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Release into Environment of Genetically Modified Organisms Act¹

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RT I 2004, 30, 209
Entry into force 01.05.2004

Chapter 1 GENERAL PROVISIONS

§ 1. Scope of application of Act

(1) The purpose of this Act is:
1) to prevent possible adverse effects to human health and the environment upon release of genetically modified organisms into the environment or upon placing genetically modified organisms on the market and to ensure safe application of genetic engineering and the development thereof in an ethically responsible manner;

2) to prevent the admixture of non-GM crops and GM crops and the unintended presence of genetically modified organisms in other products.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(2) This Act regulates:

1) the release of genetically modified organisms into the environment for a purpose other than placing on the market;

[RT I, 08.07.2014, 3 – entry into force 01.08.2014]

2) placing on the market of genetically modified organisms, and products containing or composed of such organisms;

3) the handling of GM crops.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(3) This Act does not apply to:

1) modification of genes of human beings by means of genetic engineering;

2) organisms produced using such genetical modification proceedings or methods involving mutagenesis or by fusing the cells (including protoplasts) of such organisms, which may exchange genetic material also by using conventional breeding methods;

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

3) medicinal products for humans containing or composed of genetically modified organisms, that are addressed by other legislation;

4) contained use of genetically modified organisms, including contained use of micro-organisms;

5) transportation of genetically modified organisms by rail, road, inland water bodies, sea or air;

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

6) transportation of GM crops from one state to another via Estonia without unloading;

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

7) transportation of properly packaged seeds or plant propagating material of a GM crop authorised to the market of the European Union;

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(4) Clauses 3 to 5 of subsection 2 of § 5 of this Act apply in the event specified in clause 4 of subsection 3 of this section.

(5) [Repealed – RT I, 08.11.2010, 1 – entry into force 18.11.2010]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 proceedings provided in this Act, taking into consideration the specifications provided for in this Act.

§ 2. Definitions

(1) For the purposes of this Act 'organism' means any biological entity capable of replication or of transferring genetic material.

(2) Genetically modified organism is an organism in which genetic material has been altered in a way that does not occur naturally.

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

(4) For the purpose of this Act, 'product' means a preparation containing or consisting of a genetically modified organism or a combination of genetically modified organisms.

(5) For the purpose of this Act, 'accident' means the unintended release of large amounts of genetically modified organisms into the environment which is likely to have an adverse effect on human health or the environment.

(6) For the purposes of this Act, 'handling GM crops' (hereinafter *handling*) means the cultivation, transportation or storage of a genetically modified crop on the basis of a marketing authorisation of the European Union.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(7) 'Handler of a GM crop' (hereinafter *handler*) means a self-employed person or a legal person who, for the purposes of this Act, cultivates, transports or stores genetically modified crops authorised for cultivation in the European Union on the basis of a

marketing authorisation.

[RT I, 15.03.2019, 7 – entry into force 16.03.2019]

§ 3. Genetic modification

(1) Genetic modification occurs through the use of at least one of the following techniques:

- 1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material outside an organism, and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;
- 2) techniques involving the introduction into an organism of genetic material prepared outside the organism;
- 3) techniques where live cells with new combinations of genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

(2) The following techniques are not considered to result in genetic modification:

- 1) *in vitro* fertilisation;
- 2) natural processes such as: conjugation, transduction, transformation;
- 3) polyploidy induction.

(3) The provisions of subsection 2 apply on condition that the techniques do not involve the use of recombinant nucleic acid molecules or genetically modified organisms within the meaning of clause 1 of subsection 1 of this section.

§ 4. Releasing genetically modified organisms into environment and placing genetically modified organisms and products on market

(1) Release of genetically modified organisms into the environment means the removal of a genetically modified organism or a combination of genetically modified organisms from containment, or storage thereof outside such space for any purpose other than placing the genetically modified organisms on the market without taking any specific containment measures prescribed to limit their non-controlled spread.

(2) The measure specified in subsection 1 of this section constitute a physical barrier or a physical barrier combined with a chemical or biological barrier which precludes any contact between a genetically modified organism and other organisms or which precludes the release of a genetically modified organism into the environment.

(3) Placing a genetically modified organism or product on the market means making such organism or product available to a third party whether in return for payment or free of charge.

(4) Placing on the market does not include:

- 1) making genetically modified micro-organisms, including cell culture collections, available in operations regulated by Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms (OJ L 117, 8.5.1990, pp. 1-14);
- 2) making genetically modified micro-organisms not specified in clause 1 of this subsection available only for such operations where adequate strict containment measures are used for limiting contacts with the human population and the environment and ensuring a high level of protection;
- 3) making genetically modified organisms available for the purpose of using them only upon such deliberate release into the environment, which complies with the requirements established in Part B of the Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, pp. 1-39).

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

§ 5. Gene Technology Committee

(1) The Gene Technology Committee is an advisory body established within the area of government of the Ministry of the Environment.

(2) The function of the Gene Technology Committee is to:

- 1) advise governmental authorities in issues of gene technology and environmental risks arising from genetically modified organisms or products;
- 2) advise notifiers applying for authorisation for release of genetically modified organisms into the environment, and notifiers applying for authorisation for placing genetically modified organisms or products on the market;
- 3) review notifications for authorisation for release of genetically modified organisms into the environment, notifications for authorisation for placing genetically modified organisms or products on the market and notifications for contained use of genetically modified organisms;
- 4) give an opinion on the deliberate release of genetically modified organisms into the environment, placing genetically modified organisms or products on the market and contained use of genetically modified organisms indicated in the notifications;
- 5) provide consultations to the Labour Inspectorate on issues related to the contained use of genetically modified micro-organisms;
- 6) provide consultations to the Ministry of Rural Affairs on issues related to the conduct of animal experiment involving genetically modified animals.

