N.B. Unofficial translation, legally binding only in Finnish and Swedish
MINISTRY OF SOCIAL AFFAIRS AND HEALTH, FINLAND

# Chemicals Act 599/2013

## Chapter 1

## 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 the European Union chemicals legislation and certain national obligations regarding chemicals. The Act also implements 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.

This Act is also applied to biocidal products, the efficacy of which is based on a micro-organism.

### Section 3

#### Application of the Act in defence administration

Provisions concerning necessary exceptions regarding compliance with this Act, the REACH Regulation and the CLP Regulation on the activities of defence administration may be given by government decree, if necessary, for the purposes of defence.

The exceptions may concern the following topics:

1) communication in the supply chain and the responsibilities of downstream users;

2) authorisation procedure under the REACH Regulation;

3) classification, labelling and notifications under the CLP Regulation;

4) disclosure of information to supervisory authorities.

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

Due diligence and care must be applied when applying this Act and the chemicals legislation of the European Union in defence administration in order to prevent damage to human health, the environment and property.

**Section 4**

**Exceptions regarding compliance with the chemicals legislation of the European Union**

Provisions concerning exceptions 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 of the Reach Regulation, may be issued by government decree. Provisions necessary to preventing harm to human health and the environment caused by the chemicals mentioned in the Annex may also be given by government decree.

**Section 5**

**Relationship to other legislation**

Provisions on the prevention of harm caused by chemicals to human health and the environment and of the physical harm caused by chemicals are also laid down in the following acts:

1) Environmental Protection Act (86/2000);

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 (719/1994);

9) Radiation Act (592/1991);

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).

Provisions on the safety of consumer goods and consumer services are laid down in the Consumer Protection Act (920/2011) to the extent that they are not covered in this Act or in the chemicals legislation of the European Union.

**Section 6**

**Definitions**

For the purposes of this Act:

1) *chemicals legislation of the European Union* means the following EU regulations and the acts adopted on the basis of these regulations:

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 the *REACH Regulation*;

b) Regulation (EC) No 1272/2008 of the European Parliament and of the Council on the 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 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 the *Biocidal Products Regulation*;

d) Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, hereinafter the *Detergent Regulation*;

e) Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals, hereinafter the *PIC Regulation*;

f) Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants and amending Directive 79/117/EEC, hereinafter the *POP Regulation* and

g) Regulation (EC) No 1102/2008 of the European Parliament and of the Council on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury, hereinafter the *Regulation on Export Ban for Mercury*;

2) *chemical* means substances and mixtures as they are defined in the REACH Regulation and the CLP Regulation;

3) *article* means an object 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 must be classified or labelled in accordance with the CLP Regulation or for which a safety data sheet must 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 an actor that manufactures, imports, places on the market, exports, stores, packages, distributes or uses a chemical in some other way referred to in this Act or the chemicals legislation of the European Union.

## Chapter 2

## Supervisory authorities and their tasks

#### Section 7

#### Ministries

The general steering, monitoring and development of activities in accordance with this Act and the highest management and control of the supervision of compliance with the Act and the provisions issued under the Act are the responsibility of:

1) the Ministry of Social Affairs and Health as concerns the prevention of physical hazards and harm caused by chemicals to human health; and

2) the Ministry of the Environment as concerns the prevention of hazards and harm caused by chemicals to the environment.

#### Section 8

#### Finnish Safety and Chemicals Agency

The task of the Finnish Safety and Chemicals Agency is to supervise compliance with the bans and restrictions concerning production and placing on the market, as referred to in this Act and the provisions issued under it, the REACH Regulation, the CLP Regulation, the Detergent Regulation, the Biocidal Products Regulation and Articles 3 and 4 of the POP Regulation, unless otherwise provided in this Act.

#### Section 9

#### Finnish Environment Institute

The Finnish Environment Institute supervises compliance with the provisions issued in and under section 23, the POP Regulation, the PIC Regulation and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (SopS 107/2004), hereinafter the *Rotterdam Convention*, unless otherwise provided by law.

#### Section 10

**Occupational health and safety authority**

The occupational health and safety authority supervises compliance with this Act and the provisions issued under it and the chemicals legislation of the European Union in all work where the employer is bound by the Occupational Safety and Health Act.

If, in connection with its supervisory activities, the occupational health and safety authority finds that the provisions of the present Act or the chemicals legislation of the European Union are likely to have been violated when placing a chemical or a device or article containing the chemical on the market or in use, 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 ban the release of the device or article containing the chemical on the market or for use, complying, where applicable, with the provisions in section 18(4) of the said Act. The inspector must transfer the matter to the Regional State Administrative Agency, which will then take the matter to the Finnish Safety and Chemicals Agency.

In addition to the provisions on the provision of information and the disclosure of confidential information laid down in section 52, the Act on Occupational Safety and Health Enforcement and Cooperation on Occupational Safety and Health at Workplaces is applied to the supervisory and inspection activities of the occupational safety and health authority.

