

NB: Unofficial translation, legally binding only in Finnish and Swedish

Ministry of Social Affairs and Health, Finland

Act on Cosmetic Products (492/2013)

Chapter 1

General provisions

Section 1

Scope of application

This Act lays down provisions on the implementation of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, hereafter referred to as the *EU Cosmetics Regulation*.

Section 2

Relationship with other statutes

(1) This Act does not apply to the medicinal products referred to in the Medicines Act ([395/1987](#)) or to the medical devices referred to in the Medical Devices Act ([629/2010](#)). Likewise, the Act does not apply to the biocidal products referred to in the Chemicals Act ([744/1989](#)).

(2) The Act applies to the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 as regards the control of cosmetic products referred to in this Act.

(3) Provisions on the safety of consumer services are laid down in the Consumer Safety Act ([920/2011](#)).

(4) In addition to what is laid down in this Act, provisions on the supervision of claims concerning the marketing of cosmetic products are laid down in the Consumer Protection Act ([38/1978](#)).

(5) The Act on the Use of Animals for Experimental Purposes ([62/2006](#)) applies to the supervision of Article 18(1)(c) and (d) of the EU Cosmetics Regulation.

(6) The Act on the Use of Animals for Experimental Purposes [62/2006](#) has been repealed by the Act on the Protection of Animals used for Scientific or Educational Purposes [497/2013](#), which entered into force on 1 August 2013.

Chapter 2

Tasks of the authorities

Section 3

Ministry

The supreme management, guidance, monitoring and development of the supervision of cosmetic products are the responsibility of the Ministry of Social Affairs and Health.

Section 4

Competent authority

(1) The Finnish Safety and Chemicals Agency acts as the competent authority referred to in Article 34 of the EU Cosmetics Regulation.

(2) Finnish Customs also acts as the competent authority referred to in Article 34 of the EU Cosmetics Regulation in situations referred to in Article 5(3), Article 6(5) and Articles 7, 11, 13, 24-26, 28 and 30.

Section 5

Supervisory authorities and their tasks

(1) The Finnish Safety and Chemicals Agency supervises compliance with this Act and the EU Cosmetics Regulation in matters concerning the manufacturing, placing on the market and making available on the market of cosmetic products.

(2) Finnish Customs supervises compliance with this Act and the EU Cosmetics Regulation when cosmetic products are imported to Finland from outside the European Union and compliance with the export prohibition referred to in section 12.

(3) Finnish Customs also supervises compliance with the EU Cosmetics Regulation in connection with the unloading of a consignment in Finland and the associated storage when cosmetic products are delivered to Finland from European Union Member States.

(4) In the supervision referred to in subsections 2 and 3, Finnish Customs also complies with sections 13, 14, 19 and 20 of the Customs Act ([1466/1994](#)) in addition to this Act.

(5) The Finnish Medicines Agency is responsible for supervising the good laboratory practice referred to in Article 10(3) of the EU Cosmetics Regulation. The provisions on the use of experts, on access to information and on the disclosure of confidential information laid down in sections 15 and 16 as well as the provisions on the notification of changes in the laboratories' operations, on the supervision of laboratories, on imposing conditions and restrictions for approval, on the cancellation of approval, on the authority of the inspectors, on the issuing of orders and on the rectification procedure concerning orders laid down in the Medicines Act apply to the authority of the Finnish Medicines Agency concerning the approval and inspection of laboratories performing safety tests.

Section 6

Cooperation between the authorities

The Finnish Safety and Chemicals Agency, Finnish Customs and the authorities supervising compliance with the Consumer Protection Act cooperate in an appropriate manner in the supervision laid down in Article 20 of the EU Cosmetics Regulation.

Chapter 3

Supervisory tools of the supervisory authorities and appeal

Section 7

Prohibitions and orders

(1) If the importer, manufacturer or distributor referred to in Article 2, or the responsible person (*operator*) referred to in Article 4 of the EU Cosmetics Regulation, fails to comply with the provisions laid down in this Act or the EU Cosmetics Regulation, the supervisory authority may:

- 1) prohibit the operator from continuing or repeating the procedure that is in non-compliance with the provisions;
- 2) order the operator to carry out the measures necessary for eliminating the risk or carry out such measures at the operator's expense;
- 3) order the operator to otherwise fulfil the obligations laid down in this Act or the EU Cosmetics Regulation.

(2) The supervisory authority may also prohibit the operator from placing on the market a cosmetic product that does not comply with the legislation or from making the product available on the market or otherwise prohibit the operator from delivering it and order that the operator must, efficiently and immediately, withdraw from the market cosmetic products that do not comply with the legislation.

(3) The supervisory authority may also stop the manufacturing or production process to the extent that it is necessary for preventing any risk. The supervisory authority must act in the matter in an urgent manner.

