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Chemicals Act
Passed 6 May 1998
(RT<sup>1</sup> I 1998, 47, 697),
entered into force 7 June 1998,
amended by the following Acts:
16.12.2004 entered into force 31.12.2004 - RT I 2004, 89, 612;
13.10.2004 entered into force 19.11.2004 - RT I 2004, 75, 521;
12.05.2004 entered into force 27.05.2004 - RT I 2004, 45, 315;
17.12.2003 entered into force 01.01.2004 - RT I 2003, 88, 591;
12.11.2003 entered into force 13.12.2003 - RT I 2003, 75, 499;
11.06.2003 entered into force 01.09.2003 - RT I 2003, 51, 352;
12.02.2003 entered into force 01.04.2003 - RT I 2003, 23, 144;
19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387;
19.06.2002 entered into force 01.08.2002 - RT I 2002, 61, 375;
05.06.2002 entered into force 01.07.2002 - RT I 2002, 53, 336;
28.04.99 entered into force 28.05.99 - RT I 1999, 45, 512.
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#### Chapter 1

#### **General Provisions**

## § 1. Scope of application of Act

- (1) This Act provides the legal basis for organisation of the handling of chemicals and for the restriction of economic activities involving the handling of chemicals, and provides the principal safety requirements for the handling of chemicals and the procedure for notification of chemicals.
- (2) The provisions of this Act also apply in areas concerning the handling of chemicals which are regulated by other Acts in so far as such areas are not regulated by the other Acts.
- (2<sup>1</sup>) The requirements for the manufacture, use and technical inspection of equipment used in the handling of chemicals arise from the Pressure Equipment Safety Act (RT I 2002, 49, 309; 2003, 88, 594), taking account of the specifications provided for in this Act.

(12.02.2003 entered into force 01.04.2003 - RT I 2003, 23, 144)

(3) The provisions of the Administrative Procedure Act (RT I 2001, 58, 354; 2002, 53, 336; 61, 375; 2003, 20, 117; 78, 527) apply to administrative proceedings prescribed in this Act, taking account of the specifications provided for in this Act. (19.06.2002 entered into force 01.08.2002 - RT I 2002, 61, 375)

## § 2. Definition of chemical

- (1) For the purposes of this Act, a chemical is a substance or preparation in the natural state or obtained by any production process.
- (2) A substance is a chemical element and its compounds in the natural state or obtained by any production process, together with any additive necessary to preserve the stability of the product and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

  (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- (3) A preparation is a mixture composed of two or more substances.

### § 3. Identification of chemicals

(1) Chemicals are identified by the name of the substance or preparation, and the European Inventory of Existing Commercial Chemical Substances (hereinafter EINECS) code, the European List of Notified Chemical Substances (hereinafter ELINCS) code or the Chemical Abstracts Service (hereinafter CAS) code.

(13.10.2004 entered into force 19.11.2004 - RT I 2004, 75, 521)

- (2) The name of a substance shall characterise the composition and structure of the substance.
- (3) The manufacturer or importer of a preparation shall name the preparation.
- (4) The names of chemicals handled in Estonia shall be written using the Latin alphabet.
- (5) (Repealed 13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)

## § 4. Handling of chemicals

The handling of chemicals is the manufacture, processing, packaging, storage, carriage, placing on the market and use of chemicals or any other activity concerning chemicals.

(13.10.2004 entered into force 19.11.2004 - RT I 2004, 75, 521)

- § 4<sup>1</sup>. Placing on market of chemicals
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- (1) Placing on the market of chemicals means an activity by which a chemical is made accessible for a charge or without charge either for the purpose of distribution or putting into service. Import of chemicals to the territory of the European Union is also deemed to be placing on the market of chemicals.
- (2) Manufacturers, representatives of manufacturers, importers or distributors of chemicals within the meaning of the Product Safety Act (RT 2004, 25, 167) are persons responsible for the placing on the market of chemicals.
- (3) A person responsible for the placing on the market of a chemical has the right to place the chemical on the market if:
- 1) the hazardous qualities of the chemical have been determined;
- 2) the risk arising from the chemical to health, the environment or property has been assessed;
- 3) the chemical has been identified, classified, packaged and labelled;
- 4) requirements for notification and other requirements arising from this Act are met.
- (4) The requirements for identification, classification, packaging and labelling of dangerous chemicals shall be established by a regulation of the Minister of Social Affairs.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- § 5. Dangerous chemicals
- (1) Dangerous chemicals are chemicals which due to their intrinsic properties may cause damage to health, the environment or property.

