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Biocidal Products Act[1]

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Chapter 1
GENERAL PROVISIONS

§ 1. Scope of application of Act

(1) This Act establishes the requirements and conditions applicable to biocidal products and the marketing and use thereof as well as for the state supervision over compliance with the established requirements for the purpose of ensuring the safety of biocidal products to human and animal health and to the environment.

(2) This Act does not apply to the following products:
1) plant protection products regulated by the Plant Protection Act and relevant legislation of the European Union;
2) medicinal products regulated by the Medicinal Products Act and relevant legislation of the European Union;
3) medical devices regulated by the Medical Devices Act;
4) cosmetic products regulated by the Public Health Act;
5) materials or articles intended to come into contact with food or an ingredient thereof, which are regulated by the Food Act and relevant legislation of the European Union;
6) food or food additives, enzymes, artificial flavourings or processing aids regulated by the Food Act and relevant legislation of the European Union;
7) feed regulated by the Feed Act.
[RT I 2010, 37, 224 – entry into force 09.07.2010]

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

§ 2. Biocidal product and harmful organism

(1) ‘Biocidal product’ means an active substance, active substances or a preparation containing one or more active substances in the form supplied to the user with the intention of destroying, deterring, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by chemical or biological means.

(2) ‘Low-risk biocidal product’ means a biocidal product which contains as active substance(s) only one or more of those listed in Annex I A to 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, pp. 1–63) (hereinafter *Biocidal Products Directive*) and does not contain any substances of concern and which, under the conditions of use, poses only a low risk to humans, animals and 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.

§ 3. Components and residues of biocidal product

(1) ‘Active substance of a biocidal product’ (hereinafter *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 which may be used in biocidal products and are listed in Annex I to the Biocidal Products Directive;
2) low-risk active substances which may be used in biocidal products and are listed in Annex I A to the Biocidal Products Directive. These active substances are not carcinogenic, mutagenic, toxic for reproduction, sensitising or bioaccumulative and do not readily degrade;
3) basic substances listed in Annex I B to the Biocidal Products Directive. As a general rule, a basic substance is not used or marketed as a biocidal product, but in certain cases it is used as a biocide either directly or in a product consisting of the substance and a simple dilution which itself is not a substance of concern.

(3) A biocidal product may contain a substance of concern that has an inherence 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 present risks of such an effect. As a general rule, a substance of concern is a dangerous substance for the purposes and under the Chemicals Act or a substance whose unwanted effect is supported by evidence. A substance of concern is not an active substance for the purposes of this Act.

(4) For the purposes of this Act, ‘residues’ means one or more of the substances present in a biocidal product, the metabolites of such substances or substances resulting from their degradation or reaction, or compounds which remain as a result of using a biocidal product.

§ 4. Biocidal product-types

Based on their use, biocidal products are divided into four main groups and 23 product-types under Annex V to the Biocidal Products Directive.

§ 5. Letter of access

For the purposes of this Act, 'letter of access' means a written agreement of the owner(s) of the data of studies, which gives the competent authority the consent to use the data specified in and protected by this Act when granting a biocidal product authorisation to another applicant.

§ 6. Competent authority

The steps specified in this Act are taken and the administrative decisions specified in this Act are made by the Health Board, unless otherwise provided by this Act.

§ 7. [Omitted – RT I 2010, 37, 224 – entry into force 09.07.2010]

§ 8. General requirements for placing on market and use of biocidal product and active substance

(1) The placing of a biocidal product or an active substance on the market means an activity by which the biocidal product or active substance is, whether in return for payment or free of charge, made available for use or distribution in the customs territory of the European Community. Importation and storage of a biocidal product and an active substance is also deemed to constitute placing on the market, unless storage is followed by their export or removal from circulation.

(2) An active substance may be placed on the market for the purpose of using it as a biocidal product or as a component of a biocidal product only if the substance has been included in Annex I, I A or I B of the Biocidal Products Directive.

(3) A biocidal product may placed on the market and used in Estonia if it has received proper authorisation from the Health Board (hereinafter *authorisation*), unless otherwise provided for in this Act.

Chapter 2
INCLUSION OF ACTIVE SUBSTANCE IN ANNEX TO BIOCIDAL PRODUCTS DIRECTIVE

§ 9. General conditions of inclusion of active substance in annex to Biocidal Products Directive

(1) An active substance is included in Annex I, I A or I B of the Biocidal Products Directive on the basis of a decision of the European Commission if it complies with the established requirements and, where necessary, the possible cumulative effects arising from the use of biocidal products containing the same active substance has been taken into account. The active substance is included in the relevant annex, indicating the product-type in whose composition it is permitted to use the active substance and the term of validity of the inclusion.

(2) An active substance is included in an annex to the Biocidal Products Directive for the first time for up to ten years. If necessary, the term of the inclusion of the active substance in the annex may be renewed, but not for more than ten years at a time.

(3) The inclusion of an active substance in an annex to the Biocidal Products Directive may be reviewed at any time if there is information that the active substance no longer complies with the established requirements. The inclusion of the active substance may be renewed for the period that is spent on submitting and reviewing additional materials.

§ 10. Applying for inclusion of active substance and additional product-type for use of active substance in annex to Biocidal Products Directive

(1) To include an active substance in Annex I, I A or I B to the Biocidal Products Directive, the applicant must, at one's own discretion, submit the following to the competent authority of a Member State:
1) a dossier on the active substance, which complies with the requirements of the relevant parts of Annex II A or Annex IV A and, where necessary, Annex III A to the Biocidal Products Directive;
2) the dossier or the biocidal product containing the active substance, which complied with the requirements of the relevant parts of Annex II B or IV B and, where necessary, Annex III B to the Biocidal Products Directive.

(2) To use an active substance included in Annex I, I A or I B to the Biocidal Products Directive in a product-type not included in an annex, the application must submit the following to the competent authority for the purpose of including the new product-type in an annex:
1) the dossier specified in clause 1) of subsection (1) of this section or the relevant letter of access;
2) the dossier specified in clause 2) of subsection (1) of this section.