(3) The membership of the Gene Technology Committee is established by an order of the Government of the Republic, taking into account that the Gene Technology Committee should comprise of members who hold a relevant academic degree and represent various relevant research areas. The statutes of the Gene Technology Committee are approved by a regulation of the Government of the Republic. The statutes of the Gene Technology Committee establish the rights, obligations, rules of procedure, procedure for making decisions, operations procedure and procedure for remuneration of the Committee.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(4) The Gene Technology Committee includes:

- 1) two members to be appointed on the proposal of the minister responsible for the field;

[RT I, 29.06.2014, 109 – entry into force 01.07.2014, based on subsection 4 of § 107³ of the Government of the Republic Act, the

words 'Minister of the Environment' have been replaced with the words 'minister responsible for the field.')

2) one member to be appointed on the proposal of the minister responsible for the field;

[RT I, 29.06.2014, 109 – entry into force 01.07.2014, based on subsection 4 of § 107³ of the Government of the Republic Act, the words 'Minister of Economic Affairs and Communications' have been replaced with the words 'minister responsible for the field.')

3) four members to be appointed on the proposal of the minister responsible for the field. One of these four members must represent crop growers and one must represent crop processors;

[RT I, 29.06.2014, 109 – entry into force 01.07.2014, based on subsection 4 of § 107³ of the Government of the Republic Act, the words 'Minister of Agriculture' have been replaced with the words 'minister responsible for the field.')

4) one member to be appointed on the proposal of the minister responsible for the field;

[RT I, 29.06.2014, 109 – entry into force 01.07.2014, based on subsection 4 of § 107³ of the Government of the Republic Act, the words 'Minister of Social Affairs' have been replaced with the words 'minister responsible for the field.')

5) two members to be appointed on the proposal of the Rector of the University of Tartu;

6) one member to be appointed on the proposal of the Rector of the Estonian University of Life Sciences;

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

7) one member to be appointed on the proposal of the Rector of Tallinn University of Technology;

8) three members to be appointed on the proposal of the President of the Estonian Academy of Sciences;

9) two members to be appointed on the proposal of environmental organisations.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

Chapter 2

RELEASE OF GENETICALLY MODIFIED ORGANISMS INTO ENVIRONMENT FOR PURPOSE OTHER THAN PLACING ON MARKET

[RT I, 08.07.2014, 3 - entry into force 01.08.2014]

§ 6. Release of genetically modified organisms into environment

(1) Genetically modified organisms may be released into the environment for a purpose other than placing on the market only on the basis of a written authorisation of the minister responsible for the field (hereinafter *authorisation*). The specific list of data included in the authorisation and the form of the authorisation is established, based on the provisions of subsection 5 of § 12 of this Act, by a regulation of the minister responsible for the field.

[RT I, 08.07.2014, 3 – entry into force 01.08.2014]

(2) A person wishing to release genetically modified organisms into the environment submits a notification for a corresponding authorisation to the Ministry of the Environment.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

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

(4) Authorisation is required where genetically modified organisms or products are to be released into the environment for a purpose other than that indicated in the marketing authorisation issued in a Member State of the European Union.

§ 7. Notification for release of genetically modified organisms into environment

(1) The notification must contain:

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

1) the name, personal identification or registry code, address and contact details of the notifier;

2) the names and qualifications of the persons to engage in the release into the environment of the genetically modified organisms;

3) the name and characteristics of the genetically modified organisms to be released into the environment;

4) the purpose of the release into the environment of the genetically modified organisms;

5) the location, to the accuracy of the rural municipality or city, of the release into the environment of the genetically modified organisms;

6) a description of the method of the release into the environment of the genetically modified organisms, and the characteristics of the receiving environment;

7) a description of the presumed interactions between the genetically modified organisms and the receiving environment;

8) the environmental monitoring plan;

9) a description of waste treatment measures;

10) an emergency response plan and a description of remediation methods and measures to be taken in the event of accident;

11) a description of the potential impact on human health and the environment;

12) the date of payment of the state fee.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(2) A summary of the dossier conforming to the requirements of Council Decision 2002/813/EC establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release of genetically modified organisms into the environment for purposes other than for placing on the market (OJ L 280, 18.10.2002, pp. 62–83) is appended to the notification.

(3) An environmental risk assessment concerning the release of genetically modified organisms into the environment is appended to the notification containing an evaluation of the potential adverse effects of the release of genetically modified organisms into the environment. The risk assessment concerning the release of genetically modified organisms into the environment must deal with the direct, indirect, immediate, delayed, cumulative and long-term impact on human health and the environment, and set out a risk management plan.

(4) A detailed list of the data to be submitted in a notification, the form of notifications, the risk assessment procedure and a list of data to be submitted in the risk assessment are established by a regulation of the minister responsible for the field based on the requirements provided in subsections 1 to 3 of this section. In establishing the regulation, the minister responsible for the field takes account of Commission Decision 2002/623/EC 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release of genetically modified organisms into the environment and repealing Council Directive 90/220/EEC (OJ L 200, 30.07.2002, pp. 22–33).

(5) The minister responsible for the field may accept that

- 1) releases of the same genetically modified organism or of a combination of genetically modified organisms on the same site, or
- 2) on different sites for the same purpose and within a defined period may be notified in a single notification.

(6) A notifier who has already released, based on an earlier authorisation, the genetically modified organisms specified in the notification into the environment includes in the notification additional information concerning the results and environmental impact of such release.

(7) The notifier may use the data concerning the release of genetically modified organisms into the environment or results thereof from notifications previously submitted by other notifiers, provided that these notifiers have given their agreement in writing.

§ 8. Additional information

(1) For each following release into the environment of a genetically modified organism or combination of organisms, previously notified in the context of the same research project, a new notification is submitted, which may include references to the data presented in the previous notification and to the outcome of the release into the environment provided therein.

