

(3) If the accreditation or the declaring of a measurer as professionally competent is suspended or declared invalid, the accredited authority or the measurer will have the right to request that the Estonian accreditation body refund the paid annual fee for the full months in which the right covered by the annual fee remained unexercised. The portion of the annual fee to be refunded will be returned to the applicant within one month as of the receipt of the application.

(4) The principles of setting the annual fee and the rates of the fee will be established by a regulation of the minister responsible for the field.

[RT I, 01.07.2016, 12 – entry into force 11.07.2016]

## **Chapter 5 TECHNICAL REGULATIONS AND STANDARDS**

### **Division 1 General Provisions**

#### **§ 39. Technical regulations**

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

(3) A reasonable interval will 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 will 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 will 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 will 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 will 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 are 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 will 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 will 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 will, 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 are laid down and, where necessary, a reference to the standard is made. A standard may be referred to directly or in general in a technical regulation. In terms of its legal meaning, a reference to a standard is recommended or mandatory.

[RT I, 10.05.2014, 1 – entry into force 20.05.2014]

(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 will be given with or without a date. In the event of a reference with a date, the standard will be adhered to as of the date and, in the event of a standard without a date, the standard will 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) A reference to a standard is deemed recommended if other solutions besides following the referred standard can be applied for the purpose of complying with the requirements of law. In the present case another solution does not mean the obligation to follow another standard.

[RT I, 10.05.2014, 1 – entry into force 20.05.2014]

(5) A reference to a standard is mandatory if only the referred standard may be followed for the purpose of complying with the requirements of law. A mandatory reference to a standard may be a direct or general reference.

[RT I, 10.05.2014, 1 – entry into force 20.05.2014]

(6) A mandatory reference to a standard must not be made in a technical regulation. By way of exception, a mandatory reference may be made upon performance of obligations of Estonia, which arise from international law or legislation of the European Union, provided that it is the only way of complying with the requirements arising from law.

[RT I, 10.05.2014, 1 – entry into force 20.05.2014]

(7) Where a recommended reference to a standard is set out in a technical regulation, compliance with the relevant requirements of law is presumed upon adherence to the referred standard with regard to the requirements covered by the standard.

[RT I, 10.05.2014, 1 – entry into force 20.05.2014]

## § 43. Notification

(1) The European Commission and contracting states of the European Economic Area will 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 will submit the draft legislation to the authority coordinating notification. The draft legislation will 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 will be established and the authority coordinating notification will be appointed by a regulation of the Government of the Republic.

## Division 2 Organisation of Standardisation

### § 44. Estonian standardisation body and performance of obligations arising from European standardisation regulation

[RT I, 10.05.2014, 1 – entry into force 20.05.2014]

(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 will be represented by a government agency as a member.

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

(2<sup>1</sup>) The obligations of the standardisation body of the state, which arise from Regulation (EU) No 1025/2012 of the European Parliament and of the Council on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, pp 12–33 (hereinafter *European standardisation regulation*)), are performed by the Estonian standardisation body.

[RT I, 10.05.2014, 1 – entry into force 20.05.2014]

(2<sup>2</sup>) In the field of telecommunications, the obligations of the standardisation body of the state set out in the regulation specified in subsection (2<sup>1</sup>) of this section are performed by the Technical Regulatory Authority.

[RT I, 10.05.2014, 1 – entry into force 20.05.2014]

(3) [Repealed – RT I, 10.05.2014, 1 – entry into force 20.05.2014]

### § 45. Obligations of Estonian standardisation body

(1) The Estonian standardisation body:

- 1) maintains the Estonian standardisation system and organises standardisation activities in Estonia;
- 2) performs the obligations of the standardisation body of the state arising from the European standardisation regulation;
- 3) performs the obligations arising from membership in international and European standardisation organisations and participates in the work of the organisations whose member it is;
- 4) performs standardisation obligations assumed under international agreements and standardisation obligations delegated by the state;
- 5) in the official publication made available on its website, publishes 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;
- 6) uses the EVS trademark and ensures that it is not misused.