§ 11. Proceedings of inclusion of active substance and additional product-type for use of active substance in annex to Biocidal Products Directive

(1) If the applicant wants to have the dossiers processed in Estonia, the applicant must:
1) submit the documents required in § 10 of this Act to the Health Board on paper as well as digitally;
2) submit to the Health Board a proposal for approval of an expert chosen for the professional evaluation of the dossiers along with reasons for the suitability of the expert;
3) immediately after the existence of the data required in the dossiers and relevant documents (hereinafter *completeness of dossier*) have been verified and the dossier has been declared complete, organise the professional evaluation of the dossiers by the relevant expert approved by the Health Board.

(2) The professional evaluation of dossiers may be carried out by an independent Estonian or foreign natural or legal person who

has experience in the professional evaluation of the dossiers of biocidal products, plant protection products or other similar substances (hereinafter *evaluator*). The evaluator must take into account the requirements provided for in this Act and the relevant instructions of the European Commission for professional evaluation.

(3) The Health Board will evaluate the prior experience and independence of the expert chosen by the applicant and inform the applicant about the suitability of the expert or submit a reasoned opinion on the unsuitability of the expert. If the Health Board does not approve the choice of expert, the applicant will submit a new proposal.

(4) The Health Board will examine the completeness of the submitted dossiers within three months after the submission of the dossiers. This period may be renewed to up to six months if the competent authorities of the other Member States and the European Commission need to be consulted on the completeness of the dossiers. The Health Board will immediately inform the applicant in writing about declaring the dossiers complete.

(5) If the dossiers have been declared complete, the applicant will send the English summaries of the dossiers to the European Commission and the competent authorities of other Member States.

(6) If necessary, the evaluator has the right to receive further information for the professional evaluation of the active substance and the applicant must inform the Health Board thereof. The Health Board must inform the European Commission and the competent authorities of other Member States about a request for further information.

(7) The professional evaluation must be made within 12 months after the dossiers have been declared complete. The time designated for evaluation is not included in the period between the submission of a request for further information and the receipt of further information.

(8) The applicant will submit a summary of the results of the professional evaluation to the Health Board immediately after the expiry of the term specified in subsection (7).

(9) The Health Board will send a copy of the summary of the evaluation results to the European Commission, the competent authorities of other Member States and to the applicant along with the recommendation to include the active substance in Annex I, I A or I B to the Biocidal Products Directive or to refuse to do so.

(10) After the dossiers have been declared complete, the Health Board has the right to submit to the European Commission a request to appoint another Member State as the further processor of the dossiers.

§ 12. Refusal to include active substance and additional product-type for use of active substance in annex to Biocidal Products Directive and exclusion of active substance from annex

(1) The inclusion of an active substance or an additional product-type in an annex to the Biocidal Products Directive will be refused or an active substance will be excluded from an annex if the following circumstances exist:
1) as a result of an evaluation of the active substance it becomes evident that in the biocidal product to be placed on the market the active substance is used in such conditions that there is a significant risk to human and animal health or to the environment;
2) another substance that, given the current scientific and technical knowledge, poses a much smaller risk to human and animal health or to the environment has already been included in Annex I for use in biocidal products of the same product-type;
3) the chemical composition of alternative active substances is sufficient to minimise the possibilities of occurrence of resistance in the harmful organism that constitutes the target organism.

(2) In the event of refusal to include an active substance or an additional product-type in an annex to the Biocidal Products Directive or in the event of exclusion of an active substance from the annex, it must be identified that the alternative active substance has the same impact on the target organism, the use thereof will not result in significant adverse economic effects on the user and the health or environmental risks will not increase. Upon evaluation of these circumstances, the procedure established in § 11 of this Act is followed.

(3) If the inclusion of an active substance or an additional product-type in Annex I, I A or I B to the Biocidal Products Directive is refused or if an active substance is excluded from an annex, the competent authority will send to the European Commission the dossiers submitted for evaluation.

Chapter 3
AUTHORISATION OF PLACING BIOCIDAL PRODUCT ON MARKET

Division 1
Authorisation

§ 13. Conditions of granting authorisation

(1) The Health Board will grant authorisation to a biocidal product if all the active substances of the product have been included in Annex I or I A to the Biocidal Products Directive, the conditions established therein have been fulfilled and the following conditions have been fulfilled on the basis of the data given in the dossier of the biocidal product, taking into account the prescribed terms of use of the biocidal product, the prescribed terms of use of materials treated with the biocidal product and the possible consequences of use and destruction of the biocidal product:
1) the biocidal product is sufficiently effective;
2) the biocidal product has no unacceptable effect on the target organism such as resistance or cross-resistance and unnecessary suffering and pain for vertebrates;
3) the biocidal product or its residues have no unacceptable direct effect on human or animal health or indirect effect via drinking water, food, feed, the air of living and working premises or otherwise;
4) the biocidal product or its residues have no unacceptable effect on the environment, taking into account the behaviour and mobility of the biocidal product in the environment, the possible contamination of surface water, groundwater or drinking water and the impact of the biocidal product on non-target organisms;

5) the physical and chemical properties of the biocidal product have been determined and they are deemed acceptable for the purposes of the appropriate use, storage and transport of the biocidal product.

(2) It must be possible to identify the nature and quantity of the active substances of a biocidal product and, where necessary, toxicologically or ecotoxicologically significant impurities or other components or residues created upon permitted use of the biocidal product in accordance with Annex II A, II B, III A, III B, IV A or IV B of the Biocidal Products Directive.

(3) Upon processing the authorisation of a biocidal product, the provisions established by other legislation that regulates the matters of the protection of the health of distributors, users and consumers of biocidal products, protection of the health of animals, and protection of the environment.

(4) In order to ensure the compliance of a biocidal product with the requirements established in subsection (1) of this section, the authorisation may set out restrictions on the marketing and use of the biocidal product, above all, set out the permitted use of the biocidal product, users of the biocidal product, restriction of the conditions of marketing or using the product or the threshold quantities permitted upon use of the product.

(5) A biocidal product that has been classified 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, must not be authorised for marketing to, or use by the consumer for the purposes of the Consumer Protection Act.

