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Chemicals Act¹

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13.06.2018	RT I, 29.06.2018, 3	01.07.2018

Chapter 1 GENERAL PROVISIONS

§ 1. Purpose and scope of regulation of Act

This Act regulates the handling of chemicals and the restriction of economic activities relating to the handling of chemicals for the purpose of protecting human life and health, property and the environment, and ensuring the free movement of goods.

§ 2. Scope of application of Act

(1) This Act applies to chemicals and to products containing them and to the handling thereof insofar as it is not regulated by another act, international agreement adopted by the Riigikogu or European Union law.

(2) 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 (OJ L 396, 30.12.2006, pp. 1#850) (hereinafter *REACH Regulation*) applies to the production, placing on the market and use of chemicals as substances, in mixtures or in articles.

(3) Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, pp. 1#1355) (hereinafter the *CLP Regulation*) applies to the classification, labelling and packaging of chemicals.

(4) The definitions used in this Act have the meaning specified in the relevant regulations of the European Union, unless otherwise provided for in this Act.

(5) Upon carriage of chemicals by rail, road, waterways and air, the legislation applicable to the respective mode of transport, taking account of the specifications of this Act.

(6) The provisions of the Administrative Procedure Act apply to the administrative proceedings specified in this Act, taking into account the specifications provided for in this Act.

§ 3. Chemical, hazardous chemical and handling of chemical

(1) For the purposes of this Act, a chemical is a substance or mixture for the purposes of the REACH Regulation.

(2) A hazardous chemical is a substance or mixture that meets the physical, health or environmental hazard criteria set out in parts 2-5 of Annex I to the CLP Regulation.

(3) For the purposes of this Act, the handling of a chemical is the making, manufacture, processing, packaging, storage, carriage, making available of a chemical or any other activity relating to a chemical.

Chapter 2 REQUIREMENTS FOR HANDLING CHEMICAL

Division 1 Determining of hazardousness of chemical

§ 4. Determining of hazardousness of chemical

The intrinsic properties of a chemical that determine the hazardousness of a chemical are identified in accordance with Article 13 of the REACH Regulation and Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.05.2008, pp. 1#739).

§ 5. Good laboratory practices

(1) Good laboratory practices are adhered to in the non-clinical studies of the safety to health and the environment of chemicals, including medicinal products and veterinary medicinal products, cosmetic products, plant protection products, food additives and substances that are ingredients in additives in feedingstuffs. The purpose of adherence to good laboratory practices is to guarantee the reliability and comparability and the mutual recognition of the results obtained in laboratories.

(2) Good laboratory practices constitute a quality system that 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 documents and preservation of materials related to such studies.

(3) A non-clinical study of safety 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 and chemical properties of the substance and the danger it presents to health and the environment. The results of a study are subject to submission to the relevant authorities for the assessment and management of the risks arising from the chemical and for the establishment of necessary legislation and issue of an administrative decision.

(4) The laboratory conducts a study must comply with the requirements for good laboratory practices and, upon submission of the results of the survey, prove that it adhered to the good laboratory practices upon conducting the survey.

(5) The requirements and procedure for good laboratory practices will be established by a regulation of the minister responsible for the field.

§ 6. Good laboratory practices control authority

(1) By a contract, the minister responsible for the field will authorise an agency internationally recognised in the field of assessment of quality management systems to act as an agency that assesses and certifies the compliance of laboratories conducting studies (hereinafter *good laboratory practices control authority*).

(2) Expenses related to the performance of the functions of the good laboratory practices control authority are covered from the state budget via the Ministry of Social Affairs. Expenses arising from the direct assessment and certification of the compliance of a laboratory carrying out a survey with the good laboratory practices are paid by the laboratory whose compliance with the requirements for good laboratory practices is assessed and certified.

(3) If the contract specified in subsection (1) of this section is terminated unilaterally or if there is another reason that prevents the good laboratory practices control authority from continuing to perform the contract, the Ministry of Social Affairs will authorise another agency internationally recognised in the field of assessment of quality management systems to act as the good laboratory practices control authority or otherwise organise the further performance of the functions of the good laboratory practices control authority.

§ 7. Functions of good laboratory practices control authority

(1) In its operations, the good laboratory practices control authority follows the requirements and procedure for assessment and certification of compliance with the requirements for good laboratory practices.

(2) The functions and responsibilities of the good laboratory practices control authority are as follows:
1) to prepare and submit to the Ministry of Social Affairs an action plan for the assessment and inspection of the compliance with the requirements for laboratories following good laboratory practices and situated in Estonia;

- 2) to assess the compliance of laboratories observing good laboratory practices with the requirements established for good laboratory practices, and issue written certificates in proof of compliance with good laboratory practices;
- 3) at least once during every two calendar years after the day following the issue of a certificate, to verify the continued compliance of the laboratory with the requirements for good laboratory practices;
- 4) to carry out special inspections of laboratories following good laboratory practices, where necessary;
- 5) to inform the Ministry of Social Affairs about deficiencies detected upon inspection;
- 6) to suspend the validity of the certificate or revoke the certificate if it has established that the laboratory violates the requirements for 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;
- 8) to ensure, in compliance with the requirements provided by the Archives Act, the preservation of the documents related to the assessment and certification of compliance with the requirements for good laboratory practices;
- 9) to ensure the confidentiality of trade secrets learned in the course of inspection.

(3) The requirements and procedure for assessment of compliance with the requirements for good laboratory practices will be established by the minister responsible for the field.

Division 2

General Requirements for Handling of Chemical

§ 8. Conditions of handling of chemical

- (1) A chemical must be handled in a manner that is not hazardous to human life or health, property or the environment.
- (2) The handler of a chemical must have the necessary information concerning the physical and chemical properties, hazards, safety requirements and rendering harmless of such chemical as well as the knowledge and skills, experience and attitudes necessary for handling the chemical (hereinafter *competence*).
- (3) The competence of the handler of a hazardous chemical includes:
 - 1) knowledge of the properties of the chemical being handled based on the method of handling;
 - 2) the skill of assessing hazards and risks related to handling a chemical on the basis of the safety data sheet, labelling and other information;
 - 3) the ability to use primary emergency equipment in practice and to give emergency medical aid;
 - 4) knowledge of occupational safety measures and measures for the protection of health and the environment.
- (4) If the packaging of a chemical or information submitted concerning a chemical does not allow for the safe handling of the chemical, the handler of the chemical will remove the chemical from handling. The handling of the chemical removed from handling will continue in accordance with the Waste Act as that of hazardous waste.
- (5) The labelling of a chemical designated for placing on the Estonian market must be in Estonian. By way of exception, it is permitted to deliver, for the purpose of use in research and development, a chemical that is labelled in another language understandable to the recipient and complies with the requirements of the CLP Regulation.
- (6) Requirements for handling chemicals and place of handling, including special requirements for the handling of ammonium nitrate and means of transport, may be established by a regulation of the minister responsible for the field.

