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If a whole or part of a section has been amended, the date of the amending law appears in square brackets at the end of the section. If a whole section, paragraph or clause has been deleted, the date of the deletion appears in square brackets beside the deleted section, paragraph or clause.

The *Saeima*<sup>1</sup> has adopted and  
the President has proclaimed the following Law:

## Law On Circulation of Genetically Modified Organisms

### Chapter I General Provisions

#### Section 1. Terms Used in this Law

The terms used in this Law are as follows:

1) **organism** – any biological entity replicable (capable of replication) or capable of transferring genetic material;

1<sup>1</sup>) **genetically modified organism** – an organism, with the exception of human beings, in which the genetic material has been altered using methods of genetic modification referred to in Clause 2 of this Section in a way that does not occur naturally by mating or natural recombination;

1<sup>2</sup>) **micro-organism** – any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, and animal and plant cells in culture;

1<sup>3</sup>) **genetically modified micro-organism** – a micro-organism in which the genetic material has been altered using at least any of the methods referred to in Clause 2 of this Section in a way that does not occur naturally by mating or natural recombination;

2) **methods of genetic modification:**

a) recombinant nucleic acid techniques – the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

b) methods involving the direct introduction into an organism or micro-organism of genetic material formed outside the organism, or micro-organism including micro-injection, macro-injection, micro-encapsulation;

c) cell and protoplast fusion or hybridisation methods – formation of cells with new genetic material combinations through the fusion of two or more cells from systematically remote groups of organisms and utilising techniques that do not occur naturally;

<sup>1</sup> The Parliament of the Republic of Latvia

3) **circulation of genetically modified organisms** – activities related to the contained use of genetically modified organisms and deliberate release of genetically modified organisms;

4) **contained use of genetically modified micro-organisms** – any activity performed in relation to genetically modified micro-organisms that are controlled using specific measures which effectively limit the contact of such micro-organisms with the environment and their impact on it;

4<sup>1</sup>) **deliberate release of genetically modified organisms** – deliberate release into the environment of genetically modified organisms for experiments or placing on the market, not using specific measures to limit a direct contact of the genetically modified organisms with the environment;

5) **release into the environment of genetically modified organisms for experiments** – release into the environment of genetically modified organisms for experiments related to their further utilisation in agriculture or in other sectors of the economy, or for any other specified purposes, not using specific measures to limit a direct contact of the genetically modified organisms with the environment, as well as the use in clinical trials of such medicinal products which contain genetically modified organisms, consist of or are produced from them;

6) **placing on the market of genetically modified organisms** – making available genetically modified organisms or the products containing thereof to the third parties in return for payment or free of charge. Placing on the market includes activities that are related to:

a) the circulation of such food which contains genetically modified organisms, consists of or is produced from them,

b) the circulation of such feed which contains genetically modified organisms, consists of or is produced from them,

c) the circulation of seeds of genetically modified crops and of plant propagating material,

d) the cultivation of genetically modified crops,

e) the circulation of genetically modified animals,

f) the use of genetically modified organisms in other sectors of the economy;

7) **co-existence** – an aggregate of such measures that are used in order to prevent indirect presence of genetically modified organisms in conventional and organic crops or apiculture products;

8) **risk assessment** – a scientific evidence based set of measures to identify the potential adverse direct or indirect, short-term or long-term effects of the genetically modified organisms on human and animal health and on the environment;

9) **emergency situation** – a situation that is related to the escape of genetically modified organisms from control when such escape may cause a short-term or long-term threat to human and animal health or on the environment.

[18 June 2009; 21 June 2012]

## **Section 2. Purpose of this Law**

The purpose of this Law is to achieve high level of safety in all stages of circulation of genetically modified organisms in order to prevent the negative impact on human and animal health or the environment, to preserve biological diversity, to promote the development of sustainable agriculture and biotechnology, as well as the co-existence of genetically modified crops concurrently with organic and conventional farming.