§ 14. Applying for authorisation

(1) An authorisation can be applied by a person responsible for placing the biocidal product on the market in Estonia for the first time or their representative who has been registered in Estonia or another Member State as an undertaking or who has an office in Estonia or another Member State.

(2) Upon applying for an authorisation, the following must be submitted to the Health Board:
1) a biocidal product dossier that complies with the requirements of the relevant parts of Annex II B and, where necessary, Annex III B to the Biocidal Products Directive, a low-risk biocidal product dossier or a relevant letter of access;
2) a biocidal product dossier that complies with the requirements of the relevant parts of Annex II A and, where necessary, Annex III A to the Biocidal Products Directive regarding each active substance contained in the biocidal product or a relevant letter of access;
3) a proposal for the approval of the expert chosen for the professional evaluation of dossiers along with the reasons of the suitability of the expert.

(3) Upon applying for an authorisation, the dossiers and other relevant documents must be submitted in Estonian or English on paper as well as digitally.

(4) The Health Board will create a folder or file regarding each application, which contains at least the administrative decisions made on the application and the dossiers as well as summaries of the dossiers.

(5) The Health Board will submit the materials specified in subsection (4) of this section to the European Commission or to the competent authorities of other Member States at their request and, if necessary, send them the entire information that is necessary for understanding the substance of the application as well as ensure that the applicant submits a copy of the dossier when requested.

§ 15. Biocidal product dossier

(1) The biocidal product dossier sets out the results of studies and the required information in accordance with the relevant parts of Annex II A and Annex II B and, where necessary, Annex III A and Annex III B of the Biocidal Products Directive. The dossier must contain a detailed description of the studies as well as a detailed description of the methods used or bibliographic references to the methods used. The information given in the dossier on the properties of the biocidal product or its active substance and effect must be sufficient to assess the compliance of the biocidal product or active substance with the requirements established in subsection 13 (1).

(2) Upon applying for an authorisation of a low-risk biocidal product, a dossier with the following information must be submitted to the Health Board:
1) the applicant’s name and registry code or personal identification code and the address of the branch or office;
2) the contact details of the manufacturer of the biocidal product and active substance, and the address of the place of manufacture;
3) if possible, the relevant letter of access;
4) the trade name of the biocidal product;
5) the full composition of the biocidal product;
6) the physical and chemical properties of the biocidal product, which are appropriate to the use, storage and transport of the biocidal product;
7) the product-type and use of the biocidal product;
8) the users of the biocidal product;
9) the method of application of the biocidal product;
10) the efficacy data of the biocidal product;
11) the analytical methods;
12) the classification, packaging and labelling of the biocidal product along with specimen of the labelling;
13) the safety data sheet of the biocidal product.

(3) Information that is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied in the dossier and the same applies where it is not scientifically necessary or technically possible to supply the information. In such cases, an adequate justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation which the applicant has the right to access.

§ 16. Application proceedings

(1) The Health Board will check the completeness of the submitted dossiers not later than within three months as of the submission of the dossiers and inform the applicant in writing of declaring the dossiers complete.

(2) The dossiers are professionally evaluated in accordance with clause 11 (1) 3) and subsections 11 (2), (3) and (6) to (8).

(3) The professional evaluation must comply with the criteria established in Annex VI to the Biocidal Products Directive.

§ 17. Granting of authorisation in case of frame-formulation

(1) A frame-formulation of biocidal products describes biocidal products of a group that have the same use and user type, contain the same active substances and are of the same product-type. Variations in the composition of biocidal products covered by the frame-formulation in comparison with the composition of a biocidal product that has already been granted authorisation may lie only in a lower percentage of the active 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 Health Board will establish the frame-formulation of biocidal products on the basis of a relevant application submitted upon application for authorisations or on its own initiative and issue it to the applicant along with authorisations.

(3) If the owner of the frame-formulation applies for an authorisation for a new biocidal product based on the frame-formulation, the application must be processed and a decision made not later than within 60 days.

§ 18. Term of validity of authorisation

(1) An authorisation is granted for a fixed term of up to ten years.

(2) The term of validity of an authorisation must not exceed the term of validity of the inclusion of the active substance contained in the biocidal product in Annex I or Annex I A to the Biocidal Products Directive.

(3) The term of validity of an authorisation may be renewed if the authorisation holder has submitted the dossiers specified in subsection 14 (2) of this Act and other relevant documents and the biocidal product satisfies the conditions set out in § 13 of this Act. An authorisation may also be renewed for the period of processing of the submitted documents.

(4) Upon applying for the renewal of an authorisation, the applicant must take into account the time limits of processing of the submitted documents.

§ 19. Modification of authorisation

(1) The Health Board may review an authorisation at any time if new information has been obtained on a biocidal product or the active substance thereof, based on which it can be presumed that the conditions specified in § 13 of this Act have not been satisfied.

(2) An authorisation will be modified:
1) if, on the basis of developments in scientific and technical knowledge, it has become evident that, to protect human and animal health and the environment, the conditions of use of an authorisation and, in particular, the manner of use and the amounts used need to be modified so that the conditions established in § 13 of this Act are satisfied;
2) at a reasoned request of the holder.

(3) Upon modification of an authorisation, the use of the biocidal product may be modified only within the limits of the uses of the active substance permitted in Annexes I and I A to the Biocidal Products Directive.

(4) If the need to modify the conditions of use of an active substance contained in a biocidal product, which are set out in Annex I o I A to the Biocidal Products Directive, arises from the modification of an authorisation, the active substance will be evaluated before the modification of the authorisation in accordance with the procedure established in Chapter 2 of this Act.

(5) In order to modify an authorisation, the Health Board has the right to request additional information from the authorisation holder or from the person applying for the modification of the authorisation.

(6) If necessary, the Health Board may renew the term of validity of the authorisation for a period required for submission of additional information and the time may be extended until the completion of the evaluation of the additional materials.