**Section 11**

**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 the provisions issued under it;

2) compliance with the terms and conditions set for the use of biocidal products in the authorisation decision referred to in Article 17 of the Biocidal Products Regulation or in section 30 of this Act;

3) compliance with Articles 3 and 4 concerning the use of substances in the POP Regulation;

4) compliance with the following provisions of the REACH regulation: Articles 14 and 37 concerning the conditions and risk reduction measures for the use of substances, Title VII on the use of substances requiring authorisation and Article 67 on restrictions on the use of substances

in the supervision of activities that pose a threat of environmental pollution in accordance with the Environmental Protection Act to the extent that the supervision concerns the operator's obligation to prevent harmful environmental effects in the use and storing of chemicals.

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 in accordance with the provisions lad down in section 24 and the chemicals legislation of the European Union.

**Section 13**

**Customs**

Finnish Customs supervises compliance with the European Union legislation concerning the import, export and transit of chemicals and articles containing chemicals and the provisions in this Act concerning biocidal products in connection with the import, export and transit of biocidal products.

In the supervision of compliance with the 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 performed when importing substances and mixtures and articles containing them;

2) the authorisation referred to in Title VII of the REACH Regulation has been granted when importing substances subject to authorisation and mixtures containing them;

3) the restrictions referred to in Article 67 of the REACH Regulation are observed when importing substances and mixtures and articles containing them;

4) the bans 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 the import and export of the chemicals referred to in Annex I of the PIC Regulation and articles containing them and the export ban on the chemicals and articles referred to in Annex V are complied with;

6) the export ban under Article 1 of the Regulation on Export Ban for Mercury is complied with;

7) the obligations regarding the authorisation of biocidal products and the import of treated articles in the Biocidal Products Regulation are complied with.

When a shipment arrives in Finland from a member state of the European Union, Customs supervises compliance with restrictions under Annex XVII of the REACH Regulation and obligations related to the authorisation of biocidal products and the import of treated articles under the Biocidal Products Regulation and this Act.

The Customs Act (1466/1994) is applied in the supervision, unless otherwise provided in this Act.

**Section 14**

**Finnish Defence Forces**

The Finnish Defence Forces supervises compliance with this Act and the chemicals legislation of the European Union in the military activities of the Finnish Defence Forces or in the training organised for this purpose, as well as in targets kept confidential for the purposes of national

defence and in crisis management missions. More detailed provisions on the supervision shall be issued by decree of the Ministry of Defence.

## Chapter 3

## Other duties of authorities

#### Section 15

#### Competent authorities

The Finnish Safety and Chemicals Agency acts 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 as well as the appointed body referred to in Article 45 of the CLP regulation.

The Finnish Environment Institute acts as the competent authority referred to in Article 15 of the POP Regulation and as the designated national authority under Article 4 of the PIC Regulation. The Finnish Environment Institute also acts as the designated national authority referred to in the Rotterdam Convention, unless otherwise provided in the PIC Regulation.

#### Section 16

#### National advisory service

The Finnish Safety and Chemicals Agency organises a national helpdesk to provide an advisory service under Article 124 of the REACH Regulation, Article 44 of the CLP Regulation and Article 81 of the Biocidal Products Regulation for manufacturers, importers, downstream users, distributors and any other interested parties.

#### Section 17

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

The Finnish Safety and Chemicals Agency keeps registers of the notifications submitted to it under this Act, authorisation decisions on biocidal products issued by it, individuals who have completed the qualification and the special qualification related to biocidal products, and registered companies performing pest control using biocidal products.

The Finnish Safety and Chemicals Agency holds the following registers:

1) chemical products register that contains information referred to in section 22;

2) information in the chemical products register under Article 45 of the CLP Regulation;

3) biocidal products register that contains information on the biocidal products authorised under this act and the Biocidal Products Regulation;

4) qualifications and company register that contains information on individuals who have completed the qualification related to biocidal products referred to in section 38 and the special qualification referred to in section 41 as well as on companies performing pest control using the

biocidal products registered under section 44 and the persons in charge of these activities in the companies.

The registers may issue information other than information that is confidential under section 56 as copies and through the general information network, with the exception of information referred to in paragraph 2, subsection 2 of this section in accordance with Article 45 of the CLP Regulation. The Finnish Safety and Chemicals Agency may forward this information to the Poison Information Centre for the purpose of issuing instructions for the treatment of poisonings.

Other information necessary for the supervision of compliance with this Act and the provisions issued under it may also be stored in the registries of the Finnish Safety and Chemicals Agency.

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

#### Section 18

#### Finland's Advisory Committee on Chemicals

Upon a proposal by the Ministry of Social Affairs and Health, the government may set up an Advisory Committee on Chemicals, the task of which is to promote cooperation between authorities, central organisations and other actors in the management of risks related to chemicals. The operating period of the committee is three years.

Further provisions on the composition and tasks of the advisory committee shall be given by government decree.

## Chapter 4

## Activities are guided by general principles and the duties of the operator

#### Section 19

#### General principles guiding activities

In addition to the provisions of the chemicals legislation of the European Union, the following principles are applied to activities involving the use of chemicals:

1) the operators are sufficiently aware of the effects of the chemical on human health and the environment and of the requirements related to the sales of the chemical;

2) due diligence and care is applied to the prevention of harm to human health and the environment, while taking into account the amount and hazardousness of the chemical;

3) when reasonably possible, the choice between the existing chemicals or methods to use in the prevention of the harm caused by chemicals is made based on which one that is the least hazardous.

