Biocides Act[1]

Passed 12 May 2004

(RT[2] I 2004, 45, 315),

entered into force 27 May 2004.

Chapter 1

General Provisions

§ 1. Scope of application of Act

(1) This Act provides the requirements for the handling of biocidal products and supervision over compliance with the requirements for the handling of biocidal products.

(2) This Act does not apply to chemicals used as biocidal products if they are used as:

1) plant protection products within the meaning of the Plant Protection Act (RT I 2004, 32, 226);

2) medicinal products, including immunologic preparations, within the meaning of the Medicinal Products Act (RT I 1996, 3, 56; 49, 954; 1997, 93, 1564; 1998, 36/37, 554; 1999, 58, 608; 2001, 53, 308; 2002, 18, 97; 53, 336; 62, 377; 63, 387; 82, 480; 2003, 26, 156; 88, 591);

3) medical devices or cosmetic products within the meaning of the Public Health Act (RT I 1995, 57, 978; 1996, 3, 56; 49, 953; 1997, 37/38, 569; 1999, 30, 415; 88, 804; 2001, 23, 128; 2002, 32, 187; 53, 336; 61, 375; 63, 387; 90, 521; 2003, 26, 156 and 160);

4) food additives or artificial flavourings, in materials and articles intended to come into contact with food, or as chemicals prescribed for compliance with the hygiene requirements for milk, egg and fishery products within the meaning of the Food Act (RT I 1999, 30, 415; 2002, 13, 81; 61, 375; 63, 387; 102, 603; 2004, 27, 177; 34, 236);

5) medical feedingstuffs, additives in feedingstuffs, products used in animal nutrition or feed materials within the meaning of the Feedingstuffs Act (RT I 2002, 18, 97; 63, 387; 2003, 48, 340; 88, 591; 2004, 34, 236).

(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 into account the specifications provided for in this Act.

§ 2. Biocidal products

(1) Biocidal products are active substances or preparations containing one or more active substances intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism.

(2) Low-risk biocidal product is a biocidal product which contains one or more of active substances and which does not contain any substances of concern and which, under the conditions of use, does not pose a risk to humans, animals or the environment.

(3) Harmful organism means any organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or for the environment.

(4) Substances of concern mean any substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to create such an effect. Active substances are not substances of concern.

§ 3. Active substance

(1) Active substance means a substance or micro-organism including a virus or a fungus having general or specific action on or against harmful organisms.

(2) Active substances used in biocidal products are classified as follows:

1) active substances permitted for inclusion in biocidal products;

2) active substances permitted for inclusion in low-risk biocidal products;

3) basic substances permitted for inclusion in biocidal products, which may be used as liquefiers, solvents or diluents in biocidal products or, in some cases, also as biocidal products, but which are generally used otherwise.

(3) The lists of active substances to be used in biocidal products are established by the Commission regulation.

§ 4. Placing of biocidal product on market

(1) Placing of a biocidal product on the market means any supply or subsequent storage of the biocidal product. Importation of a biocidal product is also deemed to constitute placing of the biocidal product on the market.

(2) Storage followed by disposal or exportation of a biocidal product from the customs territory of the European Union is not deemed to be placing on the market.

§ 5. Residues

For the purposes of this Act, residues are substances present in a biocidal product which remains as a result of its use including the metabolites of such substances and products resulting from their degradation or reaction.

§ 6. General requirements for handling of biocidal products and active substances

(1) A biocidal product may be placed on the market and used only if an authorisation has been granted for the placing on the market or use of the biocidal product or the biocidal product is registered, unless otherwise provided for in this Act.

(2) Regardless of the provisions of subsection (1) of this section, the basic substances specified in clause 3 (2) 3) of this Act may be placed on the market and used as biocidal products.

(3) Active substances may be placed on the market only as biocidal products or their ingredients. Active substances included in the list of active substances may be placed on the market in order to include them in the composition of a biocidal product if they are classified, packaged and labelled as required.

(4) As an exception, active substances not included in the list of active substances may be placed on the market in order to include them in the composition of a biocidal product if a dossier which complies with the requirements of this Act is communicated to Member States of the European Union and the active substances to be placed on the market are supplied with information that the active substances are prescribed to be included in the composition of the biocidal product and the active substances are classified, packaged and labelled as required.

(5) The provisions of subsection (4) of this section do not apply to substances used pursuant to § 29 of this Act.

(6) Information on biocidal products which may be used in Estonia shall be entered in the biocides register. The biocides register is a national register which is founded and the statutes of which are established by the Government of the Republic.

§ 7. Competent authority

(1) The acts and operations provided for in this Act are performed and the administrative acts provided for in this Act are issued by the Chemicals Notification Centre, unless otherwise provided for in this Act.

(2) The Chemicals Notification Centre shall inform the Commission and the competent authorities of other Member States of the European Union (hereinafter Member States) of any biocidal products which have been authorised to be placed on the market or registered and of all other decisions specified in §§ 14–29 of this Act at the end of each quarter.

(3) The Chemicals Notification Centre shall draw up an annual list of the biocidal products authorised to be placed on the market or registered and shall communicate that list to the Commission and the competent authorities of other Member States of the European Union.

(4) If a dossier is communicated to the Chemicals Notification Centre in connection with proceedings for inclusion of an active substance in the list of active substances commenced in another Member State of the European Union or a temporary authorisation relating to a biocidal product granted in another Member State, the Chemicals Notification Centre shall organise the evaluation of the dossier. The Chemicals Notification Centre shall promptly inform the Commission and the competent authorities of other Member States of the European Union if the dossier fails to comply with the requirements.

Chapter 2

Lists of Active Substances

§ 8. Inclusion of active substance in list and removal of active substance from list

(1) Inclusion of active substances in a list of active substances mandatory for the Member States of the European Union (hereinafter list) and removal of active substances from the list shall be decided by the Commission.

(2) An active substance shall be included in the list for up to ten years if the biocidal products, low-risk biocidal products or basic substances used in biocidal products which contain the active substance meet the requirements provided for in subsections 17 (2)-(4) of this Act.

§ 9. Application for inclusion of active substance in list

(1) In order to include an active substance in the list, an applicant shall submit the following to the Chemicals Notification Centre:

1) a standard format application;

2) a dossier for the active substance satisfying the requirements;

3) a dossier for at least one biocidal product containing the active substance which is intended to be used.

(2) The format of applications for inclusion of an active substance in the list shall be established by a regulation of the Minister of Social Affairs.

