

**Translation from Finnish**

**Legally binding only in Finnish and Swedish**

**Ministry of Social Affairs and Health**

## **Chemicals Act**

*(599/2013; amendments up to 547/2023 included)*

By decision of Parliament, the following is enacted:

### **General provisions**

#### **Section 1**

##### **Objectives of the Act**

The objective of this Act is to protect health and the environment from the hazards and harm caused by chemicals.

#### **Section 2**

##### **Scope of application**

This Act lays down provisions on the enforcement of European Union chemicals legislation and certain national obligations regarding chemicals. The framework for market surveillance, cooperation with economic operators and surveillance of products entering the Union market is laid down in Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011, hereinafter referred to as the Market Surveillance Regulation. Provisions on market surveillance, external border controls in accordance with Articles 25–28 of the Market Surveillance Regulation, supervisory authorities and requests for review of decisions of supervisory authorities are laid down in the Act on the Market Surveillance of Certain Products (1137/2016), hereinafter referred to as the Market Surveillance Act. (260/2022)

This Act also applies to biocidal products the effectiveness of which is based on a micro-organism.

#### **Section 3 (716/2021)**

##### **Application of the Act in the defence administration and in production supporting national defence**

Provisions on necessary derogations regarding compliance with this Act, the REACH Regulation, the CLP Regulation and the Biocidal Products Regulation in the activities of the defence administration may be issued by government decree where necessary for the purposes of national defence.

The derogations may concern the following:

- 1) communication in the supply chain and the responsibilities of downstream users;
- 2) the authorisation procedure under the REACH Regulation;
- 3) the classification, labelling and notifications under the CLP Regulation;
- 4) the authorisation procedure under the Biocidal Products Regulation;
- 5) disclosure of information to supervisory authorities.

Necessary derogations from submitting the information referred to in section 22b concerning the defence administration and production supporting national defence may also be laid down by government decree with respect to items whose production directly supports national defence.

The defence administration may also derogate from the requirements laid down in this Act, the REACH Regulation and the CLP Regulation if the requirements concerning the secrecy of documents laid down in section 24, subsection 1, paragraph 10 of the Act on the Openness of Government Activities (621/1999) or in the Act on International Information Security Obligations (588/2004) are satisfied, or if the derogation is otherwise necessary due to the nature, purpose or special functions of national defence.

Due diligence and care shall be observed when applying this Act and European Union chemicals legislation in the defence administration and in production supporting national defence in order to prevent damage to human health, the environment and property.

#### **Section 4**

##### **Derogations regarding compliance with European Union chemicals legislation**

Provisions on derogations from complying with the restrictions concerning the hazardous substances, mixtures and articles referred to in Article 67 of the REACH Regulation, in accordance with the provisions in Annex XVII thereof, and provisions necessary for preventing and combating harm to health and the environment caused by the chemicals referred to in the said Annex may be issued by government decree.

#### **Section 5**

##### **Relationship to other legislation**

Provisions on preventing and combating harm caused by chemicals to health and the environment and the physical hazards and harm caused by chemicals are also laid down in the following acts:

- 1) Environmental Protection Act (527/2014); (554/2014)
- 2) Act on Environmental Protection in Maritime Transport (1672/2009);
- 3) Waste Act (646/2011);
- 4) Act on the Safe Handling and Storage of Dangerous Chemicals and Explosives (390/2005);

- 5) Health Protection Act (763/1994);
- 6) Occupational Safety and Health Act (738/2002);
- 7) Act on Plant Protection Products (1563/2011);
- 8) Act on the Transport of Dangerous Goods (541/2023); (547/2023)

Paragraph 8 as amended by Act 547/2023 enters into force on 1 September 2023. Previous form of wording:

- 8) Act on the Transport of Dangerous Goods (719/1994);
- 9) Radiation Act (859/2018); (711/2020)
- 10) Act on Cosmetic Products (492/2013);
- 11) Medicines Act (395/1987);
- 12) Medical Devices Act (629/2010);
- 13) Act on the Safety of Toys (1154/2011);
- 14) Narcotics Act (373/2008); (711/2020)
- 15) Tobacco Act (549/2016). (711/2020)

To the extent not covered in this Act or in European Union chemicals legislation, provisions on the safety of consumer goods and consumer services are laid down in the Consumer Safety Act (920/2011).

## **Section 6**

### **Definitions**

In this Act:

- 1) European Union chemicals legislation means the following EU Regulations and statutes issued pursuant thereto:
  - a) Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, hereinafter referred to as the REACH Regulation;
  - b) Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, hereinafter referred to as the CLP Regulation;
  - c) Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products, hereinafter referred to as the Biocidal Products Regulation;

- d) Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, hereinafter referred to as the Detergents Regulation;
- e) Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals, hereinafter referred to as the PIC Regulation;
- f) Regulation (EU) No 2019/1021 of the European Parliament and of the Council on persistent organic pollutants, hereinafter referred to as the POP Regulation; and (716/2021)
- g) Regulation (EU) No 2017/852 of the European Parliament and of the Council on mercury, and repealing Regulation (EC) No 1102/2008, hereinafter referred to as the Mercury Regulation; (756/2018)
- 2) chemical means substances and mixtures as they are defined in the REACH Regulation and the CLP Regulation;
- 3) article means an article as defined in the REACH Regulation;
- 4) treated article means a treated article as defined in the Biocidal Products Regulation;
- 5) hazardous chemical means a substance or a mixture that shall be classified or labelled in accordance with the CLP Regulation or for which a safety data sheet shall be submitted under the REACH Regulation;
- 6) biocidal product means a biocidal product as defined in the Biocidal Products Regulation and in chapter 5;
- 7) operator means anyone who manufactures, imports, places on the market, exports, stores, packages, distributes or uses a chemical in some other manner referred to in this Act or in European Union chemicals legislation.

## **Chapter 2**

### **Supervisory authorities and their functions**

#### **Section 7**

##### **Ministries**

General guidance, monitoring and development of activities in accordance with this Act and supreme direction and guidance in supervising compliance with the Act and provisions issued pursuant thereto are vested in:

- 1) the Ministry of Social Affairs and Health with respect to preventing and combating physical hazards and harm caused by chemicals to health; and
- 2) the Ministry of the Environment with respect to preventing and combating hazards and harm caused by chemicals to the environment.

#### **Section 8 (756/2018)**

##### **Finnish Safety and Chemicals Agency**

Unless otherwise provided in this Act, it is a function of the Finnish Safety and Chemicals Agency to supervise compliance with this Act and provisions issued pursuant thereto, with the REACH Regulation, the CLP Regulation, the Detergents Regulation and the Biocidal Products Regulation, and with the prohibitions and restrictions of production and placing on the market referred to in Articles 3 and 4 of the POP Regulation and Articles 5 and 8 of the Mercury Regulation.

## **Section 9**

### **Finnish Environment Institute**

The Finnish Environment Institute supervises compliance with the provisions issued in and pursuant to section 23, the POP and PIC Regulations and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (Finnish Treaty Series 107/2004), hereinafter referred to as the Rotterdam Convention, unless otherwise provided elsewhere by law.

