

Law on the Use of Genetically Modified Microorganisms in a Closed Environment¹

Adopted on 21.11.2001
RT I 2001, 97, 603
entered into force according to § 24.

Chapter 1 general settings

§ 1. Scope of the Act

(1) This Act regulates the safe use of genetically modified microorganisms in a closed environment with the aim of protecting human health and the environment.

[RT I 2002, 61, 375 - entry into force. 01.08.2002]

¹

(1) § 5–12 of this Act shall not apply to the transport of genetically modified microorganisms by road, railway, inland waterways, sea and air.

[RT I 2008, 48, 266 - entry into force. 23.11.2008]

(2) The Administrative Procedure Act applies to the administrative procedure prescribed in this Act, unless this Act provides otherwise.

[RT I 2002, 61, 375 - entry into force. 01.08.2002]

§ 2. Definitions used in the law

For the purposes of this law, the following are:

1) *microorganism* – a microbiological form of being capable of reproduction or transfer of heredity factors, including virus, viroid and animal or plant cell culture; 2) *genetically modified microorganism* – a microorganism whose heredity factors have been changed in a way that differs from the natural exchange of genetic material; 3) *genetic modification* – activity where at least one method of modification is used within the meaning of § 3 of the Act on the Release of Genetically Modified Organisms into the Environment; 4) *use in a closed environment* – genetic modification of a microorganism or cultivation, storage, destruction, transfer or use of a modified microorganism in a way that excludes the exit of the genetically modified microorganism from its intended environment and the access of a foreign organism to it; [RT I 2008, 48, 266 - entry into force. 23.11.2008] 5) *committee* – genetic technology committee within the meaning of § 5 of the Act on the release of genetically modified organisms into the environment; 6) *user* – a person who is responsible for the safe use of a genetically modified microorganism in a closed environment; 7) *accident* – an incident involving the use of a genetically modified microorganism that threatens or may endanger human health or the environment; 8) *application* – documentation containing the required information for submission to the Labor Inspectorate.

Chapter 2 SAFE USE OF GENETICALLY MODIFIED MICROORGANISMS

§ 3. General requirements

(1) A genetically modified microorganism may be used in a closed environment only in compliance with the requirements established in and on the basis of this Act.

(2) A genetically modified microorganism may be used in a closed environment after submitting a notification and application and obtaining written permission from the Labor Inspectorate, unless otherwise provided by law.

(3) The user implements measures to prevent possible dangers to human health and the environment from the use of genetically modified microorganism.

§ 4. Risk analysis

(1) The user performs a risk analysis to clarify the safety of use of the genetically modified microorganism.

(2) When performing a risk analysis, the user assesses the possibility of a hazard, hazard elements and possible consequences of the hazard and determines the hazard class of the closed environment, the use of genetically modified microorganisms that meet the requirements is safe for human health and the environment. The risk analysis must, among other things, deal with the safety measures

for the disposal of waste and waste water and disposal from the closed environment.

[RT I 2008, 48, 266 - entry into force. 23.11.2008]

(3) The risk analysis is based on:

1) an assessment of the harmful effects resulting from the properties of the recipient and donor organism and the introduced genetic material, recombinant nucleic acid carrier and genetically modified microorganism;

2) when taking into account harmful effects arising from use;

3) in assessing the extent of adverse effects and the probability of their functioning.

(4) During the internal control of the working environment, the user regularly reviews the results of the risk analysis and the applicable safety measures. The user performs a new risk analysis if:

1) there is a doubt or there is evidence that the risk analysis is no longer correct according to new scientific and technical data;

2) there is a suspicion or there is evidence that the closed environment no longer guarantees safety or the specified hazard class is no longer correct;

3) a new genetically modified microorganism is introduced or created.

[RT I 2008, 48, 266 - entry into force. 23.11.2008]

(5) The risk analysis report shall be attached to the application.

(6) The user shall keep the risk analysis protocol for five years.

(7) The list of data included in the risk analysis and the procedure for performing the risk analysis shall be established by the minister responsible for the field by regulation .

