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Act on the introduction of genetically modified organisms into the environment [1]

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Amended by the following acts

Reception	Publication	Enforcement
07.12.2006	RT I 2006, 58, 439	01.01.2007
11.01.2007	RT I 2007, 6, 32	01.02.2007
14.02.2007	RT I 2007, 22, 114	01.07.2007
18.12.2008	RT I 2009, 3, 15	01.02.2009
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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).
13.10.2010	RT I, 08.11.2010, 1	18.11.2010, partially 01.01.2011
08.12.2010	RT I, 17.12.2010, 19	01.01.2011
19.02.2014	RT I, 13.03.2014, 4	01.07.2014
20.06.2014	RT I, 08.07.2014, 3	01.08.2014
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.
11.06.2015	RT I, 30.06.2015, 4	01.09.2015, on the basis of § 107^4 subsection 2 of the Government of the Republic Act, the word "Ministry of Agriculture" was replaced by the word "Ministry of Rural Affairs" in the corresponding case
21.11.2018	RT I, 12.12.2018, 3	01.01.2019
20.02.2019	RT I, 15.03.2019, 7	16.03.2019
10.06.2020	RT I, 01.07.2020, 1	01.01.2021
17.06.2020	RT I, 10.07.2020, 2	01.01.2021
11.05.2022	RT I, 27.05.2022, 1	06.06.2022
23.11.2022	RT I, 16.12.2022, 2	01.01.2023
23.01.2023	RT I, 07.02.2023, 2	17.02.2023
20.06.2023	RT I, 30.06.2023, 1	01.07.2023; On the basis of § 105.19 subsection 6 of the Government of the Republic Act, the word "Environment Ministry" throughout the text is replaced by the word "Climate Ministry" in the corresponding case

Chapter 1
general settings

§ 1. Scope of the Act

(1) The purpose of this Act is to:

1) prevent possible negative consequences for human health and the environment when genetically modified organisms are released into the environment or marketed, and to ensure the safe use of genetic technology and its development in an ethically acceptable manner;

2) to avoid the mixing of non-genetically modified crops and genetically modified crops and the unintended presence of genetically modified organisms in other products.

[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(2) This Act regulates:

1) release of genetically modified organisms into the environment for purposes other than marketing;

[RT I, 08.07.2014, 3 - enters into force. 01.08.2014]

2) marketing genetically modified organisms or products containing or consisting of them;

3) handling of genetically modified crops.

[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(3) This Act does not apply to:
1) the transformation of human genes using genetic engineering;
2) in relation to organisms obtained by genetic transformation procedures or methods, obtained by mutagenesis, or by fusion of cells, including protoplasts, of organisms that can exchange genetic material also by traditional breeding methods;
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]
3) in relation to human medicines that contain or consist of genetically modified organisms and whose use is regulated by other legislation;
4) using genetically modified organisms, including microorganisms, under closed conditions;
5) in relation to the transport of genetically modified organisms, which takes place by rail, road, inland water body, sea or air;
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]
6) when transporting a genetically modified crop from one country to another through Estonia without reloading;
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]
7) Transportation of properly packaged seed or propagating material of a genetically modified crop permitted on the European Union market.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(4) In the case specified in Clause 3, Clause 4 of this section, Clauses 3-5 of Clause 2 of § 5 of this Act shall apply.

(5) [Repealed - RT I, 08.11.2010, 1 - entry into force. 18.11.2010]

(6) The provisions of the Administrative Procedure Act apply to the administrative procedure provided for in this Act, taking into account the specifics of this Act.

§ 2. Definitions

(1) For the purposes of this Act, an organism is any independent biological form of being capable of reproduction or the transfer of heredity factors.

(2) A genetically modified organism is an organism whose heredity factors have been changed in a way that is not possible naturally.

(3) [Repealed - RT I, 08.11.2010, 1 - entry into force. 18.11.2010]

(4) For the purposes of this Act, a product is a product containing or consisting of genetically modified organisms.

(5) In the sense of this Act, an accident is the release of genetically modified organisms on a significant scale and unintentionally into the environment, which may be dangerous to human health or the environment.

(6) For the purposes of this Act, the handling of a genetically modified crop (hereinafter *referred to as handling) is the cultivation, transport or storage of a genetically modified crop based on a marketing authorization of the European Union.*
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(7) The operator of a genetically modified crop (hereinafter *the operator*) is a self-employed person or a legal person who, within the meaning of this Act, grows, transports or stores genetically modified crops permitted for cultivation in the European Union on the basis of a marketing permit.
[RT I, 15.03.2019, 7 - enters into force. 16.03.2019]

§ 3. Genetic modification

(1) Genetic modification takes place when at least one of the following methods is used:
1) recombinant nucleic acid technology, with which modified combinations of genetic material are created outside the organism, which are introduced into the host organism, where they do not occur naturally, but they are able to continue to replicate;
2) transfer of hereditary material produced outside the organism to the organism;
3) obtaining living cells with modified genetic material by the fusion of two or more cells in a way that does not occur in nature.

(2) The following are not considered genetic modification:
1) fertilization outside the parent organism;
2) conjugation, transduction, transformation or any other natural process;
3) induced polyploidy.

(3) The provisions of subsection 2 of this section apply on the condition that no recombinant DNA molecules or genetically modified organisms are used within the meaning of subsection 1 point 1 of this section.

§ 4. Release of a genetically modified organism into the environment and marketing of a genetically modified organism and product

(1) The release of a genetically modified organism into the environment is the removal or storage of genetically modified organisms or their combination from a closed space for a purpose other than marketing without the implementation of measures to prevent its uncontrolled spread.

(2) The remedy specified in subsection 1 of this section is a physical barrier or a physical barrier combined with a chemical or biological barrier that prevents the genetically modified organism from coming into contact with other organisms or entering the environment.

(3) Marketing a genetically modified organism or product is making such an organism or product available to a third party for a fee or free of charge.

