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TRANSLATED FROM THE ICELANDIC

Act No. °134/1995, on Product Safety and Official Market Control, as amended by Acts No. 82/1998, 76/2002, 68/2004, 62/2005, 108/2006 and 98/2009 ACT

## on Product Safety and Official Market Control

### CHAPTER I

## Scope

### Article 1

This Act covers goods traded in Iceland for professional purposes or exported to [other Member States of the European Economic Area, Member States of the Charter of the European Free Trade Association or the Faroe Islands.] This Act also covers the provision of services in connection with the exchange of goods. This Act applies equally to products offered for consideration or not.

However, this Act shall not apply to second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the recipient is clearly informed of this before the business transaction takes place or is aware of it.

The provisions of this Act apply to products offered to consumers but neither to products nor services almost entirely produced or processed with further production in mind or for entrepreneurial purposes.

[The provisions of Art. 8 and 9 of this Act do not apply to products being subject to special Acts or regulationsconcerning safety of goods. Where provisions of special Acts are unsatisfactory or not as strict as the provisions of Chapters IV or V of this Act the provisions of these Chapters shall apply. The same applies to the duties of producers and distributing parties as may be applicable.]

### Article 2

Producers may only market safe products.

Products intended for sale, rent and any other delivery for commercial purposes, shall be designed in such a way that they meet the requirements which are, for reasons of public interest, provided for in laws and regulations or standards on safety and the protection of health and the environment.

With official market control an effort is made to ensure that products on the market comply with the relevant rules in force.

### CHAPTER II

## **Definitions**

# The Concept of the Product

## Article 3

For the purposes of this Act product shall mean any movable property, such as all manufactured products and raw materials. A movable property which has been incorporated in another movable property is also considered a product.

### **Producer and Distributor**

## Article 4

1. Producer shall mean the manufacturer of a finished product or a component part of a product or the producer of any raw material or a person who processes or acquires products from natural sources, provided that he is [established in the European Economic Area, in a Member State of the Charter of the European Free Trade Association or the Faroe Islands.] Producer shall also mean any other person who puts his name, trade mark or other distinctive mark on the product, or the person who reconditions the product. When the manufacturer is not [established in the European Economic Area, in a Member State of the Charter of the European Free Trade

Association or the Faroe Islands], his representative shall be considered as producer. When neither the manufacturer nor his representative are [established in the European Economic Area, in a Member State of the Charter of the European Free Trade Association or the Faroe Islands] the importer shall be considered as producer. Other professionals in the supply chain are also considered producers in so far as their activity may affect the safety properties of a marketed product.

Distributor shall mean any professional in the supply chain whose activity does not affect the safety properties of a product.

### Official Market Control and Market Surveillance

## Article 5

Official market control shall mean the organized efforts of the government to ensure that products on the market comply with regulations on safety and the protection of health and the environment. Official market control is divided into market surveillance and administrative action which have as their object the enforcement of regulations on product safety.

Market surveillance shall mean the organized supervision of products on the market. Market surveillance is divided into product inspection on the one hand and, on the other hand, an organized gathering of information on products on the market, inter alia by receiving information concerning products which are considered dangerous. Product inspection shall mean the examination of a product and determination as to whether it meets special or general requirements relating to it.

# **Surveillance Authority**

Surveillance authority, according to the provisions of this Act, shall mean an authority which is, by this Act or a separate Act on the safety of a specific product or product category, entrusted with and responsible for surveillance and administrative action in Iceland.

## **Inspection Bodies**

## Article 7

An inspection body is a neutral body, which has been accredited in accordance with the laws and regulations in force concerning the activities of accredited independent inspection bodies. [The Consumer Agency] is responsible for the accrediting of inspection bodies on behalf of the Icelandic government, in accordance with the laws and regulations in force at the time.

## [Notified Party

### Article 7a

A notified party is one which the authorities deem qualified to assess the conformity of a product against the provisions of Acts and rules applying to such products and of which authorities have given notice to the EFTA Surveillance Authority and the EU Secretariat as being fit to undertake an assessment of conformity in respect of specific products in accordance with the Acts and rules applying to the product concerned.]