§ 9. Duty to keep records of hazardous chemical

- (1) A person handling a chemical in the framework of economic and professional activities keeps records of handled hazardous chemicals and preserves the records for ten years. The records of hazardous chemicals must indicate the movement of each quantity of a chemical in the enterprise from its acquisition to processing, delivery or rendering harmless.
- (2) The procedure for keeping records of hazardous chemicals will be established by a regulation of the minister responsible for the field.

§ 10. Notification of accident upon handling of chemical

The handler of a chemical must immediately inform the Alarm Centre of environmental pollution or another accident arising from handling a chemical. In the event of an environmental nuisance arising from an accident, the Alarm Centre will forward the obtained information to the Environmental Inspectorate as soon as possible

and if the accident occurred in a dangerous enterprise or in an enterprise liable to be affected by a major accident, to the Technical Regulatory Authority.

§ 11. Placing of detergent on market

(1) Detergents to be placed on the market must comply with Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents (OJ L 104, 08.04.2004, pp. 1–35) (hereinafter *Detergents Regulation*).

(2) A person applying for derogation under the Detergents Regulation for placing a detergent on the market must pay the state fee at the rate established in the State Fees Act before submitting an application.

§ 12. Submission of information on hazardous mixture and detergent

(1) An importer and downstream user of a hazardous mixture must, before placing the mixture on the Estonian market, submit to the Health Board information in accordance with Article 45 of the CLP Regulation, which will be used for the purpose of developing and implementing measures for prevention and treatment of intoxication.

(2) The person responsible for placing a detergent on the market must submit to the Health Board the information specified in Article 9(3) of the Detergents Regulation, which will be used for the purpose specified in subsection (1) of this section.

§ 13. Safety adviser

(1) The safety adviser is appointed by an undertaking whose activities include the carriage of dangerous goods by road, rail and inland waterways, freight forwarding as well as the packaging, loading and unloading of dangerous goods in relation to carriage.

(2) For the purposes of this section, the carriage of dangerous goods means the carriage of dangerous cargo in accordance with international agreements.

(3) The safety adviser is a competent person who acts for the benefit of an undertaking and whose duty is to ensure the safety of the carriage of dangerous goods and the compliance of the carriage of dangerous goods with requirements. The safety adviser must have completed a safety adviser training course in an educational establishment experienced in organising formal or supplementary training in the field of dangerous cargo, passed an exam and obtained a respective certificate.

(4) The safety adviser certificate is valid for five years. The validity of the certificate will be extended for another five years if the holder of the certificate has completed the respective supplementary training and passed the exam within one year before the date of expiry of the certificate.

(5) The safety adviser examination is organised by the Road Administration and, in the field of railway, by the Technical Regulatory Authority. The safety adviser examination may also be held by a training establishment, provided that the competent authority has been informed thereof and at least one representative of the competent authority takes part in the work of the examination committee.

(6) A state fee must be paid for taking the safety adviser examination and for obtaining the safety adviser certificate.

(7) Requirements for competence and functions of safety advisers and safety adviser curriculum and examination as well as the certificate form will be established by a regulation of the minister responsible for the field.

Division 3 Restrictions on and other special requirements for handling of chemical

§ 14. Chemical prohibited to public

(1) Chemicals and products the placing on the market or use of which is prohibited to the public under Annex XVII of the REACH Regulation must not be made available to the consumer for the purposes of the Consumer Protection Act.

(2) Chemicals and products referred to in subsection (1) of this section may be made available only in wholesale trade and by way of cashless transactions.

(3) Chemicals and products specified in subsection (1) of this section may be acquired and possessed only by persons who use them lawfully in their economic or professional activities or research and development activities.

§ 15. Restrictions relating to explosive precursor

(1) Upon making available, using, possessing and introducing an explosive precursor which is subject to the restrictions established in Regulation (EU) No 98/2013 of the European Parliament and of the Council on the marketing and use of explosives precursors (OJ L 39, 09.02.2013, pp. 1–11), the restrictions established in the Regulation are adhered to.

(2) The precursor of a restricted explosive may be made available only in wholesale trade and by way of cashless transactions.

(3) A trader who makes the precursor of a restricted explosive available in the market by way of wholesale trade submits a notice of economic activities in the field of wholesale trade in accordance with the General Part of the Economic Activities Code Act.

(4) In addition to the data specified in subsections 15 (1) and (3) of the General Part of the Economic Activities Code Act, the notice of economic activities sets out the details of the precursor of a restricted explosive to be made available. The details of the precursor given in the notice of economic activities are not made public.

(5) Upon transfer and delivery of the substances listed in Annex II to Regulation (EU) No 98/2013 of the European Parliament and of the Council or mixtures containing these substances as well as the precursor of a restricted explosive, the trader may, for the purpose of verifying the lawfulness of the transaction, demand that the recipient provide further information on the planned use and user of the substance, mixture and the precursor of the restricted explosive.

§ 16. Notification of suspicious transaction made with explosive precursor as well as of loss and theft of explosive precursor

Via the e-mail address or telephone number designated for such purpose the Police and Border Guard Board must be notified of a suspicious transaction made with a substance or mixture listed in Annex II to Regulation (EU) No 98/2013 of the European Parliament and of the Council, the precursor of a restricted explosive as well as of the substantial loss and theft of the same. The Police and Border Guard Board may forward the received information to the supervisory authority and to the Estonian Internal Security Service.

§ 17. Requirement for transit of high nitrogen ammonium nitrate

(1) By way of transit, high nitrogen ammonium nitrate may be brought to the Estonian customs territory only if it has passed a test of resistance to detonation in accordance with Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers (OJ L 304, 21.11.2003, pp. 1#194) (hereinafter *Fertiliser Regulation*).

(2) High nitrogen ammonium nitrate is solid ammonium nitrate both as a substance on its own as well as in a mixture of substances, which contains more than 28 mass per cent of ammonium nitrate-based nitrogen.

(3) The requirements of this section do not apply to ammonium nitrate used as an explosive substance under the Explosive Substances Act.

