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Biocides Act

Adopted on 14.05.2009
RT I 2009, 29, 174
entry into force on 19.06.2009, partly in accordance with § 53.

Amended by the following acts

Reception	Publication	Enforcement
30.09.2009	RT I 2009, 49, 331	01.01.2010 In the Act, the words "Kemikaalide Informationekskus" were replaced by the word "Health Board" in the corresponding case.
22.04.2010	RT I 2010, 22, 108	01.01.2011 shall enter into force on the day specified in the decision of the Council of the European Union on the annulment of the exception established for the Republic of Estonia on the basis of Article 140(2) of the Treaty on the Functioning of the European Union, Council of the European Union 13.07.2010. a decision No. 2010/416/EU (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; effective date changed 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, titles of ministers replaced on the basis of § 107³ subsection 4 of the Government of the Republic Act.
17.02.2015	RT I, 10.03.2015, 1	20.03.2015, partially 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

Chapter 1
general settings

§ 1. Scope of the Act

(1) This Act provides the legal basis for making biocides and products treated with biocides available on the market and their use, limiting economic activity related to the use of biocides, and organizing state supervision over the fulfillment of the requirements set forth in this Act and the relevant regulation of the European Union with the aim of protecting health, the environment and property and ensuring the free movement of goods movement.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

(1¹) The requirements and conditions for making biocides and products treated with biocides available on the market are established in Regulation (EU) No. 528/2012 of the European Parliament and of the Council concerning the making available and use of biocides on the market (text applicable in the EEA) (OJ L 167, 27.06.2012, page 1–123) (hereinafter referred to as *the Biocides* Regulation).
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

(1²) This Act applies to making biocides and products treated with biocides available on the market and to their use in cases not regulated by the Biocides Regulation.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

(2) This Act does not apply to the following products:
1) a plant protection product to which the Plant Protection Act and relevant European Union legislation apply;
2) a medicine to which the Medicinal Products Act and relevant European Union legislation apply;
3) medical device to which the Medical Device Act and relevant European Union legislation apply;
[RT I, 17.05.2020, 1 - enters into force. 26.05.2021]
4) a cosmetic product to which the Public Health Act applies;
5) material or object intended for contact with food or their component, to which the Food Act and relevant European Union legislation apply;

6) food or food additive, enzyme, flavoring or excipient, to which the Food Act and relevant European Union legislation apply;
7) feed to which the Feed Act applies.
[RT I 2010, 37, 224 - entry into force. 09.07.2010]

(3) The provisions of the Administrative Procedure Act apply to the administrative procedure prescribed in this Act, taking into account the peculiarities of this Act and the Biocides Regulation.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

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

§ 5[1]. Terms

In this Act, terms are used in the sense of the Biocides Regulation, unless otherwise provided in this Act.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

§ 6. Competent authority

The actions provided for in this Act and the Biocides Regulation are performed and administrative acts are issued by the Board of Health, unless otherwise provided for in this Act or the Biocides Regulation.
[RT I, 10.03.2015, 1 - enters 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 using biocide
[RT I, 10.03.2015, 1 - entered into force. 20.03.2015]

(1) Making a biocide available on the market is an activity by which a biocide is made available for use or distribution in the customs territory of the European Union for a fee or free of charge. The import and storage of the biocidal product are also considered to make it available, unless the storage is followed by its export or removal from circulation.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

(2) [Repealed - RT I, 10.03.2015, 1 - entered into force. 20.03.2015]

(3) A biocidal product is allowed to be made available and used in Estonia if it has received an appropriate permit or registration certificate in accordance with this Act or the biocidal regulation.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

Chapter 2
ADDITION OF THE ACTIVE SUBSTANCE TO THE APPENDIX OF THE BIOCIDE DIRECTIVE
[Repealed - RT I, 10.03.2015, 1 - entered into force. 20.03.2015]

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

Chapter 3
AUTHORIZATION OF THE AVAILABILITY OF THE BIOCIDE
[Repealed - RT I, 03.02.2023, 2 - entered into force. 01.06.2023]