[21 June 2012]

## **Section 3. Circulation Principles of Genetically Modified Organisms**

A decision related to the circulation of genetically modified organisms shall be taken by observing the following principles:

1) a risk assessment principle which provides for the assessment of risk prior to the activities related to the circulation of genetically modified organisms, including in relation to the particular ecosystem which may be affected by deliberate release of genetically modified organisms;

2) a principle of sustainable development which provides that the circulation of genetically modified organisms may be permitted if the relevant activity is aimed at promotion of the national economic development and the basic principles of sustainable development and preservation of biological diversity specified in the laws and regulation governing environmental protection are being observed;

3) a principle of precaution which provides for the relevant temporary risk management measures for reduction of danger until the assessment of risk and the development of risk management, if an uncertainty is present at the risk assessment process related to the possible negative impact on human and animal health or the environment when genetically modified organisms are deliberately released;

4) a principle of public information and participation which provides that authorities promote public education and informing, hear out and evaluate public opinion regarding issues related to the circulation of genetically modified organisms;

5) a principle of ensuring supervisory and control measures which provides that the deliberate release of genetically modified organisms is authorised only if for the relevant genetically modified organism a method of determination and traceability is ensured.

*[18 June 2009; 21 June 2012]*

#### **Section 4. Scope of Application of the Law**

(1) This Law prescribes the competence of State authorities, the rights and duties of natural and legal persons (hereinafter – person), the principles, supervision and control for the circulation of genetically modified organisms including those for co-existence of modified crops, public participation, liability and legal protection of persons, as well as security measures and circulation of information for the prevention of any possible emergency situation.

(2) This Law shall not apply to:

1) the medicinal use of gene therapy;

2) the use of such medicinal products in clinical trials which contain genetically modified organisms, consist of or are produced from them, except for the risk assessment in accordance with the laws and regulations regarding deliberate release of genetically modified organisms, the procedures for monitoring and issuance of a permit, as well as the procedures for the provision of information regarding the circulation of genetically modified organisms and public involvement in the decision-making process;

3) organisms and micro-organisms, which occur when using the following methods [on condition that the referred to methods do not involve the use of recombinant-nucleic acid molecules or genetically modified organisms (micro-organisms)]:

a) mutagenesis;

b) cell fusion, including protoplast fusion, as the result of which the exchange of genetic material occurs, even when the traditional cultivation methods are used (applies only to organisms);

c) in vitro fertilisation;

d) conjugation, transduction, transformation and similar natural processes;

e) polyploidy induction;

f) cell fusion, including protoplast fusion, of prokaryotic species, as a result of which the exchange of genetic material by known physiological processes may occur (applies only to micro-organisms);

g) cell fusion, including protoplast fusion, of any eukaryotic species, production of hybridomas and plant cell fusions (applies only to micro-organisms);

h) self-cloning, as a result of which micro-organisms acquired are not dangerous to humans, animals or plants and cannot cause diseases thereof – separation of nucleic acid from the cells of such organisms followed or not followed by all the relevant nucleic acids, fermentative or mechanical processing of parts thereof or synthetic equivalent thereof, in order to cause the modification of genetic material, and administration of the acquired genetic material in the cells of organisms of the same species or phylogenetically closely related species, using which the exchange of genetic information is possible also in natural physiological conditions (applies only to micro-organisms);

4) contained use of such genetically modified organisms which conform to the harmlessness criteria specified in the laws and regulations regarding the procedures for contained use of genetically modified organisms and issuance of a permit.

*[18 June 2009; 21 June 2012]*

## **Chapter II Competence of Bodies**

### **Section 5. Competence of the Cabinet**

(1) The Cabinet shall:

1) determine the procedures for contained use of genetically modified organisms, the procedures for issuance, amending and cancelling of a permit;

2) determine the procedures for deliberate release of genetically modified organisms and the procedures for monitoring and issuance, extending, amending and cancelling of a permit, as well as the procedures for providing information regarding circulation of genetically modified organisms and the public involvement in the decision-making process, and the procedures for restricting or prohibiting the growing of genetically modified crops;

3) determine the methodology for the risk assessment of genetically modified organisms;

4) issue regulations regarding co-existence of genetically modified crops governing the requirements for co-existence of genetically modified crops and the procedures for the supervision, control and registration of growers of genetically modified crops, deletion thereof from the Register of Growers of Genetically Modified Crops and exchange of information included in the Register of Growers of Genetically Modified Crops;

5) determine the amount of the State fee to be paid for preparation of the risk assessment's opinion of genetically modified organisms, as well as the procedures for the payment thereof;

6) approve the by-law of the Supervisory Council of Genetically Modified Organisms.