(3) Before the submission of an application, a state fee shall be paid according to the rates provided for 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).

(4) Before expiry of the term provided for in the list, the renewed inclusion of an active substance in the list may be applied for a period of ten years.

§ 10. National proceedings regarding inclusion of active substance in list

(1) The Chemicals Notification Centre shall verify whether the submitted dossiers comply with the requirements.

(2) If dossiers comply with the requirements, the Chemicals Notification Centre shall communicate a summary of the dossiers to the Commission and the competent authorities of other Member States of the European Union, shall commence evaluation of the content of the dossiers and inform the applicant thereof.

(3) The Chemicals Notification Centre has the right to receive additional information from an applicant for full evaluation of an active substance to be made and the Commission and the competent authorities of other Member States of the European Union shall also be informed of the request for additional information.

(4) An evaluation shall be carried out within twelve months. The term for proceedings shall be suspended from the date of submission of a request for additional information until the date the additional information is received.

(5) The Chemicals Notification Centre shall send a copy of the evaluation results to the Commission and the competent authorities of other Member States of the European Union and to the applicant and shall recommend to include the active substance in the list or refuse inclusion of the active substance in the list.

(6) If the renewed inclusion of an active substance in the list is applied for, the Chemicals Notification Centre may, if necessary, grant an authorisation for use of the active substance until completion of the evaluation proceedings, including the time for the submission of additional information specified in subsection (3) of this section.

§ 11. Rejection of application for inclusion of active substance in list

The Chemicals Notification Centre shall reject an application for inclusion of an active substance in the list if:

1) the results of evaluation of the active substance indicate that, under regular conditions according to which the active substance may be used in authorised biocidal products, it poses a risk to health or the environment;

2) a similar active substance included in the list of active substances presents a significantly lower level of risk to health or the environment, taking into account the developments in science and technology.

§ 12. Initiation of amendment of list of active substances

(1) The Chemicals Notification Centre may, at any time, initiate proceedings regarding amendment of the list or removal of an active substance from the list if:

1) the active substance included in the list is suspected not to meet with a requirement set thereto;

2) under regular conditions according to which the active substance included in the list may be used in authorised biocidal products, a risk to health or the environment arises;

3) the active substance permitted for inclusion in biocidal products and included in the list of active substances presents a significantly lower level of risk to health or the environment, taking into account the developments in science and technology.

(2) A person may apply for amendment of the list if the person submits the following to the Chemicals Notification Centre:

1) a dossier for the active substance satisfying the requirements;

2) a dossier for at least one biocidal product in which the active substance is used.

§ 13. National proceedings regarding refusal to include active substance in list and amendment of list

(1) If refusal to include an active substance in the list and removal of an active substance from the list is considered, an assessment of an alternative active substance or substances shall take place to demonstrate that it can be used with similar effect on the target organism without significant economic and practical disadvantages for the user and without an increased risk for health or for the environment.

(2) The Chemicals Notification Centre shall communicate a reasoned proposal to refuse inclusion of an active substance in the list or the results of an evaluation carried out to amend the list to the Commission and the competent authorities of other Member States of the European Union. The proposal to refuse inclusion of the active substance in the list shall also be sent to the applicant.

(3) The refusal to include an active substance in the list and removal of an active substance from the list shall be carried out under the following conditions:

1) the chemical diversity of the active substances should be adequate to minimise occurrence of resistance in the target organism;

2) the active substance, when used under normal conditions in authorised biocidal products, presents a significantly different level of risk;

3) it should be applied only to active substances used in products of the same product type;

4) it should be applied only after allowing the possibility of acquiring experience from use in practice, if it is not already available.

Chapter 3

Permission to Place Biocidal Products on Market

Division 1

Authorisation for Placing on Market of Biocidal Products

§ 14. Application for authorisation

(1) A person who wishes to place a biocidal product on the market in Estonia for the first time or a representative thereof shall submit a written application for an authorisation for placing on the market of the biocidal product to the Chemicals Notification Centre. An applicant for the authorisation must be registered as an undertaking in the Republic of Estonia or in another Member State of the European Union or a branch of the applicant must be registered in the Republic of Estonia or in another Member State of the European Union.

(2) Upon application for an authorisation, the following shall be submitted to the Chemicals Notification Centre:

1) a standard format application;

2) an identity document of the applicant for the authorisation or a representative thereof and, in the case of a representative, documents certifying the right of representation or their notarially authenticated copies, and documents which certify that the applicant or a branch thereof is registered in the Republic of Estonia or in another Member State of the European Union;

3) a dossier for the biocidal product;

4) dossiers for active substances contained in the biocidal product.

(3) Applications shall be submitted in Estonian.

(4) Before the submission of an application, a state fee shall be paid according to the rates provided for in the State Fees Act.

(5) The format of applications for an authorisation for placing on the market of a biocidal product and the format of the authorisations shall be established by a regulation of the Minister of Social Affairs.

(6) The Chemicals Notification Centre shall prepare materials which sum up the application regarding each application and at least a copy of the application, a list of decisions made regarding the application and summaries of the dossiers shall be appended to the materials.

(7) The Chemicals Notification Centre shall submit the summary materials at the request of the Commission and the competent authorities of other Member States of the European Union and shall also forward all the information which is necessary to understand the content of the application or evaluate a dossier.

§ 15. Review of applications

(1) The Chemicals Notification Centre shall review an application for an authorisation promptly but not later than within 120 days as of submission of the application.

(2) The Chemicals Notification Centre shall decide to satisfy or reject an application on the basis of the submitted dossiers.

(3) If necessary, the Chemicals Notification Centre shall demand that the applicant submit additional material. Among other things, additional information on tests already conducted and the conduct of additional tests or submission of tests on a biocidal product or its active substances may be requested.

(4) If additional materials are requested, the term for the review of an application is deemed to commence as of submission of all the materials necessary for decision-making.

§ 16. Frame-formulation of biocidal product

(1) Frame-formulation of a biocidal product means specifications for a group of biocidal products having the same use and user type and this group contains the same active substances of the same specifications and biocidal products which belong to the same group. A variation in the frame-formulation of a biocidal product is the allowance of a reduction in the percentage of the active substance or basic substance or an alteration in percentage composition of one or more non-active substances or the replacement of one or more pigments, dyes, perfumes by others presenting the same or a lower risk, and which do not decrease the efficacy of the biocidal product.

(2) The Chemicals Notification Centre shall, on request of the holder of an authorisation or on its own initiative, establish a frame-formulation of a biocidal product and communicate it to the holder of the authorisation.