Section 1
Marketing authorization
[Repealed - RT I, 03.02.2023, 2 - entered into force. 01.06.2023]

§ 13. Conditions for granting a distribution license
[Repealed - RT I, 03.02.2023, 2 - entered into force. 01.06.2023]

§ 14. Application for distribution license
[Repealed - RT I, 03.02.2023, 2 - entered into force. 01.06.2023]

§ 15. Biocide dossier
[Repealed - RT I, 03.02.2023, 2 - entered into force. 01.06.2023]

§ 16. Application processing
[Repealed - RT I, 10.03.2015, 1 - entry into force. 20.03.2015]

§ 17. Issuing a distribution license in case of a framework definition
[Repealed - RT I, 03.02.2023, 2 - entered into force. 01.06.2023]

§ 18. Validity period of distribution license
[Repealed - RT I, 03.02.2023, 2 - entry into force. 01.06.2023]

§ 19. Change of distribution license
[Repealed - RT I, 10.03.2015, 1 - entered into force. 20.03.2015]

§ 20. Revocation of distribution license
[Repealed - RT I, 10.03.2015, 1 - entered into force. 20.03.2015]

§ 21. Mutual recognition of distribution licenses
[Repealed - RT I, 03.02.2023, 2 - entered into force. 01.06.2023]

§ 22. Peculiarities of mutual recognition of low-risk biocide marketing authorization
[Repealed - RT I, 10.03.2015, 1 - entered into force. 20.03.2015]

Section 2
Exceptions to marketing authorisation

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

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

Chapter 4
INFORMATION AND COOPERATION

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

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

Chapter 5
AVAILABILITY AND USE OF BIOCIDE

[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

Section 1
Making the biocidal product available

[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

§ 32. Classification, packaging and labeling of biocides

(1) The biocide to be made available must be classified, labeled and packaged before being made available in accordance with the Chemicals Act and the legislation established on the basis thereof or Regulation (EC) No. 1272/2008 of the European Parliament and of the Council, which deals with the classification, labeling and packaging of substances and mixtures and which amends the directives 67/548/EEC and 1999/45/EC and declare them invalid and amend Regulation (EC) No. 1907/2006 (text applicable in the EEA) (OJ L 353, 31.12.2008, p. 1–1355), the Biocides Regulation and the requirements of this Act according to
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(2) The packaging of the biocidal product must enable the biocidal product to be clearly distinguished from food and feed.

(3) Biocides intended for use by the consumer within the meaning of the Consumer Protection Act, which can be mistaken for food or fodder, must contain ingredients that make its consumption objectionable.

(4) [Repealed - RT I, 03.02.2023, 2 - entered into force. 01.06.2023]

(5) The labeling of the biocidal product must be in Estonian and must not contain information that would mislead the user or direct him to use the biocidal product for non-intended purposes.

(6) The classification, packaging and labeling requirements determined in this section do not apply to the transport of biocides.

(7) The disinfectant used in a public place must correspond to the area of use prescribed by the holder of the permit or registration certificate, and it must be accompanied by a user manual and information about the holder of the permit or registration certificate and the ingredients of the disinfectant, if necessary, other information that enables targeted and safe use of the biocidal product.
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(8) The disinfectant specified in subsection 7 of this section must have the following information visible to the consumer:
1) the number assigned to the biocidal product by the competent authority or the European Commission;
2) commercial name of the biocide;
3) identity data of each active substance and its concentration in metric units;
4) instructions for use, if necessary, the time required for the effect of the biocide;
5) depending on the product, hazard pictograms, catchphrases, danger phrases, warning phrases or a paragraph with additional information required in Regulation (EC) No. 1272/2008 of the European Parliament and of the Council 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 - entered into force. 20.03.2015]

(1) A biocidal product that is classified as a toxic, carcinogenic, mutagenic or reproductively toxic chemical or has endocrine-disrupting properties or a neurotoxic or immunotoxic effect on development in accordance with the provisions of Article 19(4) of the Biocides Regulation may not be made available to the consumer within the meaning of the Consumer Protection Act.
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(2) Biocides intended for professional use may not be made available to the consumer within the meaning of the Consumer Protection Act.
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(3) Biocides intended for professional use may only be made available in wholesale trade.