[RT I, 10.05.2014, 1 – entry into force 20.05.2014]

(2) The Estonian standardisation body ensures 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 ensures 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 will 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**

[Repealed – RT I, 10.05.2014, 1 – entry into force 20.05.2014]

#### **§ 47. Standardisation scheme**

[Repealed – RT I, 10.05.2014, 1 – entry into force 20.05.2014]

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

(1) The costs of drawing up and translating an Estonian standard are covered by interested persons. The drawing up and translating an Estonian standard commissioned by a state authority are financed by the state via the budget of the interested ministry.

(2) Interested persons can make proposals on drawing up or translating an Estonian standard to the Estonian standardisation body.

(3) The state finances the performance of the obligations of the Estonian standardisation body set out in clause 45 (1) 2) and subsections 45 (2) and (4) of this Act, compensates the membership fees of international and European standardisation bodies and the costs of participating in their work and, if agreed separately, the state also finances other activities of the standardisation body. Funds are allocated in the budget of the area of government of the Ministry of Economic Affairs and Communications.

[RT I, 10.05.2014, 1 – entry into force 20.05.2014]

## **Chapter 6 MARKET SUPERVISION AND SUPERVISION OVER CONFORMITY ASSESSMENT BODIES**

### **Division 1 Organisation of Market Supervision**

#### **§ 49. Organisation of market supervision**

(1) In harmonised areas market supervision of products is 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 supervision authority 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 supervision**

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

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

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

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

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

- 1) building materials and products;
- 2) electrical equipment;
- 3) radio equipment;

[RT I, 17.05.2016, 1 – entry into force 13.06.2016]

- 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 supervision has been placed within its competence by this Act or legislation adopted on the basis of this Act.

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

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

(8) The Labour Inspectorate exercises state supervision 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 supervision authority.

## **§ 51. Cooperation and exchange of information between authorities participating in market supervision**

(1) For the purpose of facilitating cooperation and exchange of information between the authorities participating in market supervision, the minister responsible for the field form a market supervision council in the Ministry of Economic Affairs and Communications.

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

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

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

(4) The composition and rules of procedure of the market supervision council will be approved by a directive of the minister responsible for the field.

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

## **§ 52. Market supervision programmes**

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

(2) Market regulatory authorities publish their market supervision 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 supervision operations**

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

(2) Market regulatory authorities publish their supervision 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 Supervision Measures**

### **§ 54. State supervision**

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

(1) The market supervision authority has 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) The market supervision authority may, for the purpose of exercising the state supervision provided for in this Act, take special measures of state supervision provided for in §§ 30, 31, 32, 49, 50, 51 and 52 of the Law Enforcement Act on the grounds and in accordance with the procedure provided for in the Law Enforcement Act.

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

### **§ 55. Publication of information**

(1) The market supervision authority makes 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) The market supervision authority 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 supervision authority may perform the obligation with the means and pursuant to the procedure provided for in the Substitutive Enforcement and Penalty Payment Act.

(3) The market supervision authority does 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, applies to publication of information.

### **§ 56. Specifics of state supervision**

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

(1) On the conditions set out in § 50 of the Law Enforcement Act, the market supervision authority may enter the premises where a product is made, stored or offered for sale.

(2) The market supervision authority has the right to:

1) if a product may pose 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) if a product that may pose 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) if a product 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 and organise the immediate withdrawal of a dangerous product from the market;

6) demand, coordinate and organise jointly with economic operators the recall of a dangerous product from consumers and, where necessary, the destruction of the product. A product must be recalled from consumers if other measures are insufficient.

(3) The market supervision authority has the right to take the measures specified in subsection (2) of this section also if a product complies with § 6 of this Act, but the market supervision authority has evidence that the product is dangerous.

(4) The market supervision authority 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 in accordance with the procedure laid down in Regulation (EC) No 764/2008. This requirement does not apply to measures taken on the grounds set out in Article 3 of Regulation (EC) No 764/2008.

