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# Contained Use of Genetically Modified Micro-organisms Act<sup>1</sup>

Passed 21.11.2001

RT I 2001, 97, 603

Entered into force in accordance with § 24

Amended by the following acts

Passed	Published	Entry into force
19.06.2002	RT I 2002, 61, 375	01.08.2002
22.10.2008	RT I 2008, 48, 266	23.11.2008
22.04.2010	RT I 2010, 22, 108	01.01.2011, will enter into force on the date specified in the decision of the Council of the European Union concerning abrogation of the derogation established with regard to the Republic of Estonia on the basis of Article 140 (2) of the Treaty on the Functioning of the European Union, Decision No. 2010/146/EU of the Council of the European Union of 13 July 2010 (OJ L 196, 28.07.2010, pp. 24-26).
20.05.2010	RT I 2010, 29, 151	20.06.2010
08.12.2011	RT I, 29.12.2011, 1	01.01.2012, in part 01.01.2014 and 01.11.2014
19.02.2014	RT I, 13.03.2014, 4	01.07.2014
19.06.2014	RT I, 12.07.2014, 1	01.01.2015
19.06.2014	RT I, 29.06.2014, 109	01.07.2014, the ministers' official titles have been replaced on the basis of subsection 107 <sup>3</sup> (4) of the Government of the Republic Act.

## Chapter 1 GENERAL PROVISIONS

### § 1. Scope of application of Act

(1) This Act regulates the safe contained use of genetically modified micro-organisms with a view to protecting human health and the environment.

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

(1<sup>1</sup>) Sections 5–12 of this Act do not apply to the transport of genetically modified micro-organisms by road, rail, inland waterway, sea or air.

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

(2) The administrative procedure provided for in this Act is governed by the Administrative Procedure Act, unless otherwise provided by this Act.

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

## § 2. Definitions

For the purposes of this Act:

- 1) 'micro-organism' means any microbiological form of existence, including a virus, viroid, or animal or plant cell culture, which is capable of replication or of transferring genetic material;
- 2) 'genetically modified micro-organism' means a micro-organism in which the gene factors have been altered in a way that differs from natural recombination of genetic material;
- 3) 'genetic modification' means an activity whereby at least one of the modification techniques for the purposes of § 3 of the Release into Environment of Genetically Modified Organisms Act is used;
- 4) 'contained use' means the genetic modification of a micro-organism or the culturing, storing, inactivating, transporting or using of a modified micro-organism in a manner that precludes the exiting of the genetically modified micro-organism from the prescribed environment or access to the environment by an extraneous organism;  
[RT I 2008, 48, 266 - entry into force 23.11.2008]
- 5) 'committee' means the gene technology committee for the purposes of § 5 of the Release into Environment of Genetically Modified Organisms Act;
- 6) 'user' means a person who is responsible for the safe contained use of a genetically modified micro-organism;
- 7) 'accident' means an incident upon using a genetically modified micro-organism, which presents or could present a hazard to human health or the environment;
- 8) 'request' means documentation to be submitted to the Labour Inspectorate, which contains required information.

## Chapter 2 SAFE USE OF GENETICALLY MODIFIED MICRO-ORGANISMS

### § 3. General requirements

- (1) The contained use of a genetically modified micro-organism is permitted only in accordance with the requirements provided for in and on the basis of this Act.
- (2) The contained use of a genetically modified micro-organism may be commenced after a notification and request have been submitted and the Labour Inspectorate has granted written consent, unless otherwise provided by law.
- (3) The user takes measures to prevent hazards arising from the use of a genetically modified micro-organism to human health and the environment.