(2) The notifier or authorisation holder is required to immediately inform the Ministry of the Environment in writing where:

- 1) the notifier or authorisation holder plans to release the genetically modified organism or combination of organisms into the environment in a manner other than the one indicated in the notification;
- 2) during processing the notification, new information has become available regarding the possible negative consequences of releasing the genetically modified organism or combination of organisms into the environment;

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

3) following the grant of authorisation, new information has become available, regarding the possible negative consequences of releasing the genetically modified organism or combination of organisms into the environment.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(3) Upon granting the authorisation, the minister responsible for the field takes into account the information specified in clauses 1 and 2 of subsection 2 of this section.

(4) The Ministry of the Environment publishes the information specified in clause 3 of subsection 2 of this section in at least one national daily newspaper. The requirements for the contents of the information to be submitted to and published by the Ministry of the Environment are established by a regulation of the minister responsible for the field.

(5) Upon becoming evident of the facts specified in subsection 2 of this section, the notifier or authorisation holder:

- 1) reviews the measures specified in the notification and adjusts them as necessary;
- 2) takes measures necessary to protect human health or the environment.

§ 9. Review of notification for release of genetically modified organisms into environment

(1) The Ministry of the Environment verifies whether the notification meets the requirements provided for in this Act and legislation established on the basis thereof and forward a proper notification to the Gene Technology Committee, informing the notifier thereof in writing. The Ministry of the Environment forwards a summary of the notification to the European Commission in accordance with the requirements of Council Decision 2002/813/EC.

(2) Upon reviewing a notification, the Gene Technology Committee:

- 1) assesses the possible harmful effects to human health and the environment relating to the release of genetically modified organisms into the environment, which may become evident directly or indirectly, including upon transfer of genes from genetically modified organisms to other organisms, and the likelihood of emergence of these effects;
- 2) where necessary, requires information from governmental authorities, state agencies and research institutions;
- 3) where necessary, performs or orders tests for verification of the information submitted in the notification;
- 4) where necessary, makes a reasoned request that the notifier submit additional relevant information.

(3) Before performance of the tests or surveys for verification of information, the notifier covers the justified costs of tests or surveys. The costs of tests or surveys are also covered by the notifier where authorisation is not granted on the ground specified in subsection 4 of § 12 of this Act.

[RT I, 08.07.2014, 3 – entry into force 01.08.2014]

§ 10. Publication of notification and authorisation

(1) The Ministry of the Environment publishes, at the expense of the notifier, a notice concerning the commencement of processing of a notification and of the grant of authorisation in the official publication *Ametlikud Teadaanded* and in at least one national daily newspaper within seven days after the date of receipt of the notification or grant of authorisation.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(2) The notice must contain, as a minimum, the following information:

- 1) the name of the notifier and, where the notifier is a legal person, the registry code, and the address and other contact details of the notifier;
- 2) a summary of the notification or authorisation;
- 3) the name of the genetically modified organisms and the location, to the accuracy of the rural municipality or city, of the release

into the environment of the genetically modified organisms;

4) a notation as to where the notification can be examined;

5) the term within which an opinion can be presented or proposals can be made concerning the release into the environment of the genetically modified organisms.

(3) The term specified in clause 5 of subsection 2 of this section must not be shorter than thirty days and not longer than sixty days.

(4) The minister responsible for the field provides a written response to the proposal specified in clause 5 of subsection 2 of this section within two weeks after receipt of the proposal, informing the person whether the proposal has been accepted or rejected and providing the reasons underlying acceptance or rejection.

§ 11. Conclusion and proposal of Gene Technology Committee

(1) Within 60 days after receiving a notification for release of genetically modified organisms into the environment, the Gene Technology Committee makes one of the following written conclusions:

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

1) the planned release of genetically modified organisms into the environment complies with this Act and legislation established on the basis thereof, is safe to human health and the environment and does not have an adverse impact on the ecosystem functioning;

2) the safety of the planned release of genetically modified organisms into the environment to human health and the environment has not been sufficiently proven and it may have an adverse impact on the functioning of the ecosystem;

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

3) the planned release of genetically modified organisms into the environment complies with this Act and legislation established on the basis thereof and is safe to human health and the environment, provided that the additional requirements set forth in the conclusion are complied with.

(2) Within the term specified in subsection 1 of this section, the Gene Technology Committee makes a proposal to the minister responsible for the field to:

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

1) grant authorisation, where the release of genetically modified organisms into the environment complies with this Act and legislation established on the basis thereof, and is safe to human health and the environment;

2) refuse to grant authorisation, where the release of genetically modified organisms into the environment does not comply with this Act or legislation established on the basis thereof or the safety of the release into the environment to human health or the environment has not been sufficiently proven;

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

3) grant an authorisation and thereby establish additional requirements which prevent possible threats, where the notification complies with the requirements established by legislation.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(3) The Gene Technology Committee submits a proposal to the minister responsible for the field for establishment of additional requirements along with the reasons therefor.

§ 12. Grant, amendment, suspension and revocation of authorisation

(1) The provisions of the Administrative Procedure Act concerning open proceedings apply to the grant and amendment of authorisation, taking into account the specifications arising from this Act. The provisions concerning open proceedings do not apply to the suspension or revocation of authorisation.

(2) After receiving a proposal from the Gene Technology Committee, but not later than within 90 days following the receipt of a proper notification, the minister responsible for the field grants authorisation or informs the notifier in writing of the refusal to grant authorisation and provides the reasons thereof in writing. Authorisation can be granted for up to ten years.

(3) The minister responsible for the field does not grant authorisation where:

1) upon releasing the genetically modified organism into the environment, the safety of the genetically modified organism to human health or the environment has not been sufficiently proven or the taking of all the proper measures for the purpose of reducing the environmental risk to the maximum extent is not ensured;

2) the notification contains false information;

3) the release of the genetically modified organism into the environment does not comply with legislation.