(3) If a biocidal product complies with the frame-formulation of a biocidal product which is already authorised or registered, the applicant for the authorisation may submit, in addition to the documents specified in subsection 14 (2) of this Act, also the written consent of the person to whom the frame-formulation of the biocidal product was issued regarding grant of access to the frame-formulation of the biocidal product.

(4) If a biocidal product complies with the frame-formulation of a biocidal product which is already authorised or registered, the term for the review of an application is up to 60 days if the applicant for the authorisation has submitted the written consent of the person specified in subsection (3) of this section regarding access to the frame-formulation of the biocidal product.

§ 17. Conditions of grant of authorisation

(1) In order to receive an authorisation, active substances contained in a biocidal product must be included in the list specified in subsection 3 (3) of this Act.

(2) It shall be possible to determine the nature and quantity of the active substances of a biocidal product and any toxicologically or ecotoxicologically significant impurities and co-formulants, and its residues of toxicological or environmental significance.

(3) Upon evaluation, the effect of a biocidal product shall be determined in the light of current scientific and technical knowledge and on the basis of the requirements for the evaluation of dossiers established in this Act or legislation issued on the basis thereof, the possible presumed conditions of use of the biocidal product, the possibilities to use materials treated with the biocidal product and the possible consequences of use and destruction of the biocidal product to make sure that, when properly used for the purpose intended, the biocidal product:

1) is sufficiently effective;

2) has no unacceptable effect on the target organisms such as resistance or cross-resistance, and, in the case of vertebrate animals, unnecessary suffering and pain;

3) has no unacceptable effects itself or as a result of its residues, directly on human or animal health or indirectly through drinking water, food, feedingstuffs or indoor air;

4) has no unacceptable effects itself or as a result of its residues on surface water and groundwater;

5) has no unacceptable effect itself, or as a result of its residues, on the environment having particular regard to its fate and distribution in the environment, contamination of surface waters, groundwater and drinking water and its impact on non-target organisms;

6) has no other effects prohibited by legislation.

(4) The physical and chemical properties of a biocidal product must have been determined and be deemed acceptable for purposes of the appropriate handling of the product.

(5) Grant of an authorisation shall be refused if the requirements provided for in this section are not complied with and compliance therewith cannot be sufficiently guaranteed by establishing secondary conditions of the authorisation and if inaccurate or misleading information is submitted.

(6) The Chemicals Notification Centre may temporarily refuse to grant an authorisation for the placing on the market of a biocidal product which complies with the requirements provided for in this section if the Centre finds that the biocidal product may be harmful in terms of human or animal health or to the environment. In the specified case, the Chemicals Notification Centre shall communicate materials for the final decision-making to the Commission and shall inform the Commission and the competent authorities of other Member States of the European Union of the decisions made and the reasons therefor.

§ 18. Secondary condition of authorisation

(1) The secondary condition of an authorisation is a restriction established on the placing on the market or handling of an authorised biocidal product which may mean restriction of the authorised use of the biocidal product, the user type of the biocidal product, the conditions for handling or placing on the market or determination of the quantity of the biocidal product which may be handled.

(2) An authorisation may establish secondary conditions if they help to ensure compliance with the requirements provided for in § 17 of this Act.

§ 19. Term of authorisation

(1) An authorisation shall be granted for an unspecified term for up to ten years.

(2) The term of an authorisation shall not exceed the shelf-life of the active substance contained in the biocidal product.

(3) The term of an authorisation may be extended after the holder of the authorisation has submitted the documents specified in subsection 14 (2) of this Act and if the requirements provided for in § 17 of this Act are complied with at the same time.

(4) Upon submission of an application, an applicant shall take the terms for the processing of applications for authorisations into account.

§ 20. Grant of authorisation for placing on market of biocidal products authorised in Member State of European Union

(1) An authorisation for the placing on the market of a biocidal product which is authorised in a Member State of the European Union shall be granted taking into account the specifications provided for in this section.

(2) In order to apply for an authorisation, the documents specified in clauses 14 (2) 1) and 2) of this Act, an authorisation granted in a Member State of the European Union and summaries of the dossiers specified in clauses 14 (2) 3) and 4) of this Act or the notarially authenticated copies of their translations into Estonian shall be submitted.

(3) The term for the processing of documents specified in subsection (2) of this section is up to 120 days.

(4) If the Chemicals Notification Centre decides that a biocidal product authorised to be placed on the market on the basis of an authorisation granted in a Member State of the European Union does not comply with the requirements provided for in § 17 of this Act and the Centre decides to refuse grant of an authorisation or to establish secondary conditions by the authorisation, the Centre shall promptly inform the Commission and the competent authorities of other Member States of the European Union and the applicant for the authorisation of the decision and the reasons therefor.

(5) The Chemicals Notification Centre may refuse to grant an authorisation for the placing on the market of biocidal products which are used for the control of birds, fish and animal parasites. The Chemicals Notification Centre shall inform the Commission and the competent authorities of other Member States of the European Union of the decision and the reasons therefor.

§ 21. Amendment of authorisation

(1) The Chemicals Notification Centre shall amend an authorisation:

1) in order to ensure compliance with the requirements provided for in § 17 of this Act;

2) at the request of the holder of the authorisation.

(2) If a holder of an authorisation applies for amendment of the authorisation, the holder shall justify the application thereof and shall submit the information necessary for the decision-making to the Chemicals Notification Centre. Before the submission of an application, a state fee shall be paid according to the rates provided for in the State Fees Act.

(3) The Chemicals Notification Centre may request that a holder of an authorisation submit additional material necessary for amendment of the authorisation.

(4) If, upon amendment of secondary conditions, restrictions on the placing on the market of a biocidal product are reduced, the reduction is permitted only to the extent in the case of which the requirements provided for in § 17 of this Act are still complied with.

(5) If amendment of a secondary condition of an authorisation brings about the need to amend the requirements provided for an active substance contained in a biocidal product, the proceedings prescribed in Chapter 2 shall be conducted before amendment of the authorisation.

§ 22. Revocation of authorisation

(1) The Chemicals Notification Centre shall revoke an authorisation if:

1) the active substance is no longer included in the list;

2) the biocidal product no longer complies with the requirements set out in § 17 of this Act:

3) the holder of the authorisation has, upon application for the authorisation, intentionally submitted inaccurate or misleading information;

4) so requested by the holder of the authorisation.