### § 4. Risk analysis

- (1) The user carries out a risk analysis for identifying the safety of use of a genetically modified micro-organism.
- (2) Upon carrying out the risk analysis, the user assesses the possibility of the hazard, the elements of the hazard, the possible consequences of the hazard, and identifies the hazard class of the containment whereby the use of the genetically modified micro-organism in compliance with the requirements of the contained use is safe to human health and the environment. Among other things, the risk analysis must also cover the safety measures for inactivating waste and waste water and for removal of waste and waste water from the containment.  
[RT I 2008, 48, 266 - entry into force 23.11.2008]
- (3) The risk analysis is based on:
  - 1) assessing the adverse impact arising from the characteristics of the genetic material inserted into the recipient and donor organism, the carrier of the recombinant nucleic acid and the genetically modified micro-organism;
  - 2) taking into account adverse impact arising from use;
  - 3) assessment of the extent and probability of adverse impact.
- (4) In the course of the internal control of the working environment, the user regularly examines the results of the risk analysis and the measures taken. The user will carry out a new risk analysis if:
  - 1) based on fresh research and technology data, it is suspected or there is evidence that the risk analysis is no longer correct;
  - 2) it is suspected or there is evidence that the containment no longer ensures safety or that the attributed hazard class is no longer correct;
  - 3) a new genetically modified micro-organism is introduced or created.  
[RT I 2008, 48, 266 - entry into force 23.11.2008]
- (5) The minutes of the risk analysis are enclosed with the request.

(6) The user preserves the minutes of the risk analysis for five years.

(7) The list of the data given in a risk analysis and the procedure for carrying out a risk analysis will be established by a regulation of the responsible for the field.

#### **§ 5. Attribution of hazard class**

(1) Based on the results of a risk analysis, the user attributes the following hazard classes to the containment:

- 1) hazard class 1 if the use is not hazardous;
- 2) hazard class 2 if the hazardousness of the use is minor;
- 3) hazard class 3 if the hazardousness of the use is moderate;
- 4) hazard class 4 if the use is extremely hazardous.

(2) In the event of a suspicion arising upon attributing a hazard class, the containment is attributed the highest hazard class and the requirements established to the hazard class are applied.

(3) If a genetically modified micro-organism is used in a greenhouse, vivarium or other special conditions, special requirements will apply to the use based on the hazardousness of the use.

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

#### **§ 6. General principles of safe contained use of genetically modified micro-organism**

(1) The user ensures that the requirements for safe use of micro-organisms specified in subsection (2) of this section and the requirements applicable to hazard classes are applied.

(2) The user must follow the following requirements:

- 1) take measures to prevent the release of a genetically modified micro-organism into the working environment and nature;
- 2) for prevention of the hazard, use technical collective protection equipment and, if necessary, provide the employees with protective clothing or other personal protective equipment;
- 3) keep the protective equipment in a working condition and maintain and inspect it;
- 4) if necessary, identify whether there are genetically modified micro-organisms exist outside the containment;
- 5) organise the training of the employees;
- 6) if necessary, establish a committee for resolution of safety-related issues;
- 7) draw up safety instructions for the employees and inspect adherence thereto;
- 8) in the event of a place of use of any hazard class between 2 and 4, install the warning sign 'Biological hazard' and other relevant warning signs on the door of the room or facilities and in a visible place in the room where genetically modified micro-organisms are used;
- 9) prohibit eating, drinking, storage of food and the use of cosmetic products;
- 10) prohibit mouth pipetting;
- 11) install shower rooms and provide the employees with antiseptic skin cleaning substances;
- 12) acquire disinfection substances for inactivating genetically modified micro-organisms;
- 13) ensure the safe storing of micro-organism waste and contaminated laboratory equipment until it is inactivated.

#### **§ 7. Reporting of use of genetically modified micro-organism**

(1) Before the first use of a genetically modified micro-organism in a room or facility or the commencement of use corresponding to the requirements of a higher hazard class, the user will submit to the Labour Inspectorate a respective notification that is enclosed with the request for consent.

(2) The notification must contain the following information:

- 1) the user's name, address, registry code, telephone and fax numbers, and e-mail address;
- 2) the hazard class;
- 3) the address of the building used for work, the size of the room used, and the number and location of the room in the layout of the building;
- 4) the name and qualifications of the person in charge of safety;
- 5) the waste storage and inactivation plan;
- 6) documents certifying the fulfilment of the requirements provided for in subsection 13 (1) of this Act and safety measures taken for the protection of human health and the environment.

#### **§ 8. Request for use of genetically modified micro-organism**

(1) In order to use genetically modified micro-organisms for the first time in accordance with the requirements of hazard class 1, the user will submit to the Labour Inspectorate a request of hazard class 1 and obtains written consent from the Labour Inspectorate.