(4) The following must be specified in an authorisation:

1) the name and main characteristics of the genetically modified organisms to be released into the environment and the purpose of releasing it into the environment;

2) the name, registry code or personal identification code, address and contact details of the person to release the genetically modified organism into the environment;

3) minimum requirements for the safe release of the genetically modified organism into the environment and all proper measures for reducing the environmental risk as much as possible, including handling and storage requirements;

4) the location of the release of the genetically modified organism into the environment;

5) the extent of and requirements for environmental monitoring and the terms for submission of reports concerning the results of environmental monitoring;

6) the term of validity of the authorisation.

(5) A genetically modified organism may be released into the environment only on the terms and conditions established in the authorisation. The genetically modified organism cannot be placed on the market on the basis of the authorisation.

(6) The minister responsible for the field temporarily suspends an authorisation where after the grant of the authorisation, possible risks relating to the release of the genetically modified organism into the environment become evident.

(7) During the temporary suspension of an authorisation, the minister responsible for the field may amend the terms and conditions

of the authorisation or revoke the authorisation on the basis of a risk assessment carried out on a proposal of the Gene Technology Committee and at the expense of the authorisation holder.

(8) The minister responsible for the field revokes an authorisation where:

- 1) the notification contains false information;
- 2) the authorisation holder fails to comply with the provisions provided for in the authorisation;
- 3) upon release of the genetically modified organism into the environment, the safety to human health or the environment has not been sufficiently proven or the taking of all proper measures for reducing the environmental risk as much as possible is not ensured;
- 4) the release of the genetically modified organism into the environment does not comply with legislation.

[RT I, 08.07.2014, 3 – entry into force 01.08.2014]

§ 13. Simplified procedure for release of genetically modified organisms into environment

The release of genetically modified organisms into the environment in accordance with a simplified procedure is carried out in accordance with Commission Decision 1994/739/EC establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants (OJ L 292, 12.11.1994, pp. 31–34).

§ 14. Provision of information on results on deliberate release of genetically modified organisms into environment

(1) After the deliberate release of genetically modified organisms into the environment, the authorisation holder submits to the Ministry of the Environment an environmental monitoring report in compliance with Commission Decision 2003/701/EC establishing a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market (OJ L 254, 08.10.2003, pp. 21–28).

(2) Where necessary, the minister responsible for the field establishes, by a regulation, the requirements for the contents of environmental monitoring reports concerning the release into the environment of genetically modified organisms other than genetically modified higher plants and the requirements for presenting the results of environmental monitoring.

§ 15. Extension of term validity of authorisation

(1) An authorisation holder submits a notification for extension of the term of validity of the authorisation to the Ministry of the Environment at least nine months prior to the expiry thereof.

(2) For extension of an authorisation, a written notification is submitted together with the following documents and information:

- 1) a copy of a valid authorisation;
- 2) an environmental monitoring report;
- 3) new information, where any, concerning the potential threat to human health or the environment which could result from the release of genetically modified organisms into the environment;

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

4) where necessary, a proposal to amend the terms or conditions of the authorisation.

(3) The provisions of §§ 9-12 of this Act and the requirements of the legislation established on the basis of subsection 1 of § 6 of this Act apply to the review of notifications for extension of authorisations, to making the notifications public and to the extension of authorisations.

(4) During reviewing the extension of an authorisation, the authorisation holder may continue to release genetically modified organisms into the environment until the final decision is made concerning extension of the authorisation.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

Chapter 3

PLACING GENETICALLY MODIFIED ORGANISMS OR PRODUCTS ON MARKET

§ 16. Placing genetically modified organisms or products on market

(1) Genetically modified organisms or products may be placed on the market only based on the written authorisation of the minister responsible for the field (hereinafter marketing authorisation). The specific list of data to be included in the marketing authorisation and the form of marketing authorisations are established, based on the provisions of subsection 5 of § 22 of this Act, by a regulation of the minister responsible for the field.

(2) In order to obtain a marketing authorisation, a person wishing to place a genetically modified organism or product on the market submits a notification to the Ministry of the Environment.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(3) No marketing authorisation is required for the placing on the market, within the Republic of Estonia, of genetically modified organisms or products which have been placed on the market or released into the environment based on a marketing authorisation issued in a Member State of the European Union.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(4) Marketing authorisation is required where the genetically modified organisms or products are to be placed on the market for a purpose other than the purpose indicated in the marketing authorisation issued in a Member State of the European Union.

§ 17. Notification for marketing authorisation

(1) The notification must contain:

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

- 1) the name, personal identification code or registry code, address and contact details of the producer or importer and distributor;

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

- 2) the purpose of placing the product on the market;
- 3) where necessary, the geographical area of placing the product on the market;
- 4) the name of the product and the name and characteristics of the genetically modified organism contained in the product;
- 5) a description and conditions of use of the product;
- 6) a description of an appropriate environment for the product;
- 7) a description of the presumed interaction between the genetically modified organisms contained in the product and the environment receiving such organisms;
- 8) the name of the field of use of the product and a description of the planned manner of use thereof;
- 9) the conditions for preservation and storage of the product;
- 10) a list of measures to be taken in the event of misuse of the product;
- 11) a description of the outcome of research carried out with the product and of the test releases into the environment of the product, including a description of the effect of the product on human health and the environment;
- 12) the proposed design of the packaging and labelling of the product including, where necessary, an overview of types of packaging to prevent the release into the environment of the genetically modified organisms or products;
- 13) an estimate of the volume of production or import of the product;
- 14) a description of the means and conditions of transport of the products;
- 15) an environmental monitoring plan prepared taking into account Council Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release of genetically modified organisms into the environment and repealing Council Directive 90/220/EEC (OJ L 280, 18.10.2002, pp. 27–36);
- 16) a description of waste treatment measures as necessary;
- 17) an emergency response plan and a description of remediation methods and measures to be taken in the event of accident;
- 18) [Repealed – RT I, 08.11.2010, 1 – entry into force 18.11.2010]
- 19) a summary of the notification in compliance with the requirements of Council Decision 2002/812/EC establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms or 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 – entry into force 18.11.2010]

(2) A risk assessment related to the genetically modified organisms or products, prepared in conformity with the provisions of subsection 3 of § 7 of this Act, is appended to the notification.

