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Biocidal Products Act[1]

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RT I 2009, 29, 174
Entry into force 19.06.2009, in part pursuant to § 53.

Amended by the following acts

Passed	Published	Entry into force
30.09.2009	RT I 2009, 49, 331	01.01.2010 The words ‘Chemicals Notification Centre’ have been replaced with ‘Health Board’ in the Act.
22.04.2010	RT I 2010, 22, 108	01.01.2011, will enter into force on the date specified in the decision of the Council of the European Union regarding the abrogation of the derogation established in favour of the Republic of Estonia on the ground provided for in Article 140(2) of the Treaty on the Functioning of the European Union, Decision No. 2010/416/EU of the Council of the European Union of 13 July 2010 (OJ L 196, 28.07.2010, pp. 24-26).
16.06.2010	RT I 2010, 37, 224	09.07.2010
23.02.2011	RT I, 25.03.2011, 1	01.01.2014; date of entry into force amended01.07.2014 [RT I, 22.12.2013, 1]
05.12.2013	RT I, 22.12.2013, 1	01.01.2014
19.02.2014	RT I, 13.03.2014, 4	01.07.2014
05.06.2014	RT I, 29.06.2014, 1	01.07.2014
19.06.2014	RT I, 12.07.2014, 1	01.01.2015
19.06.2014	RT I, 29.06.2014, 109	01.07.2014, the ministers’ official titles have been replaced on the basis of subsection 107³ (4) of the Government of the Republic Act.
17.02.2015	RT I, 10.03.2015, 1	20.03.2015, in part01.07.2015
09.12.2015	RT I, 30.12.2015, 1	18.01.2016
21.11.2018	RT I, 12.12.2018, 3	01.01.2019
10.06.2020	RT I, 01.07.2020, 1	01.01.2021
17.06.2020	RT I, 10.07.2020, 2	01.01.2021

Chapter 1
GENERAL PROVISIONS

§ 1. Scope of application of Act

(1) This Act provides for the legal ground for making available on the market and use of a biocidal product and a treated article, restricting economic activities related to using a biocidal product and organisation of state

supervision over the adherence to the requirements provided for in this Act and in the relevant regulation of the European Union with the aim of protecting health, the environment and property as well as ensuring the free movement of goods.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(1^1) The requirements and conditions of making available on the market and use of a biocidal product and a treated article are established in Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (Text with EEA relevance) (OJ L 167, 27.06.2012, pp 1–123) (hereinafter *Biocidal Products Regulation*).
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(1^2) This Act applies to making available on the market and use of a biocidal product and a treated article in events not regulated by the Biocidal Products Regulation.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(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 administrative proceedings prescribed in this Act, taking account of the specifications provided for in this Act and in the Biocidal Products Regulation.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

§ 2.–§ 5.[Repealed – RT I, 10.03.2015, 1 – entry into force 20.03.2015]

§ 5^1. Definitions

This Act uses definitions within the meaning of the Biocidal Products Regulation, unless otherwise provided for in this Act.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

§ 6. Competent authority

The steps and administrative decision specified in this Act and in the Biocidal Products Regulation are taken and made by the Health Board, unless otherwise provided by this Act or the Biocidal Products Regulation.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

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

§ 8. General requirements for making available and use of biocidal products

[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(1) Making a biocidal product available on the market means an activity by which a biocidal product is for a charge or without charge made available for use or distribution in the customs territory of the European Union. Making a biocidal product available also includes the import and warehousing thereof, except where warehousing is followed by the export of the biocidal product or removal of the biocidal product from circulation.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(2) [Repealed – RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(3) A biocidal product is permitted to be made available and used in Estonia if it has obtained the relevant authorisation or registration certificate in accordance with this Act or the Biocidal Products Regulation.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

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

[Repealed -RT I, 10.03.2015, 1 - entry into force 20.03.2015]

§ 9.–§ 12.[Repealed – RT I, 10.03.2015, 1 – entry into force 20.03.2015]

Chapter 3
PERMITTING MAKING BIOCIDAL PRODUCT AVAILABLE

[RT I, 10.03.2015, 1 - entry into force 20.03.2015]

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 making available 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 making available or using the product or the threshold quantities permitted upon use of the product.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(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 making available to, or use by the consumer for the purposes of the Consumer Protection Act.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

§ 14. Applying for authorisation

(1) An authorisation can be applied by a person responsible for making the biocidal product available 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.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(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) [Repealed – RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(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