#### Section 20

#### Language requirement for information on chemicals

The labelling of biocidal products, plant protection products under the Act on Plant Protection Products and hazardous chemicals must be done in both Finnish and Swedish. Further provisions on the names of substances mentioned in Annex VI of the CLP Regulation may be given by decree of the Ministry of Social Affairs and Health.

Safety data sheets under Article 31 of the REACH Regulation must be provided to the recipient of the chemical either in Finnish or in Swedish or in both of these languages depending on the choice of the recipient.

The Finnish Safety and Chemicals Agency may require an operator applying for authorisation for a biocidal product to supply the information in Finnish or Swedish according to provisions 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 on marketing, labelling and packaging in the chemicals legislation of the European Union, the marketing of chemicals may not refer to a chemical in a manner that is misleading or untruthful as concerns the risks posed by the chemical to human health or the environment.

In addition, the provisions in article 72 of the Biocidal Products Regulation are applied to the marketing of the biocidal products referred to in Chapter 5.

**Section 22**

**Providing information on a chemical**

An operator that is responsible for placing a hazardous chemical on the market or in use in Finland must provide information on the chemical to the Finnish Safety and Chemicals Agency.

An operator referred to in subsection 1 above and an operator who has been issued an authorisation decision under section 30 must also provide information to the Finnish Safety and Chemicals Agency on the amounts of biocidal products and hazardous chemicals it has placed on the market or in use.

Further provisions on submitting information referred to in subsections 1 and 2 above shall be given by a decree of the Ministry of Social Affairs and Health.

**Section 23**

**Notification on export**

Anyone who exports a chemical from the European Economic Area must submit a notification and otherwise follow the procedure laid down in the PIC Regulation.

Anyone who exports a chemical from the European Economic Area must submit a notification to the Finnish Environment Institute, provided that the chemical is within to the scope of the Rotterdam Convention but is not mentioned in Annex I of the PIC Regulation. Pursuant to the

Rotterdam Convention, the Finnish Environment Institute will forward the notification to the competent authority in the receiving country.

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

**Section 24**

**Test laboratories**

The study on the health and environmental impacts of chemicals submitted to authorities and required by the chemicals legislation of the European Union must be conducted in 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 of a laboratory as an authorised test laboratory provided that the laboratory demonstrates compliance with the directive referred to in subsection 1. As concerns the authority of the Finnish Medicines Agency in the approval and inspection of laboratories performing tests on chemicals, the provisions of the Medicines Act concerning the supervision of laboratories, setting conditions and restrictions for approval, and cancelling approval as well as on the authority of the inspectors, on issuing orders and on the rectification procedure concerning orders are applied.

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

**Section 25**

**Placing restrictions on the retail trade of chemicals and the obligation to provide information**

A chemical must not be made available through retail if it is evident that use of the chemical may entail particular health risks.

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

To the extent that the substance has not been mentioned in Annex XVII of the Reach Regulation, further provisions on the following topics may be given by government decree:

1) age limits concerning the retail and other supply of a hazardous chemical or a chemical that is otherwise harmful to health, conditions set for the storing of such chemicals, and retail restrictions concerning the prevention of a health hazard caused by their evident misuse;

2) conditions for the sale of a chemical harmful to health in pharmacies;

3) realisation of the obligation to provide information that concerns the recipient of a chemical that is harmful to health.

The provisions laid down previously in this section do not apply to:

1) medicinal products intended for humans 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.

## Chapter 5

## Authorisation of biocidal products

#### Section 26

#### Biocidal product

For the purposes of this Act, 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 anti-fouling product that is intended to prevent the growth of microbes and more developed plant and animal species from attaching themselves to vessels, the equipment in fish farms and other structures used in water(*antifouling product*);

3) a biocidal product intended for use as a fly control product or insecticide, 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 due authorisation for the product, unless otherwise provided later in this Act or in the Biocidal Products Regulation. Decisions concerning the authorisation are made by the Finnish Safety and Chemicals Agency.

#### Section 28

#### Applying for authorisation

Authorisation for a biocidal product may be applied by the actor responsible for placing a biocidal product on the market in Finland for the first time. The applicant must have a permanent office in the area of the European Union.

The authorisation can be sought until the active substance has been approved under the Biocidal Products Regulation.

To enable the assessment of the criteria for the authorisation, the application must contain the necessary information on the effects of the product on human health and the environment as well as on the effectiveness and other properties of the product. Further provisions on the application and on information to be included in the application shall be given by decree of the Ministry of the Environment.

**Section 29**

**Criteria for authorisation**

A biocidal product is authorised if the following criteria are met:

1) a biocidal product may only contain active substances that have been evaluated or are being evaluated under Commission Regulation (EC) No 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, but that have yet to be approved as concerns the group of products in question;

2) the biocidal product and products treated with it or the residues resulting from its use do not cause evident harm to human health or the environment when used in accordance with the conditions for authorisation;

3) the biocidal product is sufficiently efficient and fit for the purpose for which it is intended;

4) there are methods used to determine the active substances contained by the biocidal product and such substances contained by the product or residue resulting from the use of the product that may have significant effects on human health and the environment.