(4) In order to deal with the sale of biocides intended for professional use, the economic activity notification must be submitted in the field of wholesale trade.

(5) In addition to the provisions of the General Part of the Code of Economic Activities, the following data shall be provided in the notice of economic activity:
1) place of business or places of business, in the case of e-commerce, website address;
2) goods that you want to sell (biocide intended for professional use).

(6) Persons who make biocides available on the market must have knowledge of the dangerous properties of biocides, risk management and conditions of use, and be prepared to advise users of biocides if necessary.
[RT I, 10.03.2015, 1 - enters into force. 01.07.2015]

§ 34. Place of storage and making available of biocide
[RT I, 10.03.2015, 1 - entered into force. 20.03.2015]

(1) In order to ensure the health and environmental safety of people and animals, the biocide must be stored and made available in such a way as to prevent contamination of food, medicine and feed, as well as other goods.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

(2) There must not be open packages of biocides at the place where biocides are stored and made available. It is forbidden to repackage the biocide at the place of storage and making it available.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

(3) A biocidal whose packaging is broken may not be made available. Such a product must be disposed of immediately and destroyed in accordance with the procedure provided for in the Waste Act, taking into account the biocidal safety data sheet.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

(4) The provisions of subsection 2 of this section do not apply to biocides belonging to product type 1 in accordance with Annex V of the Biocides Regulation.
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

§ 35. Biocidal product and active substance safety data sheet
[Repealed - RT I, 10.03.2015, 1 - entered into force. 20.03.2015]

§ 36. Advertising of biocide

Biocidal advertising must meet the requirements set forth in § 27 of the Advertising Act.

§ 37. Information on poisoning

According to Article 45 of Regulation (EC) No. 1272/2008 of the European Parliament and of the Council, before placing a dangerous biocidal product on the market in Estonia, information according to Annex VIII of the same regulation must be submitted to the Health Board, which is used for the purpose of developing and implementing measures to prevent and treat poisoning cases.
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

Section 2
Use of biocide

§ 38. General requirements for the use of biocide

(1) A person who uses a biocidal product to destroy, repulse, render harmless or to control their unwanted effects must control harmful organisms only in the manner and under the conditions prescribed in the biocidal label and in the instructions for use.
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(2) [Repealed - RT I, 10.03.2015, 1 - entered into force. 01.07.2015]

(3) [Repealed - RT I, 10.03.2015, 1 - entered into force. 01.07.2015]

§ 38 1 . Professional user of biocide

(1) A professional user of a biocidal product is a person who has the appropriate training and who uses biocides in the course of economic or professional activities, which are prescribed for professional use by a permit or registration certificate granted to make the biocidal product available and used on the market.

(2) The professional user of biocides must have knowledge of the hazardous properties, risk management and conditions of use of biocides used in professional activities, as well as skills in the safe use of biocides, obtained during level or occupational training, for which there is an appropriate certificate or certificate.
[RT I, 10.03.2015, 1 - enters into force. 01.07.2015]

§ 38 2 . Training for professional users of biocides

(1) The training institution organizes the training of the professional user of biocides in accordance with the requirements set forth in the Adult Training Act, the Vocational Education Institution Act and this Act.
[RT I, 10.03.2015, 1 - enters into force. 01.07.2015]

(2) When drawing up the study and training plan, the training institution must take as a basis the standards of the 4th and 5th level of the profession of harmful organism exterminator and submit its plan to the provider of the profession of harmful organism exterminator before organizing the training in order to obtain a position and suggestions within the meaning of the Professional Act.
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

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§ 38 . Professional pest control service provider

[RT I, 03.02.2023, 2 - entered into force. 01.06.2023]

(1) A professional pest control service provider is an entrepreneur whose economic or professional activity is the provision of pest control services and which has at least one appropriately trained specialist for this purpose.