(2) Not less frequently than once every seven years, the Cabinet shall approve the strategic guidelines for the development of the national system of biosafety and the development plan of such system.

(3) The Cabinet may specify provisional prohibitions and containment for the placing on the market of genetically modified organisms permitted in the European Union in Latvia or in particular territory thereof, if in accordance with new or additional scientific data, the release of the particular genetically modified organism may cause harm to human and animal health or to the environment. The European Commission and Member States of the European Union shall be notified without delay regarding the referred to prohibition or containment.

(4) The Cabinet may specify restrictions or prohibitions on growing of genetically modified crops permitted in the European Union:

1) in especially protected nature territories in order to prevent threats to the biological diversity of the particular territory;

2) for a particular genetically modified crop in Latvia or separate territory thereof, in conformity with the environmental policy objectives, agricultural policy objectives, land use policy, spatial development planning documents, socio-economic considerations, attempts to avoid the presence of genetically modified organisms in other products, or other reasons arising from the State policy.

*[18 June 2009; 16 December 2010; 21 June 2012; 25 September 2014; 18 June 2015 / See Paragraph 6 of the Transitional Provisions]*

## **Section 6. Competence of the Ministry of Agriculture**

(1) The Ministry of Agriculture in co-operation with scientific organisations, associations and foundations shall develop and shall, jointly with the State authorities responsible for the control and supervision of genetically modified organism circulation, implement a unitary policy in the following fields:

1) circulation of genetically modified organisms;

2) co-existence;

3) development of the national system of biosafety.

(2) The Ministry of Agriculture shall prepare and during the process of granting a permit for growing a specific genetically modified crop submit to the European Commission a request to exclude Latvia or separate territory thereof from the territory of geographical operation of the permit for growing the respective genetically modified crop.

*[18 June 2015]*

## **Section 7. Competence of the State Plant Protection Service**

The State Plant Protection Service shall:

1) organise and conduct the development and operation of the State information system accessible to the public – Register of Growers of Genetically Modified Crops;

2) examine notifications and take decisions regarding the inclusion of genetically modified crop growers within the Register of Growers of Genetically Modified Crops;

3) ensure the supervision and control of co-existence of genetically modified crops;

4) ensure the supervision and control for the circulation of seeds of genetically modified crop varieties and plant propagating material;

5) determine genetically modified organisms in seeds and plant propagating material;

6) participate in the interlaboratory testing programmes organised by international organisations;

7) introduce internationally recognised methods related to identifying genetically modified organisms in seeds and plant propagating material;

8) ensure the identification of genetically modified organisms in seeds and plant propagating material in foreign laboratories if the performance thereof is not possible in Latvia;

9) perform supervision and control of such genetically modified organisms, which are grown by crop growers not registered with the Register of Growers of Genetically Modified Crops.

*[18 June 2009; 25 September 2014]*

## **Section 8. Competence of the Food and Veterinary Service**

The Food and Veterinary Service shall ensure the supervision and control of circulation of genetically modified food and animal feed (except seeds).  
[25 September 2014]

### **Section 9. Competence of the State Scientific Institute “Institute of Food Safety, Animal Health and Environment “BIOR””**

The State scientific institute “Institute of Food Safety, Animal Health and Environment “BIOR”” shall:

1) on the basis of the laws and regulations regarding circulation of genetically modified organisms and taking into account the binding opinion of the Scientific Expert Commission on risk assessment and monitoring programme of genetically modified organisms, and proposals of recommendatory nature of the Supervisory Council of Genetically Modified Organisms, issue a permit for:

a) contained use of genetically modified micro-organisms,

b) release into the environment of genetically modified organisms for experiments,

c) placing on the market of genetically modified organisms, with the exception of a permit for the activities specified in Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 regarding genetically modified food and feed (Text with EEA relevance) (hereinafter – Regulation No 1829/2003 of the European Parliament and of the Council);