(3) A detailed list of the data to be submitted in a notification, the form for notifications, the risk assessment procedure and a list of the data to be presented in the risk assessment are established by a regulation of the minister responsible for the field based on the requirements provided in subsections 1 to 3 of this section. In establishing the regulation, the minister responsible for the field takes Commission Decision 2002/623/EC into account.

(4) Where it has been proven, based on scientific research or results of the release into the environment of the genetically modified organisms, that placing genetically modified organisms or products on the market is safe to human health and the environment, then with the consent of the Gene Technology Committee the information specified in subsection 2 of this section need not be submitted.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(5) Where the notifier has placed on the market, based on an earlier marketing authorisation, or released into the environment the genetically modified organisms or products specified in the notification, the notifier appends the results of the placing on the market of the genetically modified organisms or products and the environmental impact thereof, regardless of where they were placed on the market.

(6) The notifier may refer to data concerning the placing on the market modified organisms or results thereof from notifications previously submitted by other notifiers, provided that these notifiers have given their agreement in writing.

(7) A separate notification is submitted for each new product which contains the same genetically modified organisms but is prescribed to be used in a different manner.

§ 18. Review of notifications for placing genetically modified organisms or products on market

(1) After verifying its compliance with the requirements, the Ministry of the Environment forwards the notification to the Gene Technology Committee and informs the notifier thereof in writing. The Ministry of the Environment forwards a summary of the notification to the European Commission.

[RT I, 08.07.2014, 3 – entry into force 01.08.2014]

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

(3) Upon reviewing a notification, the Gene Technology Committee:

- 1) [Repealed – RT I, 08.07.2014, 3 – entry into force 01.08.2014]
- 2) assesses the measures planned for ensuring the safety of the product;
- 3) assesses the potential adverse effect on human health and the environment which may be the direct or indirect result of transfer of genes from genetically modified organisms to other organisms;
- 4) requires information from governmental authorities, state agencies and research institutions as necessary;
- 5) performs or orders tests or analyses, as necessary, for verification of the information submitted in the notification.

(4) Before submitting a notification, a state fee at the rate specified in the State Fees Act is paid for reviewing the notification. The notifier covers any justified costs of tests or surveys to be performed for verification of information before performance of the tests or surveys. The costs of tests or surveys are also covered by the notifier where the marketing authorisation is not granted on the

grounds specified in subsection 4 of § 22 of this Act.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

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

§ 19. Publication of notifications and authorisations for placing genetically modified organisms or products on market

The provisions of § 10 of this Act apply to the publication of the notifications and authorisations for placing genetically modified organisms or products on the market.

§ 20. Conclusion and proposal of Gene Technology Committee

(1) After receiving a notification for placing on the market of genetically modified organisms or products, the Gene Technology Committee prepares a written conclusion in accordance with the provisions of subsection 1 of § 11 of this Act.

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

(3) The Gene Technology Committee has the right to request more specific information concerning the placing on the market of genetically modified organisms or products from the notifier. The reasons for such request are provided.

(4) The Gene Technology Committee submits to the minister responsible for the field a proposal for setting additional conditions together with the reasons therefor.

(5) Where necessary, the Gene Technology Committee has the right to provide an opinion concerning a notification for a marketing authorisation submitted in another Member State or reasonably request additional information concerning such notification.

§ 21. Assessment report

(1) After receiving a proposal from the Gene Technology Committee, but not later than within 90 days following the receipt of a proper notification, the minister responsible for the field draws up a written assessment report whereby the minister makes the initial decision to grant or refuse the marketing authorisation. The notifier does not have any legitimate expectation to obtain the authorisation on the basis of the initial decision made in the assessment report.

(2) Where the initial decision to grant the marketing authorisation to the notifier has been made in an assessment report, the Ministry of the Environment sends the assessment report to the notifier and the European Commission without delay. The requirements for assessment reports are established by a regulation of the minister responsible for the field.

(3) Where the initial decision to refuse to grant the marketing authorisation to the notifier has been made in an assessment report, the Ministry of the Environment sends the assessment report to the European Commission no sooner than 15 days after sending the assessment report to the notifier and no later than 105 days following the receipt of the valid notification.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

§ 22. Grant of marketing authorisation

(1) The provisions of the Administrative Procedure Act concerning open proceedings apply to the grant of a marketing authorisation, taking into account the specifications arising from this Act.

[RT I, 08.07.2014, 3 – entry into force 01.08.2014]

(2) The minister responsible for the field grants a marketing authorisation of genetically modified organisms or products or refuses to grant a marketing authorisation and informs the notifier thereof after completion of the European Union standard procedure regarding the assessment report. In the course of the standard procedure the European Commission, within 60 days after the submission of the assessment report, gathers the comments and reasoned objections of the Member States and the public and on the basis thereof the minister responsible for the field, within 105 days after the submission of the assessment report of the European Commission, makes a decision to grant or refuse the marketing authorisation. The calculation of the term of processing the marketing authorisation is suspended for the time limit which the minister responsible for the field has additionally granted to the notifier for submission of additional information.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(3) The maximum term of validity of a marketing authorisation is ten years. Within 30 days, the minister responsible for the field informs the Member States and the European Commission of granting a marketing authorisation.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(4) The minister responsible for the field does not grant a marketing authorisation where:

1) placing the genetically modified organisms or products on the market poses a risk to human health or the environment;

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

2) the notification contains false information;

3) placing genetically modified organisms or products on the market does not comply with legislation.