[Repealed – RT I, 10.03.2015, 1 – entry into force 20.03.2015]

§ 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) [Repealed – RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(4) [Repealed – RT I, 10.03.2015, 1 – entry into force 20.03.2015]

§ 19. Modification of authorisation

[Repealed – RT I, 10.03.2015, 1 – entry into force 20.03.2015]

§ 20. Cancellation of authorisation

[Repealed – RT I, 10.03.2015, 1 – entry into force 20.03.2015]

§ 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

[Repealed – RT I, 10.03.2015, 1 – entry into force 20.03.2015]

Division 2
Derogations of Authorisation

[Repealed -RT I, 10.03.2015, 1 - entry into force 20.03.2015]

§ 23.–§ 25.[Repealed – RT I, 10.03.2015, 1 – entry into force 20.03.2015]

Chapter 4
INFORMATION AND COOPERATION

[Repealed -RT I, 10.03.2015, 1 - entry into force 20.03.2015]

§ 26.–§ 31.[Repealed – RT I, 10.03.2015, 1 – entry into force 20.03.2015]

Chapter 5
MAKING AVAILABLE AND USE OF BIOCIDAL PRODUCT

[RT I, 10.03.2015, 1 - entry into force 20.03.2015]

Division 1
Making Biocidal Product Available

§ 32. Classification, packaging and labelling of biocidal products

(1) A biocidal product to be made available 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.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

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

(3) A biocidal product available to the consumer for the purposes of the Consumer Protection Act, which may be mistaken for food or feed, 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 making available

[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(1) 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 made available to the consumer for the purposes of the Consumer Protection Act.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(2) Biocidal products for professional use under the Biocidal Products Regulation must not be made available to the consumer for the purposes of the Consumer Protection Act.

(3) Biocidal products for professional use may be made available only in wholesale trade.

(4) In order to engage in the sale of biocidal products for professional use, a notice of economic activities in the field of wholesale trade must be submitted.

(5) In addition to the information required in the General Part of the Economic Activities Code Act, a notice of economic activities must contain the following information:
1) the place(s) of business, the address of the website in the case of e-commerce;
2) the goods to be sold (the biocidal product for professional use).

(6) The persons making a biocidal product available on the market must have knowledge of the dangerous properties, risk control and terms of use of the biocidal product and the readiness to advise users of the biocidal product, where necessary.
[RT I, 10.03.2015, 1 – entry into force 01.07.2015]

§ 34. Place of storage and making available of biocidal product

[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(1) In order to ensure human and animal health and environmental safety, a biocidal product must be stored and made available in such a manner that the contamination of medicinal products, food and feed as well as other goods is precluded.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(2) There may be no open packaging of a biocidal product at the place of storage and making available of the biocidal product. It is prohibited to repackage the biocidal product at the place of storage and making available.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(3) A biocidal product whose packaging is not intact must not be made available. 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.

[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

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

[Repealed – RT I, 10.03.2015, 1 – entry into force 20.03.2015]

§ 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

An authorisation holder who is responsible for placing a hazardous biocidal product on the market in the Republic of Estonia must, before placing the biocidal product on the market, submit to the Poisoning Information Centre of the Health Board information specified in Article 45 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council, which is used for the purpose of developing and applying measures for the prevention and treatment of poisoning cases.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

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, render harmless or control the unwanted effect of harmful organisms (hereinafter *pest control operator*) must do so exclusively in the manner and on the conditions indicated on the labelling and in the instructions for use of the biocidal product.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(2) [Repealed – RT I, 10.03.2015, 1 – entry into force 01.07.2015]

(3) [Repealed – RT I, 10.03.2015, 1 – entry into force 01.07.2015]

§ 38^{1}. Professional user of biocidal product

(1) 'Professional user of a biocidal product' means a person who has relevant qualifications and, in economic or professional activities, uses biocidal products designated for professional use based on the authorisation or registration certificate granted for making the biocidal product available on the market and using the biocidal product.

(2) The professional user of a biocidal product must have knowledge of the dangerous properties, risk control and terms of use of the biocidal products used in the professional activities and the skills of the safe use of the biocidal product, which have been obtained in the course of formal or professional training certified by a relevant certificate.
[RT I, 10.03.2015, 1 – entry into force 01.07.2015]

§ 38^{2}. Training of professional user of biocidal product

(1) A training establishment organises the training of the professional user of a biocidal product in accordance with the requirements of the Adult Education Act, the Vocational Educational Institutions Act and this Act.