§ 20. Cancellation of authorisation

(1) The Health Board will cancel an authorisation if:
1) the active substance is no longer included in Annex I or I A of the Biocidal Products Directive;
2) the conditions established in subsection 13 (1) of this Act are no longer satisfied;
3) the holder has supplied false or misleading particulars upon applying for the authorisation;
4) the holder so requests.

(2) If the Health Board cancels an authorisation on its own initiative, the Health Board must inform the authorisation holder about the intent of cancelling the authorisation and give the holder a chance to express its opinion.

(3) When cancelling the authorisation, a period of grace for the disposal or for the storage, marketing and use of existing stocks may be granted. The length of the period must be in accordance with the reason for the cancellation and the legislation in force. The term of validity of the inclusion of the active substance in Annex I or I A to the Biocidal Products Directive must also be taken into account.

§ 21. Mutual recognition of authorisations

(1) The following documents must be submitted to the Health Board in order to apply for the recognition of an authorisation granted in another Member State:
1) a summary of the dossier as required in clause 14 (2) 1) of this Act and Section X of Annex II B to the Biocidal Products Directive;
2) a certified copy of the first English authorisation granted or a certified copy of the Estonian or English translation of the authorisation.

(2) The proceedings of the mutual recognition of authorisations last up to 120 days.

(3) The Health Board may demand that the applicant modify the conditions of use indicated on the labelling of a biocidal product so that the product satisfies the conditions established in § 13 if the Health Board establishes in the course of evaluation that:
1) the target organism of the biocidal product is not present in harmful quantities in Estonia;
2) the resistance of the target organism to the biocidal product or the unacceptable and intolerable effect of the biocidal product on the target organism has been identified, or
3) the climate or other circumstances of the state where the biocidal product was first authorised and Estonia differ significantly and an unchanged authorisation may therefore present unacceptable risks to human and animal health or the environment.

(4) If the Health Board decides that a biocidal product authorised in a Member State does not satisfy the conditions established in § 13 and it has a ground for refusal to place the product on the market in Estonia or for allowing to place the product on the market only in the event of modification of the conditions of use, the Health Board will immediately inform the European Commission, other competent authorities of the Member States and the applicant about the decision by a relevant letter of explanation that sets out the name and description of the product and the reasons of the proposal.

(5) The Health Board may, in adherence to the association agreement with the European Union, refuse the mutual recognition of authorisations of biocidal products of product-types 15, 17 and 23 set out in Annex V to the Biocidal Products Directive. The Health Board must inform the European Commission and the competent authorities of other Member States about such a decision and the reasons thereof.

§ 22. Specifics of mutual recognition of authorisation of low-risk biocidal product

(1) In the event of the mutual recognition of the authorisation of a low-risk biocidal product, the data required in subsection 15 (2) of this Act must be submitted instead of the documents required in clause 21 (1) 1), whereby only a relevant summary may be submitted on efficacy.

(2) The proceedings of mutual recognition of the authorisation of a low-risk biocidal product last up to 60 days.

(3) The Health Board may temporarily refuse the mutual recognition of the authorisation of a low-risk biocidal product if the Health Board finds that the biocidal product does not meet the criteria set out in subsection 2 (2) of this Act. The Health Board will immediately inform the competent authority that evaluated the dossier of the biocidal product about the non-compliance of the biocidal product.

(4) If the Health Board and the competent authority that evaluated the dossier of the biocidal product specified in subsection (3) of this section fail to reach an agreement on the risk level of the biocidal product within 90 days, the Health Board will refer the matter for resolution to the European Commission.

(5) If as a result of the proceedings in the European Commission the first authorisation of the biocidal product is deemed justified, the Health Board must recognise it and grant an authorisation to the given biocidal product.

Division 2
Derogations of Authorisation

§ 23. Provisional authorisation

(1) Until the inclusion of an active substance in Annex I or I A to the Biocidal Products Directive, the Health Board may grant provisional authorisation to place on the market a biocidal product that contains an active substance that has not been included in the aforementioned annexes and that was not available on the market before 14 May 2000 for a purpose other than scientific research and development or manufacturing research and development.

(2) The placing of a biocidal product on the market may be authorised in accordance with subsection (1) of this section if the competent authority has made certain that all the following conditions have been fulfilled:
1) based on the evaluation of the dossier, the active substance complies with the requirements of the active substance;
2) the biocidal product satisfies the conditions established in § 13;
3) no Member State has submitted reasoned objections regarding the completeness of the dossiers based on the summary of the dossiers received.

(3) If the evaluation of the dossier of the active substance is not completed in three years, but there is reason to believe that the active substance will be included in Annex I or I A to the Biocidal Products Directive, the Health Board may renew the provisional authorisation for one more year.

(4) The Health Board will inform the European Commission and the competent authorities of other Member States about the decisions made on provisional authorisations.

(5) If the European Commission and other Member States decide that the active substance does not comply with the requirements established thereto, the Health Board must cancel the authorisation granted in accordance with subsection (1) of this section.

§ 24. Authorisation by way of derogation

(1) By way of derogation, the Health Board may provisionally authorise the contained and controlled use of such a biocidal product that does not comply with the requirements provided for in this Act if there are no other means of combating a threat. Such an

authorisation is granted for a period of up to 120 days.

(2) The Health Board will immediately inform the European Commission and the competent authorities of other Member States about a decision specified in subsection (1) of this section along with the reasons of the decision.

(3) The Health Board may renew a provisional authorisation, grant an authorisation repeatedly or cancel an authorisation on the basis of a respective decision of the European Commission made by the Commission on the basis of materials sent in accordance with subsection (2) of this section.

§ 25. Research and development

(1) For the purpose of scientific research and development, tests may be conducted with a biocidal product or a substance used as the active substance in a biocidal product, which involve the placing of the biocidal product or active substance on the market if the persons responsible for placing it on the market or the persons carrying out scientific research and development preserve detailed written information on the identity, labelling and supplied amounts of the biocidal product or active substance, and the names and address of the persons whom the biocidal product or active substance was supplied, and draw up a dossier that contains all the available information on the possible effect of the biocidal product or active substance on human or animal health and on the environment. This information must be sent to the competent authority at its respective request.