- (2) (Repealed 13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- (3) The minimum hazard level of a chemical is the quantity of the chemical at which the chemical may cause damage to health, the environment or property.
- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- (4) The threshold quantity of a dangerous chemical is the quantity of the chemical at which the handling of such chemical in an enclosed area may cause damage to health or death of person or other major accident with serious consequences.
- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- (5) The procedure for recording dangerous chemicals shall be established by a regulation of the Minister of Social Affairs
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- § 6. Dangerous enterprises and enterprises liable to be affected by major accident
- (1) Dangerous enterprises are enterprises where chemicals are handled in greater quantities than the minimum hazard level.
- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- (2) (Repealed 12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- (3) Enterprises liable to be affected by a major accident are enterprises where dangerous chemicals are handled in greater quantities than the threshold quantities.
- (4) Enterprises liable to be affected by a major accident are divided into category B and A enterprises on the basis of the increase of hazard and the threshold quantity established for the chemicals handled in the enterprises.
- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- § 7. Competent state agency
- (1) The Government of the Republic shall found a Chemicals Notification Centre in the area of government of the Ministry of Social Affairs.
- (2) The Chemicals Notification Centre is the competent state agency whose duties are to:
- 1) collect information concerning chemicals which are imported into Estonia or produced in Estonia by high or lower volume production and which are banned or severely restricted, or which contain a new substance;

- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- assess the risk arising from notified substances to human beings and the environment, and the compliance of submitted information to legislation and where necessary, require additional information or studies for the assessment of the risks, to forward the results of risk assessment to the person who notified of the substance and to the relevant state agencies together with recommendations for reducing the risk, and to report to the European Commission; (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- 3) perform administrative functions and administrative acts based on Regulation 304/2003/EC of the European Parliament and of the Council concerning the export and import of dangerous chemicals (OJ L 063, 06.03.2003, pp. 1–26) on banned and severely restricted chemicals;
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- 4) exchange information with the competent state agencies of other states, the European Commission and international organisations;
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- 5) comply with the obligations prescribed for state agencies in subsection VII (4) of the Paris Convention on the prohibition of the development, production, stockpiling and use of chemical weapons and on their destruction of 13 January 1993;
- (28.04.99 entered into force 28.05.99 RT I 1999, 45, 512)
- 6) collect information concerning the physico-chemical properties of and health hazards related to chemicals and preparations on the market and the first aid and methods of treatment in case of intoxication;
- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- 7) ensure the communication of information related to intoxication to the population and medical staff;
- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- 8) grant an authorisation for and register biocidal products imported into the Republic of Estonia or manufactured in the Republic of Estonia;
- (12.05.2004 entered into force 27.05.2004 RT I 2004, 45, 315)
- 9) maintain a biocides register and be the authorised processor of the biocides register. (12.05.2004 entered into force 27.05.2004 RT I 2004, 45, 315)

- (3) The Rescue Board, local offices the Rescue Board and the Technical Inspectorate act as competent authorities in the issues related to the safety of enterprises liable to be affected by a major accident.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521;16.12.2004 entered into force 31.12.2004 RT I 2004, 89, 612)
- (4) The functions of the Rescue Board related to the safety of enterprises liable to be affected by a major accident are:
- 1) to assess compliance with the requirements established for enterprises liable to be affected by a major accident in the part of the emergency plan;
- 2) to assess, in co-operation with the Technical Inspectorate, the compliance of safety reports with the established requirements;
- 3) to organise the collection of information concerning compliance with the requirements imposed upon the activities of enterprises liable to be affected by a major accident and the exchange of information with the competent agencies of other states and international organisations;
- 4) to maintain a list of enterprises liable to be affected by a major accident.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- (5) The functions of the Technical Inspectorate related to the safety of enterprises liable to be affected by a major accident are:
- 1) to assess compliance with the requirements established for the activities of enterprises liable to be affected by a major accident;
- 2) to assess, in co-operation with the Rescue Board, the compliance of safety reports with the established requirements;
- 3) to co-operate with the competent agencies of other states.

(13.10.2004 entered into force 19.11.2004 - RT I 2004, 75, 521)

## § 8. Chemical Safety Commission

- (1) The Government of the Republic shall form a Chemical Safety Commission comprising representatives of government agencies and other experts.
- (2) The duties of the Chemical Safety Commission are to:
- 1) assess current problems concerning chemical safety in the Republic of Estonia and the European Union;
- 2) evaluate and provide opinions on the chemical safety policy and strategies in the Republic of Estonia and the European Union;
- 3) make proposals to government agencies for development and application of chemical safety strategies;
- 4) evaluate the legislation regulation chemical safety and drafts thereof;
- 5) to make proposals to the Minister of Social Affairs for the conduct of studies, the publication of printed matter, the organisation of training and the harmonisation of terminology in the field of chemical safety;
- 6) to exchange information and make proposals for co-ordination the activity of different institutions in the field of chemical safety.