(2) Upon drawing up a curriculum or a training programme, the training establishment must rely on the level 4 or level 5 professional standard of a pest control operator and submit the curriculum or programme before the organisation of training to the body that awards the profession of a pest control operator within the meaning of the Professions Act in order to obtain an opinion and proposals.
[RT I, 10.03.2015, 1 – entry into force 01.07.2015]

§ 38^{3}. Pest control using biocidal product for professional use

(1) 'Professional pest control service provider' means an entrepreneur whose economic or professional activity comprises the provision of the pest control service and who has at least one specialist with relevant qualifications for that purpose.

(2) A professional pest control service provider has a relevant legal relationship with a responsible specialist specified in § 39 of this Act or is, as a self-employed person, competent to act as a responsible specialist.

(3) An entrepreneur who is not a professional pest control service provider, but in whose economic activities biocidal products for professional use are used must ensure that the pest control operator is competent and complies with the requirements provided for in subsection 38^1(2) of this Act.
[RT I, 10.03.2015, 1 – entry into force 01.07.2015]

§ 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 level 5 professional qualifications of a pest control operator 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.
[RT I, 10.03.2015, 1 – entry into force 01.07.2015]

(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 competent authority on the basis of the Recognition of Foreign Professional Qualifications Act, taking account of the specifications arising from this Act. The competent authority provided for in subsection 7 (2) of the Recognition of Foreign Professional Qualifications Act is the Ministry of Social Affairs.
[RT I, 30.12.2015, 1 - entry into force 18.01.2016]

§ 40. Notification obligation

(1) To provide a professional pest control service, a notice of economic activities must be submitted.

(2) In addition to the information required in the General Part of the Economic Activities Code Act, a notice of economic activities must contain the following information:
1) the name and personal identification code or, upon absence of the latter, the date of birth of the responsible specialist;
2) the telephone number and e-mail address of the responsible specialist;
3) the number and term of validity of the certificate of the qualifications of the responsible specialist, the name of the body awarding the profession, and the place and date of awarding the profession.
[RT I, 10.03.2015, 1 – entry into force 01.07.2015]

§ 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 harmful organisms on site and is responsible for preventing the harmful effect of pests and for the destroying of pests.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(3) The possessor of the site creates conditions required for safe pest control on site and, jointly with the person engaged in pest control, draws up a pest management plan.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(4) The pest control operator draws up a pest control report for the possessor of the site, which must be kept for at least five years.

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

Chapter 6
STATE FEES AND CHARGES

[RT I, 10.03.2015, 1 - entry into force 20.03.2015]

§ 42. State fees for processing documents in Health Board

[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(1) An applicant for the approval of the active substance of a biocidal product, an applicant for a relevant authorisation for a biocidal product or an applicant for a registration certificate in accordance with this Act must, before the submission of documents to the Health Board in accordance with the Biocidal Products Regulation, pay a state fee at the rate provided for in the State Fees Act for the following steps:
1) the validation of an application submitted for the approval of an active substance;