(2) Upon revocation of an authorisation on the initiative of the Chemicals Notification Centre, the Chemicals Notification Centre shall inform the holder of the authorisation of an intention to revoke the authorisation and the holder of the authorisation shall be allowed to present the opinion thereof.

(3) Upon revocation of an authorisation, a term may be granted for the destruction, storage, placing on the market or use of the existent supply of a biocidal product. The duration of the term shall be in accordance with the reasons for revocation of the authorisation, but shall not exceed six months.

(4) The Chemicals Notification Centre may temporarily suspend an authorisation granted for the placing on the market of a biocidal product which complies with the requirements provided for in § 17 of this Act if the Centre finds that the biocidal product may be harmful in terms of human or animal health. The Chemicals Notification Centre shall communicate materials for the final decision-making to the Commission and shall inform the Commission and the competent authorities of other Member States of the European Union of the decisions made and the reasons therefor.

Division 2

Registration of Biocidal Products

§ 23. General provisions

(1) Low-risk biocidal products may be placed on the market and used if they are registered with the Chemicals Notification Centre.

(2) The provisions of §§ 14-22 of this Act apply to the registration of low-risk biocidal products, taking into account the specifications provided for in §§ 23-25 of this Act.

(3) The format of registration applications and registration certificates shall be established by a regulation of the Minister of Social Affairs.

§ 24. Registration proceedings

(1) In order to register a low-risk biocidal product, an applicant shall submit a registration application together with the name and address of the applicant and the dossier of the low-risk biocidal product to the Chemicals Notification Centre.

(2) The Chemicals Notification Centre shall make a decision within 60 days as of receipt of the registration application and the dossier which complies with the requirements if the active substance contained in the biocidal product is included in the list of active substances permitted to be used in biocidal products or in the list of active substances permitted to be used in low-risk biocidal products.

(3) If, according to the Chemicals Notification Centre, a low-risk biocidal product registered in a Member State of the European Union does not comply with the description provided for in subsection 2 (2) of this Act, the Centre may temporarily refuse to register the product and shall promptly inform the competent authority responsible for the verification of the appropriate dossiers of its doubt.

(4) If the Chemicals Notification Centre and a competent authority of another Member State of the European Union do not reach an agreement on the matter of registration within 90 days, the materials shall be communicated for decision-making to the Commission pursuant to the procedure provided for in subsection 20 (4) of this Act.

(5) If the Chemicals Notification Centre decides that a biocidal product registered in another Member State of the European Union does not comply with the requirements provided for in § 17 of this Act, and the biocidal product must not be registered or secondary conditions must be determined by an authorisation, the provisions of subsection 20 (4) of this Act apply. If the Commission approves a decision of the Chemicals Notification Centre and communicates the matter to the competent authority of the Member State of the European Union which initially registered the biocidal product and the latter confirms the legality of the initial registration, the Chemicals Notification Centre is required to register the biocidal product.

§ 25. Acts to be performed if registration is challenged

(1) If another Member State of the European Union temporarily refuses registration of a low-risk biocidal product registered in the Republic of Estonia, the provisions of subsection 24 (4) of this Act apply.

(2) If, as a result of the contestation, another Member State of the European Union refuses registration of a biocidal product registered in the Republic of Estonia, the Chemicals Notification Centre shall re-review the registration decision and shall request additional information from the holder of the registration certificate, if necessary. The term for proceedings shall be suspended from the date of submission of a request for additional information until the date the additional information is received or until expiry of the term therefor.

(3) During re-review of a registration decision, the registration certificate shall not be revoked.

(4) As a result of a re-review of a registration decision, the Chemicals Notification Centre may, with a reasoned explanation, revoke the registration decision or once more confirm the legality of the registration decision.

Division 3

Exceptions to Grant of Authorisation

§ 26. Application of regulation relating to grant of authorisations

Sections 26-29 of this Act provide for the special cases of grant of an authorisation for the placing on the market of a biocidal product and the provisions of §§ 14-19 and 21-22 apply thereto, taking into account the specifications provided for in §§ 27-29 of this Act.

§ 27. Temporary authorisation for placing on market of biocidal products

(1) The Chemicals Notification Centre may grant a temporary authorisation for up to three years for the placing on the market of biocidal products which contain active substances not included in the list if the substances were not on the market before 14 May 1998. The authorisation may be granted if the marketing purposes do not include scientific research or development or process-orientated research and development. Such authorisation shall be granted until a decision on inclusion of the active substances in the list is made.

(2) A temporary authorisation may be granted if, after evaluation of the biocidal product and dossiers submitted by the applicant for the authorisation:

1) it is decided that the active substance complies with the requirements for inclusion in the list;

2) it is decided that the biocidal product complies with the requirements provided for in subsections 17 (2)-(4) of this Act;

3) no Member State of the European Union submits an objection regarding the completeness of the dossiers on the basis of the received summary.

(3) If the Standing Committee on Biocidal Products of the Commission has decided that an active substance does not comply with the requirements for inclusion of the active substance in the list, the Chemicals Notification Centre shall revoke the temporary authorisation immediately.

(4) If inclusion of an active substance in the list or evaluation of documents organised therefor is not completed after three years, the Chemicals Notification Centre may extent the temporary authorisation once more by up to one year if it is decided that the biocidal product complies with the requirements of subsection (2) of this section.

(5) The Chemicals Notification Centre shall inform the Commission and the competent authorities of other Member States of the European Union of decisions made on temporary authorisations.

§ 28. Grant of authorisation in exceptional circumstances

(1) The Chemicals Notification Centre may, in order to prevent unforeseen danger which cannot be contained by other means, grant an authorisation for the placing on the market of a biocidal product which does not comply with the requirements of this Act. The authorisation may be granted for a term of 120 days.

(2) The Chemicals Notification Centre shall inform the Commission and the competent authorities of other Member States of the European Union of the decision specified in subsection (1) of this section.

(3) The Chemicals Notification Centre may extend the term of a temporary authorisation on the basis of a corresponding decision of the Commission or shall revoke the authorisation if the Commission makes a corresponding decision.

§ 29. Scientific research and development

(1) By way of derogation from the requirements provided for in § 6 of this Act, the Chemicals Notification Centre may permit the use of an unauthorised biocidal product or active substance in scientific research and development or the placing on the market of a biocidal product or active substance for that purpose if:

1) in the case of scientific research and development, the persons concerned draw up and maintain written records detailing the properties of the biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product and compile a dossier containing all available data on the possible effects of the biocidal product or active substance on human or animal health and their impact on the environment or property. The specified information shall, if requested, be made available to the Chemicals Notification Centre;

2) in the case of process-oriented research and development, the information specified in clause 1) of this subsection is notified to the competent authority of the Member State of the European Union where and before placing on the market occurs and to the competent authority of the Member State of the European Union where the experiment or test is to be conducted.