2) amend or cancel a permit for contained use of genetically modified organisms, as well as release into the environment for trials and placing on the market, if there are threats that the respective genetically modified organism may cause harm to human and animal health or the environment;

3) examine the opinions of the European Food Safety Authority, the European Medicines Agency and other competent authorities of other Member States of the European Union regarding the risk assessment related to deliberate release of genetically modified organisms, and prepare an opinion in accordance with Regulation No 1829/2003 of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as well as the laws and regulations regarding deliberate release of genetically modified organisms, the procedures for monitoring and issuance of permit, and the procedures for the provision of information regarding the circulation of genetically modified organisms and the public involvement in the decision-making process;

4) organise and conduct the development and operation of the State information system accessible to the public – the Register of Genetically Modified Organism Circulation;

5) determine genetically modified organisms in food and animal feed samples;

6) perform the functions of a reference laboratory in identifying genetically modified organisms;

7) participate in the interlaboratory testing programmes organised by international organisations;

8) introduce internationally recognised methods for identification of genetically modified organisms;

9) ensure the examination of genetically modified organism samples in foreign laboratories if the performance thereof is not possible in Latvia.

[25 September 2014]

### **Section 10. Competence of the State Agency of Medicines**

[21 June 2012]

### **Section 11. Competence of the State Limited Liability Company “Latvian Environment, Geology and Meteorology Centre”**

Having received an application from a person which deliberately releases genetically modified organisms, the State limited liability company “Latvian Environment, Geology and Meteorology Centre” shall prepare a monitoring programme. On the basis of the results of the performed monitoring, the persons, which deliberately release genetically modified organisms, shall inform the Ministry of Agriculture regarding the risk management and environmental protection measures to be implemented when performing activities with genetically modified organisms and deliberately releasing them.

[21 June 2012]

### **Section 12. Competence of the State Environmental Service**

The State Environmental Service, in accordance with the laws and regulations regarding environmental protection and environmental impact assessment, shall control the conformity with the environmental protection conditions while the release into the environment of genetically modified organisms for experiments takes place and during cultivation of genetically modified crops.

[21 June 2012]

### **Section 13. Competence of the Nature Protection Board**

The Nature Protection Board shall prepare and submit to the Environment State Bureau recommendations to be included in the conditions regarding the impact assessment on the protected territories of European significance (Natura 2000) in conformity with the procedures laid down in the laws and regulations regarding environmental impact.

### **Section 14. Competence of the State Labour Inspectorate**

The State Labour Inspectorate, in conformity with the laws and regulations regarding labour protection when coming into contact with biological substances, shall ensure the supervision and control of such safety and labour protection measures which are related to the contained use of genetically modified micro-organisms.

[21 June 2012]

### **Section 15. Scientific Expert Commission**

(1) The Scientific Expert Commission is a group of experts, which examines risk assessment documents submitted by persons, as well as prepares and submits to the State scientific institute “Institute of Food Safety, Animal Health and Environment “BIOR”” a scientifically substantiated opinion regarding the risk assessment of genetically modified organisms and a monitoring program. On the basis of its opinion, a decision to issue the permit referred to in Section 9, Clauses 1 and 2 of this Law, to refuse to issue it and to amend or cancel the permit is taken.

(2) The Scientific Expert Commission shall prepare and submit proposals to the State scientific institute “Institute of Food Safety, Animal Health and Environment “BIOR”” regarding improvement of the development strategy of the national biological safety system and promote the public involvement in the decision-making process on circulation of genetically modified organisms.

(3) The Scientific Expert Commission shall prepare and submit to the State scientific institute “Institute of Food Safety, Animal Health and Environment “BIOR”” a scientifically substantiated opinion regarding opinions of the risk assessment of genetically modified organisms referred to in Section 9, Clause 3 of this Law.

(4) The operation of the Scientific Expert Commission according to the resources granted from the State budget shall be ensured by the State scientific institute “Institute of Food Safety, Animal Health and Environment “BIOR””.