Section 8

Temporary prohibition

(1) The supervisory authority may impose the prohibition referred to in section 7(2) on a temporary basis if it has reasons to suspect that the cosmetic product is not in compliance with the legislation and that it causes or may cause a serious risk to human health. The temporary prohibition will remain in force until the matter is finally resolved under the section in question. The supervisory authority must act in the matter in an urgent manner.

(2) Provisions on the obligation of the Finnish Safety and Chemicals Agency to introduce temporary measures are laid down in Article 27 of the EU Cosmetics Regulation.

Section 9

Ordering a recall

Provisions on the obligation of the Finnish Safety and Chemicals Agency to order the operator to recall cosmetic products causing a health risk are laid down in Articles 25 and 26 of the EU Cosmetics Regulation.

Section 10

Ordering the operator to provide information

(1) If the Finnish Safety and Chemicals Agency has issued a prohibition or order referred to in sections 7-9, or if the cosmetic product or its use involves a health risk, the Finnish Safety and Chemicals Agency may obligate the operator to publicly provide information on the matter within a specific period of time and in the manner it specifies. The Finnish Safety and Chemicals Agency may also obligate the operator to provide the end users with the information and instructions that are necessary for ensuring safety.

(2) The Finnish Safety and Chemicals Agency may, at the expense of the operator, provide information on the matters referred to in subsection 1 if the operator has failed to comply with the order to provide information issued by the authority or if, because of the urgent nature of the matter, the provision of information is necessary due to a risk to human health.

Section 11

Order to dispose of the product

If the prohibitions and orders referred to in sections 7, 9 and 10 cannot be considered adequate for preventing a health risk, the supervisory authority may order that the cosmetic product in the possession of the operator and the cosmetic product recalled by the operator under section 9 be disposed of or, if this is not considered appropriate, issue an order regarding what should otherwise be done with the product.

Section 12

Prohibiting exports

(1) If the cosmetic product is hazardous to health and the risk is of a serious nature, the supervisory authority may prohibit exports of the product or its transport through Finland.

(2) The supervisory authority may also impose the prohibition referred to in subsection 1 on a temporary basis if there are reasons to suspect that the cosmetic product may cause a health risk. The temporary prohibition will remain in force until the matter is finally resolved under the subsection in question.

Section 13

Right to access information and carry out inspections

(1) Notwithstanding secrecy provisions, the supervisory authority has the right to access the information necessary for the supervision of compliance with this Act and the EU Cosmetics Regulation from the operator and other individuals bound by the obligations laid down in this Act, the provisions issued under it and the cosmetics legislation of the European Union.

(2) The supervisory authority has the right to carry out inspections necessary for supervising compliance with this Act and the EU Cosmetics Regulation. The supervisory measures may, however, only be extended to facilities permanently used for human habitation if the inspection is necessary for examining the matters targeted in the inspection and there are reasons to suspect a health offence, referred to in [Chapter 44, section 1 of the Criminal Code \(39/1889\)](#). Outside experts, referred to in section 15 below, may not be granted the right to inspect facilities permanently used for human habitation.

Section 14

Right to take samples and carry out investigations

(1) The supervisory authority has the right to take samples of a cosmetic product if it is necessary for supervising compliance with this Act or the EU Cosmetics Regulation.

(2) If the operator so requests, the sample referred to in subsection 1 above must be compensated for on basis of its fair value, unless it is concluded that the cosmetic product is non-compliant with this Act or the EU Cosmetics Regulation. However, if under a separate provision a fee is charged for the sample or the examination of the sample, no compensation needs to be paid for the sample.

(3) If the cosmetic product is not in compliance with the requirements laid down in this Act or the EU Cosmetics Regulation, the supervisory authority may obligate the operator to compensate for the costs arising from the purchase, testing and examination of the product.

Section 15

Using an expert

(1) In its supervisory activities, the supervisory authority may use a qualified outside expert who possesses the expertise necessary for carrying out inspections, examinations and reports during the investigation of matters that are important to the supervision process.

(2) Provisions concerning criminal liability for acts in office are applied to the expert referred to in subsection 1 above during his or her performance of the assisting duties related to the supervisory activities. Provisions on tort liability are laid down in the Tort Liability Act ([412/1974](#)).

Section 16

Right to receive information from other authorities and disclose confidential information

(1) In addition to what is laid down in the Act on the Openness of Government Activities ([621/1999](#)), and notwithstanding secrecy provisions and other restrictions concerning access to information, the authorities supervising compliance with this Act and the EU Cosmetics Regulation have the right to receive from other supervisory authorities information necessary for pre-trial investigation or supervision and to use the samples obtained by others for the investigations necessary for the supervision process.

(2) In accordance with what is laid down in subsection 1, the supervisory authority may disclose information obtained in connection with the supervisory activities on the financial position of an individual or a community, trade or professional secrets, or the personal conditions of an individual to the National Supervisory Authority for Welfare and Health, the Finnish Food Safety Authority

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and the Finnish Competition and Consumer Authority for the supervision laid down in the law to competent authorities in other EU countries in accordance with Articles 29 and 30 of the EU Cosmetics Regulation and to pre-trial investigation authorities for preventing and investigating a criminal offence and to a prosecutor for consideration of charges.