(2) In the case of manufacturing research and development, the information specified in subsection (1) of this section must be submitted to the competent authority of the Member State of the place of marketing and to the competent authority of the Member State of testing before the unauthorised biocidal product or only the substance used as the active substance in the biocidal product is placed on the market for the purpose of testing.

(3) The respective consent of the Health Board is required for the placing on the market and use of an unauthorised biocidal product or a substance used as the active substance in a biocidal product in tests conducted for research and development purposes, in the course of which the biocidal product or the active substance may enter into the environment or damage human or animal health or the environment. To that end the persons responsible for marketing or scientific research and development must submit to the Health Board data identifying the researcher and the researched biocidal product or its active substance as well as available data on the health and environmental risks arising from the research.

(4) On the basis of the data and other relevant available information submitted in accordance with subsection (3) of this section, the Health Board will assess the risks arising from the use of the biocidal product or active substance in the tests and make proposals on the amounts used, areas treated or on other relevant research conditions or on the restriction or prohibition of research to the European Commission and the competent authorities of other Member States.

(5) In accordance with a relevant decision of the European Commission, the Health Board will authorise the research or tests specified in subsection (3) of this section, specifying the restrictions on the amounts used and the areas treated or other relevant research conditions, or prohibit such research.

Chapter 4
INFORMATION AND COOPERATION

§ 26. Using information submitted by other person

(1) In proceedings of application for the inclusion of an active substance in Annex I or I A of the Biocidal Products Directive or proceedings of application of the authorisation of a biocidal product, the Health Board has, in the interests of the applicant, the right to use information submitted by another person in previous proceedings in the Republic of Estonia or another Member State:
1) if the applicant has received a letter of access from the person who submitted the initial information;
2) if 15 years have passed from the first inclusion of the active substance that was not available on the market as an active substance or a component of a biocidal product before 14 May 2000 in Annex I or I A to the Biocidal Product Directive;
3) after 14 May 2014 or sooner, depending on the requirements established by the national legislation of the Member States regarding the protection of data in the given period if the active substance or the biocidal product containing it was placed on the market before 14 May 2000;
[RT I 2010, 37, 224 – entry into force 09.07.2010]
3^1) after the date until which the European Commission extended the transitional period of reviewing data submitted on certain active substances if the active substance or the biocidal product containing it was placed on the market before 14 May 2000;
[RT I 2010, 37, 224 – entry into force 09.07.2010]
4) if ten years have passed from the first inclusion of an active substance that was used as an active substance or in the composition of a biocidal product before 14 May 2000 in Annex I or I A to the Biocidal Products Directive as an active substance or for use in a new product-type, or
5) if five years have passed from the submission of new data for keeping an active substance in Annex I or I A to the Biocidal Products Directive or amendment of the conditions of the authorisation of a biocidal product or after the expiry of the dates or time limits specified in clause 2), 3) or 3^1) of this subsection.
[RT I 2010, 37, 224 – entry into force 09.07.2010]

(2) In the event of refusal to include an active substance in an annex or in the event of exclusion of an active substance from the annexes, the European Commission, relevant Scientific Committees and the competent authorities of the Member States may use the information also if the conditions listed in subsection (1) of this section have not been fulfilled.

§ 27. Confidential information

(1) An applicant for an authorisation may request that the Health Board declare the information contained in the applicant's dossiers or information submitted otherwise as confidential information. Information the publication of which may harm the

economic or business interests of the applicant may be declared confidential information. The request must be reasoned.

(2) The Health Board will decide on the basis of the reasons given by the applicant, which information to declare confidential. Information declared confidential by the Health Board must be treated as confidential information also by other Member States, their competent authorities and the European Commission.

(3) The Health Board must take any and all measures to prevent the disclosure of confidential information that has been declared confidential on the basis of this Act and of confidential information received from the European Commission or from the competent authorities of other Member States of the European Union.

(4) Confidential information may be submitted to the European Commission and competent authorities of the Member States of the European Union. Upon submission of such information, the Health Board must indicate that the information is confidential.

(5) If the applicant so requests, the Health Board will take measures to ensure the confidentiality of the composition of a biocidal product as a whole.

(6) After an authorisation has been granted, the following is not confidential information:
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 all active substances in the biocidal product and the name of the biocidal product;
5) the names of chemicals which are regarded as dangerous and contribute to the classification of the biocidal product;
6) physical and chemical data concerning the active substance and biocidal product;
7) the ways of rendering the active substance and biocidal product harmless;
8) summaries 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 manufacturing, use, storage and transport;
10) safety data sheets;
11) research and test methods;
12) methods of disposal of the biocidal product or active substance and of its packaging;
13) measures to be taken in the case of the accidental discharge of the biocidal product to the environment;
14) first aid and medical advice to be given in the case of injury to persons.

(7) If the applicant or manufacturer or importer of the biocidal product or active substance later discloses previously confidential information, they must inform the competent authority that processes or processed their application.

§ 28. Mutual use of data

(1) In the case of a biocidal product the placing on the market and use of which has already been authorised, the competent authority may, in accordance with § 26, agree that a second or subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the second or subsequent applicant can provide evidence that the biocidal product is similar and its active substances are the same as the one formerly authorised, including degree of purity and nature of impurities.

(2) A person who intends to apply for an authorisation of a biocidal product (hereinafter *prospective applicant*) must, before carrying out experiments involving vertebrate animals, enquire of the Health Board whether the biocidal product for which an application is to be made is similar to a biocidal product for which authorisation has been granted, and as to the name and address of the holder of such authorisation (hereinafter *data owner*).

(3) The enquiry specified in subsection (2) of this section must be supported by a document with which the prospective applicant intends to apply for authorisation on their own behalf and that the required dossiers or letters of access are available.

(4) If the enquirer's intent to apply is sufficiently proven, the Health Board will provide the name and address of the data owner to the prospective applicant and inform the data owner about the enquiry.

(5) If, according to the decision of the Health Board, the person's intent to apply for the authorisation is sufficiently reasoned, the data owner must submit the relevant animal testing data to the prospective applicant.