*[25 September 2014]*

## **Section 16. Monitoring Council of Genetically Modified Organisms**

(1) The Supervisory Council of Genetically Modified Organisms is a consultative authority established by the Cabinet which co-ordinates the development of the national system of biosafety. The Supervisory Council of Genetically Modified Organisms shall promote co-operation between the authorities which control and supervise the circulation of genetically modified organisms and scientific establishments which perform research in this field, as well as shall promote the co-operation of the authorities involved in the implementation of the national policy regarding the circulation of genetically modified organisms and the improvement of the national policy instruments.

(3) The Supervisory Council of Genetically Modified Organisms, taking into account the opinion expressed by the public on the circulation of genetically modified organisms, shall submit proposals of recommendatory nature to the State scientific institute “Institute of Food Safety, Animal Health and Environment “BIOR”” regarding issuance of the permit referred to in Section 9, Clause 1, Sub-clauses “b” and “c” of this Law.

(3) The by-law and composition of the Supervisory Council of Genetically Modified Organisms shall be approved by the Cabinet. The by-law shall establish the institutional composition, rights, functions and agenda of the Supervisory Council of Genetically Modified Organisms.

(4) The functions of the secretariat of the Supervisory Council of Genetically Modified Organisms shall be performed by the Ministry of Agriculture within the funds provided for this purpose in the State budget for the current year.

*[18 June 2009; 25 September 2014]*

## **Chapter III**

### **Contained Use of Genetically Modified Micro-organisms**

*[21 June 2012]*

## **Section 17. Activities Related to the Contained Use of Genetically Modified Micro-organisms**

The activities related to the contained use of genetically modified micro-organisms may be performed by a scientific establishment which has been registered in the Register of Science Establishments (hereinafter – scientific establishment).

*[21 June 2012]*

## **Section 18. Containment Levels for Use of Genetically Modified Micro-organisms**

(1) For each activity related to the contained use of genetically modified micro-organisms in conformity with the laws and regulations regarding the procedures for contained use of genetically modified micro-organisms and issuance of a permit, on the basis of the risk assessment performed and the laws and regulations regarding the labour protection



requirements when coming into contact with biological substances, a containment level shall be determined.

(2) The activities related to the contained use of genetically modified micro-organisms are divided into four safety classes:

1) activities, which do not cause any risk or cause an insignificant risk, shall comply with the first safety class. Such activities conform to the containment of the first level, which is determined in order to protect human health or the environment;

2) activities, which cause a small risk, shall comply with the second safety class. Such activities conform to the containment of the second level, which is determined in order to protect human health or the environment;

3) activities, which cause a moderate risk, shall comply with the third safety class. Such activities conform to the containment of the third level, which is determined in order to protect human health or the environment;

4) activities, which cause a huge risk, shall comply with the fourth safety class. Such activities conform to the containment of the fourth level, which is determined in order to protect human health or the environment.

(3) Safety measures shall be performed in conformity with the relevant containment level in accordance with the laws and regulations regarding the procedures for the contained use of genetically modified micro-organisms and issuance of a permit and laws and regulations regarding the labour protection when coming into contact with biological substances.

*[21 June 2012]*

## **Section 19. Rights and Obligations when Performing Activities Related to the Contained Use of Genetically Modified Micro-organisms**

(1) The contained use of genetically modified micro-organisms may be commenced if, in accordance with the laws and regulations regarding the procedures for contained use of genetically modified micro-organisms and issuance of permit, the following conditions are observed:

1) the scientific establishment is provided with equipment and installations;

2) the risk assessment of a genetically modified micro-organism has been performed and the containment level has been determined;

3) a notification to the State scientific institute "Institute of Food Safety, Animal Health and Environment "BIOR"" on commencement of operation has been provided in accordance with specific procedures.

(2) In order to perform activities related to the contained use of genetically modified micro-organisms complying to the third and fourth safety class, a permit of the State scientific institute "Institute of Food Safety, Animal Health and Environment "BIOR"" shall, in accordance with the laws and regulations regarding the procedures for the contained use of genetically modified micro-organisms and issuance of permit, be received. Without a permit it is allowed to perform activities related to the contained use of genetically modified micro-organisms which conform to the first and second safety class if the conditions of Paragraph one of this Section are observed.