(13.10.2004 entered into force 19.11.2004 - RT I 2004, 75, 521)

## Chapter 2

Organisation of Handling of Chemicals

§ 9. (Repealed - 13.10.2004 entered into force 19.11.2004 - RT I 2004, 75, 521)

## § 9<sup>1</sup>. Good laboratory practices

(1) Good laboratory practices must be adhered to in the non-clinical studies of the safety to health and the environment of all chemicals, including medicinal products, veterinary medicinal products, cosmetic products, pesticides, food additives and substances which are ingredients in additives in feedingstuffs in order to guarantee the reliability and comparability of the results

obtained by laboratories observing good laboratory practices, and the mutual recognition of the results so obtained.

- (2) Good laboratory practices mean a quality system which regulates the planning, conduct, recording and reporting of non-clinical studies of the safety of substances to health and the environment, and the preparation of documentation and preservation of materials related to such studies.
- (3) Non-clinical study of the safety of substances to health and the environment (hereinafter study) means a test or a series of tests in the process of which a substance is studied under laboratory conditions or in the field with the aim to obtain information concerning the physical or chemical properties of the substance and the danger it presents to health and the environment, and the results of which are subject to submission to the relevant authorities for the assessment and management of the risks arising from the chemicals and for the establishment of necessary legislation.
- (4) Laboratories who have the right to conduct studies shall comply with the requirements of good laboratory practices and in the conduct of tests, shall adhere to the requirements and procedure established for good laboratory practices by a regulation of the Minister of Social Affairs.
- (5) A contract under public law shall be entered into based on the Administrative Cooperation Act (RT I 2003, 20, 117; 82, 552; 2004, 53, 367) between the Minister of Social Affairs and a body internationally recognised in the field of assessment of quality management systems whereby the Minister of Social Affairs authorises such body to act as the authority assessing and attesting the compliance of laboratories engaged in the non-clinical studies of the safety of substances to health and the environment with the requirements of good laboratory practices (hereinafter authority for control over good laboratory practices).
- (6) In its operation, the authority for control over good laboratory practices shall observe the requirements for assessment and attestation of compliance with the requirements of good laboratory practices which shall be established by a regulation of the Minister of Social Affairs.

- (7) The authority for control over good laboratory practices has the following functions:
- 1) to prepare a plan of action for the assessment and control of the compliance with the requirements of laboratories observing good laboratory practices situated in the Republic of Estonia; such plan shall be approved by the Minister of Social Affairs;
- 2) to assess the compliance of laboratories observing good laboratory practices with the requirements set for good laboratory practices, and issue written certificates in proof of compliance with the requirements set for good laboratory practices (hereinafter certificates);
- 3) to verify, after having issued a certificate in proof of compliance with the requirements set for good laboratory practices to a laboratory, the continuing conformity of the laboratory to the requirements set for good laboratory practices at least once during every two calendar years;
- 4) in addition to the regular checks provided in clause 3) of this subsection, carry out special checks of laboratories observing good laboratory practices where necessary;
- 5) to inform the Ministry of Social Affairs of deficiencies detected in the course of checks;
- 6) to suspend or revoke a certificate if the authority establishes that a laboratory is violating the requirements of good laboratory practices;
- 7) to submit a report concerning its activities in the area of good laboratory practices during the past year to the Ministry of Social Affairs by the end of the second month of the current year;
- to ensure, in conformity to the requirements provided by the Archives Act (RT I 1998, 36/37, 552; 1999, 16, 271; 2000, 92, 597; 2001, 88, 531; 93, 565; 2002, 53, 336; 61, 375; 63, 387; 82, 480; 2004, 28, 188), the preservation of the documents related to the assessment and attestation of compliance with the requirements set for good laboratory practises;
- 9) to guarantee the protection of the business secrets which the authority has access to in the course of the checks.