(4) Marketing does not include:
1) making available genetically modified microorganisms, including culture collections, in operations regulated by Directive 2009/41/EC of the European Parliament and of the Council on the use of genetically modified microorganisms in a closed environment (OJ L 125, 21.05.2009, p. 75 -97);
[RT I, 07.02.2023, 2 - enters into force. 17.02.2023]
2) making genetically modified microorganisms not mentioned in point 1 of this subsection available only for operations in which

appropriate strict isolation measures are used to limit exposure of the population and the environment and to create a high level of protection;

3) making genetically modified organisms available to be used only in such intentional release into the environment that complies with Directive 2001/18/EC of the European Parliament and of the Council on the intentional release of genetically modified organisms into the environment and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, pp. 1–39) to the requirements stated in part B.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

§ 5. Genetic technology commission

(1) The Genetic Technology Commission is established under the jurisdiction of the Ministry of Climate and has an advisory function.

(2) The task of the Genetic Technology Commission is to:

1) advise government agencies on issues of genetic technology and genetically modified organisms or products being dangerous to the environment;

2) advise applicants for a permit to release a genetically modified organism into the environment and a marketing permit for a genetically modified organism or product;

3) review applications for release of a genetically modified organism into the environment and marketing of a genetically modified organism or product, as well as applications for the use of genetically modified microorganisms in a closed environment;

4) give an assessment of the release of the genetically modified organism specified in the application, the marketing of the genetically modified organism or product, or the use in a closed environment;

5) advise the Labor Inspectorate on issues related to the use of genetically modified microorganisms in a closed environment;

6) to advise the Agriculture and Food Board on matters of conducting animal experiments with genetically modified animals.
[RT I, 16.12.2022, 2 - enters into force. 01.01.2023]

(3) The composition of the Genetic Technology Commission shall be established by the Government of the Republic by an order, considering that the Genetic Technology Commission is made up of members holding relevant academic degrees who represent several relevant scientific fields. The Statute of the Genetic Technology Commission shall be approved by the Government of the Republic by regulation. The statutes of the Genetic Technology Commission determine the commission's rights, obligations, work procedures, decision-making procedures, administration procedures and remuneration procedures.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(4) The composition of the Genetic Technology Commission includes:

1) two members at the proposal of the minister responsible for the field;
[RT I, 29.06.2014, 109 - entered into force. 01.07.2014, on the basis of paragraph 4 § 107³ of the Government of the Republic Act, the word "environmental minister" was replaced by the words "minister responsible for the field".]

2) one member at the proposal of the minister responsible for the field;
[RT I, 29.06.2014, 109 - entered into force. 01.07.2014, on the basis of subsection 4 § 107³ of the Government of the Republic Act, the words "minister of economy and communications" were replaced by the words "minister responsible for the field".]

3) four members at the proposal of the minister responsible for the field. One of them must represent the crop growers and one the crop processors;
[RT I, 29.06.2014, 109 - entered into force. 01.07.2014, on the basis of paragraph 4 § 107³ of the Government of the Republic Act, the word "minister of agriculture" was replaced by the words "minister responsible for the field".]

4) one member at the proposal of the minister responsible for the field;
[RT I, 29.06.2014, 109 - entered into force. 01.07.2014, on the basis of paragraph 4 § 107³ of the Government of the Republic Act, the word "social minister" was replaced by the words "minister responsible for the field".]

5) two members at the proposal of the rector of the University of Tartu;

6) one member at the proposal of the rector of the Estonian University of Life Sciences;
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

7) one member at the proposal of the Rector of Tallinn University of Technology;

8) three members at the proposal of the President of the Academy of Sciences;

9) two members at the proposal of environmental organizations.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

Chapter 2
RELEASE OF GENETICALLY MODIFIED ORGANISMS FOR PURPOSES OTHER THAN MARKETING
[RT I, 08.07.2014, 3 - enters into force. 01.08.2014]

§ 6. Release of a genetically modified organism into the environment

(1) A genetically modified organism may be released into the environment for purposes other than marketing based on the written permission of the minister responsible for the field (hereafter *permission*). The specified list of data contained in the permit and the form of the permit shall be established by regulation of the minister responsible for the field based on the provisions of § 12 subsection 5 of this Act .
[RT I, 08.07.2014, 3 - enters into force. 01.08.2014]

(2) A person wishing to release a genetically modified organism into the environment shall submit an application for a permit to the Ministry of Climate.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(3) [Repealed - RT I, 08.11.2010, 1 - entry into force. 18.11.2010]

(4) A permit is required if such an organism or product is intended to be released into the environment for a purpose other than that stated in the marketing permit issued in a member state of the European Union.

§ 7. Application for releasing a genetically modified organism into the environment

(1) The application must contain:
[RT I, 08.11.2010, 1 - entered into force. 18.11.2010]
1) the name of the applicant, his personal or registry code, address and contact details;
2) the names and training of the persons who will deal with the release of the genetically modified organism into the environment;
3) the name and description of the genetically modified organism released into the environment;
4) the purpose of releasing the genetically modified organism into the environment;
5) on the release of a genetically modified organism into the environment with the precision of the municipality or city;
6) characterization of the method of releasing the genetically modified organism into the environment and the environment receiving it;
7) characterization of the supposed mutual influence of the genetically modified organism and its host environment;
8) environmental monitoring plan;
9) characterization of waste management;
10) a description of the action plan to be implemented in the event of an accident and the methods and remedies for damage elimination;
11) characterization of the possible impact on human health and the environment.
12) the date of payment of the state fee.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(1 1) The application is submitted in accordance with the standard data formats, if they are established in accordance with the law of the European Union.
[RT I, 07.02.2023, 2 - enters into force. 17.02.2023]

(2) The application shall be accompanied by a brief summary of the application in accordance with the decision of the Council of the EU 2002/813/EC, which, in accordance with the Directive 2001/18/EC of the European Parliament and the Council of the EU, establishes a consolidated form of information related to the intentional release of genetically modified organisms into the environment for purposes other than marketing (OJ L 280, 18.10 .2002, pp. 62–83).

(3) The application shall be accompanied by a risk analysis of the release of the genetically modified organism into the environment, in which the possible negative consequences of the release of the genetically modified organism into the environment are assessed. The risk analysis of releasing a genetically modified organism into the environment must address the direct, indirect, immediate, late, cumulative and long-term effects on human health and the environment and include a risk reduction plan.

(4) The specified list of data to be submitted in the application, the form of the application, the procedure for conducting the risk analysis and the list of data to be submitted in the risk analysis shall be established by a regulation of the minister responsible for the field based on the requirements set forth in subsections 1-3 of this section .
[RT I, 07.02.2023, 2 - enters into force. 17.02.2023]

(5) With the prior consent of the minister responsible for the field, data may be submitted in one application:
1) on genetically modified organisms or their combination designated for release into the environment at the same location;
2) on genetically modified organisms or their combination designated for release into the environment in different places, but for the same purpose and within a limited time.