(4) The test of resistance to detonation must be taken and the passing of the test must be assessed in accordance with the relevant provisions of Annex III to the Fertiliser Regulation and in a laboratory accredited for such tests in accordance with the Fertiliser Regulation.

(5) A document certifying resistance to detonation will be valid for 180 calendar days as of the date of taking the test.

(6) At a border crossing point, the possessor of high nitrogen ammonium nitrate must submit to the Tax and Customs Board a document certifying the passing of the test of resistance to detonation or a certified copy thereof along with a customs declaration. Along with the document certifying resistance to detonation, a document allowing for the identification of the batch must be submitted, indicating the ammonium nitrate-based nitrogen content in the product, the product quantity of the batch, the date of production and other relevant information for identifying the batch.

§ 18. Odourisation of gaseous fuel

(1) Gaseous fuel that is odourless following production may be placed on the market after a clearly perceptible odouriser has been added to it so that the gas can be perceived in the air when the gas content in the air is five fifths of the lower explosion limit of the gas.

(2) For the purposes of this Act, gaseous fuel means fuel that is in a gaseous state at the temperature of 15°C and pressure of 1 bar.

(3) Odourless gaseous fuel may be placed on the market for the purpose of sale to eligible consumers via a gas piping with an operating pressure of 5 bar for the purpose of use in an industrial process, further processing or other special use if gas is not transmitted from the distribution point to small consumers via the gas piping designated for such instances.

(4) In the case of odourless gaseous fuel, measures must be taken to detect its leak.

§ 19. Reporting duty of undertaking engaged in offshore oil and gas operations

(1) An undertaking registered in Estonia, which itself or via a subsidiary is responsible for offshore oil and gas operations, must, at the request of the European Commission or the Government of the Republic or a competent authority appointed by the latter, submit a report on each major accident that it is involved in. If the report was not submitted directly to the European Commission, the report will be submitted to the European Commission by the Government of the Republic or the competent authority appointed by the latter.

(2) Oil and gas operations include all activities associated with an installation or connected infrastructure, including design, planning, construction, operation and decommissioning thereof, relating to exploration and production of oil or gas, but excluding conveyance of oil and gas from one coast to another.

(3) For the purposes of this section, a major accident means, in connection with an installation or connected infrastructure:

- 1) an incident involving an explosion, fire, loss of well control, or release of oil, gas or hazardous substances involving, or with a significant potential to cause, fatalities or serious personal injury;
- 2) an incident leading to serious damage to the installation or connected infrastructure involving, or with a significant potential to cause, fatalities or serious personal injury;
- 3) any other incident leading to fatalities or serious injury to five or more persons who are on the offshore installation where the source of danger occurs or who are engaged in an offshore oil and gas operation in connection with the installation or connected infrastructure; or
- 4) any major environmental incident resulting from incidents referred to in clauses 1) to 3).

(4) For the purposes of this section, an installation means a stationary, fixed or mobile facility, or a combination of facilities permanently inter-connected by bridges or other structures, used for offshore oil and gas operations or in connection with such operations. An installation includes mobile offshore drilling units only when they are stationed in offshore waters for drilling, production or other activities associated with offshore oil and gas operations.

Chapter 3 DANGEROUS ENTERPRISE AND ENTERPRISE WITH MAJOR HAZARD

§ 20. Scope of application of Chapter

(1) The requirements set out in this Chapter apply to dangerous enterprises handling a hazardous chemical and to enterprises with a major hazard.

(2) The requirements applicable to dangerous enterprises and to enterprises with a major hazard do not apply to:

- 1) a national defence establishment;
- 2) an establishment posing a hazard created by ionising radiation;
- 3) the transport of dangerous substances and directly related intermediate temporary storage by road, rail, internal waterways, sea or air, outside an establishment, including loading and unloading and transport to and from another means of transport at docks, wharves or marshalling yards;
- 4) the transport of hazardous chemicals in pipelines (including pumping stations) outside an establishment;
- 5) the exploration, extraction and processing of minerals in mines and quarries, including by means of boreholes;
- 6) the offshore exploration and exploitation of minerals;
- 7) waste land-fill sites, including underground waste storage;
- 8) the storage of gas at underground offshore sites including both dedicated storage sites and sites where exploration and exploitation of minerals is carried out.

(3) The exclusions set out in subsection (2) of this section do not apply to:

- 1) onshore underground gas storage in natural strata, aquifers, salt cavities and disused mines;
- 2) chemical and thermal processing operations and storage related to those operations which involve dangerous substances;
- 3) operational tailings disposal facilities (including tailing ponds or dams) containing dangerous substances.

§ 21. Definitions for the purposes of this Chapter

(1) 'Establishment' means the whole location under the control of an operator of a dangerous enterprise or enterprise with a major hazard where dangerous substances are present in one or more installations, including common or related infrastructures or activities.

(2) 'Installation' means a technical unit within an establishment and whether at or below ground level, in which dangerous substances are produced, used, handled or stored; it includes all the equipment, structures, pipework, machinery, tools, private railway sidings, docks, unloading quays serving the installation, jetties, warehouses or similar structures, floating or otherwise, necessary for the operation of that installation.

(3) 'Dangerous enterprise' means an establishment where a chemical is handled in a quantity that exceeds the minimum level of hazardousness and falls short of the threshold quantity. A dangerous enterprise is a category C enterprise.

(4) 'Enterprise with a major hazard' means an establishment where a chemical is handled in a quantity that exceeds the threshold quantity. Enterprises with a major hazard are divided into enterprises with a major hazard of categories B and A based on the increase of hazardousness.

(5) The 'minimum level of hazardousness' and 'threshold quantity' of a chemical means a limit quantity that classifies an establishment as a dangerous enterprise or an enterprise with a major hazard.

(6) 'Major accident' means an occurrence such as a major emission, fire, or explosion resulting from uncontrolled developments in the course of the operation of an enterprise, and leading to serious danger to human health or the environment, immediate or delayed, inside or outside the establishment, and involving one or more hazardous chemicals.

(7) 'Hazard' means the intrinsic property of a hazardous chemical or physical situation, with a potential for creating damage to human health or the environment.

(8) 'Risk' means the likelihood of a specific effect occurring within a specified period or in specified circumstances.

(9) 'Storage' means the presence of a hazardous chemical for the purposes of warehousing, depositing in safe custody or keeping in stock.

