

Act No 134/1995 on Product Safety and Official Market Control

ACT on Product Safety and Official Market Control No. 134 of 22 December 1995

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. 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.

This Act does not cover products subject to special laws or regulations on product safety, such as legislation on the safety of foodstuffs, medicinal and toxic products and dangerous substances, and the business activities of persons or bodies operating in accordance with such legislation.

Where the provisions of these separate Acts are insufficient or not as strict as the provisions of Chapters IV and V of this Act, the provisions of these Chapters shall apply.

Article 2

Producers may only market safe products.

Products intended for sale, rent and any other deliverance 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

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. 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, his representative shall be considered as producer. When neither the manufacturer nor his representative are established in the European Economic Area 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

Article 6

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 Icelandic Metrology and Accreditation Service 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.

Safe Product

Article 8

Safe product shall mean any product which, under normal or reasonably foreseeable conditions of use, does not present any specific risk or only the minimum risks compatible with the product's normal conditions of use, provided that it meets the requirements made for reasons of public interest in respect of safety and the protection of health and the environment.

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.

Article 9

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:

1. The characteristics of the product, including its composition, packaging, instructions for assembly and maintenance.
2. Its effect on other products, where it is reasonably foreseeable that it will be used with other products.
3. General instructions accompanying the product, such as the labelling, any instructions for its use and disposal and any other indication or information provided by the producer.
4. The safety of the product for sensitive users, for example children.

Article 10

In the absence of separate laws or regulations containing specific provisions on product safety, the Minister may, in accordance with the standards and practices covering product safety on the common market of the Member States of the European Economic Area and after obtaining the opinion of the surveillance authority, provide for the following in a regulation:

1. Requirements that a product must meet to be considered safe.
2. Methods which the producer can apply to prove that products are in conformity with the rules in force, for example by labelling, certification, declaration of conformity, test report, technical specifications etc.
3. The labelling of a product, any instructions for its use and disposal, warnings as to potential risks when using the product and any other indication or information to the consumer. It may be

stipulated that warnings and instructions, regarding the use of a product intended for distribution in Iceland, shall be written in the Icelandic language.

CHAPTER III
Market Surveillance and Market Control
Market Control

Article 11

The Icelandic Metrology and Accreditation Service and the relevant surveillance authorities shall ensure that products on the market comply with the safety regulations in force.

The Icelandic Metrology and Accreditation Service 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

Producers and distributors shall, in accordance with this Act and in connection with the investigation of a case, when requested by the surveillance authorities, submit their records of the suppliers and those who offer their products for sale.

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 Icelandic Metrology and Accreditation Service

The function of the Icelandic Metrology and Accreditation Service 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 publicize notifications and, if necessary, warn against dangerous products in circulation which come under this Act, take care of communications with the EFTA Surveillance Authority as well as the duty to report in accordance with the provisions of Council Directive 83/189/EEC.

Article 15 Other Surveillance Authorities

Unless otherwise provided for in a separate Act, the function of surveillance authorities, other than the Icelandic Metrology and Accreditation Service, 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 Icelandic Metrology and Accreditation Service may establish a cooperation committee for cooperation with other surveillance authorities and inspection bodies.

A cooperation committee discusses programs of operations in market surveillance, comments on individual products and product categories and submits proposals on administrative action to the Icelandic Metrology and Accreditation Service and the surveillance authorities, which then take the final decision.

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 Icelandic Metrology and Accreditation Service 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 of Commerce 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** Article 17

The provisions of this Chapter apply to procedures for the application of legal remedies open to the Icelandic Metrology and Accreditation Service 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.

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.

CHAPTER V **Legal Remedies Open to Surveillance Authorities.** **Withdrawal and Prohibition of the Sale of the Product** Article 20

The surveillance authority can prohibit the sale or deliverance of a product, stating the reasons for the prohibition, if the product does not meet the formal requirements, for example concerning labelling, instructions, certificates, declarations of conformity and test 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 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 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 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 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 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 prohibited the sale of a product on the grounds that the product does not fulfill 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.

Article 24

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**

Article 26

The employees of the inspection body, the Icelandic Metrology and Accreditation Service 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 Commerce.

The Icelandic Metrology and Accreditation Service and other surveillance authorities are responsible for the daily implementation of this Act.

The Minister of Commerce 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 and custody if an infringement is not punishable by more severe penalties according to another Act.

Article 29

This Act shall enter into force immediately. At the same time Act No. 24 of 1 February 1935 on the Control of Foodstuffs and Other Consumer Products and Household Necessities, as amended, is repealed.

Done at Reykjavik, 22 December 1995.

Vigdís Finnbogadóttir