- (8) If one of the parties to the contract under public law terminates the contract, or any other circumstance arises which prevents the control authority specified in subsection (6) of this section from carrying out its administrative task, the Ministry of Social Affairs shall organise further performance of the administrative task.
- (9) The costs related to the performance of the administrative task shall be paid out of state budget funds through the budget of the Ministry of Social Affairs.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- § 10. Determination of hazardousness of chemicals, assessment and classification of risk
- (1) The hazardousness of a chemical is determined, and the risks related thereto are assessed based on the physical and chemical properties, and the health and environmental hazards thereof.
- (2) The dangerous properties of chemicals are generally determined by the methods provided by Annex V to Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ P 196, 16.08.1967, pp. 1–98), taking account of the requirements provided by the Animal Protection Act (RT I 2001, 3, 4; 2002, 13, 78; 61, 375; 63, 387; 96, 566; 2004, 38, 257 and 258). The health and environmental hazards of preparations are also determined by conventional methods.
- (3) In addition to the methods specified in subsection (2) of this section, the properties of chemicals entered in the EINECS may also be determined by other internationally recognised methods.
- (4) Chemicals are classified by the dangerous properties characteristic of them, taking account of the risk involved in using the chemicals.
- (5) Annex I to Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (hereinafter Annex I) sets out an index of dangerous substances for which harmonised

classification and labelling have been agreed at Community level, including the corresponding classification and labels.

- (6) The substances not listed in Annex I specified in subsection (5) of this section shall be classified according to the regulation of the Minister of Social Affairs specified in subsection 41 (1) of this Act.
- (7) Assessment of the risks related to substances entered in the EINECS shall be carried out in adherence to:
- 1) Council Regulation 793/93/EEC on the evaluation and control of the risks of existing substances (OJ L 084, 05.04.1993, pp. 1–75);
- 2) Commission Regulation 1488/94/EC laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation 793/93/EEC (OJ L 161, 29.06.1994, pp. 3–11).
- (8) The person responsible for placing on the market of a dangerous chemical substance which is listed in EINECS but not specified in Annex I shall determine the properties of such substances based on relevant information at the disposal of the person and package and label the substance based on such information until the time the substance is entered in Annex I.
- (9) The requirements of assessment of health and environmental risks presented by new substances shall be established by a regulation of the Minister of Social Affairs.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- § 11. Organisation of handling of dangerous chemicals
- (1) The following shall be established by a regulation of the Minister of Social Affairs:
- 1) (Repealed 13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- 2) (Repealed 12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- 3) restrictions on the handling of chemicals that are dangerous to the population and the environment;

- 4) requirements set for detergents and the handling thereof. (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- (2) The following shall be established by a regulation of the Minister of Economic Affairs and Communications:
- 1) (Repealed 13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- 2) requirements for storage facilities for and places of loading, unloading and transhipment of chemicals, and for other structures necessary for handling of chemicals in ports, road transport terminals, railway stations and airports, and special requirements for handling ammonium nitrate;
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- 3) requirements for means of transport based on the hazards of chemicals;
- 4) the minimum hazard level of chemicals, the threshold quantities of dangerous chemicals, the hazard category of enterprises liable to be affected by a major accident and the procedure for the identification of dangerous enterprises;
- 5) the curricula of the training, qualification requirements and the format of certificates of training for safety advisers.
- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- (3) (Repealed 12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- (4) The procedure for preparation and submission of data sheets, safety reports and emergency plans in dangerous enterprises and enterprises liable to be affected by a major accident and maintenance of a list of enterprises liable to be affected by a major accident shall be established by a regulation of the Minister of Social Affairs..
- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- (5) (Repealed 13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- § 12. Maximum limits for dangerous substances in earth, groundwater, surface water, seawater, sediments and organisms

Maximum limits for dangerous substances in earth, groundwater, surface water, seawater, sediments and organisms shall be established by a regulation of the Minister of the Environment. (12.11.2003 entered into force 13.12.2003 - RT I 2003, 75, 499)

- § 13. Restrictions on handling dangerous chemicals in dangerous enterprises and enterprises liable to be affected by major accident
- (1) The quantity of dangerous chemicals handled in dangerous enterprises or enterprises liable to be affected by a major accident shall not exceed:
- 1) the threshold quantity established for category B enterprises liable to be affected by a major accident, in dangerous enterprises;
- 2) the threshold quantity established for category A enterprises liable to be affected by a major accident, in category B enterprises liable to be affected by a major accident.
- (2) The Government of the Republic may prohibit, restrict or suspend the activities of an enterprise liable to be affected by a major accident or a dangerous enterprise in the following circumstances:
- 1) the activities of the enterprise cause a possible risk of a major accident;
- 2) the government agencies which have supervisory authority file a justified application;
- 3) the rural municipality or city council in whose administrative territory the enterprise is located files a justified application through the Ministry of Internal Affairs;
- 4) a major accident concerning a dangerous chemical occurs in the enterprise;
- 5) the undertaking submits false information to the supervisory agency;
- 6) the undertaking submits false information to the Chemicals Notification Centre concerning the properties or quantities of chemicals handled;
- 7) the undertaking fails to submit a data sheet, safety report or emergency plan pursuant to the procedure established by the Minister of Internal Affairs;
- 8) the undertaking does not have a liability insurance for compensation for damage caused by a major accident with the worst possible consequences.
- (3) If the prevention of a major accident requires swift action, a rescue service agency has the right to temporarily suspend the activities of an enterprise or to impose prohibitions and restrictions.
- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- § 14. Seat of enterprise liable to be affected by major accident