## **Safe Product**

## Article 8

[Safe product shall mean any product which, under normal or reasonably foreseeable conditions of use, including durability as well as requirements stipulated concerning installation, maintenance and how this shall be taken into use, being considered to be non-hazardous for individuals, their health and property, provided that the product meet general requirements stipulated on account of public interests concerning safety and health and protection as well as

the environment. Upon the assessment of safety regard shall in particular be had for the following:

- 1. The nature of the product, including the assembly thereof, packing material and assembly guidances and, where applicable, installation and maintenance guidelines.
- 2. The effect of the product on other goods if it is foreseeable that the product will be used with other goods.
- 3. The presentation of the product, markings and, if applicable, contents of remarks and guidances concerning use and disposal in addition to any indications and information concerning the product.
- 4. As to whether the product is made of specific groups or consumers who may be specifically endangered by the products, children and the elderly.]

The availability of other products on the market, which are considered safer, or the possibility of increasing the safety of the product, shall not by itself constitute grounds for considering the product to be dangerous.

The provisions of paragraph 1 and 2 apply to the provision of services in connection with the exchange of goods, as appropriate.

## [Withdrawal and Product taken off the Market

## Article 8a

Withdrawal denotes any arrangement which is aimed at a hazardous product which manufacturers or distributing parties have already delivered or offered to consumers and which will be returned.

The removal of a product from the market denotes any arrangement which is aimed at preventing a hazardous product from going into distribution or being displayed or offered to consumers.]

The manufacturing and distribution of a product, as well as the provision of services in connection with the exchange of goods, shall always be in accordance with the provisions of the laws, regulations and other administrative provisions on product safety in force at the time.

In cases where there are no specific legal provisions on the safety of a product, its safety shall be assessed with regard to the following:

[A product is deemed to be safe if it meets conditions revealed in Icelandic standards introducing European standards reference to which has been published in this Country and in the European Community Gazette in conformity with the provisions of the Directive of Safety of a Product. In the instances in which provisions on the safety of a product is not to be found in rules or standards in conformity with para. 1 and 2 the safety of the product shall i.a. be assessed having regard for the following:

- 1. Icelandic standards.
- 2. Requests by the Secretariat of the European Union where there are revealed standardization rules on the assessment of the safety of a product.
- 3. Current Laws and rules on good professional practices relating to the safety of a product within the profession concerned.
- 4. European standards other than those referred to in para. 2.
- 5. Other pertaining items, including the nature of a product, other goods with which this is used, the technical stage and technique and the safety which consumers may rightfully expect.

  In case there are no special provisions in the European Union's Directives concerning the safety of specific goods the pertaining product will be deemed to be safe if it is in conformity with special rules contained [in the National Laws of the EEA–State, a Member State of the Charter of the European Free Trade Association or the Faroe Islands] wherein it is being marketed,

provided that such rules be in conformity with the basic rules of the European Union and the EEA-Agreement concerning permissible restrictions as it pertains to the safety of a product.]

## [Article 9a

A manufacturer of a product is in duty bound to disclose about any danger which may attach to the use thereof if the hazardous properties are not obvious and to make precautionary arrangements to limit the hazard. The granting of such information does not lead to exemption from other provisions of the present Act.

Manufacturers and distributing parties shall make appropriate arrangements in order to prevent a hazardous product from entering the market, e.g. by charging a notified party with the checking of a declaration of conformity when this is required in accordance with the Laws and rules applying to the product concerned, effecting sampling tests of marketed products, taking complaints for consideration and granting information on the hazardous properties of the product, its manufacturer and the reference No. of the product or, where applicable, the production batch to which it belongs.

A distributing party of a product is in duty bound to take great care to the effect that safety requirements in force be abided by and not to deliver products which he is bound to know are not meeting these requirements having regard for the information he has in his keeping and in the capacity of a skilled person.