## **Section 10**

### **Occupational safety and health authority**

The occupational health and safety authority supervises compliance with this Act, with provisions issued pursuant thereto, and with European Union chemicals legislation in all work where the employer is required to comply with the Occupational Safety and Health Act.

If the occupational health and safety authority observes in the course of supervisory activities that provisions of this Act or of European Union chemicals legislation have probably been infringed when placing a chemical or a device or article containing the chemical on the market or bringing it into use, then an inspector referred to in the Act on Occupational Safety and Health Enforcement and Cooperation on Occupational Safety and Health at Workplaces (44/2006) may temporarily prohibit release of the device or article containing the chemical onto the market or for use, in compliance with the provisions of section 18, subsection 4 of the said Act, as appropriate. The inspector shall refer the matter to the Regional State Administrative Agency, which will submit it for consideration by the Finnish Safety and Chemicals Agency.

In addition to the provisions laid down in section 52 concerning the right to information and the disclosure of non-disclosable information, the supervisory and inspection activities of the occupational safety and health authority are governed by the Act on Occupational Safety and Health Enforcement and Cooperation on Occupational Safety and Health at Workplaces.

## **Section 11 (711/2020)**

### **Centre for Economic Development, Transport and the Environment and municipal environmental protection authority**

The Centre for Economic Development, Transport and the Environment and the municipal environmental protection authority supervise:

- 1) compliance with this Act and provisions issued pursuant thereto;
- 2) compliance with the terms and conditions set for the use of biocidal products in the authorisation referred to in Article 17 of the Biocidal Products Regulation or in section 30 of this Act;
- 3) compliance with Articles 3 and 4 of the POP Regulation concerning the use of substances;
- 4) compliance with the following provisions of the REACH Regulation: Articles 14 and 37 concerning conditions and risk reduction measures for the use of substances, Title VII on the use of substances requiring authorisation, and Article 67 concerning restrictions on the use of substances;

when supervising activities that pose a threat of environmental pollution in accordance with the Environmental Protection Act to the extent that such supervision concerns an operator's obligation to prevent and combat harmful environmental effects in the use and storage of chemicals;

- 5) compliance with obligations concerning the use and temporary storage of mercury, mercury compounds and mixtures of mercury laid down in Article 7, and compliance with prohibitions concerning the use of mercury-added products and compounds laid down in Article 8 and the use of mercury laid down in Article 9 of the Mercury Regulation.

The Centre for Economic Development, Transport and the Environment provides guidance to the municipal environmental protection authority in the supervisory activities referred to in subsection 1.

## **Section 12**

### **Finnish Medicines Agency**

The Finnish Medicines Agency ensures that good laboratory practice is observed in research activities, as laid down in section 24 and in European Union chemicals legislation.

## **Section 13 (260/2022)**

### **Customs**

Customs serves as the market surveillance authority referred to in Articles 25–28 of the Market Surveillance Regulation in supervising compliance with European Union chemicals legislation with respect to the import, export and transit of chemicals and articles containing them referred to in this Act, and in supervising compliance with the provisions of this Act concerning biocidal products in the context of the import, export and transit of biocidal products.

When supervising compliance with European Union chemicals legislation, it is the particular duty of Customs to ensure that:

- 1) the registrations and notifications referred to in Title II of the REACH Regulation have been completed when importing substances and mixtures and articles that contain them;

- 2) the authorisation referred to in Title VII of the REACH Regulation has been granted when importing substances subject to authorisation and mixtures that contain them;
- 3) the restrictions referred to in Article 67 of the REACH Regulation are observed when importing substances and mixtures and articles that contain them;
- 4) the prohibitions and restrictions referred to in the POP Regulation are complied with when importing substances referred to in Annexes I and II to the Regulation;
- 5) the obligations related to importing and exporting the chemicals referred to in Annex I of the PIC Regulation and articles that contain them, and the export ban on the chemicals and articles referred to in Annex V are complied with;
- 6) the export restrictions laid down in Article 3 and the import restrictions laid down in Article 4 of the Mercury Regulation regarding mercury, mercury compounds and mixtures of mercury, and the ban on the export and import of mercury-added products laid down in Article 5 of the said Regulation are complied with;
- 7) the obligations regarding the authorisation of biocidal products and importing of treated articles in the Biocidal Products Regulation are complied with.

Customs supervises compliance with restrictions under Annex XVII of the REACH Regulation, and with obligations related to the approval of biocidal products and the importing of treated articles under the Biocidal Products Regulation and this Act, as a market surveillance authority at the time of unloading and associated storage of the goods consignment in Finland when a shipment arrives from a European Union Member State.

Unless otherwise laid down in this Act, the provisions of both the Market Surveillance Act and the Customs Act (304/2016) shall be observed in supervision.

## **Section 14 (199/2017)**

### **Finnish Defence Forces**

The Finnish Defence Forces supervise compliance with this Act and European Union chemicals legislation in military activities of the Finnish Defence Forces and in training organised for this purpose, and at sites that require special protection for the purposes of national defence, and in crisis management tasks. Further provisions on supervision are issued by decree of the Ministry of Defence.

## **Chapter 3**

### **Other functions of public authorities**

## **Section 15 (711/2020)**

### **Competent authorities and designated organs**

The Finnish Safety and Chemicals Agency serves as the competent authority referred to in Article 121 of the REACH Regulation, Article 43 of the CLP Regulation, Article 81 of the Biocidal Products Regulation and Article 8 of the Detergents Regulation. The Finnish Safety and Chemicals Agency also serves as the competent authority referred to in Article 8(2) and 8(3) of the Mercury Regulation with respect to new manufacturing processes and the placing on the market of new mercury-added products.

The Finnish Environment Institute serves as the competent authority referred to in Article 19 of the POP Regulation and referred to in Article 17 of the Mercury Regulation with the exception of functions referred to in subsection 1, and as the designated national authority under Article 4 of the PIC Regulation. The Finnish Environment Institute also serves as the designated national authority referred to in the Rotterdam Convention, unless otherwise provided in the PIC Regulation. (716/2021)

The Finnish Safety and Chemicals Agency and the Poison Information Centre attached to the Hospital District of Helsinki and Uusimaa each serve as the appointed body referred to in Article 45 of the CLP Regulation in its own field.

## **Section 16**

### **National helpdesk**

The Finnish Safety and Chemicals Agency arranges a national helpdesk to provide advice for manufacturers, importers, downstream users, distributors and other concerned parties in accordance with Article 124 of the REACH Regulation, Article 44 of the CLP Regulation and Article 81 of the Biocidal Products Regulation.

## **Section 17 (711/2020)**

### **Registries of the Finnish Safety and Chemicals Agency**

The Finnish Safety and Chemicals Agency maintains registers of notifications submitted thereto under this Act, of authorisations on biocidal products that it issues, of persons who have completed the qualification and special qualification related to biocidal products, and of registered undertakings engaged in pest control using biocidal products.

For the purpose of discharging the functions referred to in this Act, the Finnish Safety and Chemicals Agency maintains:

- 1) a chemical products register containing the information referred to in section 22;
- 2) a biocidal products register containing information on biocidal products authorised nationally in accordance with this Act and with the Biocidal Products Regulation;
- 3) a register of qualifications and undertakings containing information on persons who have completed the qualification related to biocidal products referred to in section 38 and the special qualification referred to in section 41, and on the undertakings performing pest control using biocidal products and the persons in charge of these operations that have been registered in accordance with section 44.