Section 17

Executive assistance

The police have the obligation to provide executive assistance for supervising compliance with this Act, the regulations and orders issued under it, and the EU Cosmetics Regulation and for enforcing them. Provisions on the executive assistance given by the police are laid down in the Police Act ([493/1995](#)).

The Police Act [493/1995](#) has been repealed by the Police Act [872/2011](#), which entered into force on 1 January 2014. On executive assistance, see [section 40 of the Police Act \(493/1995\)](#), and from 1 January 2014, [Chapter 9, section 1 of the Police Act \(872/2011\)](#).

Section 18

Notice of a conditional fine and notice of enforced compliance and enforced suspension

(1) The Finnish Safety and Chemicals Agency may enforce a prohibition or an order that it has issued under this Act by issuing a notice of a conditional fine, by informing the operator that the measure that has been left unperformed will be carried out at the expense of the neglecting party, or by issuing a notice concerning the suspension of activities.

(2) The conditional fine is ordered to be paid by an Administrative Court. Otherwise, provisions regarding a notice of a conditional fine, a notice of enforced compliance and a notice of enforced suspension are laid down in the Act on Conditional Fines ([1113/1990](#)).

Section 19

Charges

Provisions on the criteria for chargeable performances by authorities under this Act, on the size of the charges and on other criteria for the charges are laid down in the Act on Criteria for Charges Payable to the State ([150/1992](#)).

Section 20

Appeals

(1) The appeal procedure for decisions issued by an authority under this Act is laid down in the Administrative Judicial Procedure Act ([586/1996](#)).

(2) Notwithstanding what is provided in subsection 1, the temporary prohibition imposed by the supervisory authority referred to in section 8 and the temporary export prohibition referred to in section 12(2) may not be separately appealed.

(3) In the decisions made under sections 7 and 9 -11 above, it may be ordered that the decision must be complied with, the appeal notwithstanding, unless decided otherwise by the appellate authority.

Chapter 4

Requirements concerning cosmetic products

Section 21

Language requirements concerning the labelling and product information file of cosmetic products

(1) The information referred to in Article 19(1)(b-d) and (f) and 19(2-4) of the EU Cosmetics Regulation must be provided in Finnish and Swedish, as laid down in section 34 of the Language Act ([423/2003](#)).

(2) The product information file referred to in Article 11 of the EU Cosmetics Regulation, which is kept in Finland, must be made accessible to the Finnish Safety and Chemicals Agency and Finnish Customs at the address indicated on the labelling of the cosmetic product in Finnish, Swedish or English.

Section 22

Cosmetic products that are sold unpackaged

For cosmetic products that are not sold in pre-packaged form, but that are packaged at the point of sale at the purchaser's request or that are pre-packaged for immediate sale, the purchaser must be provided with the information referred to in Article 19(1) of the EU Cosmetics Regulation by means of a separate leaflet or other report if they are not otherwise clearly visible at the time of the purchase. The information referred to in Article 19(1)(a), (c), (d), (f) and (g) of the EU Cosmetics Regulation, which are necessary for the safe use of the cosmetic product, must, however, always be provided to the purchaser with the product.

Chapter 5

Penalties

Section 23

Cosmetics violation

(1) A person who intentionally or negligently breaches

1) the prohibition on export or transit laid down in section 12(1),

2) the requirement concerning the language of the labelling or product information file of cosmetic products laid down in section 21, or

3) the obligations concerning the provision of information on cosmetic products laid down in section 22,

must be sentenced for a *cosmetics violation* to a fine unless a more severe penalty for the act is provided elsewhere in the law.

(2) Unless a more severe penalty for the act is provided elsewhere in the law, a person who intentionally or negligently breaches the following obligations or prohibitions laid down in the EU Cosmetics Regulation must also be sentenced for a cosmetics violation:

- 1) obligations of responsible persons laid down in Article 5;
- 2) obligations of distributors laid down in Article 6;
- 3) obligations concerning the identification within the supply chain laid down in Article 7.

(3) When a person has breached a prohibition, regulation or order issued under this Act and a notice of a conditional fine has also been imposed, the court may decide to waive the punishment for the same act.

Section 24

Reference to the Criminal Code

The punishment for a health offence is laid down in [Chapter 44, section 1 of the Criminal Code](#).

Chapter 6

Entry into force

Section 25

Entry into force

- (1) This Act enters into force on 11 July 2013.
- (2) This Act repeals the Act on Cosmetic Products [\(22/2005\)](#).

Section 26

Transitional provision

Matters instituted before the entry into force of this Act will be processed in accordance with the provisions in force at the time of the Act's entry into force.