In case manufacturers or distributing parties are aware or could have been aware that a product which they have marketed endanger consumers or that considerable risk may attach to the continued use thereof without further safety arrangements or improvements they shall without delay give notice thereof to surveillance authorities. In such instances they shall disclose to a surveillance authority the activities which have been resorted to for the purpose of preventing that consumers be endangered. It is obligatory to send information in accordance with the

present paragraph to surveillance authorities [in the Member States of the European Economic Area, Member States of the Charter of the European Free Trade Association or the Faroe Islands] where the goods concerned have been marketed or delivered to consumers in another manner. In case there is a question of serious risk this information shall include at least the following items:-

- 1. Information rendering it possible to identify the product concerned or production batch accurately.
- 2. Accurate description of the hazard entailed by the product concerned.
- 3. All available information which may be necessary to trace the origin of the product.
- 4. Description of actions reverted to for the purpose of preventing consumers being endangered.

Distributing parties are in duty bound to retain documents which are necessary for tracing the origin of the product. Documents shall never be kept for a shorter time than is obligatory for the keeping of documents in accordance with the provisions of Book-keeping Acts.

If the actions stipulated in para. 1, 2 and 4 are not sufficient manufacturers and distributing parties are in duty bound to withdraw a product or remove it from the market in accordance with a decision by a surveillance authority.

Manufacturers and distribution parties shall not export a product from Iceland to countries outside the European Economic Area if it has been removed from the market due to hazard caused by it to consumers.]

## Article 10

In instances where there apply no specific Laws or rules laying down special rules relating to the safety of a product the Minister is authorized, after having received a statement from a surveillance authority, to determine the following in Regulations:-

1. Requirements which a product must meet in order to be deemed safe.

- 2. Methods which a manufacturer may apply to show the conformity of a product to rules laid down, e.g. by means of marking, a certificate, a declaration of conformity, a test report, a document containing technical information et al.
- 3. Markings, guidances and information on the use and disposal of a product, warnings as to potential risks when using the product and any other indication or information to the consumer.

  [Warnings and guidances for use ensuring safe use of a product shall be of normal reading size and written in Icelandic if this is appropriate.]

### CHAPTER III

### **Market Surveillance and Market Control**

## **Market Control**

## Article 11

[The Consumer Agency] and the relevant surveillance authorities shall ensure that products on the market comply with the safety regulations in force.

[The Consumer Agency] and other surveillance authorities are responsible for the official market control, in accordance with the provisions of Articles 14 and 15 of this Act, and administrative action, in accordance with Chapter IV and V of this Act on the procedures and legal remedies open to the surveillance authorities, such as the provisions of a separate Act, if appropriate.

## [Article 12

Duties of manufacturers and distributing parties

Manufacturers and distributing parties in accordance with this Act are in duty bound at the request of surveillance authorities to render them assistance in connection with activities intended to support the safety of consumers. They are also in duty bound to deliver a record containing information on suppliers and those offering their goods if surveillance authorities request this in connection with the investigation of a case.]

### Market Surveillance

#### Article 13

## **Inspection Bodies**

An accredited inspection body may be entrusted with market surveillance. The inspection body is responsible for the inspection of product categories, for which it has been granted accreditation, as well as for the organized gathering of information on products on the market, inter alia by receiving information or complaints concerning products which are considered dangerous.

An inspection body is authorized to inspect products located at the producer's or distributor's premises, take product samples for examination and require the producer or distributor to submit the necessary information, such as by providing access to their records of parties offering the products, certificates, declarations of conformity to rules and standards, test reports, technical data and other relevant information to prove the safety of a product.

The Minister may lay down in a regulation further provisions on surveillance and the procedures of market surveillance by an inspection body.

## Article 14

## [The Consumer Agency]

The function of [the Consumer Agency] in official market control is as follows:

- 1. To operate as a surveillance authority for all product categories which other surveillance authorities are not responsible for pursuant to special Acts.
- 2. To manage the general organization of official market control in cooperation with other surveillance authorities, with a view to ensure effectiveness and coordination.
- 3. To supervise, in cooperation with other surveillance authorities, the drawing up of contracts with inspection bodies and to prepare the contracting documents, where appropriate.
- 4. To coordinate the operations of surveillance authorities, if the characteristics of a product or

product category are such that more than one surveillance authority is responsible for official market control.