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

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

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(3) [Repealed - RT I, 03.02.2023, 2 - entered into force. 01.06.2023]

§ 39. Responsible specialist

(1) The responsible specialist is a person who is competent to manage and organize the control of harmful organisms and to advise the entrepreneur in order to ensure that the requirements stipulated in the legislation are met.

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(2) The responsible specialist must have the 5th level of the profession of harmful organism exterminator acquired to manage and organize the control of harmful organisms within the meaning of the Professional Act, according to which the person organizes the sharing of resources and the work of others and is responsible for this work.

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(3) When applying for the profession provided for in subsection 2 of this section, at least a secondary education, vocational and managerial continuing education and three years of work experience in the control of harmful organisms are required.

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(4) Competence of competence acquired in a foreign country with the requirements of this Act is assessed and certified by the competent authority on the basis of the Act on the Recognition of Foreign Professional Qualifications, taking into account the differences arising from this Act. The competent authority provided for in § 7 subsection 2 of the Act on the Recognition of Foreign Professional Qualifications is the Health Board.

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

§ 40. Notification obligation

(1) A professional pest control service provider must submit an economic activity notification.

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(2) In addition to the general part of the Code of Economic Activities, the following information is provided in the notice of economic activity:

1) the name and personal identification number of the responsible specialist, or, if it is not available, the date of birth;

2) telephone number and e-mail address of the responsible specialist;

3) the number and validity period of the certificate certifying the qualification of the responsible specialist, the name of the person issuing the invitation, the place and date of issuing the invitation.

[RT I, 10.03.2015, 1 - enters into force. 01.07.2015]

§ 41. Provision of the service of control of harmful organisms at the site

[RT I, 03.02.2023, 2 - entered into force. 01.06.2023]

(1) The object of control of harmful organisms is considered to be a building, a facility or its part or a demarcated land area belonging to them (hereinafter *object*) where the spread of harmful organisms is possible.

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(2) The owner of the facility organizes monitoring of harmful organisms on the facility and is responsible for preventing their harmful effects and destroying them.

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(3) The owner of the object creates the necessary conditions for the safe control of harmful organisms on the object and develops a control plan together with the person performing the control.

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(4) A professional pest control service provider prepares a report for the owner of the object on the control performed, which is kept for at least five years.

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(5) The detailed requirements for the implementation, plan and report of the control of harmful organisms shall be established by a regulation of the minister responsible for the field .

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

Chapter 6
STATE FEES AND FEES

[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

§ 42. State fees for processing documents at the Health Board

[RT I, 10.03.2015, 1 - entered into force. 20.03.2015]

(1) An applicant for the approval of an active ingredient of a biocidal product, an applicant for a relevant permit for a biocidal product, or an applicant for a registration certificate in accordance with this Act shall, before submitting the documents to the Health Board, pay

a state fee in accordance with the Biocides Regulation at the rate provided for in the State Fees Act for the following actions:
1) processing an application related to the approval of an active ingredient of a biocidal product as an evaluating member state;
2) processing an application for a permit for a biocidal product or a family of biocidal products as an evaluating member state;
3) processing an application for a permit for a biocidal product or a family of biocidal products as the relevant Member State;
4) processing a notice related to the permit of a biocidal product or biocidal family;
5) processing an application for a biocidal registration certificate during the transitional period;
6) processing the application for the change of the biocidal registration certificate during the transitional period;
7) processing of the application for administrative change of the biocidal registration certificate during the transition period.
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(2) The rates of the state fee charged for the operations provided for in subsection 1 of this section are reviewed at least every two years and, if necessary, appropriate changes are made to the amount of the fee, based on the actual expenses of the past period.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

§ 42[1]. Fees for the assessment of an application for authorization of a biocidal product

(1) An applicant for a Union or national permit for a biocidal product shall pay the Health Board for the assessment of the application in accordance with the biocidal regulation.