(6) If the applicant has released the genetically modified organisms specified in the application or their combination into the environment on the basis of a previously granted permit, he shall add to the application data on the results of the release and the impact on the environment.

(7) Data from an application previously submitted by another person regarding the release of a genetically modified organism into the environment and its results may be used in the application with the written consent of that person.

§ 8. Additional notification

(1) Upon the next release of the same genetically modified organism or combination of organisms previously submitted as part of the same research, a new application shall be submitted, in which the data submitted in the previous application and the results of the release may be referred to.

(2) The permit applicant or permit holder is obliged to immediately notify the Ministry of Climate in writing if:
1) he intends to introduce a genetically modified organism or a combination of organisms into the environment in a different way than stated in the application;
2) during the review of the application, new data on the potential danger of releasing a genetically modified organism or a combination of organisms into the environment has become known;
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]
3) after obtaining the permit, new data on the potential danger of releasing a genetically modified organism or a combination of organisms into the environment has become known.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(3) The minister responsible for the field takes into account the information specified in points 1 and 2 of subsection 2 of this section when granting a permit.

(4) The Ministry of Climate shall publish the information specified in Clause 2, Clause 3 of this section in at least one newspaper with nationwide circulation. The requirements for the content of the information to be submitted and disclosed to the Ministry of Climate are established by a regulation of the minister responsible for the field .

(5) When the circumstances specified in subsection 2 of this section occur, the permit applicant or permit holder must:
1) review the measures specified in the application and, if necessary, correct them;
2) take necessary measures to protect human health or the environment.

§ 9. Review of the application for the release of a genetically modified organism into the environment

(1) The Ministry of Climate checks the compliance of the application with the requirements set forth in this Act and the legislation established on its basis and forwards the appropriate application to the Genetic Technology Commission, notifying the applicant in writing. The Ministry of Climate forwards the summary of the request to the European Commission, following the requirements of EU Council Decision 2002/813/EC.

(2) When reviewing the application, the genetic technology committee:
1) assesses the possible adverse effects on human health and the environment related to the introduction of a genetically modified organism into the environment, which may occur directly or indirectly, including the transfer of genes from genetically modified organisms to other organisms, and the probability of these effects occurring;
2) requests information from government, state or scientific institutions, if necessary;
3) if necessary, performs or orders tests or analyzes to verify the data provided in the application;
4) if necessary, requires the applicant to provide additional relevant information, justifying this requirement.

(3) Reasonable costs of tests or observations to verify data shall be borne by the applicant before the tests or observations are carried out. The costs of tests or observations shall be borne by the applicant even if the permit is not granted for the reason specified in § 12 subsection 4 of this Act.
[RT I, 08.07.2014, 3 - enters into force. 01.08.2014]

§ 10. Disclosure of application and permit

(1) The Climate Ministry announces the start of the permit granting procedure and the granting of the permit in the official publication Ametlikud Teadaanded and in at least one newspaper with national circulation within seven days of receiving the application or granting the permit at the expense of the permit applicant.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(2) The notice must contain at least:
1) the name of the permit applicant, in the case of a legal entity, its registry code and address and contact details;
2) a summary of the content of the application or permit;
3) the name of the genetically modified organism and the place of release into the environment with the precision of municipality or city;
4) the place where it is possible to consult the content of the application;
5) a deadline during which it is possible to express an opinion or make proposals regarding the planned release of a genetically modified organism into the environment.

(3) The term specified in Clause 2, Clause 5 of this section may not be shorter than 30 days or longer than 60 days.

(4) The minister responsible for the field shall respond in writing to the proposal specified in clause 2, clause 5 of this section within two weeks of receiving it, giving a reasoned statement as to whether the proposal has been taken into account or not.

§ 11. Conclusion and proposal of the Genetic Technology Commission

(1) The Genetic Technology Commission makes one of the following written conclusions within 60 days after receiving an application for release of a genetically modified organism into the environment:
[RT I, 08.11.2010, 1 - entered into force. 18.11.2010]
1) the planned release of a genetically modified organism into the environment is in accordance with the requirements of this Act and the legislation established on its basis, is safe for human health and the environment, and does not negatively affect the development of the ecosystem;
2) the safety of the planned introduction of the genetically modified organism into the environment for human health or the environment has not been sufficiently proven, and it may negatively affect the development of the ecosystem;
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]
3) the planned release of a genetically modified organism into the environment is in accordance with the requirements of this Act and the legislation established on its basis and is safe for human health and the environment, if the additional conditions set in the conclusion are met.

(2) The Genetic Technology Commission makes a proposal to the minister responsible for the field within the term specified in subsection 1 of this section:
[RT I, 08.11.2010, 1 - entry into force. 18.11.2010]
1) to grant a permit if the release of a genetically modified organism into the environment is in accordance with the requirements of this Act and the legislation established on its basis and is safe for human health and the environment;
2) refuse to grant a permit if the release of a genetically modified organism into the environment is not in accordance with the requirements of legislation or the safety of the release into the environment for human health or the environment has not been sufficiently proven;
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]
3) grant a permit and thereby set additional conditions that exclude a possible danger, if the application is in accordance with the requirements of the legislation.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(3) The Genetic Technology Commission submits a proposal for setting additional conditions to the minister responsible for the field, together with reasons.

§ 12. Issuing, changing, suspending and revoking the permit
[RT I, 08.11.2010, 1 - entered into force. 18.11.2010]

(1) The open procedure provisions of the Administrative Procedure Act apply to the granting and amendment of a permit, taking into account the specifics of this Act. The provisions of the procedure open to the suspension and revocation of the permit do not apply.

(2) After receiving the conclusion of the Genetic Technology Commission, but no later than within 90 days from the submission of a proper application, the minister responsible for the field shall issue a permit or notify the applicant of the refusal to grant the permit,

giving reasons in writing. The maximum possible validity period of the permit is ten years.

(3) The minister responsible for the field does not grant a permit if:
1) when releasing a genetically modified organism into the environment, the safety for human health and the environment has not been sufficiently proven or it has not been ensured that all appropriate measures are taken to reduce the environmental risk to the greatest extent possible;
2) false information is provided in the application;
3) releasing a genetically modified organism into the environment is not in accordance with the requirements of legislation.