(10) 'Domino effects' means a higher major-accident risk in the case of an establishment or a group of establishments due to the geographical location and mutual distance of the establishments and the stock of the dangerous substances located therein.

§ 22. Duties of operator of dangerous enterprise and enterprise with major hazard

(1) A person handling hazardous chemicals must determine the hazardousness of the enterprise based on the maximum possible quantity of the chemicals handled.

(2) Based on the hazardousness of the enterprise, the operator must draw up the following documents:

1) a data sheet, risk analysis and emergency plan if the enterprise is a category C enterprise (dangerous enterprise);

2) a data sheet, risk analysis, description of the safety management system and emergency plan if the enterprise is a category B enterprise with a major hazard;

3) a data sheet, safety report and emergency plan if the enterprise is a category A enterprise with a major hazard. The safety report also contains a risk analysis and a description of the safety management system.

(3) Upon prevention of an accident and in the event of an accident, the measures set out in the risk analysis, safety report, emergency plan and description of the safety management system must be taken.

(4) If in the case of a dangerous enterprise and an enterprise with a major hazard the domino effects are likely, their operators will mutually exchange necessary information in order to take appropriate measures and cooperate upon notifying the public.

(5) To test the emergency plan, the operator of an enterprise with a major hazard organises a training exercise at least once every three years. The Rescue Board is informed of the training exercise at least 20 working days before the exercise.

(6) In the event of the permanent closure or decommissioning of a dangerous enterprise or enterprise with a major hazard, the operator of the enterprise will inform the Technical Regulatory Authority at least five working days before the permanent closure or decommissioning of the enterprise.

(7) The procedure for determining the minimum level of hazardousness and the threshold of hazardous chemicals and the enterprise hazardousness category may be established by a regulation of the minister responsible for the field.

§ 23. Drawing up, renewal and approval of mandatory document

(1) The documents specified in subsection 22 (2) of this Act (hereinafter mandatory documents) must be kept up-to-date, revised and, where necessary, renewed:

- 1) at least once every five years, thereby the emergency plan of the enterprise must be renewed at least once every three years;
- 2) if it is justified because of a change in the contact details or other circumstances, including the in the event of the modification of the nature or physical form or quantity of a hazardous chemical as well as modification of an establishment or installation, which could have significant consequences for accident hazards or could result in a change of the hazardousness category of the enterprise;
- 3) where justified by new technological knowledge about safety matters, including knowledge arising from analysis of accidents or, as far as possible, 'near misses', and by developments in knowledge concerning the assessment of hazards; or
- 4) following a major accident in an establishment.

(2) The mandatory documents must be approved by the competent authority. The competent authority is:

- 1) the Technical Regulatory Authority in the event of a data sheet and safety management system;
- 2) the Rescue Board in the event of an emergency plan of an enterprise;
- 3) the Technical Regulatory Authority in cooperation with the Rescue Board in the event of a risk analysis and safety report.

(3) Upon renewal of a mandatory document, the document must be submitted for approval within a reasonable time before the implementation of such modifications set out therein, which result in a major-accident risk or an increase thereof, but certainly before the expiry of the time limit specified in clause 1) of subsection (1) of this section. Preference must be given to the electronic submission of the document.

(4) Upon approval of the document, the Technical Regulatory Authority and the Rescue Board follow the time limits provided for in subsection 27 (5) of this Act. The Technical Regulatory Authority will coordinate the data sheet within 14 working days as of the receipt of the document. If a document has not been approved within the aforementioned time limit, including within the extended time limit, it will not be deemed to be approved by default.

(5) In the course of approval, the compliance of the submitted documents with the requirements provided by law is verified and thereby it is verified whether:

- 1) the hazardousness of the enterprise has been properly determined;
- 2) the planned measures are sufficient for preventing an accident and mitigating consequences in the event of an accident;
- 3) the risks posed to the surroundings, the sufficiency of the measures taken to reduce these risks and compliance with the plan have been taken into account upon making such changes in a dangerous enterprise or in an enterprise with a major hazard, which result in a major-accident risk or an increase thereof;
- 4) the activity licence serving as the basis for the operations of the enterprise needs to be revised if the document is submitted for approval by an undertaking operating on the basis of the activity licence.

(6) In the event of making such modifications in a dangerous enterprise or an enterprise with a major hazard, which result in a major-accident risk or an increase thereof, the Technical Regulatory Authority will communicate the respective information to the local authority for the assessment of the need for initiating planning proceedings. The local authority will assess the need for initiating planning proceedings and inform the Technical Regulatory Authority of its opinion within 30 days as of the receipt of the communication.

(7) The competent authorities cooperate upon performance of their functions, thereby exchanging information on the mandatory documents and on the approval of the documents. A summary of the approved data sheet and risk analyses will be sent by the Technical Regulatory Authority to the local authority of the location of the enterprise so that the local authority could take notice thereof.

(8) Requirements for the mandatory documents of dangerous enterprises and enterprises with a major hazard and to drawing up such documents will be established by a regulation of the minister responsible for the field.

§ 24. Informing of public

(1) The operator of an enterprise with a major hazard must preventively inform the public and the persons who may be located in the accident impact zone about the major-accident risk arising from the enterprise, safety precautions and advisable conduct in the event of an accident.

(2) In the event of an accident in a dangerous enterprise or enterprise with a major hazard, the operator will immediately inform persons located in the accident impact zone about the accident.

(3) At request, the operator of an enterprise with a major hazard will publish the list of hazardous chemicals handled in the enterprise and a summary of the risk analysis, which includes at least information about the major-accident risk, possible consequences to human life and health and to the environment, the size of the impact zone and, in the event of a major accident, the mandatory code of conduct. At request, the operator of a dangerous enterprise will publish a summary of the risk analysis. The summary of the risk analysis will also be submitted to the Technical Surveillance Authority.

(4) If a modification planned in the handling of a hazardous chemical results in exposure to a major-accident risk or a substantial increase thereof, the planning proceedings or environmental impact assessment proceedings will ensure that the public is given the chance to express their opinion before implementing it.

(5) The Rescue Board will communicate information on a cross-border major-accident risk arising from a category A enterprise with a major hazard to states that may be affected by such accident.

(6) Requirements for information given to the public and for notification of an accident will be established by a regulation of the minister responsible for the field.

§ 25. Liability insurance of operator of enterprise liable to be affected by major accident

(1) The operator of an enterprise with a major hazard must have liability insurance for indemnifying non-contractual and unlawful damage that may be caused to a third party (hereinafter *injured party*) upon handling a chemical in the enterprise.