(2) If possible, the Health Board evaluates the application internally or uses the help of contracted experts for the evaluation. The expert's hourly fee can be a maximum of 200 euros.
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(3) The application may 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 applications for biocides, plant protection products or other substances of this nature. The expert must take into account the requirements set out in the Biocides Regulation and the relevant guidelines of the European Commission on professional evaluation.

(4) The applicant pays the Health Board for the following actions as follows:
1) the initial fee for the assessment of the active substance is 71,600 euros and the maximum fee is 624,200 euros;
2) the initial fee for the assessment of additional information on the active substance is 42,100 euros and the maximum fee is 369,200 euros;
3) the initial fee for the evaluation of the license of the biocidal family is 88,400 euros and the maximum fee is 769,800 euros;
4) the initial fee for the evaluation of the national license of the biocidal product family is 80,000 euros and the maximum fee is 697,000 euros;
5) the initial fee for the assessment of the license of the biocide union is 63,100 euros and the maximum fee is 551,300 euros;
6) the initial fee for the assessment of the biocidal state permit is 42,100 euros and the maximum fee is 369,200 euros;
7) the initial fee for the preliminary evaluation of a biocidal product or biocidal product family is 31,600 euros and the maximum fee is 278,200 euros;
8) the initial fee for the follow-up evaluation of a permit for a biocidal product or biocidal family is 4,200 euros and the maximum fee is 41,400 euros;
9) the fee for the assessment of a permit for a biocidal product or family of biocidal products with the same properties is 15,500 euros;
10) the fee for the assessment of a temporary permit for a biocidal product or biocidal family is 26,100 euros;
11) the initial fee for evaluating a permit for a biocidal product or biocidal family with a simplified procedure is 21,100 euros and the maximum fee is 187,100 euros;
12) in the case of mutual recognition of a permit for a biocidal product or biocidal family, the assessment fee is 2,100 euros;
13) the initial fee for the evaluation of a significant change of a biocidal product or biocidal family is 10,500 euros and the maximum fee is 69,200 euros;
14) the initial fee for evaluating the renewal of a license for a biocidal product or biocidal family is 21,100 euros and the maximum fee is 187,100 euros;
15) the initial fee for the assessment of a less important change of a biocidal product or a biocidal family is 4,200 euros and the maximum fee is 27,100 euros.
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(5) The rates of the fee charged for the operations provided for in subsection 4 of this section are reviewed at least every two years and, if necessary, appropriate changes are made to the amount of the fee, based on the actual expenses of the past period.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

§ 42[2]. Terms and procedure for payment of fees

(1) The biocidal permit applicant shall pay the initial fee prescribed by law to the Health Board within the term prescribed in the biocidal regulation. Depending on the actual costs incurred for the assessment, the Board of Health will reimburse the applicant the overpaid amount or pay the applicant more, but in total not more than the maximum fee prescribed by law.

(2) The appraiser of the application must keep a working time record of the time spent evaluating the application, in which the time spent for the evaluation is entered in days.

(3) The calculation of the fee is based on the working time in hours, the hourly fee of the Health Board official or employee based on the personnel and economic costs of the previous calendar year, and the expert's hourly fee.

(4) If the assessment took less than the initial amount paid, the Board of Health will refund the excess amount paid to the applicant within 30 calendar days after submitting the invoice to the applicant. An amount less than 100 euros will not be returned to the applicant, if the applicant has not requested a refund.

(5) If the evaluation took more than the initial amount paid, the applicant shall pay the requested fee on the basis of the invoice submitted by the Health Board within 30 calendar days from the receipt of the invoice to the current account of the Health Board.

(6) If the applicant does not pay the amount specified in subsection 5 of this section within the prescribed time limit, the Health Board has the right to issue a mandatory demand for enforcement in accordance with the procedure provided for in the enforcement procedure code.