(2) The Chemicals Notification Centre shall establish conditions for the experiment or test which may involve damage to the environment caused by unauthorised biocidal products or active substances, which limits the quantities to be used and the areas to be treated. The Chemicals Notification Centre may also establish further conditions.

Chapter 4

Dossier and Exchange of Information

§ 30. Dossier

(1) For the purposes of this Act, a dossier is a collection of materials which sets out the properties of a biocidal product or active substance and their effect to different organisms and the environment.

(2) A dossier shall be prepared correctly taking into account the level of modern knowledge and its contents shall not be misleading.

(3) A dossier shall set out the method of the tests and experiments conducted and an analysis of the results.

(4) A dossier need not set out information which is indicated in the dossier of a biocidal product with a frame-formulation which corresponds to the biocidal product if the applicant refers thereto and submits the written consent of the person who submits the dossier regarding granting access for the applicant to the frame-formulation of the biocidal product.

(5) The requirements for the content and preparation of a dossier shall be established by a regulation of the Minister of Social Affairs.

(6) If this Act provides a requirement to submit a dossier, the written consent of another person regarding granting access for the applicant to the dossier submitted thereby earlier may be submitted instead of the dossier.

§ 31. Use of information submitted by another person

(1) Upon processing an authorisation or a registration application, the Chemicals Notification Centre shall not make use of the information submitted thereto by another person in the Republic of Estonia or another Member State of the European Union in the course of processing a previous application for an authorisation or registration application in the interests of the applicant, except if the applicant has a written consent of the person who submitted the application regarding grant of access to the submitted information.

(2) In the absence of the consent specified in subsection (1) of his section, the information submitted by another person shall not be made use of in the interests of an applicant if the information concerns:

1) an active substance permitted to be used in biocidal products or an active substance permitted to be used in low-risk biocidal products, which was not placed on the market before 14 May 2000, until 15 years have passed since inclusion of the active substance in the list;

2) an active substance which was placed on the market before 14 May 2000, until 14 May 2010;

3) an active substance which was placed on the market before 14 May 2000 and which was submitted for inclusion in the list or for placing on the market of a biocidal product containing the active substance, until ten years have passed from submission of information concerning inclusion in the list or placing on the market;

4) amendment of the requirements for an active substance permitted to be used in biocidal products or an active substance permitted to be used in low-risk biocidal products or maintenance of such active substance in the list, until five years have passed from submission of the information or until expiry of the term provided for in clauses 1) or 2) of this subsection.

(3) If proceedings are conducted regarding deletion of active substances from the list, the Commission and competent authorities of the Standing Committee on Biocidal Products and Member States of the European Union may make use of the information, regardless of the provisions of subsections (1) and (2) of this section.

§ 32. Confidential information

(1) A person who has submitted an authorisation or a registration application may apply that the Chemicals Notification Centre declare information contained in its dossiers or information submitted in any other manner to be confidential. Information the disclosure of which might

harm the applicant industrially or commercially may be declared to be confidential. Full justification will be required in each case.

(2) The Chemicals Notification Centre shall take all the steps to ensure the confidentiality of information which is declared to be confidential pursuant to this Act and information received from the Commission or competent authorities of other Member States of the European Union as confidential.

(3) Confidential information may be communicated to the Commission or competent authorities of the Member States. Upon submission of such information, the Chemicals Notification Centre is required to indicate that the information is confidential.

(4) The Chemicals Notification Centre shall take steps to ensure the confidentiality of the full composition of biocidal product formulations if it is requested by the applicant.

(5) Confidentiality shall not apply to:

1) the name and address of the applicant;

2) the name and address of the biocidal product manufacturer;

3) the name and address of the active substance manufacturer;

4) the names and content of the active substances in the biocidal product and the name of the biocidal product;

5) the names of other substances which are regarded as dangerous within the meaning of the Chemicals Act (RT I 1998, 47, 697; 1999, 45, 512; 2002, 53, 336; 61, 375; 63, 387; 2003, 23, 144; 51, 352; 75, 499; 88, 591) and contribute to the classification of the biocidal product;

6) physical and chemical data concerning the active substance and biocidal product;

7) any ways of rendering the active substance or biocidal product harmless;

8) a summary of the results of the tests required to establish the substance's or product's efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance;

9) recommended methods and precautions to reduce dangers from handling as well as from fire or other hazards;

10) safety data sheets;

11) the methods of analysis;

12) the methods of disposal of the biocidal product and of its packaging;

13) the procedures to be followed and measures to be taken in the case of spillage or leakage of the biocidal product;

14) first aid and medical advice to be given in the case of injury to persons.

(6) If an applicant for an authorisation or for registration or the manufacturer or importer should later disclose previously confidential information, the Chemicals Notification Centre shall be informed accordingly.

§ 33. Cooperation between applicants

(1) An applicant for an authorisation for the placing on the market of biocidal products or for the registration of biocidal products shall, before carrying out experiments involving vertebrate animals, enquire of the Chemicals Notification Centre to which he intends making application whether the biocidal product for which an application is to be made is similar to a biocidal product for which authorisation has been granted or which is registered, and as to the name and address of the holder of the authorisation for or registration certificate of the similar biocidal product.

(2) The enquiry specified in subsection (1) of this section shall be supported by information or reference that the prospective applicant intends to apply for an authorisation on his own behalf.

(3) If the Chemicals Notification Centre finds that the intention of the person who filed an enquiry is supported by sufficient evidence, the Chemicals Notification Centre shall satisfy the enquiry, communicate the corresponding information to the person who filed the enquiry and inform the person whose details it communicated of the person who filed the enquiry.

(4) A person who intends to apply for an authorisation for the placing on the market of a biocidal product or for the registration of a biocidal product and the holder of an authorisation for a similar biocidal product or a person who has registered a similar biocidal product shall take all reasonable steps to reach agreement on the sharing of information, so as to avoid the duplication of testing on vertebrate animals.

(5) If it is impossible to reach an agreement, a person who intends to submit an application shall not conduct testing on vertebrate animals before the person has a permission of the Chemicals Notification Centre therefor.