A biocidal product that meets the criteria for classification as toxic or a carcinogen, or a mutagen or toxic for reproduction laid down in point a or b of Article 19(4) of the Biocidal Products Regulation is not authorised to be made available on the market for use by the general public.

**Section 30**

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

The authorisation is granted for a maximum period of ten years, and it is renewed upon application provided that the criteria for authorisation continue to be met.

When approving a biocidal product, the Finnish Safety and Chemicals Agency confirms the purpose for which the product is intended and instructions for its use. In the authorisation decision, it is also possible to restrict the supply or use of a biocidal product to a certain user group or to individuals who have passed the qualification under section 38 or the special qualification under section 41. Moreover, conditions necessary for meeting the criteria for authorisation can be attached to the authorisation decision. An updated version of the safety data sheet that matches the authorisation decision must be submitted to the Finnish Safety and Chemicals Agency where necessary. Article 69 of the Biocidal Products Regulation is applied to the labelling of biocidal products referred to in this chapter where applicable.

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

**Section 31**

**Cancellation or modification of authorisation**

The authorisation of a biocidal product must be cancelled if:

1) the biocidal product no longer fulfils the criteria under section 29;

2) conditions attached to the authorisation decision have been essentially violated; or

3) incorrect or misleading information has been provided on factors affecting the authorisation.

The terms of the authorisation decision must be altered if it is necessary for scientific or technical reasons or to protect human health or the environment.

The authorisation may also be cancelled or its terms altered based on the applicant's own initiative.

Further provisions on the cancellation of authorisation and the terms of authorisation may be issued by government decree.

**Section 32**

**New information**

A person who has applied for authorisation must immediately provide the Finnish Safety and Chemicals Agency with new information concerning the active substance, the biocidal product containing the active substance and their effects, upon which he or she can reasonably be expected to be aware and that may impact the continuation of the validity of the authorisation.

**Section 33**

**Use of information in the processing of 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 owner of the information has submitted written consent for this. The protection period for data submitted under this Act ends simultaneously with the end of 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 must keep a record of tests related to scientific research and development work, and this information must be submitted to the Finnish Safety and Chemicals Agency upon request. An operator responsible for a test related to production research and

development work must notify the Finnish Safety and Chemicals Agency before the active substance or biocidal product is placed on the market.

As concerns tests that may cause emissions into the environment, the operator responsible for the test must seek permission for conducting the test from the Finnish Safety and Chemicals Agency before initiating the test. A separate test-specific permission is not required if the Finnish Safety and Chemicals Agency has granted the operator permission to undertake certain tests and defined the conditions under which the tests can be performed. In its decision regarding the permission, the Finnish Safety and Chemicals Agency may restrict the amounts of a product or active substance used in the test or the areas treated in the test or it may establish other conditions necessary for the purpose of protecting human health or the environment.

Further provisions on the time limits related to the procedure for notification and seeking permissions as well as on requirements for information concerning the test plan, the properties of the product, its impacts on the environment and human health, the amounts of a product used in the tests and instructions for its safe use may be given by decree of the Ministry of the Environment.

#### Section 35

#### Use of biocidal products

Biocidal products must be used as intended following the instructions for use. Other provisions laid down by law are also applied to the use of biocidal products.

## Chapter 6

## Certain provisions regarding biocidal products

#### Section 36

#### Submitting samples

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

#### 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 exterminators and the related training programme.

A sufficient amount of instruction in the appropriate and safe use of biocidal products, how to prevent the occurrence of pests and risks associated with the use of biocidal products, and ways to manage these risks must be included in the training.

The criteria for gaining approval as the implementer of the training are that the implementer or trainer employed by the implementer have sufficient training and experience in biocidal products

and their use and that the training programme meets the requirements established in subsection 2. Approval for an implementer of training is valid for five years.

Approval for an implementer of training may be cancelled if the criteria for approval cease to be met or if essential deficiencies are identified in the organisation of training and the operator has not remedied its activities within the appointed amount of time despite a request issued by the Finnish Safety and Chemicals Agency.

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

**Section 38**

**Qualification on the use of biocidal products intended for pest control**

If a wood preservative, rodenticide, insecticide, acaricide or other biocidal product intended to control members of the species Arthropoda can with good reason be estimated to cause harm or a hazard to human health or the environment, the Finnish Safety and Chemicals Agency may decide, in connection with issuing authorisation for the product, that it may only be used by individuals who have demonstrated their competence and who have been entered into the qualifications and company register referred to in section 17(2)(4).

The qualification on the use of biocidal products is used to demonstrate capacity for the safe and appropriate handling and use of biocidal products intended for pest control and the competence required by an exterminator. Participation in training referred to in section 37 is not a requirement for obtaining the qualification, provided that equivalent knowledge has otherwise been obtained.

The qualification contains thematic entities that focus on the appropriate and safe handling and use of biocidal products, preventing the occurrence of pests, risks related to the use of biocidal products and the management of these risks. Individuals who have passed the qualification receive a certificate, the model for which is confirmed by the Finnish Safety and Chemicals Agency. The qualification is valid for five years.

Further provisions on the contents of the qualification concerning the use of biocidal products and on obtaining the qualification may be given by government decree.