2) the validation of an application submitted for the renewal of a decision to approve an active substance;
3) the validation of an application submitted for the approval of an additional product type for using an active substance;
4) the validation of an application for national authorisation for a biocidal product and the making of a decision to grant or refuse to grant the authorisation;
5) the validation of an application for a Union authorisation for a biocidal product family;
6) the validation of an application for a Union authorisation for a biocidal product;
7) the validation of an application for a national authorisation for a biocidal product family and the making of a decision to grant or refuse to grant the authorisation;
8) the validation of an application for the renewal of a national authorisation granted to a biocidal product or to a biocidal product family and the granting of a revised authorisation or the making of a decision to refuse to grant it;
9) the validation of an application for the renewal of the Union authorisation granted to a biocidal product or to a biocidal product family;
10) the processing of an application for the addition of a product to the authorisation granted to a biocidal product family;
11) the validation of an application for a national authorisation for a biocidal product pursuant to the simplified procedure and the granting of the authorisation or the making of a decision to refuse to grant the authorisation;
12) the validation of an application for the renewal of a national authorisation granted to a biocidal product pursuant to the simplified procedure and the granting of a revised authorisation or the making of a decision to refuse to grant it;
13) the processing of an application for making a biocidal product that was granted an authorisation pursuant to the simplified procedure available in Estonia;
14) the processing of application for a national authorisation for a biocidal product pursuant to the procedure of mutual recognition in sequence or in parallel;
15) the processing of an application for a parallel trade permit for a biocidal product;
16) the processing of an application for a national authorisation of the same biocidal product;
17) the processing of an application for a national authorisation for making a biocidal product or an active substance available for research and development or using it for the same purpose;
18) the processing of an application for a provisional national authorisation for a biocidal product;
19) the processing of an application for an administrative change of the existing national authorisation for a biocidal product (e.g. change of the product name, manufacturer name or other changes that do not result in a change of the properties, quality or efficacy of the product);
20) the processing of an application for a minor change of the existing national authorisation granted to a biocidal product (e.g. change of non-active substances, instructions for use, shelf-life, conditions of storage or pack size);
21) the validation of an application for a major change of existing national authorisation granted to a biocidal product (e.g. change of the classification or product composition or other changes that may result in a change of the properties, quality or efficacy of the product) and the granting of revised authorisation or the making of a decision to refuse to grant it;
22) the validation of an application for a major change of the Union authorisation granted to a biocidal product (e.g. a change of the classification or the product composition or other changes that may result in a change of the properties, quality or efficacy of the product);
23) the processing of an application for a registration certificate of a biocidal product during the transitional period;
24) the processing of an application for a change of the registration certificate of a biocidal product during the transitional period.

(2) The rate of the state fee charged for the steps specified in subsection (1) of this section are revised at least once every two years and, where necessary, relevant changes in the amount of the fee are made based on the actual expenses of the previous period.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

§ 42[1]. Charges for evaluation of application for authorisation for biocidal product

(1) An applicant for a Union or national authorisation for a biocidal product will pay for the evaluation of the application to the Health Board in accordance with the Biocidal Products Regulation.

(2) Where possible, the Health Board evaluates an application internally or use the help of contractual experts for evaluation. The hourly rate of the expert must not exceed 150 euros.

(3) An application can be evaluated by an expert who is an independent Estonian or foreign natural or legal person and who has experience in the professional evaluation of biocidal products, plant protection products or other substances of such kind. The expert must take into account the requirements established in the Biocidal Products Regulation and the relevant instructions of the European Commission regarding professional evaluation.

(4) The applicant will pay the Health Board for the following steps:

1) the evaluation of an application submitted for the approval of an active substance whereby the initial charge is 133 865 euros and the maximum charge is 387 945 euros;
2) the evaluation of an application submitted for the renewal of a decision to approve an active substance whereby the initial charge is 39 775 euros and the maximum charge is 99 935 euros;
3) the evaluation of an application submitted for the approval of an additional product type for using an active substance whereby the initial charge is 58 440 euros and the maximum charge is 160 680 euros;
4) the evaluation of an application for authorisation of a biocidal product whereby the initial charge is 28 865 euros and the maximum charge is 158 170 euros;
5) the evaluation of an application for the renewal of the authorisation granted to a biocidal product or a biocidal product family whereby the initial charge is 21 120 euros and the maximum charge is 75 625 euros;
6) the evaluation of an application for authorisation of a biocidal product family whereby the initial charge is 55 145 euros and the maximum charge is 302 190 euros;
7) the evaluation of an application for authorisation of a biocidal product pursuant to the simplified procedure whereby the initial charge is 4340 euros and the maximum charge is 7300 euros;
8) the evaluation of an application for the renewal of authorisation granted to a biocidal product pursuant to the simplified procedure whereby the initial charge is 2350 euros and the maximum charge is 3950 euros;
9) the evaluation of an application for a major change of the authorisation granted to a biocidal product whereby the initial charge is 17 600 euros and the maximum charge is 63 020 euros.

(5) The rates of the charge levied for the steps specified in subsection (4) of this section are revised at least once every two years and, where necessary, relevant changes in the amount of the charge are made based on the actual expenses of the previous period.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

§ 42[2]. Conditions of and procedure for payment of charges

(1) An applicant for authorisation for a biocidal product must pay the statutory minimum fee to the Health Board within the time limit prescribed in the Biocidal Products Regulation. Depending on the actual expenses of evaluation, the Health Board will refund the overpaid sum to the applicant or request that the applicant pay the underpaid sum, but in any event the amount to be paid in total must not exceed the maximum charge provided by law.