(4) The following shall be entered in the permit:
1) the name and basic characteristics of the genetically modified organism released into the environment and the purpose of release into the environment;
2) the name of the person releasing the genetically modified organism into the environment, his registry or personal identification number, address and contact details;
3) the minimum necessary conditions for the safe release of the genetically modified organism into the environment and all appropriate measures to reduce the environmental risk to the greatest extent possible, including handling and storage requirements;
4) the place of release of the genetically modified organism into the environment;
5) scope and requirements of environmental monitoring and deadlines for submission of environmental monitoring results reports;
6) validity period of the permit.

(5) A genetically modified organism may be introduced into the environment only under the conditions set in the permit. A genetically modified organism cannot be marketed on the basis of a permit.

(6) The minister responsible for the field temporarily suspends the validity of the permit if, after the permit has been granted, possible dangers related to the release of the genetically modified organism into the environment have become known.

(7) During the temporary suspension of the validity of the permit, the minister responsible for the field may change the conditions of the permit or declare the permit invalid based on the proposal of the Genetic Technology Commission and based on the risk analysis performed at the expense of the permit holder.

(8) The minister responsible for the field declares the permit invalid if:
1) false information is provided in the permit application;
2) the permit holder does not fulfill the conditions set in the permit;
3) when releasing a genetically modified organism into the environment, the safety for the environment and human health has not been sufficiently proven or it has not been ensured that all appropriate measures are taken to reduce the environmental risk to the greatest extent possible;
4) releasing a genetically modified organism into the environment is not in accordance with the requirements of legislation.
[RT I, 08.07.2014, 3 - enters into force. 01.08.2014]

§ 13. Simplified procedure for releasing genetically modified organisms into the environment

The simplified release of a genetically modified organism into the environment is carried out in accordance with European Commission Decision 1994/730/EC establishing a simplified procedure for the deliberate release of genetically modified plants into the environment (OJ L 292, 12.11.1994, pp. 31–34).

§ 14. Notification of the results of the release of a genetically modified organism into the environment

(1) After the release of a genetically modified organism into the environment, the permit holder submits to the Ministry of Climate an environmental monitoring report on the functioning of this organism in the environment in accordance with European Commission Decision 2003/701/EC establishing the form for submitting the results of the release of genetically modified higher plants into the environment for purposes other than marketing (OJ L 254, 08.10 .2003, pp. 21–28).

(2) The requirements for the content of the environmental monitoring report for genetically modified organisms other than genetically modified higher plants and the procedure for informing about the results of environmental monitoring shall be established by a regulation of the minister responsible for the field, if necessary.

§ 15. Extending the validity of the permit

(1) The permit holder must submit an application to the Ministry of Climate to extend the validity of the permit at least nine months before the permit expires.

(2) In order to extend the validity of a permit, a written application is submitted and the following documents and data are attached to it:
1) a copy of the valid permit;
2) environmental monitoring report;
3) if available, new data on the potential danger that the introduction of a genetically modified organism into the environment may cause to human health or the environment;
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]
4) if necessary, a proposal to change or supplement the conditions of the permit.

(3) The provisions of §§ 9–12 of this Act and the requirements of the legislation established on the basis of § 6 (1) apply to the review, disclosure and extension of the permit validity extension application.

(4) During the process of extending the validity of the permit, the holder of the permit may continue to release the genetically modified organism into the environment on the basis thereof until the final decision on the extension is made.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

Chapter 3
MARKETING OF GENETICALLY MODIFIED ORGANISMS AND PRODUCTS

§ 16. Marketing of genetically modified organisms and products

(1) A genetically modified organism or product may be marketed based on the written permission of the minister responsible for the field (hereinafter *marketing permission*). The specified list of data contained in the marketing authorization and the format of the marketing authorization shall be established by regulation of the minister responsible for the field based on the provisions of § 22 subsection 5 of this Act .

(2) A person wishing to market a genetically modified organism or product shall submit an application for a marketing permit to the Ministry of Climate.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(3) A marketing authorization is not required for the marketing of a genetically modified organism or product in the Republic of Estonia on the basis of a marketing authorization granted in a member state of the European Union.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(4) A marketing authorization is required if the genetically modified organism or product is intended to be marketed for a purpose other than that stated in the marketing authorization granted in a member state of the European Union.

§ 17. Application for distribution permit

(1) The application must contain:
[RT I, 08.11.2010, 1 - entered into force. 18.11.2010]
1) the name of the manufacturer or importer and distributor, his personal or registry code, address and contact details;
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]
2) the purpose of marketing the product;
3) if necessary, the geographical area of product distribution;
4) the name of the product and the name and description of the genetically modified organism contained in the product;
5) product description and terms of use;
6) a description of the environment suitable for the product;
7) characterization of the assumed interaction between the genetically modified organism contained in the product and the environment receiving it;
8) name of the field of use of the product and description of the intended use;
9) product storage and storage conditions;
10) a list of measures to be used in case of misuse of the product;
11) a description of the results of studies and release tests performed on the product, including the impact on human health and the environment;
12) product packaging and labeling design, including, if necessary, an introduction to the packaging method that prevents genetically modified organism or product from entering the environment;
13) forecast of production or product import volume;
14) a description of the methods and conditions of transporting the product;
15) an environmental monitoring plan, which has been drawn up taking into account the requirements of EU Council Decision 2002/811/EC, which establishes Directive 2001/18/EC of the European Parliament and the Council of the EU on the intentional release of genetically modified organisms into the environment and which repeals EU Council Directive 90/220/ Additional instructions of EEC Annex VII (OJ L 280, 18.10.2002, pp. 27–36);
16) if necessary, characterization of waste management;
17) a description of the action plan to be implemented in the event of an accident and the methods and remedies for damage elimination;
18) [invalid - RT I, 08.11.2010, 1 - entered into force. 18.11.2010] 19) a brief summary of the application in accordance with EU Council Decision 2002/812/EC, which, in accordance with European Parliament and EU Council Directive 2001/18/EC, establishes a consolidated form of information related to the marketing of genetically modified organisms as products or as part of products (OJ L 280, 18.10. 2002, pp. 37–61); 20) the date of payment of the state fee. [RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(1^{1}) The application is submitted in accordance with the standard data formats, if they are established in accordance with the law of the European Union.
[RT I, 07.02.2023, 2 - enters into force. 17.02.2023]

(2) The application shall be accompanied by a risk analysis of the genetically modified organism or product in accordance with the provisions of § 7 subsection 3 of this Act.