**Section 39**

**Recipient of the qualification**

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

The criteria for approval as a recipient of the qualification are that the recipient or his or her employee has good knowledge of pest control and sufficient practical experience in the field. The approval is valid for five years and may be cancelled if the criteria for approval cease to be met or if essential deficiencies are identified in the organisation of the qualification and the operator has not remedied its activities within the appointed amount of time despite a request issued by the Finnish Safety and Chemicals Agency.

Provisions concerning criminal liability for acts in office are applied to the recipient of the qualification and persons in his or her employment as they perform tasks under this Act. Provisions regarding liability for damages are laid down in the Tort Liability Act (412/1974).

Further provisions on the reception of the qualification and the retaining of documents may be given by government decree.

**Section 40**

**Verification of competence**

A person who has completed a qualification on the use of biocidal products intended for pest control must submit a notification to the Finnish Safety and Chemicals Agency for the purpose of verifying competence. The notification must contain the necessary personal and contact information and an indication of the completion of the qualification referred to in section 38. Persons meeting the competence criteria are entered into the qualifications and company register referred to in section 17(2)(4) and maintained by the Finnish Safety and Chemicals Agency.

By its decision, the Finnish Safety and Chemicals Agency may cancel the registration if the person no longer meets the criteria for registration. Before cancelling the registration, the Finnish Safety and Chemicals Agency must reserve for the individual an opportunity to remedy the deficiency, unless the deficiency is so essential that its elimination is not possible within a reasonable time period.

Further provisions on the cancellation of the registration may be given by government decree.

**Section 41**

**Special qualification**

The Finnish Safety and Chemicals Agency may, in connection with the authorisation of a biocidal product causing a particular hazard or harm to human health or the environment, decide to restrict the supply or use of the product to persons holding a special qualification who have been entered into the qualifications and company register referred to in section 17(2)(4) by the Finnish Safety and Chemicals Agency. The special qualification concerning biocidal products intended for pest control may only be completed by persons holding the qualification referred to in section 38.

Training provided for the special qualification must contain a sufficient level of instruction in at least the following topics: the handling and use of substances requiring the special qualification that is appropriate and safe for the user and other persons as well as the environment and the risks associated with the use of the products and their management.

The organiser of the special qualification must issue a certificate of all examinations passed. The special qualification is valid for five years.

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

**Section 42**

**Organisation of the special qualification**

The Finnish Safety and Chemicals Agency will approve the organiser of the special qualification upon application. The organiser of the special qualification will be approved if the organiser or a person employed by the organiser has good knowledge of the topic area of the special qualification and sufficient practical experience related to it. The organiser must be able to offer sufficient information and skills on the safe use of the product. The approval is valid for five years and may be cancelled if the criteria for approval cease to be met or if essential deficiencies are identified in the organisation of the qualification and the operator has not remedied its activities within the appointed amount of time despite a request issued by the Finnish Safety and Chemicals Agency.

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

Provisions concerning criminal liability for acts in office are applied to the organiser of the special qualification and to persons in his or her employment as they perform tasks under this Act. Provisions regarding compensation for damages are laid down in the Tort Liability Act.

Further provisions on the organisation of the special qualification can be given by government decree.

**Section 43**

**Verification of the special qualification**

A person who has completed the special qualification must submit notification to the Finnish Safety and Chemicals Agency for the purpose of verifying the qualification. The notification must contain the necessary personal and contact information and an indication of the completion of the special qualification referred to in section 41. Persons who have completed the special qualification are entered into the qualifications and company register referred to in section 17(2)(4) and maintained by the Finnish Safety and Chemicals Agency.

By its decision, the Finnish Safety and Chemicals Agency may cancel the registration if the person no longer meets the criteria for registration. Before cancelling the registration, the Finnish Safety and Chemicals Agency must reserve for the individual an opportunity to remedy the deficiency, unless the deficiency is so essential that its elimination is not possible within a reasonable time period.

Further provisions on the cancellation of registration may be given by government decree.

**Section 44**

**Notification of professional pest control activities and competence required from the person in charge**

An operator engaging in professional pest control using biocidal products must give notification to the Finnish Safety and Chemicals Agency before initiating pest control activities. The operator must employ, full-time, a person in charge of pest control activities who has 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 the activities into the qualifications and company register referred to in section 17(2)(4).

The notification must contain the name and contact information of the operator and information on the person in charge of the activities and his or her qualifications.

The operator must submit a new notification at least three months after a change in the individual in charge of the activities. A notification must also be submitted to the Finnish Safety and Chemicals Agency upon termination of operations.

## Chapter 7

## Supervision

#### Section 45

#### Banning 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 take a decision to restrict or ban, for a specified period of time or until further notice, the manufacture, import, placing on the market and other supply, export or use of the chemical or article containing the chemical or other handing of the chemical equivalent to these and issue orders concerning restrictions and conditions for operations if the use of the chemical or article containing the chemical is found or justifiably assessed to cause serious harm or a hazard to human health or the environment.

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

If preventing the harm or hazard referred to in subsection 1 requires rapid measures, the Safety and Chemicals Agency may issue temporary orders on the necessary bans and restrictions. In this case, the matter must be brought to the government without delay.

#### Section 46

#### Bans and orders by the supervisory authority

If the operator does not comply with the provisions of this Act or the chemicals legislation of the European Union, the supervisory authority in question may ban the operator from continuing operations or repeating procedures in violation of the provisions or it may order the operator to otherwise fulfil the obligations laid down by law.