(2) A liability insurance contract must comply with the following terms and conditions:

1) the insurance contract has been made with the insurer who has the right to insure an insurable risk located in Estonia;

2) the insurance contract covers at least direct material damage and, in the event of damage to health, physical injury or the causing of death, also the loss of profit, unless otherwise provided by law;

3) the insured event is an unexpected occurrence relating to the handling of a chemical that the operator is in charge of, which arises from the properties of the handled chemical and as a result of which the damage specified in subsection (2) of this section has been caused to the injured party.

(3) The operator must choose a sum insured that is reasonable, considering the place of business relating to handling chemicals, the quantity and the manner of handling of chemicals, the scope of the operations and of possible damage arising therefrom, and other circumstances. The sum insured must cover at least the requirements covered by clause 2) of subsection (2) of this section and must not be smaller than 400 000 euros.

(4) A liability insurance contract concluded on the basis of this Act does not have to cover damage caused:

1) by the worsening of the quality of the environment by the operator, except for reasonable expenses relating to first rescue operations for elimination of initial damage and prevention of greater damage;

2) to property in the possession of the operator;

3) due to a defective product in the possession of the injured party whereby the provisions of § 1061 of the Law of Obligations Act apply;

4) as a result of an insured event wilfully caused by the injured party.

(5) The insurer has the right to refuse to conclude a liability insurance contract if the operator refuses to submit a risk analysis and other evidence that allows for identifying the circumstances that the insurer considers important for assessing the insurable risk.

§ 26. Authorisation obligation

(1) In an establishment, a hazardous chemical may be handled in a quantity above the minimum level or the threshold level only on the basis of an operation authorisation.

(2) An authorisation is not required under this Act if a hazardous chemical is handled on the basis of an integrated environmental permit issued under the Industrial Waste Act or on the basis of an authorisation granted under the Explosive Substances Act or the Weapons Act the proceedings of which also cover the requirements contained in the object of inspection of the operation authorisation in accordance with this Act. This does not preclude the performance of other duties or adherence to other requirements arising from this Act.

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§ 27. Application for operation authorisation

(1) To obtain an operation authorisation, an application must be submitted to the Technical Regulatory Authority. The mandatory documents required by this Act are annexed to the application.

(2) A state fee must be paid for reviewing the application.

(3) The Technical Regulatory Authority will decide the application by granting an operation authorisation or refusing to grant an operation authorisation. The time limit for reviewing the application is 60 working days as of the date of receipt of all the required documents. The time limit for reviewing an application may be extended once by up to 30 working days. If the need to organise an environmental impact assessment has become evident upon reviewing the application, the time limit for approval may be extended until a decision to declare the environmental impact assessment report compliant with the requirements has been made. If the

Technical Regulatory Authority does not decide the application within the aforementioned time limit or within the extended time limit, the operation authorisation will not be deemed to have been granted by default.

(4) The Technical Regulatory Authority will inform the local authority of the location of the enterprise about the application for an operation authorisation. The local authority will submit its opinion on the compliance of the planned operations with the plan in force within 30 working days after the receipt of the information.

(5) The Technical Regulatory Authority will forward the risk analysis, safety report and emergency plan of the enterprise to the Rescue Board for approval. The Rescue Board will approve the forwarded documents or refuse to approve them with reason within 30 working days as of the receipt of the documents. The time limit may be extended once by up to 30 working days. If the need to organise an environmental impact assessment has become evident, the time limit for approval may be extended until a decision to declare the environmental impact assessment report compliant with the requirements has been made. If a document has not been approved within the aforementioned time limit or within the extended time limit, it will not be deemed to have been approved by default.

(6) The requirements provided for in § 23 of this Act apply to the reviewing and approval of the mandatory documents.

(7) If the need to amend the plan becomes evident in the operation authorisation proceedings and the respective amendment of the plan is initiated, the operation authorisation proceedings may be suspended until the completion of the planning proceedings.

§ 28. Object of inspection of operation authorisation

An operation authorisation will be granted to a person if:

- 1) the operation of an establishment is, given the surroundings of the establishment and the hazard and risk arising from the establishment, is possible, including if, upon building the establishment or making such alteration thereto, which result in the risk of a major accident or an increase of the risk, the risks to the surroundings have been taken into account and sufficient measures have been taken to reduce these risks;
- 2) the mandatory documents comply with the requirements provided for in § 23 of this Act;
- 3) the establishment is in accordance with the plan.

§ 29. Suspension and revocation of operation authorisation

(1) If a ground for revoking an operation authorisation becomes evident, the Technical Regulatory Authority may, given the weight of the circumstances, temporarily suspend the validity of the operation authorisation. The operation authorisation will be suspended until the circumstance has been eliminated or lapsed.

(2) The Technical Regulatory Authority may revoke the operation authorisation if:

- 1) the person has given false information;
- 2) the person has repeatedly or substantively violated the safety requirements and thus caused an accident hazard;
- 3) the activities of the person in the enterprise no longer correspond to the activities described in the documents serving as the basis for issuing the operation authorisation, the hazards have clearly increased as a result of such activities and the person has failed to notify of the changed activities within the prescribed time limit and in accordance with the prescribed procedure;
- 4) by the activities permitted under the operation authorisation, the person has caused serious harm to the public order or a hazard that did not exist or was unknown at the time of granting the operation authorisation, outweighs the person's interest in continuing the operations and cannot be eliminated by amending the operation authorisation;
- 5) the person has not kept the mandatory documents up to date or adhered to a respective precept;
- 6) the person has terminated the activity serving as the basis for the operation authorisation.

§ 30. Consequences of suspension and revocation of operation authorisation

(1) In the event of suspension or revocation of the operation authorisation, the operator must ensure the safety of the enterprise. The handling of the chemical may be continued only to the extent required for ensuring safety.

(2) If the circumstance serving as the basis for suspension of the operation authorisation has not been eliminated or lapsed within the time limit of suspension of the operation authorisation, the Technical Regulatory Authority will revoke the operational authorisation.

(3) To fulfil the requirement provided for in subsection (1) of this section, the Technical Regulatory Authority may apply substitutive enforcement in accordance with the procedure provided for in the Substitutive Enforcement and Penalty Payment Act.

§ 31. Notification and publication of operational authorisation

(1) The Technical Regulatory Authority will inform the Rescue Board, the Environmental Board and the Environmental Inspectorate and the local authority of the location of the enterprise about the granting of the operation authorisation, suspension of the validity thereof and revocation of the operation permit.