(3) The specified list of data to be submitted in the application, the form of the application, the procedure for conducting the risk analysis and the list of data to be submitted in the risk analysis shall be established by a regulation of the minister responsible for the field based on the requirements set forth in subsections 1 and 2 of this section .
[RT I, 07.02.2023, 2 - enters into force. 17.02.2023]

(4) If the safety of marketing a genetically modified organism or product for human health and the environment has been proven based on scientific data or the results of the release of a genetically modified organism into the environment, the data specified in subsection 2 of this section need not be submitted with the consent of the Genetic Technology Commission.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(5) If the applicant has marketed the genetically modified organism or product specified in the application based on a previously granted marketing permit or released the genetically modified organism into the environment, he shall add to the application the results of the marketing of the genetically modified organism or product and the data on the impact on the environment, regardless of the place of marketing.

(6) The data of the previously submitted application by another person regarding the marketing results of a genetically modified organism or product may be used in the application with the written consent of that person.

(7) A separate application shall be submitted for each new product that contains the same genetically modified organism and is intended for use in a different way.

§ 18. Review of an application for the marketing of a genetically modified organism and product

(1) The Ministry of Climate forwards the application to the Genetic Technology Commission after determining its suitability and informs the applicant in writing. The Ministry of Climate will forward the summary of the request to the European Commission.
[RT I, 08.07.2014, 3 - enters into force. 01.08.2014]

(2) [Repealed - RT I, 08.11.2010, 1 - entry into force. 18.11.2010]

(3) When reviewing the application, the genetic technology commission:
1) [invalid - RT I, 08.07.2014, 3 - entered into force. 01.08.2014] 2) evaluates the measures planned to ensure product safety; 3) evaluates possible adverse effects on human health and the environment that may occur directly or indirectly when genes are transferred from genetically modified organisms to other organisms; 4) requests information from governmental, state or scientific institutions, if necessary; 5) if necessary, performs or orders tests or analyzes to verify the data provided in the application.

(4) The state fee shall be paid for the examination of the application before the application is submitted according to the rate stipulated in the State Fees Act. Reasonable costs of tests or observations to verify the data shall be borne by the applicant before the tests and observations are carried out. The costs of tests or observations shall be borne by the applicant even if the marketing authorization is not granted for the reasons specified in subsection 22 (4) of this Act.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(5) [Repealed - RT I, 08.11.2010, 1 - entry into force. 18.11.2010]

§ 19. Disclosure of application and marketing authorization of genetically modified organism and product

The provisions of § 10 of this Act shall apply to the disclosure of the marketing application and marketing authorization of a genetically modified organism or product.

§ 20. Conclusion and proposal of the Genetic Technology Commission

(1) The Genetic Technology Commission makes one written conclusion after receiving an application for a marketing permit for a genetically modified organism or product in accordance with the provisions of § 11 subsection 1 of this Act.

(2) The Genetic Technology Commission makes a proposal to the minister responsible for the field in accordance with the provisions of § 11 subsection 2 of this Act.

(3) The Genetic Technology Commission has the right to request from the applicant detailed information about the marketing of a genetically modified organism or product. This requirement must be justified.

(4) The Genetic Technology Committee submits a proposal for setting additional conditions to the minister responsible for the field, along with reasons.

(5) The Genetic Technology Committee has the right, if necessary, to give an assessment of the application for a marketing authorization submitted in a member state of the European Union or to reasonably request additional information about the application.

§ 21. Evaluation report

(1) After receiving the proposal of the genetic technology commission, but no later than within 90 days from the receipt of the proper application, the minister responsible for the field prepares a written assessment report, in which he makes a preliminary decision on granting or refusing to grant a marketing permit. Based on the preliminary decision made in the assessment report, the marketing authorization applicant does not have a legitimate expectation of obtaining the authorization.

(2) If a preliminary decision is made in the assessment report to grant the applicant a marketing permit, the Ministry of Climate shall immediately forward the assessment report to the applicant and the European Commission. The requirements for the evaluation report are established by the minister responsible for the field by regulation.

(3) If a preliminary decision is made in the assessment report to refuse the granting of a marketing permit to the applicant, the Ministry of Climate shall forward the assessment report to the European Commission no earlier than 15 days after sending the assessment report to the applicant and no later than 105 days after receiving the proper application.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

§ 22. Issuance of distribution permit

(1) The provisions of the open procedure of the Administrative Procedure Act apply to the granting of a distribution permit, taking into account the specifics of this Act.
[RT I, 08.07.2014, 3 - enters into force. 01.08.2014]

(2) The minister responsible for the field grants a marketing authorization for the marketing of a genetically modified organism or product or refuses to grant a marketing authorization and informs the applicant of this after the European Union comparative procedure of the assessment report. During the comparison procedure of the evaluation report, the European Commission collects the comments and reasoned objections of the member states and the public within 60 days from the submission of the evaluation report, on the basis of which the minister responsible for the field decides to grant or refuse a marketing authorization within 105 days from the submission of the evaluation report to the European Commission. The calculation of the deadline for granting a marketing authorization stops when

the minister responsible for the field has given the applicant a deadline to submit additional information.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(3) The maximum period of validity of the marketing authorization is ten years. The minister responsible for the field informs the member states and the European Commission about the granting of the permit within 30 days.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(4) The minister responsible for the field shall not issue a marketing permit if:
1) the marketing of a genetically modified organism or product is dangerous to human health or the environment;
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]
2) false information is provided in the application;
3) the marketing of a genetically modified organism or product is not in accordance with the requirements of legislation.

(5) The marketing authorization shall include:
1) the name, basic characteristics, identity and unique code of the product and the genetically modified organism contained therein;
2) conditions that ensure safe use of the product, including handling and storage;
3) name, personal or registry codes, addresses and contact details of the permit holder;
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]
4) special conditions for environmental protection;
5) the term of validity of the marketing authorization;
6) the obligation to provide control samples at the request of the Genetic Technology Committee;
7) environmental monitoring plan, taking into account EU Council decision 2002/811/EC;
8) product labeling requirements.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(6) The marketing permit gives the right to introduce the genetically modified organism or product entered into the permit into the environment.