(6) The prospective applicant and the data owner will agree on the use of the data and on the payment of fair and transparent compensation for it.

(7) Upon adjudication of a dispute between the prospective applicant and the data owner over the use of the data of animal testing and payment of a fee for it, the court must, among other things, take into account the owner's interest in withholding some information, given the provisions of § 27 of this Act, and the interest of the public to avoid testing on vertebrate animals.

(8) The prospective applicant is allowed to use the data obtained from the data owner solely for drawing up a dossier required for applying for the authorisation, unless agreed otherwise.

§ 29. Animal testing

(1) The Health Board decides the need for relevant animal testing for the purpose of obtaining the data required in the dossier of the biocidal product or active substance of the biocidal product, granting the applicant consent to the inclusion of the active substance in an annex to the Biocidal Products Directive or consent to testing or state the reasons for refusal to grant consent.

(2) Animal testing that is indispensable for obtaining the relevant data required in the dossier of the biocidal product or active substance of the biocidal product is conducted in Estonia in accordance with the relevant provisions of the Animal Protection Act.

§ 30. Duty to submit new information

(1) The holder of an authorisation must immediately notify the competent authority of information concerning a biocidal product or an active substance and which may affect continuing authorisation. In particular, the following must be notified:

1) new knowledge or information on the effects of the biocidal product or active substance for humans or the environment;
2) changes in the source of the active substance or in the composition of the active substance or biocidal product;
3) development of the resistance of harmful organisms;
4) changes of an administrative nature or other significant aspects.

(2) The Health Board will immediately notify the European Commission and the competent authorities of the Member States of any information specified in subsection (1) of this section.

§ 31. Exchange of information

(1) Within a period of one month from the end of each quarter, the Health Board will inform the European Commission and the competent authorities of other Member States of any biocidal products which have been authorised or for which an authorisation has been refused, modified, renewed or cancelled, as well as of all other decisions specified in §§ 14–25 of this Act, indicating at least:
1) the name or business name of the applicant for, or the holder of, the authorisation;
2) the trade name of the biocidal product;
3) the name and amount of each active substance which the biocidal product contains;
4) the name and amount of each dangerous substance which the biocidal product contains, and their classification;
5) the product-type and the use for which the biocidal product is authorised;
6) the type of formulation;
7) any proposed limits on residues which have been established;
8) conditions of the authorisation and where relevant, the reasons for the modification or cancellation of an authorisation;
9) an indication of whether the biocidal product is a low-risk biocidal product or falls within a frame-formulation.

(2) The Health Board will draw up an annual list of the authorised biocidal products and communicate that list to the European Commission and to the competent authorities of other Member States.

(3) Where the Health Board receives a summary of a dossier and has reason to believe the dossier is incomplete, it will immediately communicate its concerns to the competent authority that evaluated the dossier and will without undue delay inform the European Commission and the competent authorities of other Member States of its concerns.

(4) The Health Board will submit to the European Commission by 30 November 2009 and, thereafter, by November 30 of each third year, submit on the basis of a questionnaire drawn up by the European Commission the data on registered poisoning cases caused by biocidal products and a report on the result of supervision of biocidal products placed on the marked.

Chapter 5
PLACING ON MARKET AND USE OF BIOCIDAL PRODUCT

Division 1
Placing of Biocidal Product on Market

§ 32. Classification, packaging and labelling of biocidal products

(1) A biocidal product to be placed on the market must be classified, labelled and packaged beforehand in accordance with the Chemicals Act, legislation established on the basis thereof or 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 (Text with EEA relevance) (OJ L 353, 31.12.2008, pp. 1–1355), and with the requirements of this Act.

(2) The packaging of a biocidal product must allow for clearly distinguishing the biocidal product from food and feedingstuff.

(3) A biocidal product available to the consumer for the purposes of the Consumer Protection Act, which may be mistaken for food or feedingstuff, must contain components to discourage its consumption.

(4) Upon packaging and labelling biocidal products identified as insecticide, acaricide, rodenticide, avicide or molluscicide, the relevant special requirements established by the Plant Protection Act in conjunction with the authorisation requirements of this Act must be taken into account.

(5) The labelling of the packaging of a biocidal product must be in Estonian and it must not contain information that would mislead the user or guide the user to use the biocidal product for a purpose other than the intended purpose.

(6) The classification, packaging and labelling requirements specified in this section do not apply to the transport of biocidal products.

§ 33. Restrictions on marketing

A biocidal product that has been classified as toxic, very toxic or as a category 1 or 1 A, 2 or 1 B carcinogen, or as a category 1 or 1 A, 2 or 1 B mutagen or classified as toxic for reproduction category 1 or 1A, 2 or 1B, must not be marketed to the consumer for the purposes of the Consumer Protection Act.

§ 34. Place of storage and marketing of biocidal product

(1) In order to ensure human and animal health and environmental safety, a biocidal product must be stored and marketed in such a manner that the contamination of food, medicinal products and feedingstuffs as well as other goods is precluded.

(2) There may be no open packaging of a biocidal product at the place of storage and marketing of the biocidal product. It is prohibited to repackage a biocidal product at its place of storage and marketing.

(3) A biocidal product whose packaging is not intact must not be marketed. Such a product must be removed immediately and must be rendered harmless in accordance with the procedure established in the Waste Act, taking account of the data of the safety data sheet of the biocidal product.

§ 35. Safety data sheet of biocidal product and active substance

(1) The person responsible for the marketing of a biocidal product or active substance must draw up a safety data sheet of the biocidal product or active substance which has been classified as a dangerous chemical.

(2) The safety data sheet is drawn up and submitted in accordance with the requirements established on the basis of 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).

§ 36. Advertising of biocidal product

Every advertisement of a biocidal product must comply with the requirements of § 27 of the Advertising Act.

§ 37. Information on poisoning

(1) The Health Board has the right to use information given in the dossier of a biocidal product or active substance of a biocidal product on the composition and hazardous properties of the biocidal product for the purpose of developing and taking measures for the prevention and treatment of poisoning cases.

(2) If necessary, the confidentiality of the information specified in subsection (1) of this section is ensured.