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

(6) Upon taking market supervision measures, the market supervision authority follows the appropriate rules of procedure arising from EU harmonisation legislation.

(7) The market supervision authority has the right to obtain samples of products placed on the market from economic operators free of charge for the purpose of checking their safety or conformity and, where necessary, commission an expert assessment in order to identify the safety or conformity of products. The market supervision authority will 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 will pay the documented costs of the expert assessment.

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

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

(1) Where the restrictions listed in subsection 56 (2) of this Act are imposed on placing products on the market, and where the market supervision authority imposes or intends to impose, due to a direct threat 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 supervision authority must, to the extent that such notification is not required under some other legislation, inform the European Commission of the restrictions.

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

(2) The reasons for imposing the restrictions will be specified upon notification. Notice will 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 will 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 will 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 will be given the opportunity to submit objections. No opportunity to submit objections has to be given to the economic operator if the market supervision 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 supervision authority had to take measures without delay, the opinion of the economic operator will 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 will be encouraged to participate in taking the relevant measures.

(4) The filing of a challenge against a precept or act will 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 Coercive Payment Act is 10 000 euros.

[RT I 2010, 31, 158 – entered into force 01.01.2011]

## **Chapter 7**

# LIABILITY

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

(1) The penalty for violation of the conditions of placing a product on the market or making a product available on the market is a fine of up to 300 fine units.

(2) The penalty for the same act committed by a legal person is a fine of up to 3200 euros.  
[RT I 2010, 31, 158 – entered into force 01.01.2011]

## § 60. Failure to give notice of risks arising from products

(1) The penalty for failure to give notice of risks arising from products already placed on the market is a fine of up to 200 fine units.

(2) The penalty for the same act committed by a legal person is a fine of up to 2000 euros.  
[RT I 2010, 31, 158 – entered into force 01.01.2011]

## § 61. Misuse of conformity markings

(1) The penalty for the misuse of a conformity marking is a fine of up to 200 fine units.

(2) The penalty for the same act committed by a legal person is a fine of up to 3200 euros.  
[RT I 2010, 31, 158 – entered into force 01.01.2011]

## § 62. Proceedings

The bodies conducting extrajudicial proceedings of the misdemeanours provided for in this Chapter are, within the limits of their competence, the Consumer Protection Board, the Health Board, the Maritime Administration, the Technical Regulatory Authority, the Agricultural Board, the Environmental Inspectorate and the Labour Inspectorate.

[RT I, 12.07.2014, 1 – entry into force 01.01.2015]

# Chapter 8 IMPLEMENTING PROVISION

## § 63. Entry into force of Act

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

<sup>1</sup> Directive 2001/95/EC of the European Parliament and of the Council on general product safety (OJ L 11, 15.01.2002, 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, 11.07.1987, 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, 13.08.2008, 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 (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 (OJ L 153, 18.06.2010, pp. 1–12); Directive 2014/30/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.03.2014, pp. 79–106); Directive 2014/35/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.03.2014, pp. 357–374); Directive 2014/33/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.03.2014, pp. 251–308); Directive 2014/34/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.03.2014, pp. 309–356); Directive 2014/28/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.03.2014, pp. 1–44); Directive 2013/29/EU of the European Parliament and of the Council on the

harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (OJ L 178, 28.06.2013, pp. 27–65); Directive 2014/53/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.05.2014, pp. 62–106); Directive 2014/68/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.06.2014, pp. 164–259); Directive 2014/29/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 96, 29.03.2014, pp. 45–78); Directive 2014/32/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (OJ L 96, 29.03.2014, pp. 149–250); Directive 2014/31/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96, 29.03.2014, pp. 107–148); Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys (OJ L 170, 30.06.2009, pp. 1–37); Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 01.07.2011, pp. 88–110); Directive 2013/53/EU of the European Parliament and of the Council on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, pp. 90–131).  
[RT I, 23.03.2015, 3 - entry into force 01.07.2015]