- 5. To take administrative action in accordance with the provisions of this Act, cf. Chapters IV and V of this Act on procedures and legal remedies open to surveillance authorities.
- 6. To inspect products, receive complaints or information from individuals or undertakings and, in an organized manner, gather information on products on the market, as appropriate.
- [7. To issue notification and warn of hazardous products in the market to which this Act applies if necessary and to undertake relations with the EFTA Surveillance Agency and other surveillance authorities in the European Economic Area, such as being a link with the RAPEX Notification System of the European Union Secretariat concerning hazardous goods in the market.]

## Article 15

## **Other Surveillance Authorities**

Unless otherwise provided for in a separate Act, the function of surveillance authorities, other than [the Consumer Agency], in official market control is as follows:

- 1. To perform the surveillance which they are entrusted with, pursuant to the provisions of a separate Act laying down rules concerning the product categories which they are responsible for pursuant to a separate Act. Such rules cover at least safety and the protection of health and the environment but can also cover other aspects.
- 2. To formalize a general policy on priorities in market surveillance and on the extent of the monitoring of product categories within its range of responsibility.
- 3. To take administrative action, in accordance with the provisions of separate Acts in force in Iceland on specified products or product categories and the provisions of Chapters IV and V of this Act, as appropriate.

4. To inspect products, receive complaints or information from individuals or undertakings and, in an organized manner, gather information on products on the market, as appropriate.

### Article 16

## **Cooperation Committees**

[[The Consumer Agency] shall establish Co-operation Committees on work with other surveillance authorities and inspection establishments as may be applicable.

A Co-operation Committee shall ensure efficiency in market surveillance by discussing programs of operation and the organization of market supervision by surveillance authorities as well as comments which they receive on individual products and categories thereof and shall submit proposals to [the Consumer Agency] and surveillance authorities who will render a final administration decision on efficient surveillance of a product in accordance with the present Act or special Laws, if applicable.]

In principle only one cooperation committee should be operative on a regular basis in the field of each surveillance authority but it is, however, permitted to choose another procedure, especially if product categories are very different. It is also permitted to set up a joint cooperation committee consisting of two or more surveillance authorities.

[The Consumer Agency] decides on the number of representatives in a cooperation committee.

The cooperation committee elects a chairman from among the members of the committee.

[The Minister] is authorized to lay down in a regulation further provisions on the appointment of representatives in the cooperation committees and on their activities.

## CHAPTER IV

**Operating Procedures of the Surveillance Authorities** 

The provisions of this Chapter apply to procedures for the application of legal remedies open to [the Consumer Agency] and other surveillance authorities.

### Article 18

The surveillance authorities shall, on their own initiative or in accordance with information received, investigate matters concerning product safety coming under their surveillance.

The police shall assist the surveillance authorities, if necessary, in their investigation and in the implementation of the legal remedies provided for in this Act. [The Police shall give [the Consumer Agency] notice of accidents which it investigates if it may be assumed that these be caused by a product or services to which the present Act applies.]

## Article 19

The surveillance authorities shall always ensure that their procedures, investigations, decisions and rulings, in accordance with this Act, are always according to administrative laws. In cases where surveillance authorities take decisions on account of an acute or imminent danger it shall be a preliminary decision. The final decision shall be taken by the surveillance authority as soon as possible and it shall notify its reasoned decision to the party involved together with his means of appeal and the time prescribed for appeals.

## [Article 19a

Decisions which are made on the basis of the present Act will be referred to the Appeals

Committee of Consumer Affairs operating on the basis of Art. 4 of the Act on the Consumer

Agency and Spokesman.]

## CHAPTER V

Legal Remedies Open to Surveillance Authorities.

Withdrawal and Prohibition of the Sale of the Product

[A surveillance authority may be means of substantiation withdraw, remove from the market or prohibit the sale or delivery of a product if it does not meet formal conditions, such as concerning markings, guidances, certificates, declarations concerning conformity or testing and inspection reports.]

If the producer or distributor evidently inhibits an investigation by the surveillance authorities and the inspection of a product or fails to have satisfactory documentation on its safety available, the surveillance authority can [withdraw, remove from the market] or prohibit its sale or delivery.

The surveillance authority can, in case of reasonable suspicion that a product does not meet the safety requirements in force, decide to prohibit its sale or deliverance temporarily for the duration of an investigation which must not exceed four weeks. The prohibition may, however, be prolonged for four weeks if special circumstances, owing to the investigation, require the prolongation of the prohibition.