(5) The following information must be indicated in a marketing authorisation:

1) the name, main characteristics, identity and unique identifier of the product and the genetically modified organism contained therein;

2) conditions which ensure the safe use, including safe handling and storage, of the product;

3) the name, personal identification code or registry code, address and contact details of the authorisation holder;

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

4) special conditions related to environmental protection;

5) date of expiry of the marketing authorisation;

6) an obligation to provide control samples at the request of the Gene Technology Committee;

- 7) an environmental monitoring plan, taking account of the provisions of Council Decision 2002/811/EC;
8) product labelling requirements.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(6) A marketing authorisation grants a person the right to release into the environment the genetically modified organisms or products specified in the authorisation.

§ 23. Communication of placing genetically modified organisms or products on market

(1) After placing genetically modified organisms or products on the market, the authorisation holder submits to the Ministry of the Environment an environmental monitoring report concerning the genetically modified organisms or products, the requirements for the contents and procedure for submission of which are established by a regulation of the minister responsible for the field.

(2) Where before or after being granted a marketing authorisation, the notifier receives new information on the threats which the genetically modified organisms or products are likely to pose to human health or the environment, the notifier must immediately inform the Ministry of the Environment of such threats and apply appropriate health and environmental protection measures. The Ministry of the Environment publishes such information in at least one national newspaper. The requirements for information to be submitted to and published by the Ministry of the Environment are established by a regulation of the minister responsible for the field.

§ 24. Packaging and labelling of products

(1) Marketed products must be packaged and labelled. The labelling must be clearly visible and understandable. A product is placed on the market together with accompanying documents that bear the unique identifier of the genetically modified organism.

(2) The labelling on the package of a product must bear at least the following information:

- 1) the name of the product;
- 2) the text “ *Toode sisaldab geneetiliselt muundatud organisme* ” [this product contains genetically modified organisms];
- 3) the name of the genetically modified organism contained in the product;
- 4) the name and address of the person in charge of marketing;
- 5) a reference to possibilities of obtaining additional information.

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

(4) For products where adventitious or technically unavoidable traces of genetically modified organisms authorized in the European Union cannot be excluded, a minimum threshold may be established below which these products does not have to be labelled. The threshold levels are established by the European Commission in accordance with the provisions of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, pp. 23-26).

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

§ 25. Amendment and revocation of marketing authorisation

(1) Where, based on new scientific information, there is reason to believe that a genetically modified organism or product poses a risk to human health or the environment then, on the proposal of the Gene Technology Committee and based on the results of risk assessment carried out at the expense of the authorisation holder, the minister responsible for the field amends the conditions of the marketing authorisation or revokes the authorisation.

(1¹) The minister responsible for the field informs the Member States and the European Commission of the activities specified in subsection 1 of this section, including of learning of the information, which may result in the amendment or revocation of a marketing authorisation.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

(2) The minister responsible for the field revokes a marketing authorisation where:

- 1) false information has been given in the notification for a marketing authorisation;
- 2) the marketing authorisation holder fails to comply with the conditions provided for in the authorisation;
- 3) the genetically modified organisms or products pose a risk to human health or the environment;
- 4) placing the genetically modified organisms or products on the market does not meet the requirements of legislation.

(3) The provisions regulating open proceedings apply to the amendment of a marketing authorisation analogously to the grant of a marketing authorisation. The provisions regulating open proceedings do not apply to the revocation of a marketing authorisation.

[RT I, 08.07.2014, 3 – entry into force 01.08.2014]

§ 26. Extension of marketing authorisation

The provisions of subsections 1, 2 and 4 of § 15 and §§ 18–22 of this Act and the requirements of the legislation established on the basis of subsection 1 of § 16 of this Act apply to reviewing notifications for extension of a marketing authorisation and to making such fact public.

§ 27. Simplified procedure for placing on market of genetically modified organisms or products

Where the Gene Technology Committee finds that the placing on the market of genetically modified organisms or products has been safe to human health and the environment for a period of at least five years, the Gene Technology Committee may make a proposal to the minister responsible for the field to request application of the simplified procedure for placing on market of the genetically modified organisms or products from the European Commission.

§ 28. Genetically modified food and feed

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

Chapter 3¹ **HANDLING GM CROPS**

[RT I, 08.11.2010, 1 - entry into force 18.11.2010]

§ 28¹. Handling GM crops

(1) A handler must handle GM crops with the due care in order to prevent its genetic admixture with non-GM crops and possible damage arising therefrom.

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

(3) Before the commencement of handling, the handler appoints a person in charge of proper handling in its enterprise.
[RT I, 15.03.2019, 7 – entry into force 16.03.2019]

(4) The following must be observed upon handling a GM crop:

- 1) the growing distance requirement;
- 2) the growing period requirement;
- 3) transportation requirements;
- 4) storage requirements;

5) the requirement to remove, within the prescribed growing period, plants emerging from a GM crop grown as a preculture from the field of successive crop before the given volunteer plants which are about to emerge have started to create pollen, viable seeds or other propagating material;

6) the requirement to clean the equipment and machinery used in production.

(5) More detailed requirements for handling GM crops are established by a regulation of the minister responsible for the field.
[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

§ 28². Training to handle GM crops

(1) Persons in charge of handling GM crops and employees of enterprises engaged in handling GM crops must have undergone training in handling GM crops and they must hold a certificate proving the completion of the training.

(2) The certificate proving the completion of the training is valid for five years. Where the persons in charge of handling and the employees of the enterprises engaged in handling GM crops participate in in-service training organised by the Agriculture and Food Board during the term of validity of the certificate, the term of validity of the certificate proving the completion of the training is extended by another five years after the expiry of the term of validity.