§ 23. Notification of marketing of genetically modified organisms and products

(1) After the marketing of a genetically modified organism or product, the permit holder submits an environmental monitoring report of the genetically modified organism or product to the Ministry of Climate, the content requirements and the submission procedure are established by regulation of the minister responsible for the field .

(2) If, before or after obtaining a marketing permit, the applicant has received new information about the danger that a genetically modified organism or product may pose to human health or the environment, he must immediately inform the Ministry of Climate and take the necessary health and environmental protection measures. The Climate Ministry will immediately publish the information in at least one national newspaper and on the Climate Ministry's website. The requirements for the content of the information to be submitted and disclosed to the Ministry of Climate are established by a regulation of the minister responsible for the field .
[RT I, 07.02.2023, 2 - enters into force. 17.02.2023]

§ 24. Product packaging and labeling

(1) The product may be marketed packaged and labeled. The marking must be visually clearly visible and clearly understandable. When the product is marketed, the product must be accompanied by accompanying documents stating the unique code of the genetically modified organism.

(2) The labeling on the product packaging must contain at least the following information:
1) product name;
2) the text "The product contains genetically modified organisms";
3) the name of the genetically modified organism in the product;
4) name and address of the person responsible for marketing the product;
5) reference to the possibilities of obtaining additional information.

(3) [Repealed - RT I, 08.11.2010, 1 - entry into force. 18.11.2010]

(4) For products in which accidental or technically unavoidable traces of genetically modified organisms approved in the European Union cannot be excluded, a minimum limit may be established, below which the products in question will not be labeled. The European Commission determines the minimum rates, taking into account the provisions of the Council Decision 1999/468/EC establishing the procedures for the use of the Commission's implementing powers (OJ L 184, 17.7.1999, pp. 23–26).
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

§ 25. Change of marketing authorization and its invalidation

(1) The minister responsible for the field changes the terms of the marketing authorization or revokes the marketing authorization on the basis of a risk analysis carried out at the proposal of the Genetic Technology Commission and at the expense of the holder of the marketing authorization, if, based on new scientific data, there is reason to believe that a genetically modified organism or product poses a threat to human health or the environment.

(1^{1}) The minister responsible for the field shall inform the member states and the European Commission of the activities provided for in subsection 1 of this section, including the disclosure of information that may cause the marketing authorization to be changed or revoked.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

(2) The minister responsible for the field declares the marketing license invalid if:
1) false information is provided in the marketing license application;
2) the marketing authorization holder does not fulfill the conditions set in the marketing authorization;

3) a genetically modified organism or product is dangerous to human health or the environment;
4) the marketing of a genetically modified organism or product is not in accordance with the requirements of legislation.

(3) The provisions of the open procedure shall apply to the amendment of the marketing authorization in the same way as the granting of the marketing authorisation. The provisions of the procedure open to the invalidation of the marketing authorization do not apply.
[RT I, 08.07.2014, 3 - enters into force. 01.08.2014]

§ 26. Extending the validity of the marketing permit

The provisions of § 15 subsections 1, 2 and 4 and § 18-22 of this Act and the requirements of the legislation established on the basis of § 16 subsection 1 apply to the review and disclosure of the application for extending the validity of the marketing authorization.

§ 27. Simplified procedure for the marketing of genetically modified organisms and products

If the Genetic Technology Committee finds that the marketing of a genetically modified organism or product has been safe for human health and the environment for at least five years, the Genetic Technology Committee may make a proposal to the minister responsible for the field to request from the European Commission the application of a simplified procedure for the marketing of such a genetically modified organism or product.

§ 28. Genetically modified food and feed

Regulation 1829/2003/EC of the European Parliament and the Council of the EU on genetically modified food and feed (OJ L 268, 18.10.2003, pp. 1–23) applies to the marketing of genetically modified organisms used as food or feed, food or feed containing or consisting of genetically modified organisms).

13. chapter
Handling of genetically modified crops

[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

§ 281. Handling of genetically modified crops

(1) The operator handles the genetically modified crop with the necessary care in order to prevent its genetic mixing with the non-genetically modified crop and possible damage as a result.

(2) [Repealed - RT I, 15.03.2019, 7 - entry into force. 16.03.2019]

(3) Before starting handling, the handler appoints a person responsible for proper handling in his company.
[RT I, 15.03.2019, 7 - enters into force. 16.03.2019]

(4) When handling a genetically modified crop, the following shall be observed:
1) the requirement for growing distance;
2) cultivation period requirement;
3) transport requirements;
4) storage requirements;
5) the requirement to remove the plants sprouted from the genetically modified crop grown as a pre-crop from the field of the follow-up crop within the specified cultivation period, before the self-sown plants in the said emergence stage have started to produce pollen, viable seeds or other propagating material;
6) the requirement to clean the equipment and technology used in production.

(5) The specified requirements for the handling of genetically modified crops shall be established by a regulation of the minister responsible for the field .
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

§ 282. Training in the handling of genetically modified crops

(1) The person responsible for the handling of a genetically modified crop and the employee of a company dealing with the handling of a genetically modified crop must have undergone training in the handling of a genetically modified crop and must have a certificate proving completion of the training.

(2) The certificate proving completion of training is valid for five years. If the person responsible for the handling and the employee of the company dealing with the handling of genetically modified crops participate in additional training organized by the Agriculture and Food Board during the validity period of the certificate, the validity period of the certificate certifying the completion of the training will be extended by the following five years after the expiry of the validity period.
[RT I, 01.07.2020, 1 - enters into force. 01.01.2021]

(3) The training program for the handling of genetically modified crops, the requirements for obtaining a certificate, the procedure for issuing a certificate and the frequency of further training shall be established by a regulation of the minister responsible for the field .
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

§ 283. Notification obligation
[RT I, 15.03.2019, 7 - enters into force. 16.03.2019]

(1) In order to grow, store and transport a genetically modified crop, the operator submits an economic activity notification to the Agriculture and Food Board.
[RT I, 01.07.2020, 1 - enters into force. 01.01.2021]

(2) In addition to the provisions of the general part of the Code of Economic Activities Act, the operator shall enter the following information in the economic activity notice:

1) the name and personal identification code of the responsible person and employee of the company specified in § 28[2] subsection 1 of this Act or, in the absence thereof, the date of birth;

2) contact details of the responsible person.