(2) The Technical Regulatory Authority will make the operation authorisation public via a technical surveillance information system established on the basis of the Equipment Safety Act.

§ 32. Special requirements for planning land use and designing construction works

(1) Upon planning land use and granting design specifications and building permits, circumstances arising from the establishment must be taken into account. Thereby:

- 1) establishments with domino effects must be identified;
- 2) buildings and facilities, such as highways, public places and residential areas located in the vicinity of the existing establishment must be taken into account if the location of the buildings and facilities may increase the risk of a major accident or the severity of the consequences of a major accident;
- 3) for the purpose of ensuring safety, preserve the required distance between the establishment and residential districts, public buildings and areas, recreational areas and, where possible, between the main transport lines;
- 4) protect areas in the vicinity of the establishment that are of special interest in terms of nature or that are especially sensitive, ensuring a safe distance to that end or by taking other relevant measures;
- 5) where necessary, take additional measures in the existing establishment;
- 6) in the event of an increase of the risk of a major accident or severity of the consequences thereof, ensure the notification of the public and persons who may be located in the impact zone of an accident arising from the establishment.

(2) In the framework of the process of taking into account the circumstances listed in subsection (1) of this section, the operator of a dangerous enterprise or an enterprise with a major hazard must provide sufficient information about risks and hazards arising from the enterprise if the competent authority requests it for drawing up a plan or for granting design specifications or a building permit.

(3) If in the planning and design phase, a strategic environmental assessment or an environmental impact assessment is organised, the risks and hazards relating to the establishment will be assessed and the public will be informed in the course of these proceedings.

(4) The comprehensive, special or detailed spatial plans (hereinafter *plan*) and building design documentation must be submitted to the Rescue Board for approval in the following events:

- 1) upon selection of the location of a new establishment;
- 2) upon expansion of the operations of an existing establishment or increasing production, provided that a plan needs to be initiated or amended or a building permit needs to be granted for such an activity;
- 3) upon planning an area located in the danger zone of a dangerous enterprise and of an enterprise with a major hazard or upon planning construction works there.

(5) Upon approval, the Rescue Board assesses:

- 1) whether the plan or construction works increases the major-accident hazard or the severity of the consequences thereof;
- 2) whether the measures planned for prevention of an accident are sufficient;
- 3) before the establishment of the plan or granting of a building permit, the operator of the establishment must submit additional information to the local authority and to the Rescue Board.

(6) The Rescue Board may refuse to grant its approval if the activity planned in the plan or in the building design documentation increases the risk of a major accident or the severity of the consequences thereof and the measures planned for the prevention of an accident are not sufficient.

Chapter 4 COMPETENT AUTHORITIES IN FIELD OF CHEMICALS AND STATE SUPERVISION

Division 1 Competent Authorities in Field of Chemicals

§ 33. Competence of Health Board

The Health Board is a competent authority whose functions in the field of chemicals are as follows:

- 1) to perform administrative functions and take administrative steps based on Regulation (EU) 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals (OJ L 201, 27.07.2012, pp. 6#106) (hereinafter *PIC Regulation*), which regulates banned and severely restricted chemicals;
- 2) to ensure the communication of information related to intoxication to the population and medical staff and perform the functions in accordance with Article 45 of the CLP Regulation;
- 3) to perform administrative functions and take administrative steps on the basis of the Detergents Regulation;

- 4) to perform the tasks allotted to competent authorities of the Member States under the REACH Regulation regarding substance evaluation, preparing dossiers in compliance with Annex XV to the REACH Regulation and performing other relevant administrative functions;
- 5) to contribute to the work of the committees and the forum established under the REACH Regulation and to that of their working groups, and to cooperate with the European Commission and the European Chemicals Agency;
- 6) to perform the functions of the national helpdesk in accordance with Article 124 of the REACH Regulation and to provide advice to manufacturers, importers, downstream users and any other interested parties on their respective responsibilities and obligations under the Regulation, in particular in relation to the registration of substances;
- 7) to perform the functions imposed on the competent authorities of the Member States by the CLP Regulation regarding making proposals for harmonised classification and labelling of substances and performing other relevant administrative functions;
- 8) to perform the functions of the national helpdesk in accordance with Article 44 of the CLP Regulation and provide advice to interested parties on their respective responsibilities and obligations under the CLP Regulation;
- 9) to submit to the European Chemicals Agency a report on official inspections and other measures of ensuring fulfilment of the requirements of the REACH Regulation and CLP Regulation;
- 10) to concert the monitoring of fulfilment of the requirements of the REACH Regulation and CLP Regulation.

§ 34. Competence of Rescue Board

The Rescue Board is a competent authority whose functions in the field of chemicals are as follows:

- 1) to participate in the operation authorisation proceedings of a dangerous enterprise and enterprise with a major hazard as well as in the approval of the respective mandatory documents, thereby assessing, among other things, the risk of occurrence of a major accident, a description of the severity and extent of the consequences, the measures for mitigation of the consequences, and readiness for an emergency;
- 2) based on information received from dangerous enterprises and enterprises with a major hazard, to identify establishments or groups of establishments that may cause domino effects, and inform enterprises of the respective group thereof;
- 3) to draw up the extra-enterprise emergency plan for a category A enterprise with a major hazard;
- 4) within the limits of its competence, to participate in international cooperation and exchange information with the competent authorities of other states and with international organisations;
- 5) to inform the European Commission about a major accident in an enterprise with a major hazard;
- 6) to make recommendations for readiness for an emergency and measures of mitigation of the consequences of further accidents.

§ 35. Competence of Technical Regulatory Authority

The Technical Regulatory Authority is a competent authority whose functions in the field of chemicals are as follows:

- 1) to grant operation authorisations for dangerous enterprises and enterprises with a major hazard, including approve the mandatory documents, assessing the establishment of hazardousness, accident prevention measures and principles of prevention of a major accident;
- 2) within the limits of its competence, to participate in international cooperation and exchange information with the competent authorities of other states and with international organisations;
- 3) communicate to the European Commission the names, addresses and activities of enterprises with a major hazard;
- 4) to make recommendations for accident prevention measures.

§ 36. Competence of Police and Border Guard Board

The competence of the Police and Border Guard Board includes performance of the duties of a national contact point specified in Article 9(2) of Council Regulation (EU) No 98/2013.

§ 37. Chemical Safety Commission

(1) The Chemical Safety Commission is an advisory body established by the Ministry of Social Affairs, which comprises of representatives of government agencies and other experts.

