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Biocidal Products Act¹

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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 amended 01.07.2014 [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 4 of § 107 ³ of the Government of the Republic Act.
17.02.2015	RT I, 10.03.2015, 1	20.03.2015, in part 01.07.2015
09.12.2015	RT I, 30.12.2015, 1	18.01.2016
21.11.2018	RT I, 12.12.2018, 3	01.01.2019
13.05.2020	RT I, 17.05.2020, 1	26.05.2021
10.06.2020	RT I, 01.07.2020, 1	01.01.2021
17.06.2020	RT I, 10.07.2020, 2	01.01.2021
13.10.2021	RT I, 22.10.2021, 3	01.11.2021
18.01.2023	RT I, 03.02.2023, 2	01.06.2023
11.12.2024	RT I, 02.01.2025, 3	01.09.2025

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]

(1¹) 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]

(1²) 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 and relevant legislation of the European Union;
- [RT I, 17.05.2020, 1 – entry into force 26.05.2021]
- 4) cosmetic products regulated by the Public Health Act;
- [RT I, 02.01.2025, 3 - entry into force 01.09.2025]
- 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]

§ 5¹. 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

[Repealed -RT I, 03.02.2023, 2 - entry into force 01.06.2023]

Subchapter 1

Authorisation

[Repealed -RT I, 03.02.2023, 2 - entry into force 01.06.2023]

§ 13. Conditions of granting authorisation

[Repealed – RT I, 03.02.2023, 2 – entry into force 01.06.2023]

§ 14. Applying for authorisation

[Repealed – RT I, 03.02.2023, 2 – entry into force 01.06.2023]

§ 15. Biocidal product dossier

[Repealed – RT I, 03.02.2023, 2 – entry into force 01.06.2023]

§ 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

[Repealed – RT I, 03.02.2023, 2 – entry into force 01.06.2023]

§ 18. Term of validity of authorisation

[Repealed – RT I, 03.02.2023, 2 – entry into force 01.06.2023]

§ 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

[Repealed – RT I, 03.02.2023, 2 – entry into force 01.06.2023]

§ 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]

Subchapter 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]

Subchapter 1 Making Biocidal Product Available

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

§ 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 the Biocidal Products Regulation and this Act.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(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) [Repealed – RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(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.

(7) Disinfectants used in public places must comply with the intended use as specified by the holder of the authorisation or registration certificate and must be accompanied by instructions for use and information about the holder of the authorisation or registration certificate and the ingredients of the disinfectant, and, where appropriate, other information enabling the biocidal product to be used for the intended purpose and in a safe manner.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(8) Disinfectants specified in subsection 7 of this section must bear the following information visible to the consumer:

- 1) the number allocated to the biocidal product by the competent authority or the European Commission;
- 2) the trade name of the biocidal product;
- 3) the identity of every active substance and its concentration in metric units;
- 4) instructions for use, where applicable, the period of time needed for the biocidal effect;
- 5) depending on the product, the hazard pictograms, signal words, hazard statements or precautionary statements required by Regulation (EC) No 1272/2008 of the European Parliament and of the Council, or a supplemental information section in accordance with Article 25.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

§ 33. Restrictions on making available

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

(1) A biocidal product classified as toxic, carcinogenic, mutagenic or toxic for reproduction, or which has endocrine-disrupting properties, or developmental neurotoxic or immunotoxic effects in accordance with Article 19(4) of the Biocidal Products Regulation, must not be made available to the consumer for the purposes of the Consumer Protection Act.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

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

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(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]

(4) The provisions of subsection 2 of this section do not apply to biocidal products of product-type 1 in accordance with Annex V to the Biocidal Products Regulation.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

§ 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

Before a hazardous biocidal product is placed on the market in Estonia, information specified in Annex VIII to Regulation (EC) No 1272/2008 of the European Parliament and of the Council must be submitted to the Health Board in accordance with Article 45 of the same Regulation, which is used for the purpose of developing and applying measures for the prevention and treatment of poisoning cases.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

Subchapter 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 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, 03.02.2023, 2 – entry into force 01.06.2023]

(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]

§ 38¹. 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]

§ 38². 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 and a training programme, the training establishment must rely on the level 4 and level 5 professional standard of a pest control technician and submit the curriculum or programme before the organisation of training to the body that awards the profession of a pest control technician within the meaning of the Professions Act in order to obtain an opinion and proposals.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

§ 38³. Professional provider of pest control service

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(1) ‘Professional provider of pest control service’ 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.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(2) A professional provider of pest control service 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.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(3) [Repealed – RT I, 03.02.2023, 2 – entry into force 01.06.2023]

§ 39. Responsible specialist

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

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(2) The responsible specialist must hold the level 5 professional qualifications of a pest control technician 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, 03.02.2023, 2 – entry into force 01.06.2023]

(3) Upon applying for the profession 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 the control of harmful organisms is required.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(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 2 of § 7 of the Recognition of Foreign Professional Qualifications Act is the Health Board.
[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

§ 40. Notification obligation

(1) A professional provider of pest control service must submit a notice of economic activities.
[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(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. Provision of pest control service on site