(2) If the Labour Inspectorate has granted the user consent earlier, the user will be allowed to commence new respective genetic modification of a micro-organism in accordance with the requirements of hazard class 1 or the use of a modified micro-organism when the requirements applicable to hazard class 1 have been fulfilled.

(3) In order to use a genetically modified micro-organism for the first time in accordance with the requirements of hazard class 2 or for each new genetic modification of a micro-organism in accordance with the requirements of hazard class 2 or in order to use a modified micro-organism, the user will submit to the Labour Inspectorate a request of hazard class 2 and obtain written consent from the Labour Inspectorate.

(4) In order to use a genetically modified micro-organism for the first time in accordance with the requirements of hazard class 3 or 4 (hereinafter *risk class*) or for the genetic modification of a micro-organism in accordance with the requirements of each new risk class or for using a modified micro-organism, the user will submit to the Labour Inspectorate a risk class request and obtain written consent from the Labour Inspectorate.

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

(6) The list of information given in a request will be established by a regulation of the responsible for the field.

## **§ 9. Review of request**

(1) After the receipt of a request, the Labour Inspectorate:

- 1) checks the accuracy of the information given in the request and if the information meets the requirements established in and on the basis of this Act;
- 2) submits the request to the committee for assessment;
- 3) if necessary, makes an enquiry to state authorities and research institutions.

(2) After the receipt of a request, the committee:

- 1) assesses the containment and the protective measures described in the request and the risk to human health and the environment arising from the use of the genetically modified micro-organism;
- 2) draws up a written assessment of the request, which contains a proposal to permit or prohibit the contained use of the genetically modified micro-organism and sends the assessment to the Labour Inspectorate within 30 days after the receipt of the request.

(3) If necessary, the committee may make a following proposal to the Labour Inspectorate:

- 1) ask the user for additional information;
- 2) demand that the user change the hazard class given in the request;
- 3) permit the contained use of the genetically modified micro-organisms if the user takes additional measures precluding the risk.

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

## **§ 10. Granting consent**

(1) The Labour Inspectorate grants consent to the contained use of a genetically modified micro-organism.

(2) Before granting consent to the user, the Labour Inspectorate checks the correctness of the information given in the request, the existence of an emergency plan specified in subsection 13 (1) of this Act and the application of adequate protective measures.

(3) The Labour Inspectorate grants consent within 45 days after the receipt of a hazard class 1 or 2 request.

(4) The Labour Inspectorate grants consent within 90 days after the receipt of a risk class request. If the risk class consent has been granted to the used room earlier and all the requirements are fulfilled, the Labour Inspectorate will grant consent within 45 days after the receipt of the request.

(5) The Labour Inspectorate has the right to extend the time limit of granting the consent by 30 days if it waits for additional information from the user.

## **§ 11. Refusal to grant consent**

(1) The Labour Inspectorate will not grant consent if the safety requirement have not been fulfilled or if the protective measures taken do not ensure protection of human health or the environment against the impact of the genetically modified micro-organisms.

(2) If the Labour Inspectorate refuses to grant consent, the Labour Inspectorate will submit to the user the reasons of refusal in writing within 45 days after the receipt of the request.

## **§ 12. Granting new consent upon change of hazard class**

(1) The user will immediately inform the Labour Inspectorate of new circumstances that increase the risk upon using genetically modified micro-organisms and thus change the hazard class.

(2) The user will submit to the Labour Inspectorate a new request within 14 days after the receipt of the information specified in subsection (1) of this section.

(3) If the requirements of hazard class 2, 3 or 4 have to be followed according to new circumstances, the user will suspend its operations until it has been granted new consent.

### **§ 13. Precautions and accident**

(1) The user ensures that, before the contained use of a genetically modified micro-organism:  
1) an emergency plan is drawn up for the purpose of protecting human health and the environment in the event of an accident and the plan is communicated to the Rescue Board in writing;  
[RT I, 29.12.2011, 1 - entry into force 01.01.2012]  
2) authorities and undertakings that may be at risk are informed of the required precautions and about how to act in the event of an emergency.

(2) The user is required to update the information set out in clause 2) of subsection (1) of this section.