§ 5. Determination of danger class

(1) Based on the results of the risk analysis, the user assigns the following hazard classes to the closed environment:

1) 1st hazard class, if the use is not dangerous;

2) 2nd hazard class, if the use is of little danger;

3) 3rd danger class, if the use is moderately dangerous;

4) 4th danger class, if the use is extremely dangerous.

(2) In case of doubt arising in determining the hazard class, a higher hazard class is assigned to the closed environment and the requirements established for this hazard class are applied.

(3) If a genetically modified microorganism is used in a greenhouse, vivarium or other special conditions, special requirements apply to the use based on the dangerousness of the use.

(4) The requirements applicable to hazard classes and the special requirements specified in subsection 3 of this section shall be established by a regulation of the minister responsible for the field .

§ 6. General principles of safe use of genetically modified microorganism in a closed environment

(1) The user ensures that the requirements for safe use of the genetically modified microorganism specified in subsection 2 of this section and applied to the hazard class are applied.

(2) The user is obliged to fulfill the following requirements:

1) implement measures to prevent the genetically modified microorganism from entering the work environment and nature;

2) use common technical protective equipment to avoid danger and, if necessary, provide employees with protective clothing or other personal protective equipment;

3) keep protective equipment in working order and maintain and check them;

4) if necessary, clarify whether genetically modified microorganisms are found outside the closed environment;

5) organize employee training;

6) if necessary, form a committee to resolve issues related to safety;

7) prepare a safety manual for employees and check its implementation;

8) install 2-4. in the case of a place of use belonging to the hazard class, the warning sign «Biological danger» and other relevant safety signs on the door of this room or room complex and in a visible place in the room where genetically modified microorganisms are used;

9) prohibit eating, drinking, storing food and using cosmetics;

10) prohibit mouth pipetting;

11) set up shower rooms and provide employees with antiseptic skin cleansers;

12) acquire disinfectants necessary for the destruction of genetically modified microorganisms;

13) ensure the safe storage of microorganism waste and contaminated laboratory equipment until they are destroyed.

§ 7. Notification of the use of a genetically modified microorganism

(1) Before using a genetically modified microorganism for the first time in a room or room complex, or starting to use it in accordance with the requirements of a higher hazard class than before, the user submits a notification to the Labor Inspectorate, which is attached to the permit application.

(2) The notification must contain the following information:

1) the user's name, location address, registry code, telephone and fax number, and e-mail address;

2) danger class;

3) address of the building used for work, size of the room used, number and location on the building plan;

4) name and qualification of the person responsible for safety;

5) waste storage and disposal plan;

6) documents certifying compliance with the requirements set forth in § 13 subsection 1 of this Act and safety measures implemented to protect human health and the environment.

§ 8. Application for the use of a genetically modified microorganism

(1) For the first use of genetically modified microorganisms in accordance with the requirements of hazard class 1, the user submits an application for hazard class 1 to the Labor Inspectorate and receives a written permit from the Labor Inspectorate.

(2) If the Labor Inspectorate has already granted permission to the user, the new genetic modification or use of the modified microorganism of any new microorganism that meets the requirements of hazard class 1 may be started in the future, provided that the requirements applicable to hazard class 1 are met.

(3) For the first use of a genetically modified microorganism in accordance with the requirements of hazard class 2, or for the genetic modification of a microorganism in accordance with the requirements of each new hazard class 2, or for the use of a modified microorganism, the user submits an application for hazard class 2 to the Labor Inspectorate and receives a written permit from the Labor Inspectorate.

(4) For the first use of a genetically modified microorganism in accordance with the requirements of the 3rd or 4th hazard class (*hereinafter* risk class) or for the genetic modification of a microorganism in accordance with the requirements of each new risk class or for the use of a modified microorganism, the user submits a risk class application to the Labor Inspectorate and receives a written permit from the Labor Inspectorate.

(5) [Repealed - RT I 2002, 61, 375 - entry into force. 01.08.2002]

(6) The list of data to be submitted in the application shall be established by a regulation of the minister responsible for the field .