A rural municipality or city council shall approve the permitted seat in its administrative territory of an enterprise to be constructed which is liable to be affected by a major accident on the basis of the safety reports submitted by the undertaking. In such case:

- 1) enterprises shall be determined where the probability of a major accident or the seriousness of the consequences thereof may increase due to the vicinity of the enterprises to other dangerous enterprises or enterprises liable to be affected by a major accident;
- 2) buildings and facilities, such as highways, public places and residential areas located in the vicinity of existing enterprises shall be taken into account if the location of the buildings and facilities may increase the probability of a major accident or the seriousness of the consequences of a major accident.

(12.02.2003 entered into force 01.04.2003 - RT I 2003, 23, 144)

## § 15. Conditions for handling chemicals

- (1) The handler of a chemical is required to:
- 1) implement the necessary measures for the prevention of damage which may arise from the chemical during handling of the chemical, taking into account the quantity and hazards of the chemicals;
- 2) maintain records on dangerous chemicals handled and preserve the records for ten years;
- 3) inform the Chemicals Notification Centre of chemicals subject to notification;
- 4) inform the Technical Inspectorate and the local rescue service agency of the activities of the handler if the enterprise is a dangerous enterprise or an enterprise liable to be affected by a major accident;
- 5) immediately inform the local rescue service agency, the Technical Inspectorate and the rural municipality or city government of pollution or an accident;
- ensure compliance with the requirements or restrictions imposed upon a dangerous enterprise and an enterprise liable to be affected by a major accident and the activities thereof. (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- (2) The maintenance of records on chemicals specified in clause (1) 2) of this section shall indicate the movement of each quantity of chemicals in an enterprise from the acquisition of the chemicals to the processing, delivery or rendering harmless of the chemicals.

(12.02.2003 entered into force 01.04.2003 - RT I 2003, 23, 144)

- (3) The right to import or handle a chemical subject to notification arises when the Chemicals Notification Centre has:
- 1) given the importer information concerning the permissibility of import;
- 2) confirmed the conformity of the information submitted.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- (3<sup>1</sup>) If the activities of a handler of chemicals includes the transport of dangerous chemicals by road, rail or inland waterway, or the packaging of, loading of, filling with or unloading of dangerous chemicals related thereto, the handler shall designate a safety adviser who is responsible for the prevention of dangers arising from such activities to persons, property or the environment and knows the activities and procedures which ensure safety. A safety adviser shall undergo a training course for safety advisers and pass a corresponding examination.
- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- (4) Undertakings shall prepare data sheets, safety reports and emergency plans based on the legislation established on the basis of subsection 11 (4) of this Act, and submit such documents to the local government and rescue service agency. Data sheets and safety reports must also be submitted to the Technical Inspectorate.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- (4<sup>1</sup>) Within thirty days after the initial placing on the market of a chemical, the person responsible for placing the chemical on the market is required to submit to the Chemicals Notification Centre written information on the physical and chemical properties and health risks of preparations hazardous to health which shall be used for developing and implementation of measures for the prevention and treatment of toxicity.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- (5) (Repealed 05.06.2002 entered into force 01.07.2002 RT I 2002, 53, 336)
- (6) In order to compensate for possible damage, the owner of an enterprise liable to be affected by a major accident shall insure against liability of the owner for damage which may arise from a major accident.
- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- (7) In the event of termination of activities, an undertaking is liable for the safety of the chemicals in the possession of the undertaking until such chemicals are transferred to a new

possessor, to whom the requirements of this Act apply from the moment of acceptance of the chemicals.

### § 16. Restriction on storage and acquisition of chemicals

- (1) If a natural person is not registered in the commercial register as an undertaking, he or she may only acquire and store chemicals that are available in retail trade.
- (2) The storage and handling of chemicals specified in subsection (1) of this section shall not cause danger to the storer, the handler, fellow human beings, property or the environment.
- (3) The procedure for retail sale of dangerous chemicals shall be established by a regulation of the Government of the Republic.