(2) The evaluator of an application must keep account of the working time spent on evaluating the application, recording the time spent on evaluating based on days.

(3) The charge is calculated on the basis of the working time in hours, the hourly rate of the official or employee of the Health Board based on the staff and administrative expenses in the previous calendar year and the hourly rate of the expert.

(4) If the sum spent on the evaluation is less than the initial sum, the Health Board will refund the overpaid sum to the applicant within 30 calendar days after invoicing the applicant. A sum of less than 100 euros will not be refunded to the applicant if the applicant has not requested a refund.

(5) If the sum spent on evaluation exceeds the initial sum paid, the applicant will pay the sum requested on the basis of the invoice submitted by the Health Board within 30 calendar days as of the receipt of the invoice to the current account of the Health Board.

(6) If the applicant does not pay the sum specified in subsection (5) of this section within the prescribed time limit, the Health Board will have the right to have an enforcement agent enforce the claim for payment pursuant to the procedure provided for in the Code of Enforcement Procedure.

(7) The Health Board will issue a respective decision within five working days after the accrual of the sum specified in subsection (5) of this section.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

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, products containing biocidal products, making them available and using them under this Act, legislation established on the basis thereof and the Biocidal Products Regulation is 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 and Technical Regulatory Authority – over adherence to the requirements established to making biocidal products and treated articles available on the retail market;
[RT I, 12.12.2018, 3 - entry into force 01.01.2019]
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 Board – 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;
[RT I, 10.07.2020, 2 – entry into force 01.01.2021]
5) the Agriculture 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;
[RT I, 01.07.2020, 1 – entry into force 01.01.2021]
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 Board is authorised to use physical force on the grounds and in accordance with the procedure established in the Law Enforcement Act.
[RT I, 10.07.2020, 2 – entry into force 01.01.2021]

§ 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 established to making available and use of biocidal product and product treated with biocidal product

[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(1) The penalty for a violation of the requirements established by this Act and the Biocidal Products Regulation regarding making a biocidal product and a product treated with a biocidal product available and regarding the use of a biocidal product and a product treated with a biocidal product is a fine of up to 300 fine units.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(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 Board;
[RT I, 10.07.2020, 2 – entry into force 01.01.2021]
3) the Consumer Protection and Technical Regulatory Authority;
[RT I, 12.12.2018, 3 - entry into force 01.01.2019]
4) the Health Board;
[RT I 2010, 37, 224 – entry into force 09.07.2010]
5) the Agriculture and Food Board.
[RT I, 01.07.2020, 1 – entry into force 01.01.2021]
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 in framework of work programme regulating transitional period provided for in Biocidal Products Regulation

[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(1) Biocidal products whose active substances comply with the conditions provided for in Article 89(2) of the Biocidal Products regulation may continue to be made available and used following the registration with the Health Board.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(1^1) Biocidal products that comply with the requirements provided for in subsection (1) of this section are registered until 31 December 2024 or until the date until which the European Commission has, by its decision, extended the transitional period for the review of data submitted on certain active substances.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(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) where necessary, a relevant letter of access;
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]
4) the trade name of the biocidal product;
5) the full composition of the biocidal product and the classification of each hazardous component;
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 an active substance has been included in the list of the approved active substances of the Union, authorisation must be applied for a registered biocidal product in accordance with the requirements provided for in the Biocidal Products Regulation. An application for authorisation must be submitted not later than by the date specified in Article 89(3) of the Biocidal Products Regulation.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(4) A biocidal product registered in Estonia can continue to be made available after the date of approval of the active substance if the applicant has submitted an application for authorisation to the Health Board or to the European Chemicals Agency via the Register for Biocidal Products.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(5) [Repealed – RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(6) It is prohibited to bring to Estonia from other Member States and to make available 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).
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

(7) Subsection 1 (2), §§ 13 and 14, subsections 15 (1) and (3), § 17, subsections 18 (1) and (2), § 21, subsection 32 (1) and subsection 33 (1) of this Act apply to authorisations and registration certificates issued before 1 September 2013.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

§ 49[1]. Implementation of subsection 39 (2) of Act

The professional qualifications of a level III pest control operator acquired before 1 July 2015 for the management and organisation of pest control are equal to the professional qualifications of a level 5 pest control operator demanded in subsection 39 (2) of this Act.
[RT I, 10.03.2015, 1 – entry into force 20.03.2015]

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]