(3) In addition to the data provided in subsection 2 of this section, the person growing a genetically modified crop shall submit the following data in the economic activity notification:

1) the type, variety name and unique code of the genetically modified crop;

2) field array number, field location in the field array, field number and coordinates;

3) confirmation of the fulfillment of the notification obligation established in subsections 1 and 5 of § 28[4] of this Act; 4) confirmation of the achievement of the agreement established in § 28[4] subsection 2 of this Act.

(4) The data specified in subsections 2 and 3 of this section shall be entered in the plant health register established on the basis of § 30 subsection 1 of the Plant Protection Act.

[RT I, 15.03.2019, 7 - enters into force. 16.03.2019]

§ 28[4] . Notification

(1) A person wishing to grow a genetically modified crop shall notify the owners of fields within the notification distance in writing of the intention to grow a genetically modified crop at least three months before starting cultivation. The extent of the notification distance is twice the extent of the cultivation distance, within which the operator informs the owners of the fields within which they intend to grow a genetically modified crop.

(2) A person wishing to grow a genetically modified crop, whose field is within the cultivation distance of other fields, the owners of which intend to grow a non-genetically modified crop of the same species or a crop of another plant species that is capable of interbreeding in a field within the cultivation distance, may start cultivation of the genetically modified crop only in the said fields upon reaching a written agreement with the holders. Cultivation distance is the minimum permitted distance from the edge of a field of a genetically modified crop to a field of the same or another plant species that is capable of interbreeding with it, grown using conventional or organic farming methods, established on the basis of clause 1, clause 4, point 1 of § 28 of this Act.

(3) The content and form requirements of the notification submitted for notification of the cultivation of genetically modified crops, the scope of the notification distance and the list of documents to be added to the notification shall be established by a regulation of the minister responsible for the field .

(4) A person who has grown a genetically modified crop on the land he owns shall, during the validity of the requirement set forth in § 28 (1) (4) (2) of this Act, in the case of sale, lease or other transfer of the land, inform the acquirer or the recipient of possession of the said land in writing before the acquisition or transfer of possession from growing a modified crop. During the validity of the above-mentioned requirement, the acquirer and possessor are obliged to comply with the requirement established in § 28, subsection 4, point 5.

(5) A person wishing to grow a genetically modified crop shall notify the owner of the apiary in writing of the intention to handle the genetically modified crop, who has expressed a wish to be notified if the apiary is located up to three kilometers away from the field where genetically modified crops are intended to be grown.

[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

Chapter 4
GENETICALLY MODIFIED ORGANISM DATA

§ 29. Storage and treatment of data as a trade secret

(1) Data and permits submitted in the application for a permit to release a genetically modified organism into the environment and to market a genetically modified organism or product, except for 3[1] of this Act . the data specified in the chapter are stored in the environmental decision information system. Data on the area of release of the genetically modified organism into the environment is kept in the Estonian nature information system.

[RT I, 27.05.2022, 1 - enters into force. 06.06.2022]

(2) In the application, the applicant may make a reasoned proposal to treat part of the data as a trade secret.

(3) The minister responsible for the field decides what kind of data is kept as a business secret, and informs the applicant of the adopted decision. Data that the minister responsible for the field has recognized as a business secret are not public even if the applicant withdraws the application.

(4) The minister responsible for the field may consider as a trade secret:

1) Regulation (EC) No. 178/2002 of the European Parliament and of the Council, which lays down the general principles and requirements of food legislation, establishes the European Food Safety Authority and establishes procedures related to food safety (OJ L 31, 01.02 .2002, pp. 1-24), the information specified in points a, b and c of Article 39, paragraph 2;

2) information about the DNA sequence, except for sequences used for the discovery, identification and quantification of genetic modification;

3) breeding schemes and strategies.
[RT I, 07.02.2023, 2 - enters into force. 17.02.2023]

(4[1]) Regardless of the provisions of subsection 4 of this section:
1) the minister responsible for the field may disclose the information specified in subsection 4 of this section if urgent measures must be taken to protect human or animal health or the environment;
2) information that is part of the opinion or assessment reports of the relevant scientific committees and that is related to the expected impact on human or animal health or the environment is made public, and in which case Article 39c of Regulation (EC) No. 178/2002 of the European Parliament and of the Council applies.
[RT I, 07.02.2023, 2 - enters into force. 17.02.2023]

(5) The Agriculture and Food Board shall keep data on the certificates proving completion of the training and the documents on which they were issued in the plant health register for five years from the day the certificates expire.
[RT I, 01.07.2020, 1 - enters into force. 01.01.2021]

(6) The handler keeps accurate records of compliance with handling requirements. Documents related to handling and notification thereof are kept for at least ten years.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

§ 30. Exchange of information and consultation with the European Commission

The minister responsible for the field establishes a procedure by regulation that regulates the exchange of information and consultation with the European Commission related to the release of a genetically modified organism into the environment and the marketing of a genetically modified organism or product.

Chapter 5
STATE SUPERVISION AND DAMAGES

[RT I, 13.03.2014, 4 - enters into force. 01.07.2014]

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

(1) State supervision of compliance with the requirements of this Act and legislation established on the basis thereof is carried out by the Environmental Board, except in areas in which the duty of supervision is assigned to other law enforcement bodies.
[RT I, 10.07.2020, 2 - enters into force. 01.01.2021]

(2) The use of genetically modified plant varieties, the production and packaging of seed and propagating material containing or consisting of genetically modified organisms of agricultural and horticultural species, as well as the marketing, import and export of the said material shall be supervised by the Agriculture and Food Board in accordance with the procedure provided for in the Plant Propagation and Variety Protection Act , taking into account the specifics provided in this law.
[RT I, 01.07.2020, 1 - enters into force. 01.01.2021]

(3) The Environmental Board supervises the production and packaging for marketing purposes of forest plants containing genetically modified organisms or cultivation material consisting of them, as well as the marketing, import and export of the said material, in accordance with the requirements and procedures set forth in the Plant Propagation and Variety Protection Act, taking into account the specifics provided in this Act.
[RT I, 13.03.2014, 4 - enters into force. 01.07.2014]

(4) Plant protection products containing or consisting of genetically modified organisms shall be supervised by the Agriculture and Food Board in accordance with the procedure provided for in the Plant Protection Act, taking into account the specifics provided for in this Act.
[RT I, 01.07.2020, 1 - enters into force. 01.01.2021]