(6) If no agreement is reached, the Chemicals Notification Centre may make a decision to disclose information concerning a similar biocidal product to a person who intends to apply for an authorisation for the placing on the market of a biocidal product or for the registration of a biocidal product or require a person who has received an authorisation for the placing on the market of the biocidal product or has registered the biocidal product to disclose the information. Upon making the decision, the Chemicals Notification Centre shall take into account the interest of the person who has received the authorisation for the placing on the market of the biocidal product or who has registered the biocidal product not to disclose the information and the public interest to avoid testing on vertebrate animals.

(7) If the Chemicals Notification Centre fails to make a decision specified in subsection (6) of this section, it grants permission for the conduct of testing on vertebrate animals.

§ 34. Obligation to communicate information

(1) A person who holds an authorisation or a registration certificate is required to immediately communicate information concerning a biocidal product or active substance which has not been communicated before and which may be important as regards validity of the authorisation or registration certificate to the Chemicals Notification Centre, including:

1) new knowledge on the effects of the biocidal product or active substance for human or animal health or their impact on the environment or property and the new composition of the biocidal product or active substance, its active substances, impurities, co-formulants or residues;

2) changes in the source of the active substance or in the composition of the biocidal product;

3) development of resistance in harmful organisms.

(2) The Chemicals Notification Centre shall communicate new information to the competent authorities of the Member States of the European Union, particularly information concerning potentially harmful effects of a biocidal product for human or animal health or its harmful impact for the environment or property or the new composition of the biocidal product, its active substances, impurities, co-formulants or residues.

Chapter 5

Placing on Market and Use of Biocidal Products

Division 1

Classification, Packaging and Labelling of Biocidal Products

§ 35. Classification of biocidal products

(1) Biocidal products shall be classified according to their use and target organism.

(2) The types and main use of biocidal products shall be established by a regulation of the Minister of the Social Affairs.

§ 36. Packaging and labelling of biocidal products

(1) Biocidal products shall be packaged arising from the type, main use and level of risk associated with the handling of the biocidal products and safety requirements for the biocidal products.

(2) Biocidal products which may be mistaken for food or feedingstuffs shall be packaged to minimize the likelihood of such a mistake being made.

(3) Biocidal products which may be mistaken for food or feedingstuffs shall contain components to discourage their consumption.

(4) Biocidal products shall be labelled in Estonian and information on the label of a packaging shall not be misleading or lead to the use of the biocidal product for non-specified purposes.

(5) Biocidal products shall be packaged pursuant to the requirements provided for in the Packaging Act (RT I 1995, 47, 739; 1997, 53, 836; 2002, 53, 336; 61, 375; 63, 387; 2003, 88, 591; 2004, 2, 6), the Chemicals Act and this Act.

(6) Biocidal products shall be labelled pursuant to the requirements provided for in the Chemicals Act and this Act

Division 2

Placing on Market of Biocidal Products

§ 37. Requirements for placing on market of biocidal products

(1) Biocidal products may be placed on the market if:

1) an authorisation has been granted for the biocidal product or the biocidal product is registered pursuant to the procedure provided for in this Act;

2) the shelf-life of the biocidal product has not expired.

(2) Biocidal products to be placed on the market must be classified, packaged and labelled pursuant to the requirements provided for in this Act. The requirements for packaging and labelling do not apply to the carriage of biocidal products.

(3) Retail trade in a biocidal product classified pursuant to the Chemicals Act as toxic, very toxic or as a category 1 or 2 carcinogen, or as a category 1 or 2 mutagen, or classified as toxic for reproduction category 1 or 2, is prohibited.

(4) The person responsible for placing biocidal products on the market shall ensure that the users are informed of the properties of the biocidal product and of the safe handling thereof.

§ 38. Storage and marketing facilities of biocidal products

(1) Biocidal products to be placed on the market shall be stored and marketed separately from raw material for food, food, medicinal products and feedingstuffs.

(2) There shall not be any open packages of biocidal products in the storage and marketing facilities of biocidal products.

(3) Biocidal products the packaging of which has broken shall not be placed on the market. If the broken packaging cannot be replaced, the biocidal products shall be rendered harmless pursuant to the procedure provided for in the Waste Act (RT I 2004, 9, 52; 30, 208), taking into account the information on the safety-data sheet for the biocidal products if necessary.

§ 39. Safety-data sheets for biocidal products and active substances

(1) The person responsible for placing biocidal products on the market shall prepare safety-data sheets for biocidal products and active substances classified as dangerous.

(2) Safety-data sheets shall be prepared according to the requirements provided for in the Chemicals Act.

(3) Safety-data sheets shall be provided to the users of the biocidal product before delivery of the biocidal product by the person responsible for placing biocidal products on the market. If a safety-data sheet is amended, the person responsible for placing biocidal products on the market shall send the amended safety-data sheet to all users with known details who have purchased the biocidal product during the last twelve months.

§ 40. Placing on market of biocidal products with expired shelf-life

(1) Biocidal products with expired shelf-life shall not be placed on the market, except in the case provided for in subsection (2) of this section.

(2) The marketing of a biocidal product with expired shelf-life may be continued within one year if the quality of the biocidal product before the continuation of marketing has been re-established by the applicant or by the authorised representative thereof and the Chemicals Notification Centre has granted its consent for the further marketing of the biocidal product. The packaging of the biocidal product shall include a notation concerning extension of the shelf-life.

(3) Compliance with the requirements of the properties of a biocidal product with expired shelf-life shall be proved by laboratory testing. A report of the results of the laboratory testing shall be available to the user at the marketing facilities.

§ 41. Advertising of biocidal products

The advertising of biocidal products shall comply with the requirements provided for in § 16^1 of the Advertising Act (RT I 1997, 52, 835; 1999, 27, 388; 30, 415; 2001, 23, 127; 50, 284; 2002, 53, 336; 61, 375; 63, 387; 2004, 27, 177).

Division 3

Use of Biocidal Products

§ 42. General requirements for use of biocidal products

A biocidal product shall be used in compliance with the requirements, taking into account the instructions for use, labelling and other conditions which restrict the use of the biocidal product.

§ 43. Organisation of pest control

(1) A person who uses biocidal products intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means (hereinafter pest control), has to use them only in the manner and under the conditions prescribed on the labelling and in the instructions for use of the biocidal products.

(2) A person may engage in pest control if the person:

1) is registered in the register of economic activities and

2) has a corresponding legal relationship with a specialist in charge specified in § 44 of this Act or the sole proprietor himself or herself is competent to act as a specialist in charge or

3) is employed with an employer and holds a certificate of professional qualifications specified in subsection 44 (2) of this Act.