The information referred to in paragraph 1 of subsection 2 above is stored in a digital transaction service accessible to the national public authorities and operators referred to in subsection 2 of section 52.



Provisions governing the right to non-disclosable information are laid down separately in section 52. Provisions governing the processing of information are laid down in the Act on Information Management in Public Administration (906/2019).

Information other than that which is non-disclosable under section 56 may be provided from the registers in the form of copies and over a public data network.

Information that is necessary for supervising compliance with this Act and provisions issued pursuant thereto, and for developing such supervision, that concerns supervision sites falling within the scope of this Act and is not referred to in subsections 1 and 2 may also be recorded in the registers of the Finnish Safety and Chemicals Agency.

Further provisions on the registries referred to in subsection 2 and on their use may be issued by government decree.

The provisions laid down elsewhere in the law shall also be observed in the processing of personal data.

## **Section 18**

### **Advisory Committee on Chemicals**

On the proposal of the Ministry of Social Affairs and Health, the Government may appoint an Advisory Committee on Chemicals for a three-year term to promote cooperation between public authorities, key organisations and other operators in managing risks related to chemicals.

Further provisions on the composition and functions of the Advisory Committee are issued by government decree.

## **Chapter 4**

### **General principles guiding operations and the duties of an operator**

## **Section 19**

### **General principles guiding operations**

In addition to the provisions of European Union chemicals legislation, the following principles govern operations that involve the use of chemicals:

- 1) operators are sufficiently aware of the effects of the chemical on health and the environment, and of requirements related to sales of the chemical;
- 2) due diligence and caution are observed to prevent harm to health and the environment, having regard to the quantity and hazardous character of the chemical;
- 3) to prevent harm caused by chemicals, the least hazardous choice between existing chemicals or methods is made when reasonably possible.

## **Section 20 (711/2020)**

### **Language requirement for information on chemicals**

The labels of a biocidal product and an article treated with a biocide, of a plant protection product under the Act on Plant Protection Products, and of a hazardous chemical shall be written in both Finnish and Swedish.

Safety data sheets in accordance with Article 31 of the REACH Regulation shall be provided to the recipient of a chemical either in Finnish or in Swedish, or in both of these languages, depending on the choice of the recipient.

Information in accordance with Annex VIII to the CLP Regulation shall be submitted to the European Chemicals Agency in Finnish and Swedish, as laid down in section 22a, subsection 1. An operator making the limited submission referred to in section 22a, subsection 3 may nevertheless arrange the national helpdesk either in Finnish, Swedish or English.

The Finnish Safety and Chemicals Agency may require an operator seeking authorisation for a biocidal product to supply the information in Finnish or Swedish, as laid down in Article 33(1), article 34(2), or article 53(4) of the Biocidal Products Regulation.

## **Section 21**

### **Marketing of chemicals**

In addition to the provisions of European Union chemicals legislation concerning marketing, labelling and packaging, marketing of chemicals may not refer to a chemical in a manner that is misleading or untruthful with respect to the risks posed by the chemical to human health or the environment.

Marketing of the biocidal products referred to in chapter 5 is also governed by the provisions of Article 72 of the Biocidal Products Regulation.

## **Section 22 (711/2020)**

### **Submission of information on a chemical to the Finnish Safety and Chemicals Agency**

An operator responsible for placing or making available on the market or for use in Finland a chemical for which a safety data sheet shall be prepared in accordance with Article 31 of the REACH Regulation or Annex I to the CLP Regulation shall submit information on the chemical to the Finnish Safety and Chemicals Agency.

The operator referred to in subsection 1 above, and an operator who has received an approval decision in accordance with section 30 or the authorisation referred to in Articles 17 and 25 of the Biocidal Products Regulation, shall submit to the Finnish Safety and Chemicals Agency information on the quantities of

chemicals and biocidal products that they have placed on the market, made available on the market and put into use in Finland.

The operator shall declare the necessary personal information concerning contact persons of the operator when submitting the information referred to in subsections 1 and 2 and, with respect to subsection 2, the necessary personal information referred to in section 17, subsection 2, paragraph 3 for the register of qualifications and undertakings.

The legal basis for processing the personal data referred to in subsection 3 above is Article 6(1)(c) of Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

The information referred to in subsections 1–3 above shall be submitted electronically in the manner established by the Finnish Safety and Chemicals Agency.

Further provisions on submitting information referred to in subsections 1 and 2 above and on the content of the information to be submitted are issued by decree of the Ministry of Social Affairs and Health.

## **Section 22a (711/2020)**

### **Submission of information on a mixture to the European Chemicals Agency**

An operator required to comply with the obligations of Annex VIII to the CLP Regulation shall submit the information referred to in the said Annex to the information system maintained by the European Chemicals Agency, from which the Poison Information Centre and the Finnish Safety and Chemicals Agency obtain the information necessary for discharging their functions referred to in Article 45 of the CLP Regulation.

The Poison Information Centre shall notify the Finnish Safety and Chemicals Agency without delay if it observes significant shortcomings in the notification referred to in subsection 1.

Notwithstanding the provisions of subsection 1, with respect to a mixture intended for industrial use the operator referred to in subsection 1 may choose the limited submission referred to in Section 2.3 of Part A of Annex VIII to the CLP Regulation. The operator shall arrange a 24-hour helpdesk for rapid oral or electronic access to detailed additional information in such cases.

## **Section 22b (716/2021)**

### **Submission of information on a substance of special concern contained in an article**

The supplier of an article referred to in Article 3(33) of the REACH Regulation shall submit information in accordance with Article 33(1) of the said Regulation to the European Chemicals Agency. The information shall be submitted using the forms and software tools that the European Chemicals Agency makes available for this purpose. This obligation does not apply to the supplier of an article who only supplies the article to a consumer.

## **Section 23**

### **Notification concerning export**

Anyone exporting a chemical from the European Economic Area shall submit a notification and otherwise comply with the procedure laid down in the PIC Regulation.

Anyone exporting a chemical from the European Economic Area shall submit a notification to the Finnish Environment Institute concerning the export of any chemical that falls within the scope of the Rotterdam Convention but is not referred to in Annex I of the PIC Regulation. The Finnish Environment Institute forwards the notification to the authority of the receiving country in accordance with the Rotterdam Convention.

Further provisions on the chemicals referred to in subsection 2, on supervision of their export, and on the content, processing, timing and validity of the notification concerning export may be issued by government decree.

## **Section 24**

### **Testing laboratories**

The study concerning the health and environmental impacts of chemicals submitted to public authorities and required by European Union chemicals legislation shall be conducted at a laboratory that complies with the requirements laid down in Directive 2004/10/EC of the European Parliament and of the Council on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances, or that otherwise complies with good laboratory practice.

The Finnish Medicines Agency approves a laboratory as an authorised test laboratory if the laboratory demonstrates that it complies with the Directive referred to in subsection 1. The powers of the Finnish Medicines Agency in approving and inspecting laboratories that conduct tests on chemicals are governed by the provisions of the Medicines Act concerning the supervision of laboratories, setting conditions and restrictions for approval, revoking approval, the powers of an inspector, issuing of orders, and the procedure for requesting administrative review of an order.