In cases referred to in subsection 1 above, the Finnish Safety and Chemicals Agency may issue orders concerning a chemical or article containing a chemical with respect to banning them from being placed on the market or from being made available on the market, the return procedure or notification of the hazard inflicted, or it may order that the chemical be made harmless by taking appropriate measures. However, as concerns supervising compliance with the PIC Regulation or section 23(1) or section 23(2), the order or ban is issued by the Finnish Environment Institute.

If a chemical or article containing a chemical that is in violation of legislation might cause a serious hazard to human health or the environment and there is no other way of preventing the hazard, an inspector of the Finnish Safety and Chemicals Agency has the right to order a temporary ban on the chemical. The temporary ban is valid until the matter is finally resolved. If the ban is issued by an inspector of the Finnish Safety and Chemicals Agency, the inspector must transfer the matter to the

Finnish Safety and Chemicals Agency without delay. The Finnish Safety and Chemicals Agency must resolve the matter with urgency.

**Section 47**

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

A supervisory authority may enforce a ban or order issued under this Act by issuing notice of a conditional fine, by informing the operator that the measure that has been left unperformed will be carried out at the cost of the neglecting party, or by issuing a notice concerning the suspension of activities.

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 48**

**Right to receive information and carry out inspections**

Notwithstanding provisions related to secrecy, a supervisory authority has the right to receive information necessary for the supervision of compliance with this Act and the provisions issued under it and the chemicals legislation of the European Union from the operator and other individuals bound by the obligations laid down in this Act and the provisions issued under it and in the chemicals legislation of the European Union.

A supervisory authority has the right to perform the inspections necessary for the purpose of supervising compliance with this Act and the provisions issued under it and the chemicals legislation of the European Union in facilities other than those permanently used for human habitation.

**Section 49**

**Right to obtain samples and conduct research**

If a supervisory authority is not able to otherwise obtain information concerning a chemical necessary for supervision, it has the right to receive from the operator, free of charge, a sample of the chemical or article containing the chemical that is reasonable in size and necessary for the performance of the research. The operator must cover reasonable costs incurred by the research.

Prior to initiating the research, the operator must be reserved the opportunity to be heard. The research results must be made known to the operator, unless otherwise provided in the Act on the Openness of Government Activities, the REACH Regulation or the Biocidal Products Regulation.

**Section 50**

**Using an expert**

In its supervisory activities, a supervisory authority may employ a competent external expert to investigate a matter significant for the purposes of the supervision.

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 regarding liability for damages are laid down in the Tort Liability Act.

**Section 51**

**International exchange of information**

Notwithstanding provisions related to secrecy, a supervisory authority may disclose information required by the chemicals legislation of the European Union and international conventions approved by Finland to EU organs, international organisations and countries taking part in the cooperation as required by the legislation or conventions. When disclosing personal information abroad, the provisions of the Personal Data Act (523/1999) and the Act on International Information Security Responsibilities must be observed.

**Section 52**

**Right to receive information from other authorities and disclosing confidential information**

Notwithstanding provisions related to secrecy, supervisory authorities have the right to receive information necessary for the purposes of the supervision from another supervisory authority and to use samples obtained by another authority for research necessary for the purposes of supervision.

Notwithstanding the secrecy obligation laid down in the Act on the Openness of Government Activities, a supervisory authority may disclose information obtained in connection with the supervisory activities concerning the financial position of an individual or community, trade or professional secrets, or the personal conditions of an individual to other supervisory authorities, the National Supervisory Authority for Welfare and Health, the Finnish Food Safety Authority and the authorities referred to in section 6 of the Act on the Transport of Dangerous Goods as they implement supervision as defined by law and to the supervisory authorities of other EU member states for the purposes of supervising compliance with the chemicals legislation of the European Union.

Notwithstanding provisions related to secrecy, information obtained when performing the tasks referred to in this Act may be disclosed to the prosecutor or to the police for the purposes of preventing and solving a crime.

**Section 53**

**Executive assistance**

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

**Section 54**

**Fees**

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

The charge may be waived either partly or completely if the charge is unreasonable due to the minimal use of a chemical or biocidal product or for some other reason.

## Chapter 8

## Appeals and non-disclosure of information

#### Section 55

#### Appeals

The appeal procedure for decisions issued by authorities under this Act is laid down in the Administrative Judicial Procedure Act (586/1996), unless otherwise provided in subsections 2 and 3.

A temporary ban or restriction issued by the Finnish Safety and Chemicals Agency referred to in section 45(3) or a temporary ban referred to in section 46(3) may not be appealed.

When appealing a decision made by a Centre for Economic Development, Transport and the Environment or a municipal environmental protection authority, provisions concerning appeal and the enforcement of decisions laid down in the Environmental Protection Act are applied.

In decisions taken under sections 31 or 46 of this Act or the PIC Regulation, it is possible to order that the decision must be complied with, the appeal notwithstanding, unless decided otherwise by the appellate authority.

#### Section 56

#### Claim to protect business and professional secrets

The operator responsible for submitting the information referred to in section 22 above must identify as business or professional secrets information that it wishes not to be disclosed to parties other than the Finnish Safety and Chemicals Agency. The actor making the claim must provide grounds for it.