[RT I, 01.07.2020, 1 – entry into force 01.01.2021]

(3) The programme of the training in handling GM crops, the requirements established for obtaining a certificate, the procedure for issue of a certificate and the frequency of in-service training are established by a regulation of the minister responsible for the field.
[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

§ 28³. Duty to notify

[RT I, 15.03.2019, 7 – entry into force 16.03.2019]

(1) To cultivate, store and transport a GM crop, the handler submits a notice of economic activities to the Agriculture and Food Board.

[RT I, 01.07.2020, 1 – entry into force 01.01.2021]

(2) In addition to the information provided for in the General Part of the Code of Economic Activities, the handler includes the following information in a notice of economic activities:

- 1) the name and personal identification code of the person in charge and the employee specified in subsection 1 of § 28² of this Act or, in the event of absence thereof, their date of birth;
- 2) the contact details of the person in charge.

(3) In addition to the data provided for in subsection 2 of this section, a person cultivating a GM crop submits the following data in a notice of economic activities:

- 1) the species, variety denomination and unique code of the GM crop;
- 2) the number of the agricultural parcels, the location of the field in the agricultural parcels, the number and coordinates of the field;
- 3) a confirmation of performance of the duty to notify established in subsections 1 and 5 of § 28⁴ of this Act;
- 4) a confirmation of the attainment of the agreement provided for in subsection 2 of § 28⁴ of this Act.

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

[RT I, 15.03.2019, 7 – entry into force 16.03.2019]

§ 28⁴. Notification

(1) At least three months before the commencement of growing a GM crop, a person who would like to grow the GM crop informs

in writing the possessors of the fields that remain within the notification distance about the intention to grow the GM crop. The notification distance is the twofold growing distance and the handler informs the possessors of the fields falling within the distance about the intention to grow the GM crop.

(2) A person who would like to grow a GM crop and the growing distance of whose field includes other fields whose possessors intend to grow non-GM crops of the same species or a crop of another plant species which is able to crossbreed with the former in a field that falls within the growing distance, may commence growing the GM crop only where the person has reached a written agreement with the possessors of the said fields. In accordance with clause 1 of subsection 4 of § 28¹ of this Act, the growing distance is the minimum permitted distance from the edge of a field of a GM crop to a field of the same plant species that is grown using the conventional or organic method or that of another plant species which is able to crossbreed with the GM crop.

(3) The substantive and formal requirements for notifications informing of growing a GM crop, the length of the notification distance and the list of the documents to be annexed to the notification are established by a regulation of the minister responsible for the field.

(4) In the event of the sale, lease or other transfer of the land, the person on whose land GM crops have been grown, during the term of validity of the requirement set out in clause 2 of subsection 4 of § 28¹ of this Act and before the transfer of ownership or possession, informs the person who acquires the land or gains possession of the land about growing the GM crop. During the term of validity of the aforementioned requirement the acquirer and the possessor follow the requirement established in clause 5 of subsection 4 of § 28¹ this Act.

(5) A person who would like to grow a GM crop informs the apiary owner who has expressed the wish to be informed of any situation where the apiary is located up to three kilometres from a field where GM crops are to be grown in writing of the intention to cultivate the GM crop.

[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

Chapter 4

DATA OF GENETICALLY MODIFIED ORGANISMS

§ 29. Storage of data and classification of data as confidential business information

(1) The data submitted in notifications for release of genetically modified organisms into the environment or for placing on the market of genetically modified organisms are kept in the environmental register.

(2) The notifier may make a reasoned request in a notification for classification of a part of the data as confidential business information.

(3) The minister responsible for the field decides which data is to be maintained as confidential business information and informs the notifier of the decision. The data classified as business secret by the minister responsible for the field are not deemed to be public information even where the notifier withdraws the notification.

(4) The following data are not classified as confidential business information by the minister responsible for the field:

1) the general description of genetically modified organisms, the name and address of the notifier, the purpose, place and time of releasing the organisms into the environment, and the planned manner of use thereof;

2) the method for monitoring genetically modified organisms and the monitoring plan, and remedial action to be taken in the event of accident;

3) the environmental risk assessment information.

[RT I, 08.11.2010 – entry into force 18.11.2010]

(5) The Agriculture and Food Board retains the data of certificates proving the completion of training and the details of the documents serving as the basis for issuing the certificates in the plant health register for five years after the date of expiry of the certificate.

[RT I, 01.07.2020, 1 – entry into force 01.01.2021]

(6) A handler keeps accurate accounts of the fulfilment of the requirements. Documents relating to the handling and notification thereof are retained for at least ten years.

[RT I, 08.11.2010 – entry into force 18.11.2010]

§ 30. Exchange of information and consultations with European Commission

The minister responsible for the field establishes, by a regulation, the procedure for regulating the exchange of information and consultations with the European Commission in issues related to the release of genetically modified organisms into the environment and placing genetically modified organisms or products on the market.

Chapter 5

STATE SUPERVISION AND COMPENSATION FOR DAMAGE

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

§ 31. State supervision

(1) State supervision over compliance with the requirements of this Act and legislation established on the basis thereof is exercised by the Environmental Board, except in areas where the supervision obligation has been imposed on other law enforcement bodies.

[RT I, 10.07.2020, 2 – entry into force 01.01.2021]

(2) The Agriculture and Food Board exercises supervision over the use of genetically modified plant varieties, the production and

packaging for marketing purposes of the seed and propagating material of species of agricultural and horticultural plants containing or composed of genetically modified organisms as well as over the the marketing, import and export of such material in accordance with the procedure provided by the Plant Propagation and Plant Variety Rights Act, taking into account the specifics of this Act.