(2) The functions of the Chemical Safety Commission:

- 1) to assess current problems concerning chemical safety;
- 2) to make assessments and express opinions on the chemical safety policy and strategies;
- 3) to make proposals to government agencies for development and application of chemical safety strategies;
- 4) to assess legislation and draft legislation governing chemical safety;
- 5) to make proposals to the minister responsible for the field for carrying out chemical safety surveys, publishing chemical safety publications, organising chemical safety training and harmonising chemical safety terminology;
- 6) to exchange information and make proposals for coordinating the activity of different institutions in the field of chemical safety.

Division 2

State Supervision

§ 38. State supervision

(1) The authorities specified in this section exercise, within the limits of their competence, state supervision over the compliance with the requirements of this Act and legislation established on the basis thereof as well as over the compliance with the requirements of the relevant regulations of the European Union regarding substances, mixtures, articles containing substances and mixtures and handling such articles.

(2) The Environmental Inspectorate is competent to exercise supervision over the following:

- 1) compliance with the requirement for registration and authorisation of substances established by the REACH Regulation, compliance with the chemical safety data sheet and the exposure scenarios set out therein, and adherence to restrictions established from the point of view of environmental hazardousness;
- 2) compliance with the labelling and packaging requirements established by the CLP Regulation;
- 3) compliance with other relevant requirements for handling chemicals hazardous to the environment at the objects of supervision in its field.

(3) The competence of the Rescue Board includes exercising supervision over the prevention of accidents in dangerous enterprises and enterprises with a major hazard, mitigating the consequences of possible accidents and informing the public.

(4) The Consumer Protection Board is competent to exercise supervision over the following:

- 1) compliance with the requirements established by the REACH and CLP Regulations for labelling and packaging substances and mixtures in retail trade;
- 2) compliance with the restrictions imposed by Annex XVII to the REACH Regulation for the placing on the market and use of substances, mixtures and articles in retail trade;
- 3) compliance with the requirements established by the Detergents Directive for placing detergents on the market in retail trade;
- 4) compliance with the requirements for marketing precursors of restricted explosives in accordance with Council Regulation (EU) No 98/2013.

(5) The competence of the Technical Regulatory Authority includes exercising supervision over the following:

- 1) adherence to the requirements that form a part of the object of inspection of the operation authorisation of a dangerous enterprise and enterprise with a major hazard as well as adherence to the requirement for liability insurance;
- 2) keeping of records of a hazardous chemical in a dangerous enterprise and enterprise with a major hazard;
- 3) adherence to the requirements for placing gaseous fuel on the market.

(6) The Health Board is competent to exercise supervision over the following:

- 1) compliance with the obligations and requirements imposed by the REACH and CLP Regulations on the manufacturers and importers of substances and mixtures and producers of articles as well as compliance with requirements established to substances, mixtures and articles at their manufacturer and importer and in wholesale trade;
- 2) compliance with the requirements established by the Detergents Directive for placing detergents on the market in retail trade;
- 3) compliance with the obligations established by the PIC Regulation for exporters and importers, the category and area of use of imported chemicals;
- 4) keeping of records of hazardous chemicals.

(7) The Labour Inspectorate is competent to exercise supervision over the following:

- 1) compliance by downstream users with the requirements established by the REACH and CLP Regulations for downstream users of substances and mixtures and compliance on the downstream user's premises with the requirements established to substances, mixtures and articles;
- 2) compliance with the occupational health and safety requirements in enterprises handling chemicals and over keeping records of hazardous chemicals.

(8) The Tax and Customs board participates in state supervision by verifying the following:

- 1) in accordance with Article 17 of the PIC Regulation, compliance with the requirements for the export and import of the chemicals listed in Annex I to the Regulation and the requirements for the export of the chemicals listed in Annex V to the Regulation;
- 2) the document that certifies resistance to detonation of high nitrogen ammonium nitrate;
- 3) upon entry of a chemical and an article containing it in the Community market in accordance with the requirements set out in Section 33 of Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.08.2008, pp. 30–47), the existence of a registration or authorisation in accordance with the REACH Regulation;

4) the import of a substance, mixture and article which is subject to a prohibition or restriction on placing on the market in accordance with Annex XVII to the REACH Regulation and other legislation.

§ 39. Special measures of state supervision

The law enforcement authority may, for the purpose of exercising the state supervision provided for in this Act, take special measures of state supervision provided for in §§ 30, 31, 32, 44, 45, 49, 50, 51, 52 and 53 of the Law Enforcement Act on the grounds and in accordance with the procedure provided for in the Law Enforcement Act.

§ 40. Specifics of state supervision

(1) The law enforcement agency exercising supervision over the compliance with the requirements of the REACH and CLP Regulations submits to the Health Board, at the request of the latter, the data prescribed in Article 127 of the REACH Regulation for drawing up a report specified in Article 117 and the data required for drawing up a report specified in Article 46 of the CLP Regulation.

(2) Upon exercising supervision over enterprises with a major hazard, the Technical Regulatory Authority and the Rescue Board take into account the duties arising from Article 20 of Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.07.2012, pp. 1–C0#3F37). A hazard forecast drawn up for the purpose of exercising state supervision must contain at least the following data:

- 1) general assessment of safety issues;
- 2) geographical area of establishments covered by the hazard forecast;
- 3) list of establishments covered by the hazard forecast;
- 4) list of establishments whereby domino effects may emerge;
- 5) list of establishments whereby extra-establishment hazards may increase the major-accident risk or the severity of the consequences thereof;
- 6) types of the proceedings used;
- 7) cooperation with other authorities.

(3) The representative of the employees, the trustee of employees and the working environment representative of a dangerous enterprise and enterprise with a major hazard have the right to attend the supervisory inspection carried out at the establishment by the Technical Regulatory Authority and the Rescue Board, except where the supervisory official does not consider it necessary.

§ 41. Use of direct coercion

The Environmental Inspectorate is authorised to use physical force on the grounds and in accordance with the procedure established in the Law Enforcement Act.

§ 42. Rate of penalty payment

In the event of failure to comply with a precept the maximum penalty payment imposed in accordance with the procedure provided for in the Substitutive Enforcement and Penalty Payment Act is 32 000 euros.

Chapter 5 LIABILITY

§ 43. Violation of requirements for keeping records of hazardous chemical

(1) The penalty for failure to keep records of a hazardous chemical or existence of serious deficiencies in keeping records is a fine of up to 200 fine units.