If, of its own accord, the operator referred to in section 22 makes public information previously deemed confidential, a notification must be submitted to the Finnish Safety and Chemicals Agency.

#### Section 57

#### Restriction on trade and professional secrets concerning chemicals

Notwithstanding the provisions on business or professional secrets laid down in the Act on the Openness of Government Activities, the following information concerning chemicals may not be rendered confidential based the operator's claim referred to in section 22 of this Act:

1) trade name of the substance;

2) trade name of the mixture;

3) name of manufacturer and party submitting the notification;

4) information on the physical and chemical properties included in the notification;

5) information on how to render a substance or a mixture harmless;

6) summary of the results from studies concerning the effects of the substance or mixture on human health or the environment;

7) the purity level of the substance and any hazardous impurities or additives, if this information is necessary for the classification and labelling of the product;

8) information presented in the notification if it concerns:

a) handling, storing, transport and procedures and precautions recommended 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) as concerns the substances mentioned in Annex VI of the CLP Regulation, analytical methods that can be used to detect hazardous substances released into the environment and to determine the exposure of humans to them.

The information provided in subsection 1 above must not be made available via the general information network if the European Chemicals Agency has restricted the availability of the information under provisions in Article 119(2) of the REACH Regulation.

**Section 58**

**Restrictions to business and professional secrets concerning a biocidal product**

Notwithstanding the provisions on business and professional secrets in the Act on the Openness of Government Activities, the following information concerning biocidal products may not be rendered confidential based on a claim by an operator applying for authorisation for a biocidal product referred to in Chapter 5 of this Act:

1) name and address of applicant;

2) name and address of the manufacturer of the biocidal product and the active substances contained within it;

3) name of the biocidal product and the names of active substances contained within it and their concentrations in the product;

4) names of other substances classified as hazardous and impacting the classification of the product;

5) information on the physical and chemical properties of the active substances and the biocidal product;

6) a results summary of tests concerning the effectiveness of the biocidal product, its capacity to generate resistance and its effects on people, animals and the environment;

7) information on how an active substance or biocidal product can be rendered harmless, or information on procedures and actions in case the substance is splashed or leaks;

8) recommended methods and precautions to prevent hazards caused by handling, storing, transport, use and fire and other accidents;

9) information on what kind of first aid and treatment advice must be provided in case of an accident;

10) waste management methods used on waste from a biocidal product and its packaging and on products treated with a biocidal product;

11) safety data sheet;

12) analysis methods for active substances or substances mentioned in Annex VI of the CLP Regulation that can be used to detect substances released into the environment and to determine their residues.

## Chapter 9

## Penal provisions

#### Section 59

#### Chemical violation

Any person who intentionally or out of negligence

1) violates the language requirement regarding the provision of information on chemicals laid down in section 20 or the provision on the marketing of chemicals laid down in section 21,

2) neglects the obligation to submit information referred to in section 22,

3) neglects the notification obligation laid down in section 23(2),

4) neglects the obligation to apply for authorisation for a biocidal product laid down in section 27 or the obligation to apply for a permission or submit a notification concerning the test activities referred to in section 34,

5) violates the obligation to use a biocidal product as intended and in compliance with instructions under section 35,

6) neglects the obligation to submit the samples referred to in section 36 or

7) neglects the notification obligation laid down in section 40, 43 or 44,

shall be sentenced to a fine for a chemical violation, provided that a more severe penalty is not provided in another act.

Unless a more severe penalty is provided in another act, also persons who intentionally or out of negligence violate the following obligations or bans under the REACH Regulation are sentenced for a chemical violation:

1) registration or notification obligations to the European Chemicals Agency under Articles 5–7, 9, 11 or 17–19,

2) chemical safety assessment, reporting, application or information obligations under Article 14 or Articles 37–39,

3) the obligation to submit information referred to in Article 22, 24, 40, 41, 46 or 66 to the European Chemicals Agency,

4) the obligation in Article 31 that concerns the safety data sheet and submitting information required from it to the recipient,

5) the obligation to provide information on a substance or mixture under Article 32,

6) the obligation to provide information under Article 33 or 34 or an employer's obligation to provide information under Article 35,

7) the obligation to retain information or to submit it to a competent authority or the European Chemicals Agency under Article 36,

8) the obligation to submit additional information to a competent authority under Article 49,

9) the ban concerning placing on the market or use under Article 56 without specific authorisation granted for the substance in question by the European Chemicals Agency,

10) the obligation under Article 65 to include the authorisation number on the label or

11) the restriction concerning substances under Article 67 on their own, in a mixture or in an article laid down in Annex XVII.

Unless a more severe penalty is provided in another act, also persons who intentionally or out of negligence violate the following obligations under the CLP Regulation are sentenced for a chemical violation:

1) the obligations concerning classification, labelling and packaging referred to in Article 4 or Titles II–IV,

2) the obligation to provide information on the substance to the European Chemicals Agency referred to in Article 40 or

3) the obligation to retain information or to submit it to the competent authority, supervisory authority or the European Chemicals Agency referred to in Article 49.