(7) The Health Board shall issue a relevant decision within five working days after receipt of the amount specified in subsection 5 of this section.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

Chapter 7
STATE SUPERVISION

§ 43. State supervision
[RT I, 13.03.2014, 4 - entered into force. 01.07.2014]

State supervision of biocides and products containing biocides and their making available on the market and their use on the market is carried out by:
1) Health Board - on compliance with the requirements established for making biocides and products treated with biocides available, for biocides and products treated with biocides on the fulfillment of the established requirements and on the use of biocides at the professional pest control service provider and in the areas regulated by the Public Health Act and the Act on the Organization of Health Services;
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]
2) Consumer Protection and Technical Supervision Agency - on compliance with the labeling requirements established by § 32 (8) of this Act on objects of supervision of the Consumer Protection and Technical Supervision Agency provided for in other legislation;
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]
3) Labor inspectorate - compliance with the requirements established for the use of biocide in the field regulated by the Occupational Health and Safety Act;
4) Environmental Board - supervision of compliance with the requirements established for the use of biocides from the point of view of environmental hazards at the objects of its field;
[RT I, 10.07.2020, 2 - enters into force. 01.01.2021]
5) Agriculture and Food Board - supervision of compliance with the requirements established for the use of biocides from the point of view of animal health and feed and food safety in the objects of its field;
[RT I, 01.07.2020, 1 - enters into force. 01.01.2021]
6) Tax and Customs Board - compliance with the requirements established for making biocides available when entering the Community market of Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance and product compliance and which amends Directive 2004/42/EC and regulations (EC) No. 765/2008 and (EU) No. 305/2011 (OJ L 169, 25.06.2019, pp. 1–44), in accordance with the provisions of Chapter VII.
[RT I, 22.10.2021, 3 - enters into force. 01.11.2021]

§ 43 1. Special measures of state supervision

The law enforcement body may apply 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 basis and according to the procedure provided for in the Law Enforcement Act to carry out the state supervision provided for in this Act.
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

§ 43 2. Peculiarities of state supervision

(1) The law enforcement body has the right to prohibit the import and sale of biocides into the customs territory of the Community in the absence of a valid marketing authorization or registration certificate.
[RT I, 29.06.2014, 1 - enters into force. 01.07.2014]

(2) If, in the course of national supervision, the supervisory authority has issued an injunction regarding the restriction or temporary prohibition of the availability and use of a biocidal product in accordance with Article 88 of the Biocidal Regulation, it shall immediately notify the Health Board, which in turn shall immediately notify the European Commission and other member states.

(3) The supervisory authorities shall submit to the Health Board the data in accordance with Article 65 (3) of the Biocides Regulation by 1 July 2015 and by 1 April every fifth year thereafter. The Health Board submits the report specified in Article 65(3) of the Biocidal Regulation to the Commission based on the received data.

(4) For the purpose of carrying out state supervision, a law enforcement agency may stay and move with a vehicle, including an all-terrain vehicle and a floating vehicle, in an area of land or water, where stay and movement are prohibited or restricted by legislation for the purpose of environmental protection.
[RT I, 13.03.2014, 4 - enters into force. 01.07.2014]

§ 43 3. Use of immediate coercion

The Environmental Board is allowed to use physical force on the basis and according to the procedure provided in the Law on Law Enforcement.
[RT I, 10.07.2020, 2 - enters into force. 01.01.2021]

§ 44. Injunction
[Repealed - RT I, 13.03.2014, 4 - entered into force. 01.07.2014]

§ 45. Challenging an injunction
[Repealed - RT I, 13.03.2014, 4 - entered into force. 01.07.2014]

§ 46. Rate of extortion money
[RT I, 13.03.2014, 4 - entered into force. 01.07.2014]

In the case of failure to comply with the injunction, the maximum amount of the fine to be applied in accordance with the procedure laid down in the Substitute Enforcement and Fines Act is 32,000 euros.
[RT I, 13.03.2014, 4 - enters into force. 01.07.2014]