### Chapter 3

Safety Requirements

## § 17. General safety requirements

- (1) The handler of a chemical shall have the necessary information concerning the physicochemical properties, hazards, safety requirements and rendering harmless of such chemical.
- (2) The handler of a chemical shall adhere to the safety requirements established for the handling of the chemical. An undertaking is required to create the conditions in the enterprise for adherence to the safety requirements.
- (3) The qualifications of persons engaged in the handling of dangerous chemicals shall include:
- 1) knowledge of the properties of the chemical being handled based on the method of handling;
- 2) the ability to identify the hazards of a chemical on the basis of safety data sheets, the labelling on packaging and other information;
- 3) knowledge of the dangers related to the handling of a chemical;
- 4) the ability to use primary emergency equipment in practice and to provide first aid;
- 5) knowledge of technical safety measures and measures for the protection of health and the environment.

- (4) An undertaking is liable for the qualifications of persons in the service of the undertaking who are engaged in the handling of dangerous chemicals.
- (5) In the event of pollution arising from a chemical, the handler shall eliminate the pollution, remedy the cause of the pollution, inform an environmental supervision agency and compensate for the damage caused.

### § 18. Requirements for packaging and labelling of chemicals

- (1) The packaging of a chemical shall be durable and ensure the safe handling of the chemical.
- (2) The following information shall be clearly legible on the labelling of the packaging of a dangerous chemical:
- 1) the trade name of the chemical and the names of its components;
- 2) the name and address of the manufacturer or importer;
- 3) a danger symbol;
- 4) a description of the risk;
- 5) a description of the safety requirements;
- 6) the quantity of the chemical.
- (3) If the packaging of a chemical or information concerning a chemical does not enable the safe handling of the chemical, the chemical shall be removed from handling on the initiative and at the expense of the owner pursuant to the Waste Act (RT I 1998, 57, 861; 88, correction notice; 1999, 10, 155; 23, 353; 95, 843; 2001, 16, 72; 43, 239; 50, 283; 56, 340; 93, 565; 2002, 61, 375; 63, 387).
- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- (4) A chemical may only be retailed in sealed original packaging labelled pursuant to requirements or with equipment prescribed for such purpose.

## § 19. Chemical safety data sheet

(1) A person responsible for the placing on the market of chemicals in the Republic of Estonia (a manufacturer, importer or distributor) is required to prepare and deliver a safety data

sheet concerning a chemical classified as dangerous (hereinafter safety data sheet) to a person who uses chemicals for his or her profession activity (hereinafter user).

- (2) A the request of a user, a person responsible for the placing on the market of preparations in the Republic of Estonia is required to prepare and deliver a safety data sheet concerning a chemical not classified as dangerous but which contains:
- 1) a substance dangerous to health or the environment the content of which in a nongaseous substance is equal to or exceeds 1 per cent by weight, or the content of which in a gaseous substance is equal to or exceeds or 0.2 per cent by volume;
- a substance for which an occupational exposure limit value for the chemical risk factor has been established based on the Occupational Health and Safety Act (RT I 1999, 60, 616; 2000, 55, 362; 2001, 17, 78; 2002, 47, 297; 63, 387; 2003, 20, 120; 2004, 54, 389).
- (3) A safety data sheet shall be presented to the user upon transfer of a substance for the first time, and every time the data sheet has been updated based on current information of the heath or environmental hazard of the preparation. A safety data sheet shall be prepared in the Estonian language and presented on paper or in a format which can be reproduced in writing.
- (4) The person responsible for the placing on the market of a hazardous chemical shall submit to the Chemicals Notification Centre a safety data sheet concerning a preparation dangerous to health prepared on paper or in a format which can be reproduced in writing within at least thirty days after the initial placing on the market of the chemical.

(13.10.2004 entered into force 01.05.2006 - RT I 2004, 75, 521)

(5) The requirements for safety data sheets shall be established by a regulation of the Minister of Social Affairs.

(13.10.2004 entered into force 19.11.2004 - RT I 2004, 75, 521)

Chapter 4

Notification of chemicals

#### § 20. Notification of chemicals

- (1) The notification of a chemical is a written submission to the Chemicals Notification Centre concerning the name, properties, quantity and purpose of the handling of a chemical that is imported into or produced in Estonia by lower or high volume production and which is banned or severely restricted, or which contains a new substance.
- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- (2) The information submitted shall enable the assessment of the dangers relating to the chemical and the implementation of measures for the safe handling of the chemical.
- (3) The procedure for notification of chemicals shall be established by a regulation of the Minister of Social Affairs, which shall provide:
- 1) the requirements for the notifier and for the information submitted, depending on the quantity and purpose of handling;
- 2) the terms for responding to a notifier and commencement of handling;
- 3) the procedure for exchange of information with international organisations;
- 4) exceptions to the notification of chemicals, if a chemical is used only in scientific or process-orientated research and development;
- 5) high or lower volume production levels.
- (4) (Repealed 12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- (5) If the purpose of handling a chemical changes or if additional information concerning the hazards of a chemical become known, the handler of such chemical shall inform the Chemicals Notification Centre promptly.