(3) If a person engaged in pest control provides pest control as a service, the person must be an undertaking within the meaning of the Commercial Code (RT I 1995, 26–28, 355; 1998, 91–93, 1500; 1999, 10, 155; 23, 355; 24, 360; 57, 596; 102, 907; 2000, 29, 172; 49, 303; 55, 365; 57,

373; 2001, 34, 185; 56, 332 and 336; 89, 532; 93, 565; 2002, 3, 6; 35, 214; 53, 336; 61, 375; 63, 387 and 388; 96, 564; 102, 600; 110, 657; 2003, 4, 19; 13, 64; 18, 100; 78, 523; 88, 591).

(4) The requirements for the pest control conducted by biocidal products shall be established by a regulation of the Minister of Social Affairs.

§ 44. Specialist in charge

(1) A specialist in charge is a person who is competent to direct and organise pest control and consult undertakings such that compliance with the requirements provided by legislation is ensured.

(2) In order to direct and organise pest control, a specialist in charge shall hold a professional qualification within the meaning of the Professions Act (RT I 2001, 3, 7; 2002, 61, 375; 2003, 13, 68; 83, 559) which grants such person the right to organise the distribution of funds and the work of other persons and imposes on the person the obligation to be responsible for such work.

(3) Upon application for a professional qualification provided for in subsection (2) of this section, at least secondary education, professional in-service training, in-service training in management and three years' work experience in pest control are required.

§ 45. Registration

(1) An undertaking which wishes to engage in pest control shall submit to the register of economic activities a registration application which, in addition to the information specified in the Register of Economic Activities Act (RT I 2004, 12, 79), sets out:

1) a list of target organisms which are harmful organisms;

2) a list of the used biocidal products;

3) information concerning a specialist in charge of pest control and information relating to the certificate proving the professional qualifications of the specialist.

(2) The provisions in the Register of Economic Activities Act concerning registration proceedings apply to the making, amendment, suspension and deletion of a registration.

§ 46. Information related to intoxication

(1) The Chemicals Notification Centre shall communicate information related to intoxication included in a dossier to the Poison Information Centre. Such information may be used only in the case of a medical need, particularly in the event of accidents and in order to determine a method of prevention or treatment.

(2) Information related to intoxication shall not be used for the purposes not specified in subsection (1) of this section. Provisions ensuring the confidentiality of information apply to such information.

(3) Manufacturers or persons in charge of placing on the market are required to communicate all available information related to intoxication to the Chemicals Notification Centre.

Chapter 6

State Supervision

§ 47. Agencies exercising supervision

(1) State supervision over compliance with this Act and legislation established on the basis thereof shall be exercised by:

1) the Labour Inspectorate, over compliance with the occupational health and safety requirements in the fields regulated by 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);

2) the Environmental Inspectorate, over activities which damage or endanger the environment in the fields regulated by the Environmental Supervision Act (RT I 2001, 56, 337; 2002, 61, 375; 99, 579; 110, 653; 2003, 88, 591; 2004, 30, 209; 38, 258);

3) the Consumer Protection Board, over compliance with the requirements for the retail sale of biocidal products in the fields regulated by the Consumer Protection Act (RT I 2004, 13, 86);

4) the Tax and Customs Board, over compliance with the requirements for the importation, exportation and transit of biocidal products;

5) the Health Protection Inspectorate, over compliance with the safety requirements in wholesale trade and mass caterers, upon treatment of drinking water and bathing water, provision of services and in other fields regulated by the Public Health Act (RT I 1995, 57, 978; 1996, 3, 56; 49, 953; 1997, 37/38, 569; 1999, 30, 415; 88, 804; 2001, 23, 128; 2002, 32, 187; 53, 336; 61, 375; 63, 387; 90, 521; 2003, 26, 156 and 160);

6) the Veterinary and Food Board in the fields regulated by the Food Act (RT I 1999, 30, 415; 2002, 13, 81; 61, 375; 63, 387; 102, 603; 2004, 27, 177; 34, 236) and the Veterinary Activities Organisation Act (RT I 1999, 58, 608; 2002, 13, 79; 18, 97; 61, 375; 63, 387; 96, 566; 2004, 38, 257);

7) the Health Care Board, over compliance of providers of health care services with the safety requirements in the fields regulated by the Health Services Organisation Act (RT I 2001, 50, 284; 2002, 57, 360; 61, 375; 62, 377; 110, 661; 2003, 26, 157 and 160; 2004, 29, 192);

8) the Data Protection Inspectorate, over compliance with the requirements for data protection.

(2) Persons exercising supervision are required to:

1) present identification and explain the aim of the supervision and the operations involved to the person inspected;

2) in the event of violation of requirements, explain the nature of the violation to the person 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, except if maintaining it would endanger the health of persons or animals, the environment or property.

(3) Persons exercising supervision have the right to:

1) gain unrestricted access to the objects under inspection without giving prior notice, make measurements and take samples for analysis without charge;

2) demand explanations and documents from an operator and, with the knowledge of the operator or the representative thereof, use equipment in order to collect evidence;

3) take notes and receive extracts of documents necessary for the exercise of supervision from the operator.

(4) An operator is required to assist persons exercising supervision upon the performance of functions imposed thereon by this Act and other legislation.

§ 48. Precepts

(1) The director of an agency exercising supervision or an official authorised by the director has the right to issue a precept for termination of violations of the requirements of this Act or legislation issued on the basis thereof.

(2) A precept shall set out:

1) the name and position of the person preparing the precept and the name and address of the agency exercising supervision;

2) the place and date of issue of the precept;

3) the name and residence or location of the recipient of the precept;

4) the circumstances which are the basis for the issue of the precept or a reference to the document in which the circumstances are set out;

5) the legal basis for the issue of the precept;

6) the conclusion of the precept which shall set out the obligations of the recipient of the precept and the term for performance of the obligations;

7) a reference to the possibility of a penalty payment being applied upon failure to perform the obligations set out in the precept;

8) the procedure and term for contesting the precept;

9) the signature of the person who prepares the precept.

(3) A precept shall be prepared in two original copies of which one shall remain with the person who prepares the precept and the other shall be given to the recipient of the precept.

(4) If it is necessary to inform a third party of the precept, a copy of the precept certified by the person who prepared the precept shall be delivered to the third party by post or by electronic means.

§ 49. Contestation of precept

(1) Upon disagreement with a precept of a supervisory official, the recipient of the precept has the right to file a written challenge with the head of the agency which exercises supervision within ten working days as of the date on which the recipient of the precept became or should have become aware of the contested precept.