Chapter 8
RESPONSIBILITY

§ 47. Violation of the requirements established for making available and using biocides and products treated with biocides
[RT I, 10.03.2015, 1 - entered into force. 20.03.2015]

(1) Violation of the requirements established by this Act and the Biocides Ordinance for the making available and use of a biocidal product and a product treated with a biocidal product
shall be punished with a fine of up to 300 fine units.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

(2) For the same act, if it has been committed by a legal entity, -
shall be punished with a fine of up to 32,000 euros.
[RT I 2010, 22, 108 - entry into force. 01.01.2011]

§ 48. Procedure

(1) [Repealed - RT I, 12.07.2014, 1 - entered into force. 01.01.2015]

(2) Out-of-court procedures for misdemeanors provided for in § 47 of this Act are, according to their competence:
1) Labor Inspection;
2) Environmental Board;
[RT I, 10.07.2020, 2 - enters into force. 01.01.2021]
3) Consumer Protection and Technical Supervision Agency;
[RT I, 12.12.2018, 3 - enters into force. 01.01.2019]
4) Health Board;
[RT I 2010, 37, 224 - entry into force. 09.07.2010]
5) Agriculture and Food Board.
[RT I, 01.07.2020, 1 - enters into force. 01.01.2021]
6) [invalidated - RT I 2010, 37, 224 - entry into force. 09.07.2010]

Chapter 9
IMPLEMENTATION PROVISIONS

Section 1
Implementation of the law

§ 49. Implementation of the law within the regulatory work program of the transition period provided for in the Biocidal Regulation
[RT I, 10.03.2015, 1 - entered into force. 20.03.2015]

(1) Biocides, the active ingredients of which meet the conditions set forth in Article 89(2) of the Biocides Regulation, may continue to be made available and used after registration with the Health Board.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

(1^{1}) Biocides that meet the requirements set forth in subsection 1 of this section shall be registered until December 31, 2024, or until the deadline until which the European Commission has decided to extend the transitional period for reviewing the data submitted on certain active substances.
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

(2) The following data shall be submitted to the Health Board for registration:
1) applicant's name, registry code or personal identification number and contact information;
2) contact details of the manufacturer of the biocidal product and active substance;
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]
3) if necessary, appropriate information use consent;
[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]
4) commercial name of the biocide;
5) the complete composition of the biocide and the classification of each hazardous ingredient;
6) physical and chemical properties of the biocidal product that are relevant for the intended use, storage and transportation of the biocidal product;
7) product type and field of use of the biocide;
8) biocidal users;
9) biocidal method of use and instructions for use;
10) data on the effectiveness of the biocide;
[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]
11) biocide labeling and package size and description;

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

12) safety data sheet of the active substance;

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

13) if necessary, additional information about the biocide.

[RT I, 03.02.2023, 2 - enters into force. 01.06.2023]

(3) If the active substance is included in the Union's list of approved active substances, a permit for a registered biocidal product must be applied for in accordance with the requirements set forth in the Biocidal Regulation. The application for obtaining a permit must be submitted no later than the date specified in Article 89(3) of the Biocides Regulation.

[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

(4) A biocidal product registered in Estonia may continue to be made available on the market after the date of approval of the active ingredient, if the applicant has submitted a permit application to the Health Board or the European Chemicals Agency through the biocidal register.

[RT I, 10.03.2015, 1 - enters into force. 20.03.2015]

(5) [Repealed - RT I, 10.03.2015, 1 - entered into force. 20.03.2015]

(6) [Repealed - RT I, 03.02.2023, 2 - entered into force. 01.06.2023]

(7) [Repealed - RT I, 03.02.2023, 2 - entered into force. 01.06.2023]

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

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

Section 2
Amendment of laws related to the Biocides Act

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

Section 3

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

[1] [Standard technical note omitted.]

[RT I, 03.02.2023, 2 - entered into force. 01.06.2023]