[RT I, 01.07.2020, 1 – entry into force 01.01.2021]

(3) The Environmental Board exercises supervision over the production and packaging for marketing purposes of the forestry plants or cultivating material containing or composed of genetically modified organisms as well as over the marketing, import and export of such material in accordance with the procedure provided by the Plant Propagation and Plant Variety Rights Act, taking into account the specifics of this Act.

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

(4) The Agriculture and Food Board exercises supervision over the plant protection products containing or composed of genetically modified organisms in accordance with the procedure provided in the Plant Protection Act, taking into account the specifics of this Act.

[RT I, 01.07.2020, 1 – entry into force 01.01.2021]

(5) The Agriculture and Food Board, the Tax and Customs Board and the Consumer Protection and Technical Regulatory Authority exercise supervision over fertilisers containing or composed of genetically modified organisms in accordance with the procedure provided in the Fertilisers Act, taking into account the differences provided for in this Act.

[RT I, 01.07.2020, 1 – entry into force 01.01.2021]

(6) The Agriculture and Food Board exercises supervision over food containing or composed of genetically modified organisms in accordance with the procedure provided in the Food Act, taking into account the specifics of this Act.

[RT I, 01.07.2020, 1 – entry into force 01.01.2021]

(7) The Consumer Protection and Technical Regulatory Authority exercises supervision over compliance with requirements established for the provision of information on food containing or consisting of genetically modified organisms and over the correctness of submitted information in a retail undertaking in accordance with the procedure established in the Food Act, taking into account the differences provided for in this Act.

[RT I, 12.12.2018, 3 – entry into force 01.01.2019]

(8) The Agriculture and Food Board exercises supervision over feed containing or composed of genetically modified organisms in accordance with the procedure provided in the Feedingstuffs Act, taking into account the specifics of this Act.

[RT I, 01.07.2020, 1 – entry into force 01.01.2021]

(9) The Agriculture and Food Board exercises supervision over compliance with handling requirements.

[RT I, 01.07.2020, 1 – entry into force 01.01.2021]

§ 31¹. Special measures of state supervision

(1) To exercise the state supervision provided for in this Act, the Environmental Board may take 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 grounds and in accordance with the procedure established in the Law Enforcement Act.

[RT I, 10.07.2020, 2 – entry into force 01.01.2021]

(2) Upon exercising state supervision over compliance with handling requirements, the Agriculture and Food Board may take the special measures of state supervision provided for in §§ 30, 49, 50, 51 and 52 of the Law Enforcement Act on the grounds and in accordance with the procedure established in the Law Enforcement Act.

[RT I, 01.07.2020, 1 – entry into force 01.01.2021]

§ 31². Use of direct coercion

The Environmental Board is authorised to use physical force on the grounds and in accordance with the procedure established in the Law Enforcement Act.

[RT I, 10.07.2020, 2 – entry into force 01.01.2021]

§ 31³. Rate of non-compliance levy

The maximum rate of the non-compliance levy imposed in accordance with the Substitutional Performance and Non-Compliance Levies Act in the event of failure to comply with a prescription is 13 000 euros.

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

§ 32. Compensation for damage and remedying damage

(1) Damage caused by handling GM crops is compensated by the handler in the event of exceeding the threshold established by Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

(2) [Repealed – RT I, 08.11.2010 – entry into force 18.11.2010]

(3) The minister responsible for the field evaluates, at the expense of the polluter, whether environmental damage has been successfully eliminated.

[RT I, 08.11.2010 – entry into force 18.11.2010]

Chapter 5¹ LIABILITY

[RT I, 08.11.2010, 1 - entry into force 18.11.2010]

§ 33. Violation of requirements for release into environment of genetically modified organisms or placing on market of genetically modified organisms or products

(1) The penalty for violation of the requirements for release of genetically modified organisms into the environment or the requirements for placing genetically modified organisms or products on the market is a fine of up to 300 fine units.

(2) The penalty for the same act committed by a legal person is a fine of up to 32 000 euros.
[RT I, 08.11.2010, 1 – entry into force 01.01.2011]

§ 33¹. Violation of requirements for handling GM crops

(1) The penalty for violation of the requirements for handling GM crops is a fine of up to 200 fine units.

(2) The penalty for the same act committed by a legal person is a fine of up to 3200 euros.
[RT I, 08.11.2010, 1 – entry into force 01.01.2011]

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

(1) The penalty for violation of the requirements for packaging and labelling genetically modified organisms or products is a fine of up to 100 fine units.

(2) The penalty for the same act committed by a legal person is a fine of up to 6400 euros.
[RT I, 08.11.2010, 1 – entry into force 18.11.2010]

§ 34¹. Violation of duty to notify of growing GM crop

[Repealed – RT I, 15.03.2019, 7 – entry into force 16.03.2019]

§ 34². Violation of duty to notify of notifier or holder of authorisation

(1) The penalty for violation of the duty to notify of a notifier or a holder of authorisation is a fine of up to 200 fine units.

(2) The penalty for the same act committed by a legal person is a fine of up to 13 000 euros.
[RT I, 08.11.2010, 1 – entry into force 01.01.2011]

§ 35. Proceedings

Extrajudicial proceedings of the misdemeanours specified in this Chapter are, according to their competence, conducted by the Environmental Board, the Agriculture and Food Board, the Consumer Protection and Technical Regulatory Authority, and the Tax and Customs Board.

[RT I, 10.07.2020, 2 – entry into force 01.01.2021]

Chapter 6 IMPLEMENTING PROVISIONS

§ 36. Implementation of Act

Until the time all databases related to environmental protection are consolidated in the environmental register, the data submitted in notifications for release of genetically modified organisms into the environment or for placing on the market of genetically modified organisms are kept by the Ministry of the Environment in the form of a state agency database.

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

§ 41. Entry into force of Act

This Act will enter into force on 1 May 2004.