Division 2
Use of Biocidal Product

§ 38. General requirements of use of biocidal product

(1) A person who uses a biocidal product to destroy, deter, prevent the action of or otherwise exert a controlling effect on any harmful organism by chemical or biological means (hereinafter pest control) must do so exclusively in the manner and on the conditions indicated on the labelling and in the user manual of the biocidal product.

(2) A person may engage in pest control using a biocidal product that has been classified as toxic, very toxic or as a category 1 or 1 A, 2 or 1 B carcinogen, mutagen or biocidal product classified as toxic for reproduction or designated for another exclusively professional use if:
1) [Repealed – RT I, 25.03.2011, 1 – entry into force 01.07.2014 (entry into force amended – RT I, 22.12.2013, 1)]
2) the person has a relevant legal relationship with a person responsible specified in § 39 of this Act or is, as a self-employed person, competent to act as a responsible specialist, or
3) the person is an employee and holds a professional qualifications certificate specified in subsection 39 (2) of this Act.

(3) If a person engaged in pest control provides it as a service, the person must be an undertaking for the purposes of the Commercial Code.

§ 39. Responsible specialist

(1) ‘Responsible specialist’ means a person who is competent to manage and organise pest control and advise an undertaking so that the fulfilment of the requirements provided by law is ensured.

(2) The responsible specialist must hold the III professional qualifications of an exterminator within the meaning of the Professions Act, according to which the person organises the distribution of resources, other people’s work and is responsible for the work.

(3) Upon applying for the professional qualifications specified in subsection (2) of this section, at least secondary education, the completion of supplementary professional and management training and three years of experience in pest control is required.

(4) The compliance of the competency obtained abroad with the requirements of this Act is assessed and certified by the authority that grants the profession on the basis of the Recognition of Foreign Professional Qualifications Act, taking account of the specifications arising from this Act.

§ 40. Notification obligation

To engage in pest control, a notice of economic activities must be submitted.
[RT I, 25.03.2011, 1 – entry into force 01.07.2014 (entry into force amended – RT I, 22.12.2013, 1)]

§ 41. Organisation of pest control on site

(1) A pest control site is a building, structure or a part thereof or the accompanying area (hereinafter *site*) where harmful organisms may spread.

(2) The possessor of the site organises the monitoring of the population of harmful organisms on site and is responsible for preventing the harmful effect of pests and extermination of pests.

(3) The possessor of the site creates conditions required for safe extermination on site and, jointly with the person engaged in extermination operations (hereinafter *exterminator*), draws up a plan for the extermination of the pests.

(4) The exterminator draws up an extermination report for the possessor of the site, which must be preserved for at least five years.

(5) More detailed requirements for extermination, extermination plan and extermination report will be established by a regulation of the minister responsible for the field.

Chapter 6
STATE FEES

§ 42. State fees for processing documents

Before submitting documents to the Health Board, the applicant will pay the state fee at the rate prescribed by the State Fees Act for the following steps:
1) the processing of documents submitted upon applying for the inclusion of an active substance in an annex to the Biocidal Products Directive in the Health Board;
2) the processing of documents submitted upon applying for the inclusion of an additional product-type for the use of an active substance in an annex to the Biocidal Products Directive in the Health Board;
3) the processing of documents submitted upon applying for a biocidal product authorisation in the Health Board;
4) the processing of documents submitted upon applying for a low-risk biocidal product authorisation in the Health Board;
5) the evaluation of materials submitted for the authorisation of research and development;
6) in the case of a frame-formulation application, the establishment of the frame-formulation of biocidal products;
7) the processing of an application for a biocidal product authorisation on the basis of a frame-formulation;
8) the mutual recognition of a biocidal product authorisation;
9) the mutual recognition of a low-risk biocidal product authorisation;
10) the processing of an application for a provisional authorisation;
11) the processing of an application for renewal of period of validity of a biocidal product authorisation;
12) the processing of the administrative modifications of a biocidal product authorisation (modification of the product name, manufacturer name or other modifications that do not result in a change of the properties, quality or efficacy of the product);
13) the processing of the substantive modifications of a biocidal product authorisation (modification of the product classification, composition or other modifications that may result in a change of the properties, quality or efficacy of the product);
14) the registration of a biocidal product in the transitional period in accordance with § 49;
15) the issue of a certified extract from the register.

Chapter 7
STATE SUPERVISION

§ 43. State supervision

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

(1) State supervision over compliance with the requirements established to biocidal products, product containing biocidal products, placing them on the market and using them is, under this Act, legislation established on the basis thereof and the Biocidal Products Regulation, exercised by:
1) the Health Board – over compliance by the manufacturer and importer of biocidal products with the requirements established to making biocidal products and treated articles available and upon wholesale of products, over compliance with the requirements established to biocidal products and the use thereof by professional providers of the pest control service, and in fields regulated by the Public Health Act and the Health Services Organisation Act;
2) the Consumer Protection Board – over adherence to the requirements established to making biocidal products and treated articles available on the retail market;
3) the Labour Inspectorate – over adherence to the requirements established to the use of biocidal products in the field regulated by the Occupational Health and Safety Act;
4) the Environmental Inspectorate – over adherence to the requirements established to the use of biocidal products from the point of view of environmental hazardousness at the objects of supervision of the field;
5) the Veterinary and Food Board – over adherence to the requirements established to the use of biocidal products from the point of view of animal health and the feed and food safety at the objects of supervision of the field;
6) the Tax and Customs Board – over the adherence to the requirements established to making biocidal products available upon entering the Community market in accordance with Articles 27–29 of Regulation (EC) No. 765/2008 of the European Parliament and of the Council.
[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

§ 43[1]. Special measures of state supervision

A law enforcement agency 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, 45, 49, 50 and 51 of the Law Enforcement Act on the grounds and in accordance with the procedure provided for in the Law Enforcement Act.
[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

§ 43[2]. Specifics of state supervision

(1) In the event of absence of a valid authorisation or registration certificate, the law enforcement authority has the right to ban the import of the biocidal product to the customs territory of the Community and the sale of the product.
[RT I, 29.06.2014, 1 – entry into force 01.07.2014]

(2) If in the course of exercising state supervision the supervision authority has, in accordance with Article 88 of the Biocidal Products Regulation, made a precept on the restriction or a temporary ban of making a biocidal product available or using a biocidal

product, the supervision authority will immediately inform the Health Board thereof and the latter will, in turn, inform the European Commission and other Member States without delay.