§ 9. Review of the application

(1) After receiving the application, the Labor Inspectorate:

1) checks the accuracy of the data provided in the application and compliance with the requirements of this Act and the legislation established on its basis;

2) forwards the application to the commission for assessment;

3) if necessary, makes an inquiry to state and research institutions.

(2) After receiving the application, the commission:

1) evaluates the closed environment described in the application and the protective measures to be implemented, as well as the risk to human health and the environment that may arise from the use of a genetically modified microorganism;

2) prepares a written assessment of the application, which includes a proposal to allow or refuse to use genetically modified microorganisms in a closed environment, and forwards the assessment to the Labor Inspectorate within 30 days of receiving the application.

(3) The Commission may, if necessary, propose to the Labor Inspectorate:

1) ask the user for additional information;

2) require the user to change the hazard class presented in the application;

3) to allow the use of genetically modified microorganisms in a closed environment, if the user applies additional measures to eliminate the risk.

(4) [Repealed - RT I 2002, 61, 375 - entry into force. 01.08.2002]

§ 10. Issuance of permission

(1) Permission to use a genetically modified microorganism in a closed environment is granted by the Labor Inspectorate.

(2) Before granting permission to the user, the Labor Inspectorate checks the correctness of the data provided in the application and the existence of the emergency measures plan specified in § 13 subsection 1 of this Act and the implementation of relevant protective measures.

(3) The Labor Inspectorate issues a permit for the 1st or 2nd hazard class within 45 days of receiving the application.

(4) The Labor Inspectorate issues a permit within 90 days of receiving the application for the risk class. If the risk class permit has already been granted to the usable space and all requirements have been met, the Labor Inspectorate will issue the permit within 45 days of receiving the application.

(5) The Labor Inspectorate has the right to extend the permit granting period by 30 days if it expects additional information from the user.

§ 11. Refusal to issue a permit

(1) The Labor Inspectorate does not issue a permit if the safety requirements are not met or if the applied protective measures do not ensure the protection of human health and the environment against the effects of genetically modified microorganisms.

(2) In case of refusal to grant a permit, the Labor Inspectorate shall provide the user of the permit with a written justification for the refusal within 45 days of receiving the request.

§ 12. Issuance of a new permit when the hazard class changes

(1) The user shall immediately notify the Labor Inspectorate of new circumstances that increase the risk of using genetically modified microorganisms and therefore change the hazard class.

(2) The user submits a new application to the Labor Inspectorate within 14 days from the notification specified in subsection 1 of this section.

(3) If, according to new circumstances, the requirements of the 2nd, 3rd or 4th hazard class must be followed, the user shall suspend the activity until a new permit is obtained.

§ 13. Precautions and accidents

(1) The user ensures that before using the genetically modified microorganism in a closed environment:

1) a plan of emergency measures is prepared for the protection of people and the environment in the event of an accident, which is

notified to the Rescue Board in writing;

[RT I, 29.12.2011, 1 - enters into force. 01.01.2012]

2) institutions and companies that may be in danger are informed about the necessary safety precautions and behavior in a dangerous situation.

(2) The user is obliged to update the information specified in clause 1, clause 2 of this section.

(3) In the event of an accident, the user shall immediately inform the Labor Inspectorate and the environmental supervision authority by telephone, e-mail or fax or by other means of the following information:

- 1) time, place and circumstances of the accident;
- 2) the list and quantities of microorganisms related to the accident;
- 3) other information that helps explain the possible impact of the accident on people and the environment;
- 4) measures implemented and to be implemented.

(4) After receiving the information specified in subsection 3 of this section, the Labor Inspectorate:

- 1) checks the implementation of all relevant emergency measures;
- 2) gives recommendations to prevent similar accidents in the future.

(5) The Labor Inspectorate ensures that all accidents are investigated. The accident is investigated by the labor inspector together with the official of the environmental supervision agency. The results of the investigation are stored and kept for 55 years.

§ 14. Elimination of environmental pollution caused by an accident

(1) Environmental pollution caused by an accident shall be eliminated by the user who caused it.