Authorised test laboratories shall inform the Finnish Medicines Agency of essential changes in their operations.

## **Section 25 (711/2020)**

### **Restricting retail sales of chemicals and the obligation to disclose information**

A chemical shall not be released for retail sale if it is evident that use of the chemical may pose a particular risk to health.

The recipient of a chemical hazardous to health is obliged to provide the supplier with the necessary information on the recipient and user of the chemical and the purpose for which the chemical is used.

Further provisions may be laid down by government decree in the following respects insofar as a substance is not subject to restriction in Annex XVII to the REACH Regulation:

- 1) age limits concerning the retail and other supply of a hazardous chemical or a chemical that is otherwise harmful to health, conditions to be set for storing such chemicals, and retail sales restrictions concerning the prevention of a health hazard caused by their evident misuse;
- 2) conditions for the release of a chemical harmful to health from a pharmacy;
- 3) implementation of the obligation to disclose information concerning the recipient of a chemical that is harmful to health.

The foregoing provisions of this section do not apply to:

- 1) medicinal products intended for human beings or animals;
- 2) ammunition;
- 3) explosives referred to in the Act on the Safe Handling and Storage of Dangerous Chemicals and Explosives;
- 4) narcotics referred to in the Narcotics Act.
- 5) products referred to in the Tobacco Act.

## **Chapter 5**

### **Authorisation of biocidal products**

#### **Section 26**

##### **Biocidal product**

In this chapter, a biocidal product means:

- 1) a protective chemical intended for the treatment of timber to protect it from degradation or destruction caused by harmful organisms (wood preservative), or to prevent the growth of slime and blocking caused by the growth of harmful micro-organisms in cooling or water circulation systems, or to protect cellulose pulp and wood-containing pulp from degradation and destruction caused by harmful organisms (slimicide);
- 2) an antifouling product that is intended to prevent growth of microbes and higher forms of plant and animal species from attaching themselves to vessels, fish farming equipment or other structures used in water;
- 3) a biocidal product intended for use as a fly killer or insect repellent, for pest control of species occurring in human dwellings, cowsheds, warehouses and other indoor facilities, or for some other purpose equivalent to these.

## **Section 27**

### **Obligation to seek Authorisation**

A biocidal product may not be placed on the market or used without authorisation for the product, unless otherwise provided below in this Act or in the Biocidal Products Regulation. The Finnish Safety and Chemicals Agency decides on authorisations.

## **Section 28**

### **Applying for authorisation**

Authorisation for a biocidal product may be sought by the operator responsible for placing a biocidal product on the market in Finland for the first time. The applicant shall have a permanent establishment within the territory of the European Union.

Authorisation may be sought until the active substance has been approved under the Biocidal Products Regulation.

To enable assessment of the conditions for authorisation, the application shall include the necessary information on the health and environmental impacts, effectiveness and other properties of the product. Further provisions on applications and the information to be included therein are issued by decree of the Ministry of the Environment.

## **Section 29 (711/2020)**

### **Conditions for authorisation**

A biocidal product is authorised if the following conditions are satisfied:

- 1) the biocidal product contains only active substances that are in the work programme referred to in Article 89( 1) of the Biocidal Products Regulation, but have not yet been approved for the product-type in question;
- 2) the biocidal product and products treated with it or the residues resulting from its use do not cause evident harm to health or the environment when used in accordance with the conditions for authorisation;
- 3) the biocidal product is sufficiently effective and suitable for its intended purpose;
- 4) methods of analysis are available for determining the active substances contained in the biocidal product, and any substances contained in the product or residues resulting from its use that may have significant health and environmental impacts.

A biocidal product that meets the criteria for classification with respect to acute or specific target organ toxicity or carcinogenic character, or mutagenicity or toxicity for reproduction laid down in point a or b of Article 19(4) of the Biocidal Products Regulation is not approved to be made available on the market for use by the general public.

## **Section 30**

### **Authorisation decision and labelling of biocidal products**

An authorisation is granted for a maximum period of ten years, and renewed on application provided that the conditions for authorisation continue to be satisfied.

When authorising a biocidal product, the Finnish Safety and Chemicals Agency shall confirm the intended purpose of the product and the instructions for its use. The authorisation decision may also restrict the supply or use of a biocidal product to a certain user group or to individuals who have completed a qualification under section 38 or a special qualification under section 41. The conditions necessary for satisfying the conditions for authorisation may also be attached to the authorisation decision. A version of the safety data sheet updated to match the authorisation decision shall be submitted to the Finnish Safety and Chemicals Agency where necessary. The labelling of biocidal products referred to in this chapter is governed by Article 69 of the Biocidal Products Regulation where applicable.

Further provisions on the authorisation decision and the conditions to be attached thereto may be issued by government decree.

## **Section 31**

### **Revoking or modification of authorisation**

Authorisation of a biocidal product shall be revoked if:

- 1) the biocidal product no longer satisfies the conditions under section 29;
- 2) terms attached to the authorisation decision have been essentially infringed; or
- 3) incorrect or misleading information has been provided on factors affecting the authorisation.

The terms of the authorisation decision shall be modified if this is necessary for scientific or technical reasons, or to protect health or the environment.

An authorisation may also be revoked or its terms modified on the individual initiative of the applicant.

Further provisions on revoking an authorisation and the terms thereof may be issued by government decree.

## **Section 32**

### **New information**

An applicant for authorisation shall immediately notify the Finnish Safety and Chemicals Agency of new information concerning the active substance, the biocidal product containing the active substance and their

effects, of which the applicant may reasonably be expected to be aware, and that may affect the continued validity of the authorisation.

### **Section 33**

#### **Use of information in processing another application**

The Finnish Safety and Chemicals Agency may use information that is not generally available and that has been submitted by an applicant during the processing of another application only if the data owner has consented thereto in writing. The protection period for information submitted under this Act ends at the same time as the protection period for such information under Articles 60 or 95 of the Biocidal Products Regulation.

### **Section 34**

#### **Test activities**

The supplier or operator responsible for testing a biocidal product or its active substance that has not been approved under section 30 shall keep a record of tests related to scientific research and development work, and this information shall be submitted to the Finnish Safety and Chemicals Agency upon request. An operator responsible for a test related to production research and development work shall notify the Finnish Safety and Chemicals Agency before the active substance or biocidal product is placed on the market.

An operator responsible for a test that may involve or give rise to environmental emissions shall seek authorisation for conducting the test from the Finnish Safety and Chemicals Agency before initiating the test. No separate test-specific authorisation is required if the Finnish Safety and Chemicals Agency has granted the operator authorisation to undertake certain tests and specified the conditions under which the tests may be performed. A decision on authorisation issued by the Finnish Safety and Chemicals Agency may restrict the quantities of a product or active substance to be used in the test or the areas treated in the test, or may order other conditions that are necessary for protecting health or the environment.

Further provisions on the time limits related to the procedure for notification and seeking authorisation and on requirements for information concerning the test plan, the properties of the product, its environmental and health impacts, the quantities of a product to be used in the tests, and instructions for safe use may be issued by decree of the Ministry of the Environment.