(5) Fertilizers containing or consisting of genetically modified organisms shall be supervised by the Agricultural and Food Board, the Tax and Customs Board and the Consumer Protection and Technical Supervision Board in accordance with the procedure provided for in the Fertilizer Act, taking into account the specifics provided for in this Act.
[RT I, 01.07.2020, 1 - enters into force. 01.01.2021]

(6) Food containing or consisting of genetically modified organisms is supervised by the Agriculture and Food Board in accordance with the procedure provided for in the Food Act, taking into account the specifics provided for in this Act.
[RT I, 01.07.2020, 1 - enters into force. 01.01.2021]

(7) The Consumer Protection and Technical Supervision Agency supervises the fulfillment of the requirements for the provision of information regarding food containing or consisting of genetically modified organisms and the correctness of the information provided in the retail business in accordance with the procedure provided for in the Food Act, taking into account the specifics provided for in this Act.
[RT I, 12.12.2018, 3 - enters into force. 01.01.2019]

(8) Feed containing or consisting of genetically modified organisms shall be supervised by the Agriculture and Food Board in accordance with the procedure provided for in the Feed Act, taking into account the specifics provided in this Act.
[RT I, 01.07.2020, 1 - enters into force. 01.01.2021]

(9) The Agriculture and Food Board supervises compliance with handling requirements.
[RT I, 01.07.2020, 1 - enters into force. 01.01.2021]

§ 31[1]. Special measures of state supervision

(1) The Environmental Board may apply the special measures of state supervision provided for in §§ 30, 31, 32, 45, 46, 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, 10.07.2020, 2 - enters into force. 01.01.2021]

(2) The Board of Agriculture and Food may apply the special measures of state supervision provided for in §§ 30, 49, 50, 51 and 52 of the Law on Law and Order on the basis and according to the procedure provided for in the Law on Law and Order, when performing state supervision over the fulfillment of handling requirements.
[RT I, 01.07.2020, 1 - enters into force. 01.01.2021]

§ 31 2 . 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]

§ 31 3 . Extortion rate

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 13,000 euros.
[RT I, 13.03.2014, 4 - enters into force. 01.07.2014]

§ 32. Compensation and reparation of damage

(1) The operator shall compensate the damage caused by the handling of the genetically modified crop in case of exceeding the limit established by Regulation (EC) No. 1829/2003 of the European Parliament and of the Council.

(2) [Repealed - RT I, 17.12.2010, 19 - entered into force. 01.01.2011]

(3) The effectiveness of the elimination of environmental pollution is assessed by the minister responsible for the field at the expense of the person causing the pollution.
[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

15 . chapter RESPONSIBILITY

[RT I, 08.11.2010, 1 - enters into force. 18.11.2010]

§ 33. Violation of the requirements for releasing and marketing a genetically modified organism

(1) For violating the requirements for releasing a genetically modified organism into the environment or marketing a genetically modified organism or product -
a fine of up to 300 fine units is imposed.

(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, 08.11.2010, 1 - enters into force. 01.01.2011]

§ 33 1 . Violation of requirements for handling genetically modified crops

(1) Violation of the requirements for the handling of a genetically modified crop -
shall be punished with a fine of up to 200 fine units.

(2) For the same act, if it has been committed by a legal entity, -
shall be punished with a fine of up to 3,200 euros.
[RT I, 08.11.2010, 1 - enters into force. 01.01.2011]

§ 34. Violation of packaging and labeling requirements for genetically modified organisms and products

(1) Violation of packaging or labeling requirements for a genetically modified organism or product -
shall be punished with a fine of up to 100 fine units.

(2) For the same act, if it has been committed by a legal entity, -
shall be punished with a fine of up to 6400 euros.
[RT I, 08.11.2010, 1 - enters into force. 01.01.2011]

§ 34 1 . Violation of the obligation to inform about the cultivation of a genetically modified crop

[Repealed - RT I, 15.03.2019, 7 - entered into force. 16.03.2019]

§ 34 2 . Violation of the notification obligation of the permit applicant or permit holder

(1) Violation of the notification obligation of the permit applicant or permit holder -
shall be punished with a fine of up to 200 fine units.

(2) For the same act, if it has been committed by a legal entity, -
shall be punished with a fine of up to 13,000 euros.
[RT I, 08.11.2010, 1 - enters into force. 01.01.2011]

§ 35. Procedure

The non-judicial proceedings for the misdemeanors provided for in this chapter are the Environmental Board, the Agriculture and Food Board, the Consumer Protection and Technical Supervision Board and the Tax and Customs Board, according to their competence.
[RT I, 10.07.2020, 2 - enters into force. 01.01.2021]

Chapter 6
IMPLEMENTATION PROVISIONS

§ 36. Implementation of the Act
[Repealed - RT I, 27.05.2022, 1 - entry into force. 06.06.2022]

§ 37. – § 40. [Omitted from this text.]

§ 41. Entry into force of the Act

This Act enters into force on May 1, 2004.

1
Directive 2001/18/EC of the European Parliament and of the Council on the intentional release of genetically modified organisms into the environment and repealing Council Directive 90/220/EEC (OJ L 106, 17.04.2001, pp. 1–39), amended by Directives 2008/27/ EC (OJ L 81, 20.03.2008, pp. 45–47), (EL) 2015/412 (OJ L 68, 13.03.2015, pp. 1–8) and (EL) 2018/350 (OJ L 67, 09.03. 2018, pp. 30–45) and with regulations (EC) No. 1829/2003 (OJ L 268, 18.10.2003, pp. 1–23), (EC) No. 1830/2003 (OJ L 268, 18.10.2003, pp. 24– 28), (EU) 2019/1243 (OJ L 198, 25.07.2019, pp. 241–344) and (EU) 2019/1381 (OJ L 231, 06.09.2019, pp. 1–28);
Regulation (EU) 2019/1381 of the European Parliament and of the Council concerning the transparency and sustainability of EU-level risk assessment of the food chain and amending Regulations (EC) No. 178/2002, (EC) No. 1829/2003, (EC) No. 1831/2003, (EC) No. 2065/2003, (EC) No. 1935/2004, (EC) No. 1331/2008, (EC) No. 1107/2009 and (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231, 06.09 .2019, pp. 1–28).
[RT I, 07.02.2023, 2 - enters into force. 17.02.2023]