(2) The director of the agency exercising supervision shall review a challenge and make a decision within ten working days as of the date on which the challenge is filed. The supervisory official against whose precept the challenge is filed shall not participate in the review of the challenge.

(3) The filing of a challenge shall not discharge the recipient of the precept from the obligation to comply with the precept. The director of the agency exercising supervision may suspend compliance with a contested precept if the circumstances specified in § 81 of the Administrative Procedure Act occur until a decision is made on the challenge.

§ 50. Penalty payment

(1) Upon failure to comply with a precept within the term specified in the precept, a person exercising supervision has the right to impose a penalty payment as a coercive measure pursuant to the procedure provided for in the Substitutive Enforcement and Penalty Payment Act (RT I 2001, 50, 283; 94, 580).

(2) The upper limit of penalty payment specified in subsection (1) of this section is 10 000 kroons.

Chapter 7

Liability

§ 51. Violation of requirements for placing on market of biocidal products

(1) Failure to apply for an authorisation for the placing on the market of a biocidal product or failure to comply with the registration requirement 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.

§ 52. Violation of requirements for handling of biocidal products and active substances or violation of safety requirements or requirement to maintain confidentiality of information

(1) Violation of the requirements for the handling of biocidal products and active substances or violation of safety requirements or the requirement to maintain confidentiality of information 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.

§ 53. Proceedings

(1) The provisions of the General Part of the Penal Code (RT I 2001, 61, 364; 2002, 86, 504; 82, 480; 105, 612; 2003, 4, 22; 83, 557; 90, 601; 2004, 7, 40) and of the Code of Misdemeanour Procedure (RT I 2002, 50, 313; 110, 654; 2003, 26, 156; 83, 557; 88, 590) apply to proceedings regarding the misdemeanours provided for in §§ 51 and 52 of this Act.

(2) The agencies specified in subsection 47 (1) of this Act shall, within the limits of their competence, conduct extra-judicial proceedings in the matters of the misdemeanours provided for in §§ 51 and 52 of this Act.

Chapter 8

Implementing Provisions

§ 54. Transitional provisions

(1) Biocidal products which contain active substances listed in Annexes to the Commission Regulation No. 2032/2003 on the second phase of the 10-year work programme concerning the placing of biocidal products on the market (OJ L 307, 24.11.2003, p. 1–96) and which have been placed on the market before the entry into force of this Act may be placed on the market without an authorisation or without registration until 1 September 2006 and they shall be registered pursuant to the simplified procedure.

(2) In order to register the biocidal products specified in subsection (1) of this section pursuant to the simplified procedure, the applicant shall submit a written application to the Chemicals Notification Centre before 1 September 2006. Upon submission of the application, the applicant shall take into account the terms for proceedings regarding registration of biocidal products.

(3) Engagement in pest control without being registered in the register of economic activities is permitted until 1 January 2005.

§ 55. Amendment of State Fees Act

Chapter 7 of 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) is amended by adding Division 20^5 worded as follows:

“Division 20^5

Acts Performed on Basis of Biocides Act

§ 190^7. Grant of authorisation for placing on market of biocidal product, registration of biocidal products and inclusion of active substances in list of active substances

(1) A state fee of 5000 kroons shall be paid for the processing of an authorisation for the placing on the market of a biocidal product and proceedings regarding inclusion of an active substance in the list of active substances.

(2) A state fee of 2500 kroons shall be paid for the registration of a biocidal product.

(3) A state fee of 500 kroons shall be paid for the amendment of an authorisation for the placing on the market of a biocidal product or a registration certificate of a biocidal product.

(4) A state fee of 25 kroons per A4-format page shall be paid for a certified transcript of a register entry.

(5) A state fee of 500 kroons shall be paid for the registration of biocidal products containing active substances listed in Annexes to the Commission Regulation No. 2032/2003 (OJ L 307, 24.11.2003, p. 1–96) if the registration application is submitted before 1 September 2006.

§ 56. Amendment of Chemicals Act

Subsection 7 (2) of the Chemicals Act (RT I 1998, 47, 697; 1999, 45, 512; 2002, 53, 336; 61, 375; 63, 387; 2003, 23, 144; 51, 352; 75, 499; 88, 591) is amended by adding clauses 8) and 9) worded as follows:

„8) grant an authorisation for and register biocidal products imported into the Republic of Estonia or manufactured in the Republic of Estonia;

9) maintain a biocides register and be the authorised processor of the biocides register."

§ 57. Amendments to Public Health Act

Clause 8 (2) 20) of the Public Health Act (RT I 1995, 57, 978; 1996, 3, 56; 49, 953; 1997, 37/38, 569; 1999, 30, 415; 88, 804; 2001, 23, 128; 2002, 32, 187; 53, 336; 61, 375; 63, 387; 90, 521; 2003, 26, 156 and 160) is repealed.

§ 58. Amendment of Advertising Act

The Advertising Act (RT I 1997, 52, 835; 1999, 27, 388; 30, 415; 2001, 23, 127; 50, 284; 2002, 53, 336; 61, 375; 63, 387; 2004, 27, 177) is amended by adding § 16[1] worded as follows:

„§ 16[1]. Advertising of biocidal products

(1) Every advertisement for a biocidal product shall be accompanied by the sentences *"Biotsiidi kasutada ohutult! Enne kasutamist alati lisatud teave läbi lugeda!"* [Use biocidal products safely. Always read the label and product information before use].

(2) The sentences provided for in subsection (1) of this section shall be clearly distinguishable in relation to the whole advertisement.

(3) Advertisers may replace the word *"biotsiid"* [biocidal product] with an accurate description of the product-type being advertised.

(4) Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to man or the environment.

(5) Under no circumstances may the advertising of a biocidal product mention "*madala riskiastmega biotsiid*" [low-risk biocidal product], *"mittetoksiline*" [non-toxic], "*tervisele ohutu*" [harmless] or any similar indications."

§ 59. Amendment of Value Added Tax Act

In clause 15 (2) 3) of the Value Added Tax Act (RT I 2003, 82, 554; 2004, 30, 208), the words "Health Protection Inspectorate" are replaced by the words "Chemicals Notification Centre".

§ 60. Entry into force of Act

This Act enters into force on the day following the date of publication thereof in the *Riigi Teataja*.

[1] Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 123, 24.04.1998, p. 1–63).

[2] RT = *Riigi Teataja = State Gazette*