(2) The penalty for the same act committed by a legal person is a fine of up to 2600 euros.

§ 44. Violation of requirements for handling and safety of chemical

(1) The penalty for violation of the requirements for handling and safety of a chemical set out in this Act and in regulations established on the basis thereof, requirements for placing on the market of detergents and surface active substances used therein established in the Detergents Regulation and requirements for the export and import of hazardous chemicals established in the PIC Regulation is a fine of up to 300 fine units.

(2) The penalty for the same act committed by a legal person is a fine of up to 32 000 euros.

§ 45. Violation of requirements for making available, introduction, possession and use of precursor of restricted explosive

(1) The penalty for violation of the requirements for making available, introduction, possession or use of the precursor of an explosive restricted in accordance with Regulation (EU) No 98/2013 of the European Parliament and of the Council is a fine of up to 300 fine units.

(2) The penalty for the same act committed by a legal person is a fine of up to 32 000 euros.

§ 46. Failure to notify of suspicious transaction made with explosive precursor as well as of loss and theft of explosive precursor

(1) The penalty for failure to notify of a suspicious transaction made with a substance or mixture specified in Annex II to Regulation (EU) No 98/2013 of the European Parliament and of the Council as well as for failure to notify of a suspicious transaction made with the precursor of a restricted explosive is a fine of up to 300 fine units.

(2) The penalty for the same act committed by a legal person, –
is a fine of up to 20 000 euros.

[RT I, 29.06.2018, 3 - entry into force 01.07.2018]

§ 47. Violation of requirements established by REACH Regulation

(1) The penalty for violation of the requirements established by the REACH Regulation is a fine of up to 300 fine units.

(2) The penalty for the same act committed by a legal person is a fine of up to 23 000 euros.

§ 48. Violation of requirements established for dangerous enterprise and enterprise with major hazard

(1) The penalty for the handling of a hazardous chemical not specified the data sheet by a dangerous enterprise or an enterprise with a major hazard or for the handling of a hazardous chemical by the same in a quantity that considerably exceeds the quantity specified in the data sheet as well as for violation of other requirements established to the operations of a dangerous enterprise or an enterprise with a major hazard, if it posed a threat to human life or health or the environment, is a fine of up to 300 fine units.

(2) The penalty for the same act committed by a legal person is a fine of up to 32 000 euros.

§ 49. Violation of requirements for classification, labelling and packaging of chemicals

(1) The penalty for violation of requirements for classification, labelling and packaging of chemicals arising from the CLP Regulation is a fine of up to 300 fine units.

(2) The penalty for the same act committed by a legal person is a fine of up to 8400 euros.

§ 50. Proceedings

(1) Extrajudicial proceedings of the misdemeanours provided for in §§ 43, 44, 47 and 49 of this Act are conducted, within the limits of their competence, by:

- 1) the Labour Inspectorate;
- 2) the Environmental Inspectorate;
- 3) the Consumer Protection Board;
- 4) the Health Board.

(2) Extrajudicial proceedings of the misdemeanour provided for in § 43 of this Act are conducted by the Technical Regulatory Authority with regard to dangerous enterprises and enterprises with a major hazard.

(3) Extrajudicial proceedings of the misdemeanours provided for in §§ 44 and 47 of this Act are conducted by the Tax and Customs Board within the limits of its competence.

(4) Extrajudicial proceedings of the misdemeanours provided for in §§ 45 and 46 of this Act are conducted by the Police and Border Guard Board and within the limits of its competence and with regard to § 45, the Consumer Protection Board and, with regard to import from a third country, the Tax and Customs Board.

(5) Extrajudicial proceedings of the misdemeanour provided for in § 48 of this Act are, within the limits of their competence, conducted by:

- 1) the Rescue Board;
- 2) the Technical Regulatory Authority.

(6) The authority conducting extrajudicial proceedings may confiscate the substance, mixture or article that is prohibited to be placed on the market or subject to restrictions under other legislation and that constitutes the means or direct object of commitment of the misdemeanour provided for in this Act.

Chapter 6

IMPLEMENTING PROVISIONS

§ 51. Transitional provisions

(1) A person specified in subsection 15 (3) of this Act must submit a notice of economic activities in the field of wholesale trade in accordance with the General Part of the Economic Activities Code Act not later than by 1 March 2016.

(2) The operator of a dangerous enterprise or enterprise with a major hazard must, not later than by 1 June 2016, submit a data sheet renewed in accordance with the requirements arising from this Act and legislation established on the basis thereof.

(3) The operator of an enterprise with a major hazard must, by 1 June 2016, submit the emergency plan of the enterprise renewed in accordance with the requirements arising from this Act and legislation established on the basis thereof if modifications have been made to the enterprise's risk analysis.

(4) An enterprise that was not a dangerous enterprise or an enterprise with a major hazard, operated before the entry into force of this Act and becomes a dangerous enterprise or an enterprise with a major hazard as of the entry into force of Directive 2012/18/EU of the European Parliament and of the Council may operate without an operation authorisation compliant with this Act until 1 June 2016.

(5) A dangerous enterprise or an enterprise with a major hazard, which operated before the entry into force of this Act and whose hazardousness category changes in connection with the entry into force of Directive 2012/18/EU of the European Parliament and of the Council must make the required changes in its mandatory documentation and submit them for approval not later than by 1 June 2016.

(6) An act committed by a person before the entry into force of this Act, which can be penalised as a misdemeanour under this Act, is qualified on the basis of the section providing for the elements of the misdemeanour set out in this Act.

§ 52. –§ 57. Provisions amending other Acts have been omitted from this translation.

§ 58. Repealing of Act

The Chemicals Act (RT I 1998, 47, 697) is hereby repealed.

§ 59. Entry into force of Act

This Act will enter into force on 1 December 2015.

¹Directive 2004/9/EC of the European Parliament and of the Council on the inspection and verification of good laboratory practice (OJ L 50, 20.02.2004, pp. 28–43), amended by Regulation (EC) No 219/2009 (OJ L 87, 31.03.2009, pp. 109–154); 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 (OJ L 50, 20.02.2004, pp. 44–59), amended by Regulation (EC) No 219/2009 (OJ L 87, 31.03.2009, pp. 109–154); Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.07.2012, pp. 1–37); Directive 2013/30/EU of the European Parliament and of the Council on safety of offshore oil and gas operations and amending Directive 2004/35/EC (OJ L 178, 28.06.2013, pp. 66–106).