### **Section 35**

#### **Use of biocidal products**

A biocidal product shall be used appropriately in compliance with the instructions for use. The use of biocidal products is also governed by what is provided elsewhere by law.



## **Chapter 6**

### **Provisions on certain biocidal products**

#### **Section 36**

##### **Submitting of samples**

A person who has secured the authorisation referred to in section 30 above or an authorisation holder referred to in Article 17(2) of the Biocidal Products Regulation shall submit samples, models and drafts of the packaging, labelling and instructional leaflets referred to in Article 69(3) of the said Regulation.

#### **Section 37**

##### **Training in the use of biocidal products intended for pest control**

The Finnish Safety and Chemicals Agency approves, upon application, the implementer of training in the appropriate and safe use of biocidal products intended for professional pest controllers and the related training programme.

The training shall at least include sufficient instruction in the appropriate and safe handling and use of biocidal products, preventing the occurrence of pests, risks associated with using biocidal products, and ways of managing these risks.

A condition for approval as an implementer of training is that the implementer or any trainer in the service thereof has sufficient training and experience in biocidal products and their use, and that the training programme satisfies the requirements laid down in subsection 2. Approval as an implementer of training remains valid for five years.

Approval as an implementer of training may be revoked if the conditions for approval are no longer satisfied, or if essential shortcomings are observed in the organisation of training and the operator has not remedied its operations within the time limit provided despite a request issued by the Finnish Safety and Chemicals Agency.

Further provisions on the implementer of training, on the organisation and content of training, and on the retention of documents may be issued by government decree.

#### **Section 38**

##### **Qualification in the use of biocidal products intended for pest control**

If a wood preservative, rodenticide, insecticide, acaricide or biocidal product used for controlling other arthropods that is intended for pest control may justifiably be considered to cause harm or hazard to

human health or the environment, then the Finnish Safety and Chemicals Agency may decide when issuing an authorisation for the product that it may only be used by:

- 1) a person of demonstrated competence who the said Agency has entered in the register of qualifications and undertakings referred to in section 17, subsection 2, paragraph 3; and
- 2) a person who has completed the qualification in plant protection products referred to in section 10 of the Act on Plant Protection Products in their own agricultural operation in which pest control is not performed for another person in return for a fee or free of charge.

The qualification in the use of biocidal products is used to demonstrate a capacity for safe and appropriate handling and use of biocidal products intended for pest control and competence as a pest controller. Participation in the training referred to in section 37 is not a requirement for obtaining the qualification if equivalent knowledge has been obtained in some other manner.

The qualification includes thematic entities concerning the appropriate and safe handling and use of biocidal products, preventing the occurrence of pests, risks related to the use of biocidal products, and management of these risks. A certificate in a form confirmed by the Finnish Safety and Chemicals Agency is awarded for acceptable completion of the qualification. The qualification is valid for five years.

Further provisions on the content and completion of the qualification concerning the use of biocidal products may be issued by government decree.

## **Section 39**

### **Recipient of the qualification**

The Finnish Safety and Chemicals Agency approves recipients of the qualification in the use of biocidal products on application.

The conditions for approval as a recipient of the qualification are that the recipient, or a person in the service thereof, has good knowledge and sufficient practical experience of pest control. The approval is valid for five years and may be revoked if the conditions for approval are no longer satisfied, or if essential shortcomings are observed in the organisation of the qualification and the operator has not remedied its operations within the time limit provided despite a request issued by the Finnish Safety and Chemicals Agency.

A recipient of the qualification and a person in the service thereof are subject to provisions governing criminal liability for acts in office when performing functions in accordance with this Act. Provisions on liability for damages are laid down in the Tort Liability Act (412/1974).

Further provisions on receiving the qualification and on retention of documents may be issued by government decree.

## **Section 40 (746/2016)**

### **Verification of competence**

A person who has completed a qualification in the use of biocidal products intended for pest control shall submit a notification to the Finnish Safety and Chemicals Agency for the purpose of verifying their competence. The notification shall specify the necessary personal and contact information and evidence of completing the qualification referred to in section 38. Persons satisfying the competence criteria are entered in the register of qualifications and undertakings referred to in section 17, subsection 2, paragraph 3 maintained by the Finnish Safety and Chemicals Agency.

The Finnish Safety and Chemicals Agency may issue a decision revoking registration if a person infringes section 35 of this Act or Article 17(5) of the Biocidal Products Regulation, or if there is cause to suspect that an operation has been or may be causing harm to the environment or to health. Before revoking registration, the Finnish Safety and Chemicals Agency shall give the person an opportunity to remedy the shortcoming, unless it is so fundamental that it cannot be eliminated within a reasonable period.

## **Section 41**

### **Special qualification**

When authorising a biocidal product causing a particular hazard or harm to health or the environment, the Finnish Safety and Chemicals Agency may decide to restrict the supply or use of the product to persons who have completed the special qualification and whom the Agency has entered into the register of qualifications and undertakings referred to in section 17, subsection 2, paragraph 4. The special qualification related to biocidal products intended for pest control may only be completed by persons having the competence referred to in section 38.

Training provided for the special qualification shall at least include sufficient instruction in handling and using products requiring the special qualification appropriately in a way that is safe for the user and other persons and the environment, in the risks involved in using the products, and in managing these risks.

The organiser of the special qualification shall issue a certificate of acceptable completion of all examinations. The special qualification is valid for five years.

Further provisions on qualification requirements may be issued by government decree.

## **Section 42**

### **Organisation of the special qualification**

The Finnish Safety and Chemicals Agency approves an organiser of the special qualification on application. An organiser of the special qualification is approved if the organiser or a person in the service thereof has good knowledge and sufficient practical experience of the subject area of the special qualification. The organiser shall be able to provide sufficient information and skills with respect to safe use of the product. The approval is valid for five years and may be revoked if the conditions for approval are no longer satisfied, or if essential shortcomings are observed in the organisation of the qualification and the operator has not remedied its operations within the time limit provided despite a request issued by the Finnish Safety and Chemicals Agency.

Documents concerning the organisation and completion of the special qualification shall be retained for at least five years after organising the qualification, and shall be presented to the Finnish Safety and Chemicals Agency on request.

An organiser of the special qualification and a person in the service thereof are subject to provisions governing criminal liability for acts in office when performing functions in accordance with this Act. Provisions on liability for damages are laid down in the Tort Liability Act.

Further provisions on the organisation of the special qualification may be issued by government decree.

## **Section 43 (746/2016)**

### **Verification of the special qualification**

A person who has completed the special qualification shall notify the Finnish Safety and Chemicals Agency for the purpose of verifying their special qualification. The notification shall include the necessary personal and contact information, and evidence of completing the special qualification referred to in section 41. Persons who have completed the special qualification are entered into the register of qualifications and undertakings referred to in section 17, subsection 2, paragraph 3 maintained by the Finnish Safety and Chemicals Agency.

The Finnish Safety and Chemicals Agency may issue a decision revoking registration if the registered party infringes section 35 of this Act or Article 17(5) of the Biocidal Products Regulation, or if there is cause to suspect that an operation has been or may be causing harm to the environment or to health. Before revoking registration, the Finnish Safety and Chemicals Agency shall give the person an opportunity to remedy the shortcoming, unless it is so fundamental that it cannot be eliminated within a reasonable period.