(3) The supervision authorities will, by 1 July 2015 and thereafter by April 1 of each fifth year, submit to the Health Board the data required in Article 65(3) of the Biocidal Products Regulation. On the basis of the received data, the Health Board will submit to the European Commission the report specified in Article 65(3) of the Biocidal Products Regulation.

(4) For the purpose of exercising supervision, the law enforcement agency may, using a vehicle, including an off-road vehicle or a water craft, enter and move in a land or water area even if legislation prohibits entry to and movement in such area for environmental protection purposes.
[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

§ 43^{3}. 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.
[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

§ 44. Precept

[Repealed – RT I, 13.03.2014, 4 – entry into force 01.07.2014]

§ 45. Contestation of precept

[Repealed – RT I, 13.03.2014, 4 – entry into force 01.07.2014]

§ 46. Rate of penalty payment

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]
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.
[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

Chapter 8
LIABILITY

§ 47. Violation of requirements for marketing and use of biocidal product

(1) Violation of the requirements for the marketing and use of a biocidal product 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 32 000 euros.
[RT I 2010, 22, 108 – entry into force 01.01.2011]

§ 48. Proceedings

(1) [Repealed – RT I, 12.07.2014, 1 – entry into force 01.01.2015]

(2) The authorities that conduct extrajudicial proceedings of the misdemeanours provided for in § 47 of this Act are, within the limits of their competence:
1) the Labour Inspectorate;
2) the Environmental Inspectorate;
3) the Consumer Protection Board;
4) the Health Board;
[RT I 2010, 37, 224 – entry into force 09.07.2010]
5) the Veterinary and Food Board.
6) [Repealed – RT I 2010, 37, 224 – entry into force 09.07.2010]

Chapter 9
IMPLEMENTING PROVISIONS

Division 1
Implementation of Act

§ 49. Implementation of Act within 14-year work programme provided for in Biocidal Products Directive, which regulates transitional period

[RT I 2010, 37, 224 – entry into force 09.07.2010]

(1) Biocidal products that contain active substances that have not been included in Annex I, I A and I B to Directive 98/8/EC may be placed on the market after registration, whereby the active substances of the biocidal products must meet the requirements established in Commission Regulation (EC) No. 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (Text with EEA relevance) (OJ L 325, 11.12.2007, pp. 3–65).

(1^{1}) Biocidal products that comply with the requirements established in subsection (1) of this section are registered until 14 May 2014 or until the date to which the European Commission has, by its decision, extended the transitional period for the review of data

submitted on certain active substances.
[RT I 2010, 37, 224 – entry into force 09.07.2010]

(2) The following data must be submitted to the Health Board for registration:
1) the applicant's name, registry code or personal identification code and contact details;
2) the contact details of the manufacturer of the biocidal product and active substance, and the address of the place of manufacture;
3) if possible, a relevant letter of access;
4) the trade name of the biocidal product;
5) the full composition of the biocidal product and the classification of each hazardous components;
6) the physical and chemical properties of the biocidal product, which are appropriate to the use, storage and transport of the biocidal product;
7) the product-type and use of the biocidal product;
8) the users of the biocidal product;
9) the method of application and instructions for use of the biocidal product;
10) if possible, data on the efficacy of the biocidal product;
11) the classification, packaging and labelling of the biocidal product along with specimen of the labelling;
12) the safety data sheet of the biocidal product.

(3) If the biocidal product has been included in Annex I, I A or I B to the Biocidal Products Directive, an authorisation for the registered biocidal product must be applied for in accordance with the requirements established in this Act. The relevant documents must be submitted to the competent authority not later than by the date of inclusion of the active substance in the annex. If the biocidal product contains more than one active substance, the documents must be submitted by the date of inclusion of the last active substance to be included in the annex.

(4) A biocidal product registered in Estonia may be continuously marketed after the date of inclusion of the active substance in an annex to the Biocidal Products Directive, provided that the applicant has fulfilled the following conditions:
1) submitted to the competent authority of a Member State the documents required for authorisation;
2) informed the Health Board about applying for an authorisation and about the intent to continue marketing the biocidal product in Estonia on the basis of the mutual recognition of the authorisation. To that end, the filled-in and signed paper form of the Community Register for Biocidal Products (R4BP) must be submitted to the Health Board.

(5) After the granting of the authorisation specified in clause 1) of subsection (4) of this section in another Member State, the documents required in subsection 21 (2) of this Act must be submitted to the Health Board and the state fee must be paid within two months for the purpose of the mutual recognition of the authorisation.

(6) It is prohibited to bring to Estonia from other Member States and to market and use in Estonia biocidal products that have been included in Annex I or II to Commission Regulation (EC) No. 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, but the import of which to Estonia is prohibited under Regulation (EC) No. 304/2003 of the European Parliament and of the Council concerning the export and import of dangerous chemicals (OJ L 063, 06.03.2003, pp. 1–26).

Division 2
Amendment of Acts Related to Biocidal Products Act

§ 50. – § 52. [Omitted from this text.]

Division 3

[Repealed - RT I 2010, 37, 224 - entry into force 09.07.2010]

[1] Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (Text with EEA relevance) (OJ L 123, 24.04.1998, pp. 1–63); Directive 2007/47/EC of the European Parliament and of the Council amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (Text with EEA relevance) (OJ L 247, 21.09.2007, pp. 21–55); Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (consolidated version) (CONSLEG, 1998L0008, 26.09.2008, pp. 1–80); Directive 2009/107/EC of the European Parliament and of the Council amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods (Text with EEA relevance) (OJ L 262, 6.10.2009, pp. 40–42).
[RT I 2010, 37, 224 - entry into force 09.07.2010]