(2) If the user does not eliminate the pollution caused by the release of the genetically modified microorganism into the natural environment, it will be organized by the environmental supervision authority at the user's expense.

(3) The act specified in subsection 2 of this section shall be subject to the Substitute Enforcement and Extortion Act.

§ 15. Informing the public

The Labor Inspectorate announces the use of genetically modified microorganisms in accordance with the requirements of the risk class in accordance with the procedure provided by the Public Information Act.

Chapter 3 INFORMATION ON THE USE OF GENETICALLY MODIFIED MICROORGANISMS

§ 16. Storage of data

(1) Notifications, requests, copies of issued permits and other documents related to the use of genetically modified microorganism in a closed environment are stored in the Labor Inspectorate in accordance with the procedure provided for in the Archives Act.

(2) Names of genetically modified microorganisms, data on places of use and purposes of use of microorganisms and other relevant data are stored in the database specified in the Act on the Release of Genetically Modified Organisms into the Environment.

§ 17. Data confidentiality

(1) In the application, the user shall indicate with reason which information is necessary to be recognized as confidential in order to avoid damage to his interests.

(2) The Labor Inspectorate decides to recognize the data as confidential based on the commission's assessment and makes its decision known to the user.

(3) The following may not be recognized as confidential:

- 1) the user's name or address;
- 2) a general description or use of the genetically modified microorganism;
- 3) danger class;
- 4) measures that prevent the exit of the genetically modified microorganism from the closed environment or the access of a foreign organism to it;
- 5) effects that harm human health and the environment if the genetically modified microorganism leaves the closed environment.

(4) The Labor Inspectorate and the commission may not forward information recognized as confidential to a third party, unless the law provides otherwise.

Chapter 4 STATE SUPERVISION

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

§ 18. State supervision

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

The national supervision of the fulfillment of the requirements of this Act and the legislation established on its basis is carried out by the Labor Inspectorate and the Environmental Board.

[RT I, 10.07.2020, 2 - enters into force. 01.01.2021]

1

§ 18 . Special measures of state supervision

The law enforcement body may apply the special measures of state supervision provided for in §§ 30, 31, 32, 49, 50 and 51 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, 13.03.2014, 4 - enters into force. 01.07.2014]

2

§ 18 . 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]

3

§ 18 . Extortion rate

In the case of failure to comply with the precept, the maximum amount of the fine to be applied in accordance with the procedure laid down in the Substitute Enforcement and Fines Act is 12,800 euros.
[RT I, 13.03.2014, 4 - enters into force. 01.07.2014]

**Chapter 5
RESPONSIBILITY**

[Repealed – RT I, 12.07.2014, 1 - entry into force. 01.01.2015]

§ 19. Violation of requirements for the use of genetically modified microorganisms
[Repealed - RT I, 12.07.2014, 1 - entered into force. 01.01.2015]

§ 20. Submission of incorrect data
[Repealed - RT I, 12.07.2014, 1 - entered into force. 01.01.2015]

§ 21. Procedure
[Repealed – RT I, 12.07.2014, 1 - entered into force. 01.01.2015]

**Chapter 6
IMPLEMENTATION PROVISIONS**

§ 22. Amendment of the Act on the Release of Genetically Modified Organisms into the Environment
[Omitted from this text.]

§ 23. Implementation of the law

The user of genetically modified microorganisms in a closed environment must submit to the Labor Inspectorate an application complying with the hazard class of the closed environment by July 1, 2002 at the latest.

§ 24. Entry into force of the law

- (1) This Act enters into force on January 1, 2002, except for the case specified in subsection 2 of this section.
- (2) §§ 19–21 of this Act shall enter into force on January 1, 2003.

1

Council Directive 90/219/EEC on the isolated use of genetically modified microorganisms (OJ L 117, 8.05.1990, pp. 1–14); Council Directive 98/81/EC amending Directive 90/219/EEC on the isolated use of genetically modified microorganisms (OJ L 330, 5.12.1998, pp. 13–31).
[RT I 2008, 48, 266 - entry into force. 23.11.2008]