(3) In the event of an emergency, the user will immediately communicate the following information to the Labour Inspectorate and the environmental supervision authority by telephone, e-mail, fax or in another manner:  
1) the time, place and circumstances of the accident;  
2) the list and quantities of the micro-organisms involved in the accident;  
3) other information that helps to explain the possible impact of the accident on human health and the environment;  
4) the measures taken and to be taken.

(4) After the receipt of the information specified in subsection (3) of this section, the Labour Inspectorate will:  
1) verify that all relevant emergency measures have been taken;  
2) make recommendations for the prevention of similar accidents in the future.

(5) The Labour Inspectorate ensures that all accidents are investigated. An accident is investigated jointly by a labour inspector and an official of the environmental supervision authority. The results of the investigation are recorded and preserved for 55 years.

### **§ 14. Abatement of environmental pollution caused by accident**

(1) Environmental pollution related to an accident will be abated by the user who caused the pollution.

(2) If the user fails to abate pollution caused by the discharge of a genetically modified micro-organism into the natural environment, the environmental supervision authority will arrange it at the expense of the user.

(3) The steps specified in subsection (2) of this section are governed by the Substitutive Enforcement and Coercive Payments Act.

### **§ 15. Informing public**

The use of genetically modified micro-organisms in compliance with the requirements of the risk class is made public by the Labour Inspectorate in accordance with the procedure provided for in the Public Information Act.

## **Chapter 3 USAGE DATA OF GENETICALLY MODIFIED MICRO-ORGANISMS**

### **§ 16. Keeping data**

(1) Notifications and requests relating to the contained use of a genetically modified micro-organism, copies of granted consents and other documents are kept in the Labour Inspectorate in accordance with the procedure established in the Archives Act.

(2) The names of genetically modified micro-organisms, data on the places and purposes of use of genetically modified micro-organisms and other relevant information is kept in the database specified in the Release into Environment of Genetically Modified Organisms Act.

### **§ 17. Confidentiality of information**

(1) In a request, the user indicates which information needs to be declared confidential for preventing the harming of the interests of the user and states the reasons for confidentiality.

(2) On the basis of the assessment of the committee, the Labour Inspectorate decides whether to declare the information confidential and communicates the decision to the user.

(3) The following cannot be declared confidential:

- 1) the user's name and address;
- 2) the general description and the place of use of the genetically modified micro-organism;
- 3) the hazard class;
- 4) the measures that preclude the exiting of the genetically modified micro-organism from the containment or the access of an extraneous organism to the containment;
- 5) the impact that is harmful to human health and the environment if the genetically modified micro-organism exits from the containment.

(4) The Labour Inspectorate and the committee must not disclose confidential information to a third party, unless otherwise provided by law.

## **Chapter 4 STATE SUPERVISION**

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

### **§ 18. State supervision**

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

Within the limits of their competence, the Labour Inspectorate and the Environmental Inspectorate exercise supervision over the compliance with the requirements of this Act and legislation established on the basis thereof.

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

### **§ 18<sup>1</sup>. Special measures of state supervision**

A law enforcement authority may, for the purpose of exercising the state supervision provided for in this Act, take special measures of state supervision provided for in §§ 30, 31, 32, 49, 50 and 51 of the Law Enforcement Act on the grounds and in accordance with the procedure provided for in the Law Enforcement Act.

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

### **§ 18<sup>2</sup>. Use of direct coercion**

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

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

### **§ 18<sup>3</sup>. Rate of penalty payment**

In the event of failure to comply with a precept the maximum penalty payment imposed in accordance with the procedure provided for in the Substitutive Enforcement and Penalty Payment Act is 12 800 euros.

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

## **Chapter 5 LIABILITY**

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

### **§ 19. Violation of requirements for use of genetically modified micro-organisms**

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

### **§ 20. Giving false information**

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

### **§ 21. Proceedings**

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

## **Chapter 6**

## IMPLEMENTING PROVISIONS

**§ 22. [Omitted from this text.]**

**§ 23. Implementation of Act**

In the event of the contained use of genetically modified micro-organisms, the user must submit to the Labour Inspectorate a request corresponding to the hazard class of the containment not later than by 1 July 2002.

**§ 24. Entry into force of Act**

(1) This Act will enter into force on 1 January 2002, except in the event specified in subsection (2) of this section.

(2) Sections 19–21 of this Act will enter into force on 1 January 2003.

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