## § 21. Notification of new substance

- (1) A substance is new if it is not registered in the European Inventory of Existing Commercial Chemical Substances (EINECS).
- (2) The importer or manufacturer shall submit the requisite information concerning a new substance to the Chemicals Notification Centre.
- (2<sup>1</sup>) A new substance may be marketed only once the requirements for notification are complied with and sixty days have passed since registration of the notification or if a shorter term is provided pursuant to clause 20 (3) 2) of this Act.

- (12.02.2003 entered into force 01.04.2003 RT I 2003, 23, 144)
- (3) The European Inventory of Existing Commercial Chemical Substances shall be brought into force in Estonia by a regulation of the Minister of Social Affairs.
- (4) A state fee is collected for notification of new substances, including polymers according to the rates provided in the State Fees Act (RT I 1997, 80, 1344; 2001, 55, 331; 53, 310; 56, 332; 64, 367; 65, 377; 85, 512; 88, 531; 91, 543; 93, 565; 2002, 1, 1; 18, 97; 23, 131; 24, 135; 27, 151 and 153; 30, 178; 35, 214; 44, 281; 47, 297; 51, 316; 57, 358; 58, 361; 61, 375; 62, 377; 90, 519; 102, 599; 105, 610; 2003, 4, 20; 13, 68; 15, 84 and 85; 20, 118; 21, 128; 23, 146; 25, 153 and 154; 26, 156 and 160; 30, correction notice; 51, 352; 66, 449; 68, 461; 71, 471; 78, 527; 79, 530; 81, 545; 88, 589 and 591; 2004, 2, 7; 6, 31; 9, 52 and 53; 14, 91 and 92; 18, 131 and 132; 20, 141; 24, 165; 25, 170; 26, 173; 27, 177; 28, 189; 30, 205 and 208; 32, 226 and 228; 34, 236; 36, 251; 38, 257 and 258; 45, 315 and 317).
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- § 22. Access to information and protection of business secrets
- (1) Information concerning the hazards and safe handling of chemicals registered with the Chemicals Notification Centre is public.
- (2) The Chemicals Notification Centre is required to preserve and protect business secrets pursuant to the procedure provided by law.
- (2<sup>1</sup>) A person who submits information to the Chemicals Notification Centre may apply for the classification by the Chemicals Notification Centre of the information submitted in files or in any other form as a business secret the disclosure of which is likely to damage the person's economic or business interests. Such request shall be reasoned.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- (2<sup>2</sup>) The Chemicals Notification Centre shall decide, based on the documents submitted by the applicant which part of the submitted information is deemed to be a business secret. Such information shall only be forwarded to the European Commission or competent authorities of Member States. Upon forwarding such information, the Chemicals Notification Centre is required to indicate that the information is classified.

(13.10.2004 entered into force 19.11.2004 - RT I 2004, 75, 521)

- (2<sup>3</sup>) The Chemicals Notification Centre shall take all measures to prevent the disclosure of information classified as confidential based on this Act, and of information received in confidence from the European Commission or competent authorities of Member States.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- (2<sup>4</sup>) If a person who submitted information wishes to disclose the confidential information, the person is required to inform the Chemicals Notification Centre thereof.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- (3) The following are not business secrets:
- 1) the trade name of a substance or preparation;
- 2) the name of the notifier, manufacturer or importer;
- 3) the physico-chemical properties;
- 4) information on the safety data sheet and additional information on the hazards of a chemical;
- 5) the summary results of toxicological and ecotoxicological tests;
- 6) the analytical methods for identification of a dangerous substance;
- 7) dangerous additives;
- 8) safety measures;
- 9) methods of rendering a chemical harmless.

## Chapter 5

Supervision

(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)

- § 23. (Repealed 19.06.2002 entered into force 01.09.2002 RT I 2002, 63, 387)
- § 24. Supervision