## **Section 44**

### **Notification of professional pest control operations and competence requirements of the person in charge**

An operator engaging in professional pest control using biocidal products shall notify the Finnish Safety and Chemicals Agency before commencing pest control operations. The operator shall have a person in charge of pest control operations in their full-time service with the training referred to in section 37 or equivalent professional skills, and who has completed the qualification referred to in section 38. The Finnish Safety and Chemicals Agency enters the operator and the person in charge of operations into the register of qualifications and undertakings referred to in section 17, subsection 2, paragraph 3.

The notification shall include the name and contact information of the operator, and information concerning the person in charge of operations and the qualifications of the said person.

The operator shall submit a new notification no later than three months after any change in the person in charge of operations. The Finnish Safety and Chemicals Agency shall be notified of the termination of operations.

## **Chapter 7**

### **Supervision**

#### **Section 45 (260/2022)**

##### **Scope of application of the chapter**

Chapter 7 of this Act applies to supervision other than market surveillance of chemicals.

Notwithstanding the provisions of subsection 1, market surveillance of chemicals is governed by section 45a and section 45b, subsection 3.

The provisions of the Market Surveillance Act shall be complied with in the market surveillance of chemicals, unless otherwise provided in this Act. When applying this Act, a chemical, an article containing a chemical or a processed article is deemed to be a product referred to in the Market Surveillance Act, and a party who manufactures, or who imports, places on the market, exports, stores, packs or distributes a product in person or in the role of sole representative in the manner referred to in this Act or in European Union chemicals legislation is deemed to be an economic operator.

The provisions of European Union chemicals legislation concerning the definitions of placing on the market apply when market surveillance measures for chemicals are applied to an economic operator with respect to placing on the market and biocidal products. The placing of nationally approved biocidal products on the market nevertheless refers to placing them on the market in Finland.

#### **Section 45a (260/2022)**

##### **Right to disclose non-disclosable information in market surveillance**

In addition to the provisions laid down in section 13 of the Market Surveillance Act, the market surveillance authority may also disclose the essential information referred to in the said section to health protection authorities or specialist agencies and institutions for the purpose of assessing a hazard or risk to health.

#### **Section 45b (260/2022)**

##### **Prohibiting or restricting a chemical causing serious harm or hazard**

To the extent that a chemical is not restricted in the REACH Regulation, the Government may decide to restrict or prohibit, for a specified period or until further notice, the manufacture, import, placing on the market and other supply, export or use of the chemical or an article containing the chemical, or other equivalent handling of the chemical, and to impose operating restrictions and conditions, if use of the

chemical or of an article containing the chemical is found or can be justifiably assessed to cause serious harm or hazard to health or the environment.

The decision referred to in subsection 1 above may also be taken to invoke the safeguard clause in EU chemicals legislation.

The Safety and Chemicals Agency may issue the necessary prohibitions and restrictions on an interim basis if rapid measures are required to prevent the harm or hazard referred to in subsection 1. The matter shall be submitted to the Government for decision without delay in such cases.

## **Section 46 (711/2020)**

### **Prohibitions and orders by the supervisory authority**

If an operator fails to comply with the provisions of this Act or of European Union chemicals legislation, then the competent supervisory authority may prohibit the operator from continuing operations or repeating the infringing procedure, or may order the operator to satisfy the statutory obligations in some other manner.

The Finnish Environment Institute may issue an order concerning a prohibition on placing a chemical or an article containing a chemical on the market or making it available on the market, on removal from the market, on a recall procedure, or on notification of a resulting hazard, or may order that the chemical be appropriately rendered harmless in cases of supervising compliance with the PIC Regulation or with section 23, subsection 1 or 2. (260/2022)

Subsection 3 was repealed by Act 260/2022.

## **Section 47**

### **Conditional fine and enforced compliance and suspension**

A supervisory authority may enforce a prohibition or order that it has issued under this Act by imposing a conditional fine or notifying the operator that the undischarged measure will be discharged at the expense of the defaulting party or that the operation will be suspended.

Provisions concerning conditional fines, enforced compliance and suspension are laid down in the Act on Conditional Fines (1113/1990).

## **Section 48**

### **Right to information and inspection**

Notwithstanding non-disclosure provisions, a supervisory authority is entitled to the information that is necessary for supervising compliance with this Act and provisions issued pursuant thereto, and with European Union chemicals legislation from an operator and from any other person who is bound by the

obligations laid down in this Act and provisions issued pursuant thereto, and in European Union chemicals legislation.

A supervisory authority is entitled to perform the inspections that are necessary for supervising compliance with this Act and provisions issued pursuant thereto and with European Union chemicals legislation in facilities that are not used for residence of permanent character.

## **Section 49 (711/2020)**

### **Right to obtain samples and perform investigations**

A supervisory authority is entitled to take a sample of reasonable quantity necessary for performing investigations, free of charge, from a chemical or an article containing a chemical or from a processed article, if this is necessary for supervision. At the request of the economic operator, the supervisory authority shall pay compensation at a fair price for the chemical or article containing the chemical or processed article unless it is found that this is contrary to legislation.

If a chemical or an article containing a chemical or a processed article is contrary to legislation, then the supervisory authority may require the economic operator to reimburse the costs incurred in procuring, testing, investigating, storing and disposing of the chemical, article containing the chemical or processed article. The compensation is directly enforceable. Provisions on its collection are laid down in the Act on the Enforcement of Taxes and Public Payments (706/2007).

## **Section 50**

### **Use of specialists**

A supervisory authority may be assisted in its supervisory functions by a competent external specialist in the investigation of matters of significance for supervision.

The specialist referred to in subsection 1 above is subject to provisions concerning criminal liability for acts in office when assisting in a supervisory function. Provisions on liability for damages are laid down in the Tort Liability Act.

## **Section 51 (711/2020)**

### **International exchange of information**

Notwithstanding non-disclosure provisions, a supervisory authority may disclose the information under statute or treaty that is required by European Union chemicals legislation and by international conventions approved by Finland to EU organs, international organisations and countries involved in cooperation. International disclosure of personal data shall comply with the Personal Data Act (1050/2018) and the Act on International Information Security Responsibilities.

## **Section 52 (711/2020)**

### **Right to information from other public authorities and disclosure of non-disclosable information**

Notwithstanding non-disclosure provisions, the supervisory authorities referred to in this Act has the right, for the purpose of discharging the functions laid down in this Act, to receive from another supervisory authority the information that is necessary for supervision, and to use samples obtained by the other authority for investigations that are necessary for supervision. The right also extends to personal data, provided that this is essential for supervision.

Notwithstanding the non-disclosure obligation laid down in the Act on the Openness of Government Activities, a supervisory authority may disclose information obtained for the purpose of supervision concerning the financial status of an individual or a corporation, trade secrets, or the personal circumstances of an individual to other supervisory authorities referred to in this Act, to other public authorities and specialist agencies that require the information in order to discharge an official function related to chemical safety, and to the supervisory authorities of other European Union Member States for the purpose of supervising compliance with European Union chemicals legislation.