If the surveillance authority considers a product to be extremely dangerous, it can require an immediate withdrawal of all the product units from the market.

### Article 21

The surveillance authorities shall [withdraw, remove from the market] or prohibit the sale or delivery of a product if it is established that it does not meet the rules and requirements for product safety, provided that other and less strict remedies can not be applied.

## Article 22

The surveillance authority may, in connection with [withdrawal, when a product is removed from the market or] its prohibition of distribution and sale of a product according to this provision, require the producers and distributors to destroy all the product units in a safe way if it is considered necessary under the circumstances.

The surveillance authority may, in connection with [withdrawal when a product is removed from the market or] its prohibition of distribution and sale of a product according to this provision, require the producers and distributors, as appropriate, to modify the product in order to ensure its conformity with the rules in force, deliver to the purchasers an identical but safe product or refund the value of the product to the purchasers.

The surveillance authority can also decide that any modification or re-use of a product in another way is prohibited if it considers it dangerous or risky.

## [Article 22a

A surveillance authority is authorized to require that a product which may be hazardous under specific conditions or specific use be marked with information in Icelandic concerning that hazard.]

## Article 23

The surveillance authority shall, insofar as possible, cooperate with producers and distributors on procedures, for example concerning the acquisition of documents, inspection and testing of a product and on the preparation and making of decisions such as the termination of a sale of a product and withdrawal from the market.

If the surveillance authority has [withdrawn, removed from the market or] prohibited the sale of a product on the grounds that the product does not fulfil safety requirements, the producer and distributor are authorized to require that the product be tested by an accredited testing laboratory. Such a test does not postpone the implementation of the surveillance authority's decision.

The surveillance authority is authorized to review its decision in case of changed circumstances.

# **Inspection Costs, Daily Fines etc.**

The producer or his representative shall pay any expenses arising in connection with the product samples taken for examination. After the examination the samples shall be returned or destroyed in a safe way, as appropriate. A product sample, according to this Article, is in principle either one product unit or the minimum number of product units needed for an examination.

The producer or his representative shall pay any expenses arising in connection with the withdrawal of products. If the product fails to conform to the rules in force, he shall pay the expenses arising from inspection, examination and testing, as well as other costs. The producer or his representative shall pay any expenses arising from notifications to the general public on dangerous products, such as expenses arising from notifications in the media. The producer or his representative may take care of notifications to the general public, provided that the notification is done in such a way that a reasonably effective warning is given.

## Article 25

If the instructions of the surveillance authority are not complied with in the implementation of this Act, they can be enforced by a decision, taken by the relevant minister, on sanctions of daily fines on the producer, distributor or his representatives. Such daily fines can amount to ISK 50,000 per day, pursuant to a further decision by the relevant minister. The decision is enforceable.

In case a product is liable to cause extreme damage and the instructions of the surveillance authority, pursuant to Article 20, have not been complied with, the relevant surveillance authority shall endeavour to prevent the damage with the means available and has the power to seek the assistance of the police in this respect.

# CHAPTER VI

## **Professional Secrecy**

The employees of the inspection body, [and nominated parties,] [the Consumer Agency] and the surveillance authorities are sworn to professional secrecy on matters revealed in the course of the investigation and consideration of a case, which are protected by commercial secrecy.

## CHAPTER VII

## **Entry Into Force etc.**

## Article 27

The implementation of this Act and general issues on product safety, official market control and market surveillance come under the [Minister of Justice and Human Rights].

[The Consumer Agency] and other surveillance authorities are responsible for the daily implementation of this Act.

[The Minister] lays down in a regulation further provisions on the implementation of this Act.

## Article 28

The infringement of this Act shall be punishable with fines or [imprisonment for up to 2 years] if an infringement is not punishable by more severe penalties according to another Act.

## [Article 28a

The present Act is laid down having regard for decision by the Joint EEA Committee No. 9/2003 of 31 January 2003 to include in the EEA Agreement and adopt in domestic Laws the provisions of the Directorate by the European Parliament and the Council 2001/95/EC on the Safety of Produce.]

## Article 29

This Act shall enter into force immediately