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(1) A pest control site is a building, structure or a part thereof or the accompanying area (hereinafter *site*) where harmful organisms may spread.
[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(2) The possessor of the site organises the monitoring of harmful organisms on site and is responsible for preventing the harmful effect of harmful organisms and for the destroying of harmful organisms.
[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(3) The possessor of the site creates conditions required for safe control of harmful organisms on site and, jointly with the person engaged in pest control, draws up a pest management plan.
[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(4) The professional provider of pest control service draws up a pest control report for the possessor of the site, which must be kept for at least five years.
[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(5) More detailed requirements for pest control, pest management plan and pest control report will be established by a regulation of the minister in charge of the policy sector.
[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

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 processing of an application relating to the approval of an active substance as the evaluating Member State;
- 2) the processing of an application for an authorisation for a biocidal product or a biocidal product family as the evaluating Member State;
- 3) the processing of an application for an authorisation for a biocidal product or a biocidal product family as the Member State concerned;

(4) the processing of a notice concerning the authorisation of a biocidal product or a biocidal product family;
5) the processing of an application for a registration certificate of a biocidal product during the transitional period;

6) the processing of an application for a change of the registration certificate of a biocidal product during the transitional period;

7) the processing of an application for an administrative change of the registration certificate of a biocidal product during the transitional period.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(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]

§ 42¹. 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 200 euros.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(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 initial charge is 71,600 euros and the maximum charge is 624,200 euros for the evaluation of an active substance;

2) the initial charge is 42,100 euros and the maximum charge is 369,200 euros for the evaluation of the additional information of an active substance;

3) the initial charge is 88,400 euros and the maximum charge is 769,800 euros for the evaluation of a Union authorisation for a biocidal product family;

4) the initial charge is 80,000 euros and the maximum charge is 697,000 euros for the evaluation of a national authorisation for a biocidal product family;

5) the initial charge is 63,100 euros and the maximum charge is 551,300 euros for the evaluation of a Union authorisation for a biocidal product;

6) the initial charge is 42,100 euros and the maximum charge is 369,200 euros for the evaluation of a national authorisation for a biocidal product;

7) the initial charge is 31,600 euros and the maximum charge is 278,200 euros for the preliminary evaluation of a biocidal product or a biocidal product family;

8) the initial charge is 4,200 euros and the maximum charge is 41,400 euros for the ex-post evaluation of an authorisation for a biocidal product or a biocidal product family;

9) the charge for the evaluation of an authorisation for a biocidal product or a biocidal product family of the same specifications is 15,500 euros;

10) the charge for the evaluation of a provisional authorisation for a biocidal product or a biocidal product family is 26,100 euros;

11) the initial charge is 21,100 euros and the maximum charge is 187,100 euros for the evaluation of an authorisation for a biocidal product or a biocidal product family pursuant to the simplified procedure;

12) the charge for the evaluation of an authorisation for a biocidal product or a biocidal product family upon mutual recognition is 2,100 euros;

13) the initial charge is 10,500 euros and the maximum charge is 69,200 euros for the evaluation of a major change to a biocidal product or a biocidal product family;

14) the initial charge is 21,100 euros and the maximum charge is 187,100 euros for the evaluation of the renewal of an authorisation of a biocidal product or a biocidal product family;

15) the initial charge is 4,200 euros and the maximum charge is 27,100 euros for the evaluation of a minor change to a biocidal product or a biocidal product family.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(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]

§ 42². 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 with the requirements established to making biocidal products and treated articles available, over compliance with the requirements established to biocidal products and treated articles and the use of biocidal products by professional providers of pest control service, and in fields regulated by the Public Health Act and the Health Services Organisation Act;

[RT I, 02.01.2025, 3 - entry into force 01.09.2025]

2) the Consumer Protection and Technical Regulatory Authority – over adherence to the labelling requirements established by subsection 8 of § 32 of this Act on the objects of supervision of the Consumer Protection and Technical Surveillance Authority provided in other legislation;

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

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 hazardness 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 Chapter VII of Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.06.2019, pp 1–44).

[RT I, 22.10.2021, 3 – entry into force 01.11.2021]

§ 43¹. 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, 51, 52 and 53 of the Law Enforcement Act on the grounds and in accordance with the procedure provided for in the Law Enforcement Act.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

§ 43². 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]

§ 43³. 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 non-compliance levy

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

In the event of failure to comply with a precept the maximum non-compliance levy imposed in accordance with the procedure provided for in the Substitutional Performance and Non-Compliance Levies 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**

Subchapter 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]

(1¹) 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;

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

- 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) data on the efficacy of the biocidal product;
- 11) the labelling of the biocidal product, and the packaging size and description;
- 12) the safety data sheet of the active substance;
- 13) additional information concerning the biocidal product, if necessary.

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

[RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(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) [Repealed – RT I, 03.02.2023, 2 – entry into force 01.06.2023]

(7) [Repealed – RT I, 03.02.2023, 2 – entry into force 01.06.2023]

§ 49¹. Implementation of subsection 2 of § 39 of Act

[Repealed – RT I, 03.02.2023, 2 – entry into force 01.06.2023]

Subchapter 2
Amendment of Acts Related to Biocidal Products Act

§ 50.–§ 52.[Omitted from this text.]

Subchapter 3

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

¹[Drafting note omitted.]

[RT I, 03.02.2023, 2 - entry into force 01.06.2023]