Notwithstanding non-disclosure provisions, information obtained in discharging the functions referred to in this Act may be disclosed to a public prosecutor and to the police for the purposes of preventing and resolving a criminal offence.

## **Section 53**

### **Executive assistance**

The Police, and Customs with respect to the import, export and transit of chemicals, are required to provide executive assistance in the enforcement and supervision of compliance with this Act and provisions issued pursuant thereto. Provisions on executive assistance provided by the Police are laid down in the Police Act (493/1995).

The Police Act (493/1995) was repealed by Act 872/2011, see Police Act (872/2011), chapter 9, section 1.

## **Section 54**

### **Charges**

Provisions on charging for services of public authorities under this Act, on the general grounds for the amount of charges to be collected and on other grounds for charges are laid down in the Act on Criteria for Charges Payable to the State (150/1992).

A charge may be waived in whole or in part if the charge is unreasonable due to minimal use of a chemical or biocidal product, or for some other reason.



## **Chapter 8**

### **Request for review and non-disclosure obligation**

#### **Section 55**

##### **Request for review**

Provisions on requesting a review of a decision issued by a public authority pursuant to this Act are laid down in the Administrative Judicial Procedure Act (808/2019), unless otherwise provided in subsections 2 or 3. (711/2020)

The temporary prohibition or restriction imposed by the Finnish Safety and Chemicals Agency referred to in section 45b, subsection 3 is ineligible for review by appeal. (260/2022)

The provisions of the Environmental Protection Act concerning a request for review and the enforcement of decisions shall be observed in requesting a review of a decision issued pursuant to this Act by a Centre for Economic Development, Transport and the Environment or by a municipal environmental protection authority.

A decision issued pursuant to sections 31 or 46 of this Act or the PIC Regulation may order that the decision shall be complied with notwithstanding any request for review unless otherwise ordered by the appellate authority.

#### **Section 56**

##### **Claim for protection of trade secrets (656/2018)**

The operator responsible for submitting the information referred to in section 22 above shall separately designate as trade secrets information that it requires to remain undisclosed to parties other than the Finnish Safety and Chemicals Agency. An operator expressing this claim shall give grounds for so doing. (656/2018)

An operator referred to in section 22 that chooses to publish information that was previously deemed non-disclosable shall notify the Finnish Safety and Chemicals Agency thereof.

#### **Section 57**

##### **Limitation of trade secrecy concerning chemicals (656/2018)**

Notwithstanding the provisions on trade secrecy laid down in the Act on the Openness of Government Activities, the following information concerning chemicals shall not be non-disclosable at the behest of the operator referred to in section 22 of this Act: (656/2018)

- 1) the trade name of a substance;
- 2) the trade name of a mixture;
- 3) the name of the manufacturer and of the party submitting the notification;
- 4) information on the physical and chemical properties included in the notification;
- 5) methods of rendering a substance or mixture harmless;
- 6) a summary of the findings of studies on the effects of a substance or mixture on health or the environment;
- 7) the purity level of a substance and any hazardous impurities or additives, if this information is necessary for classifying and labelling the product;
- 8) information submitted in the notification concerning:
  - a) handling, storage, transport, and recommended procedures and precautions to prevent and manage fire and other hazards;
  - b) precautions necessitated by sudden leaks;
  - c) rescue and treatment instructions for instances of poisoning and injury;
- 9) information included in the safety data sheet;
- 10) with respect to the substances referred to in Annex VI to the CLP Regulation, analytical methods that may be used for detecting hazardous substances released to the environment, and for determining human exposure thereto.

Subsection 2 was repealed by Act 711/2020.

## **Section 58 (711/2020)**

### **Limitation of trade secrecy concerning a biocidal product**

Notwithstanding the provisions of the Act on the Openness of Government Activities governing trade secrecy, the following information concerning biocidal products shall not be non-disclosable at the behest of an operator seeking authorisation for a biocidal product referred to in chapter 5 of this Act:

- 1) the name and address of the applicant;
- 2) the name and address of the manufacturer of the biocidal product and the active substances contained therein;
- 3) the name of the biocidal product and the names of the active substances contained therein and their concentrations in the product;
- 4) the names of substances classified as hazardous and affecting the classification of the product other than those referred to in paragraph 3;
- 5) information on the physical and chemical properties of the active substances and the biocidal product;

- 6) a summary of test findings concerning the effectiveness of the biocidal product, its capacity to generate resistance, and its effects on human beings, animals and the environment;
- 7) information on how an active substance or biocidal product may be rendered harmless, or information on procedures and measures to apply in the event of splattering or leakage of the substance or product;
- 8) recommended methods and precautions to prevent hazards arising from handling, storage, transport, use, and fire and other accidents;
- 9) information on the kind of first aid and treatment advice to be provided in case of accident;
- 10) methods of managing waste generated from a biocidal product and its packaging, and from products treated with a biocidal product;
- 11) the safety data sheet;
- 12) analytical methods for active substances or substances referred to in Annex VI to the CLP Regulation that may be used to detect a substance released into the environment, and to assay the residues.

## **Chapter 9**

### **Penal provisions**

#### **Section 59**

##### **Chemical violation**

Anyone who wilfully or negligently

- 1) infringes the language requirement concerning information on chemicals laid down in section 20 or the provision on marketing of chemicals laid down in section 21,
- 2) neglects the duty to provide information referred to in sections 22, 22a or 22b,
- 3) neglects the duty of notification laid down in section 23, subsection 2,
- 4) neglects the duty to seek authorisation for a biocidal product laid down in section 27 or the duty to seek authorisation or submit a notification concerning the test activities referred to in section 34,
- 5) infringes the obligation under section 35 to use a biocidal product appropriately, and in compliance with instructions for use,
- 6) neglects the obligation to submit the samples referred to in section 36, or
- 7) neglects the notification obligation laid down in sections 40, 43 or 44,

shall be sentenced to a fine for a chemical violation, unless a more severe punishment for the act is provided elsewhere by law.

(716/2021)

Anyone who wilfully or negligently infringes the following obligations or prohibitions under the REACH Regulation shall also be sentenced for a chemical violation, unless a more severe punishment for the act is provided elsewhere by law:

- 1) the registration or notification obligations to the European Chemicals Agency under Articles 5–7, 9, 11 or 17–19,
- 2) the obligations related to a chemical safety assessment, reporting, application or the provision of information under Article 14 or Articles 37–39,
- 3) the obligation to submit information to the European Chemicals Agency referred to in Articles 22, 24, 40, 41, 46 or 66,
- 4) the obligation in Article 31 concerning the safety data sheet, and submitting information required from this document to the recipient,
- 5) the obligation to provide information on a substance or mixture in accordance with Article 32,
- 6) the obligation to provide information under Articles 33 or 34, or the obligation of an employer to provide information under Article 35,
- 7) the obligation to retain information or to submit it to a competent authority or to the European Chemicals Agency in accordance with Article 36,
- 8) the obligation to submit additional information to a competent authority in accordance with Article 49,
- 9) the prohibition under Article 56 concerning placing on the market or using without an express authorisation for the substance in question granted by the European Commission, or using the substance in a manner contrary to the terms of the authorisation concerned,
- 10) the obligation in accordance with Article 65 to include the authorisation number on labels, or
- 11) the restriction laid down in Annex XVII concerning substances under Article 67 as such, in a mixture, or in an article.