Unless a more severe penalty is provided in another act, also persons who intentionally or out of negligence violate the following obligations under the Biocidal Products Regulation are sentenced for a chemical violation:

1) authorisation or notification obligations under Article 17 or 27 or the provisions laid down in Article 89, 93, 94 or 95 on the termination of use or placing on the market,

2) the obligation to use a biocidal product in accordance with the terms and conditions and requirements for packaging and labelling cited in the authorisation under Article 17,

3) accounting and notification obligations under Article 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 to them under Article 58,

5) accounting and reporting obligations under Article 65 or 68,

6) obligations concerning classification, labelling and packaging under Article 69,

7) obligations concerning advertising under Article 72.

Unless a more severe penalty is provided in another act, also persons who intentionally or out of negligence violate the following provisions are sentenced for a chemical violation:

1) provisions in Article 3, 4 or 4 a of the Detergent Regulation regarding the placing on the market of detergents and the surfactants contained within them, the testing requirement under Article 7 or neglect the obligation to submit information under Article 9,

2) the obligation under Article 8, 10, 14 or 17 of the PIC Regulation to provide information on the export of a chemical, the obligation under Article 16 of the Regulation to provide information on transit movements, the decision taken by the importing party referred to in Article 14, the export ban under Article 15 and the obligation to provide a reference identification number in the export declaration under Article 19,

3) the ban and restriction referred to in Article 3 of the POP Regulation or fail to comply with provisions concerning storage in Article 5, or

4) the ban on the export of chemicals under Article 1 of the Export Ban for Mercury or neglect the obligation to submit information on chemicals under Article 5 of the Regulation.

When a person has breached a ban or order that has been prescribed 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 offence.

**Section 60**

**Reference to the Criminal Code**

The penalty for health offence is laid down in section 1, Chapter 44 of the Criminal Code (39/1889).

The penalty for impairment of the environment is laid down in sections 1 to 4 of Chapter 48 of the Criminal Code.

## Chapter 10

## Transitional provisions and entry into force

#### Section 61

#### Entry into force

This Act enters into force on 1 September 2013. However, its provisions in sections 9, 13, 15, 23, 46, 55 and 59 concerning the PIC Regulation will not enter into force until 1 March 2014.

This Act repeals the Chemicals Act (744/1989), hereinafter *the Chemicals Act of 1989*. Section 5 a(2); section 42(1) and section 42(2); section 45(2) and section 45(3); section 52(1)(3); and section 56 of the Chemicals Act of 1989 will, however, be applied until 28 February 2014, whereas sections 17 and 59 d of the said act will be applied until 31 May 2015 and section 27(2) of the said act until 31 December 2015.

#### Section 62

#### Decrees issued under the Chemicals Act of 1989

The following decrees issued under the Chemicals Act of 1989 will remain in force:

1) Chemicals Decree (675/1993);

2) Act on the exceptions concerning national defence in the application of chemicals legislation (996/2010);

3) Government Decree on the exceptions to Annex XVII of the REACH Regulation on restrictions on the manufacture, placing on the market and use of certain hazardous substances, mixtures and articles (647/2009);

4) Chapter 8 of the Decree on Industrial Handling and Storage of Dangerous Chemicals (59/1999);

5) Government Decision on substances that deplete the ozone layer (262/1998);

6) Ministry of Social Affairs and Health Decree on the chemicals referred to in Annex VI of the CLP Regulation (5/2010);

7) Ministry of Social Affairs and Health Decree on submitting information concerning chemicals (553/2008);

8) Ministry of Social Affairs and Health Decree on submitting quantity Information on amounts of chemicals classified as dangerous (1155/2011);

9) Decree on Advisory Committee on Chemicals (622/1990);

10) Decree on the industrial handling and storage of dangerous chemicals in the Defence Forces (78/1996);

11) Decree on supervisory authorities for the Chemicals Act in the Defence Forces (469/1992);

12) Government Decree on Biocidal Products (466/2000);

13) Ministry of Social Affairs and Health Decree on the packing and labelling of biocidal products (422/2000);

14) Ministry of the Environment Decree on the applications and notifications concerning biocidal products and their active substances (467/2000);

15) Ministry of the Environment Decree on applying for authorisation or registration of biocidal products, withdrawing such products from the market and special provisions concerning such products (20/2008).

The following decrees issued under the Chemicals Act of 1989 will remain valid until 31 May 2015:

1) Ministry of Social Affairs and Health Decree on the child-resistant packaging of hazardous chemicals and a tactile warning of danger intended for the visually impaired (414/2011); and

2) Ministry of Social Affairs and Health Decree on Chemical Classification Principles and Labelling (807/2001).

**Section 63**

**Transitional provisions**

Matters instituted before the entry into force of this Act will be processed in accordance with provisions in force at the time of the Act's entry into force, unless otherwise provided in Article 91 of the Biocidal Products Regulation.

Individuals using the products referred to in section 38 of this Act must verify their competence in accordance with section 40 by 31 December 2016 at the latest. The operators referred to in section 44 of the Act must submit the notification referred to in the section in question by 31 December 2016 at the latest.

Decisions concerning the authorisation of a biocidal product taken prior to this Act's entry into force will remain in force during the period specified in the decision, unless otherwise provided in the Biocidal Products Regulation.