- (1) The following shall exercise supervision over compliance with the requirements of this Act and legislation established on the basis thereof:
- 1) the Technical Inspectorate, over safety of handling in dangerous enterprises and enterprises liable to be affected by a major accident, calculation of hazard category, conformity of safety data sheets and safety reports, and compliance with the requirement for recording and notification of chemicals;
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- 2) rescue service agencies, over data sheets, safety reports and emergency plans;
- 3) the Labour Inspectorate, over compliance with the occupational health and safety requirements;
- 4) the Environmental Inspectorate, pursuant to the procedure provided for in the Environmental Supervision Act (RT I 2001, 56, 337; 2002, 61, 375; 99, 579; 110, 653; 2003, 88, 591);
- 5) the Consumer Protection Board, over compliance with the requirements for the retail sale of dangerous chemicals;
- 6) the Tax and Customs Board, over compliance with the requirements established for the export and import of the chemicals listed in Annex I to Regulation 304/2003/EC of the European Parliament and of the Council;
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- 7) The Health Protection Inspectorate, over notification of chemicals sold by wholesale trade and compliance with the safety requirements thereof, and over provision of services involving chemicals;
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- 8) the Ministry of Social Affairs, over performance of the administrative task specified in subsections 9 (5) and (6) of this Act.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- (2) A person exercising supervision is required to:
- 1) show his or her identification to the person being inspected and explain the aim and acts involved in the procedure of the exercise of supervision;
- 2) in the event of a violation of requirements, explain the nature of the violation to the person being inspected and demand termination of the violation;

- 3) maintain the confidentiality of information not subject to disclosure which becomes known to him or her during performance of supervisory operations.
- (3) A person exercising supervision has the right to:
- 1) obtain information necessary for the conduct of supervision, to examine the documents related to the handling of chemicals and to obtain copies of documents related to the hazards of chemicals and the safe handling thereof;
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- 2) gain unrestricted access to the objects under inspection, make measurements and take samples for analysis;
- 3) issue precepts for termination of violations of the requirements of this Act or legislation established on the basis thereof, set terms for compliance with the precepts and monitor compliance with the precepts;
- 4) to order expert assessment to establish the hazards of chemicals and evaluation of the risks arising from chemicals to health, the environment and property.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- (4) Upon failure to comply with a precept specified in clause (3) 3) of this section, an inspectorate, board or agency specified in subsection (1) has the right to impose penalty payment or apply substitutive enforcement pursuant to the procedure provided for in the Substitutive Enforcement and Penalty Payment Act (RT I 2001, 50, 283; 94, 580). The upper limit for a penalty payment is 10 000 kroons.

(12.02.2003 entered into force 01.04.2003 - RT I 2003, 23, 144)

Chapter 5<sup>1</sup>

(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)

Liability

(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)

- § 24<sup>1</sup>. Violation of requirements for recording of dangerous chemicals
- (1) Violation of the requirements for recording dangerous chemicals is punishable by a fine of up to 200 fine units.

(2) The same act, if committed by a legal person, is punishable by a fine of up to 40 000 kroons.

(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)

- § 24<sup>2</sup>. Violation of requirements for handling of dangerous chemicals, and of safety or notification requirements
- (1) Violation of the requirements for the handling of dangerous chemicals or violation of safety or notification requirements is punishable by a fine of up to 300 fine units.
- (2) The same act, if committed by a legal person, is punishable by a fine of up to 50 000 kroons.

(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)

## § 24<sup>3</sup>. Procedure

- (1) The provisions of the General Part of the Penal Code (RT I 2001, 61, 364; 2002, 86, 504; 105, 612; 2003, 4, 22; 83, 557) and of the Code of Misdemeanour Procedure (RT I 2002, 50, 313; 110, 654; 2003, 26, 156; 83, 557; 88, 590; 593) apply to the misdemeanours provided for in §§ 24¹ and 24² of this Act.
- (2) The following extra-judicial bodies conduct proceedings in matters of misdemeanours provided for in §§ 24<sup>1</sup> and 24<sup>2</sup> of this Act:
- 1) the Technical Inspectorate;
- 2) the Rescue Board and local offices the Rescue Board;

(16.12.2004 entered into force 31.12.2004 - RT I 2004, 89, 612)

- 3) the Labour Inspectorate;
- 4) the Environmental Inspectorate;
- 5) the Consumer Protection Board;
- 6) the Health Protection Inspectorate.
- (3) The Tax and Customs Board shall conduct extra-judicial proceedings in the matters of the misdemeanours provided for in § 24<sup>2</sup> of this Act.

(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387; 17.12.2003 entered into force 01.01.2004 - RT I 2003, 88, 591)

# Chapter 6

**Implementing Provisions** 

- § 25. Entry into force of Act
- (1) Clause 15 (1) 3) and §§ 18, 20 and 21 of this Act enter into force two years after the entry into force of this Act.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)
- (2) Subsection 19 (4) of this Act enters into force on 1 May 2006.
- (13.10.2004 entered into force 19.11.2004 RT I 2004, 75, 521)

<sup>&</sup>lt;sup>1</sup> RT = Riigi Teataja = State Gazette