(746/2016)

Anyone who wilfully or negligently infringes the following obligations under the CLP Regulation shall also be sentenced for a chemical violation, unless a more severe punishment for the act is provided elsewhere by law:

- 1) the obligations referred to in Article 4 or in Titles II–IV concerning classification, labelling and packaging,
- 2) the obligation referred to in Article 40 to provide information on a substance to the European Chemicals Agency,
- 3) the obligation referred to in Article 49 to retain information or submit it to the competent authority, a supervisory authority, or the European Chemicals Agency, or
- 4) the obligation referred to in Article 48 to mention the hazard classes or hazard categories of the substance in question when advertising substances and mixtures that are classified as hazardous.

(711/2020)

Anyone who wilfully or negligently infringes the following obligations under the Biocidal Products Regulation shall be sentenced for a chemical violation, unless a more severe punishment for the act is provided elsewhere by law:

- 1) the authorisation or notification obligations under Articles 17 or 27, or the provisions of Articles 89, 93, 94 or 95 on placing on the market or termination of use of biocidal products,
- 2) the obligation under Article 17 to use a biocidal product in compliance with the terms and conditions of the authorisation, and the labelling and packaging requirements,
- 3) the record-keeping and notification obligations under Articles 47 or 56,
- 4) the obligations related to the placing on the market and labelling of articles treated with biocidal products and the provision of information related thereto under Article 58,
- 5) the record-keeping and reporting obligations under Articles 65 or 68,
- 6) the obligations concerning classification, labelling and packaging under Article 69, or
- 7) the obligations concerning advertising under Article 72.

Anyone who wilfully or negligently infringes the following provisions shall be sentenced for a chemical violation, unless a more severe punishment for the act is provided elsewhere by law:

- 1) the provisions of Articles 3, 4 or 4a of the Detergents Regulation regarding the placing on the market of detergents and the surfactants contained therein, the testing requirement under Article 7, or neglect of the obligation to submit information under Article 9,
- 2) the obligation under Articles 8, 10, 14 or 17 of the PIC Regulation to provide information on the export of a chemical, the obligation under Article 16 to disclose information on transit movements, the decision taken by an importing country referred to in Article 14, the export ban under Article 15, or the obligation to provide a reference identification number in the export declaration under Article 19,
- 3) the prohibition and restriction referred to in Article 3 of the POP Regulation, or fails to comply with provisions concerning stockpiles in Article 5, or
- 4) the export restriction for chemicals laid down in Article 3 of the Mercury Regulation, the import restriction laid down in Article 4 with respect to the import of mercury mixtures listed in Annex I to the said Regulation for purposes other than disposal as waste, the obligations related to interim storage laid down in Article 7(3), the prohibitions regarding use laid down in Articles 5, 7, 8, and in Article 9(1) and (2) with respect to mercury-added products, mercury, mercury compounds or mercury mixtures, or the notification obligation laid down in Article 8(3).

(711/2020)

Prosecution or punishment may be waived with respect to a chemical violation if the financial consequences of another official decision issued as a result of the act are to be considered sufficient for the perpetrator, having regard to the seriousness of the act, or if the perpetrator violates a prohibition or order imposed on pain of conditional fine pursuant to this Act. (746/2016)

## **Section 60**

### **Reference to the Criminal Code**

Provisions on the punishment for a health offence are laid down in chapter 44, section 1 of the Criminal Code (39/1889).

Provisions on the punishment for degradation of the environment are laid down in chapter 48, sections 1 to 4 of the Criminal Code.

## **Chapter 10**

### **Entry into force and transitional provisions**

#### **Section 61**

##### **Entry into force**

This Act enters into force on 1 September 2013. However, the provisions of sections 9, 13, 15, 23, 46, 55 and 59 concerning the PIC Regulation enter into force on 1 March 2014.

This Act repeals the Chemicals Act (744/1989), hereinafter referred to as the Chemicals Act of 1989. Section 5a, subsection 2, section 42, subsections 1 and 2, section 45, subsections 2 and 3, section 52, subsection 1, paragraph 3, and section 56 of the Chemicals Act of 1989 nevertheless remain applicable until 28 February 2014, sections 17 and 59d of the said Act remain applicable until 31 May 2015, and section 27, subsection 2 of the said Act remains applicable until 31 December 2015.

#### **Section 62 (746/2016)**

##### **Decrees issued pursuant to the Chemicals Act of 1989**

The following decrees issued pursuant to the Chemicals Act of 1989 remain in force:

- 1) Government Decree on Exceptions for National Defence in the Application of Chemical Legislation (996/2010);
- 2) Government Decree on Exceptions to Annex XVII of the REACH Regulation concerning Restrictions on the Manufacture, Placing on the Market and Use of Certain Hazardous Substances, Mixtures and Articles (647/2009);
- 3) chapter 8 of the Decree on the Industrial Handling and Storage of Dangerous Chemicals (59/1999);
- 4) Government Decision on Substances that Deplete the Ozone Layer (262/1998);
- 5) Decree of the Ministry of Social Affairs and Health on Chemicals referred to in Annex VI of the CLP Regulation (5/2010);
- 6) Decree of the Ministry of Social Affairs and Health on Submitting Information concerning Chemicals (553/2008);

7) Decree of the Ministry of Social Affairs and Health on Submitting Quantity Information on Amounts of Chemicals(1155/2011);

8) Decree on the Industrial Handling and Storage of Dangerous Chemicals in the Defence Forces (78/1996);

9) Decree on the Authorities Enforcing the Chemicals Act in the Defence Forces (469/1992);

Government Decision 262/1998 on Substances that Deplete the Ozone Layer was repealed by Government Decree 766/2016 on the Certification Requirements of the Personnel and Undertakings Handling Devices Containing Fluorinated Greenhouse Gases or Ozone Depleting Substances, Ministry of Social Affairs and Health Decree 553/2008 on Submitting Information Concerning Chemicals was repealed by Ministry of Social Affairs and Health Decree 1118/2020 on Submitting Chemical Notifications and Quantity Information, Ministry of Social Affairs and Health Decree 5/2010 on the Chemicals Referred to in Annex VI to the CLP Regulation was repealed by Ministry of Social Affairs and Health Decree 1119/2020 on the Repeal of the Ministry of Social Affairs and Health Decree on the Chemicals Referred to in Annex VI to the CLP Regulation, and Government Decree 996/2010 on Exceptions for National Defence in the Application of Chemical Legislation was repealed by Government Decree 217/2022 on Exceptions for National Defence in the Application of Chemical Legislation.

## **Section 63**

### **Transitional provisions**

Matters that are pending before the entry into force of this Act are processed in accordance with the provisions that were in force at the time of entry into force of this Act, unless otherwise provided in Article 91 of the Biocidal Products Regulation.

Persons using the products referred to in section 38 of this Act shall verify their competence in accordance with section 40 by no later than 31 December 2016. The operators referred to in section 44 of the Act shall submit the notification referred to in the said section by no later than 31 December 2016.

Decisions concerning the approval of biocidal products taken prior to the entry into force of this Act remain in force for the period specified in the decision, unless otherwise provided in the Biocidal Products Regulation.