(3) The scientific establishment, when performing activities related to the contained use of genetically modified micro-organisms, has the following obligations:

1) to evaluate the performed measures of control and safety in conformity with the laws and regulations regarding the procedures for the contained use of genetically modified micro-organisms and issuance of a permit;

2) to take appropriate measures of control and safety without delay, if there is a reason to believe that these genetically modified micro-organisms no longer conform to the latest scientific knowledge;

3) to ensure the observance of the work safety and hygiene requirements of the contained use of genetically modified micro-organisms in conformity with the laws and regulations regarding labour protection when coming into contact with biological substances;

4) to suspend the activity with genetically modified micro-organisms, if taking into account the latest scientific knowledge, there is a reason to believe that it threatens human and animal health or the environment, and to inform regarding that the relevant competent authorities and the public.

*[21 June 2012; 25 September 2014]*

## **Chapter IV Deliberate Release of Genetically Modified Organisms**

*[21 June 2012]*

### **Section 20. Rights and Obligations Related to Deliberate Release of Genetically Modified Organisms**

(1) In order to release genetically modified organisms into the environment for experiments it is necessary for a person, which has created genetically modified organisms, to receive a permit of the State scientific institute “Institute of Food Safety, Animal Health and Environment “BIOR”” in accordance with the laws and regulations regarding the procedures for deliberate release of genetically modified organisms, the procedures for monitoring and issuance of a permit, as well as the procedures for the provision of information regarding the circulation of genetically modified organisms and the public involvement in the decision-making process.

(2) In order to place genetically modified organisms on the market it is necessary for a person, which has created genetically modified organisms, to receive one of the following permits:

1) a permit in accordance with the laws and regulations regarding the procedures for deliberate release of genetically modified organisms, the procedures for monitoring and issuance of permit, as well as the procedures for the provision of information regarding the circulation of genetically modified organisms and the public involvement in the decision-making process;

2) a relevant permit of the competent authority of another European Union Member State;

3) a permit specified in Regulation No 1829/2003 of the European Parliament and of the Council.

(3) A person registered in the Register of Growers of Genetically Modified Crops has the right to cultivate genetically modified crops, if the appropriate permit referred to in Paragraph two of this Section has been issued to the creator of the relevant genetically modified organism. A grower of genetically modified crops shall ensure the observation of co-existence provisions in accordance with the laws and regulations regarding co-existence of genetically modified crops.

*[21 June 2012; 25 September 2014]*

### **Section 21. Receipt of a Permit for Conducting a Clinical Trial**

*[21 June 2012]*

### **Section 22. Containment in Cultivation of Genetically Modified Crops**

(1) The Cabinet may determine a prohibition for the cultivation of genetically modified crops in Latvia or in a particular territory thereof in accordance with Section 5, Paragraphs three and four of this Law.

(2) A local government may, taking into account socio-economic, climatic or environmental circumstances or upon evaluation of the methods of agricultural activity, specify a prohibition by issuing binding rules for the cultivation of genetically modified crops in the relevant administrative territory or in a particular territory thereof upon its own initiative or on the basis of a proposal of a person.

(3) The prohibition referred to in Paragraph two of this Section shall be determined for a period of time which is not less than five years.

(4) Prior to taking of the binding rules referred to in Paragraph two of this Section, the local government shall inform the public and publish a notification regarding the intention to determine such prohibition in the newspaper issued by the local government, but, if there is no such newspaper – in another local newspaper, as well as place the notification referred to on the Internet website thereof and send information regarding the notification to the Ministry of Agriculture and the Ministry of Environmental Protection and Regional Development, which shall place this information on their Internet websites. The territory where the determination of the prohibition for cultivation of genetically modified crops is intended, as well as the place and term for the submission of public opinions, proposals and objections shall be indicated. The term for the submission of proposals and objections may not be less than 30 days from the day of publication of the notification. Non-submission of objections within the term specified by the local government shall be considered as the consent for determination of prohibition.

(5) If a local government has received a written objection against the prohibition for cultivation of genetically modified crops, it shall evaluate the submitted objection and decide upon exclusion of the particular territory, against inclusion of which the objection was expressed, from the intended prohibition zone or retaining therein, taking into account the opinion of majority of the public, the principles of proportionality and sustainable development.

(6) A local government shall notify those local governments regarding the prohibition referred to in Paragraph two of this Section, the administrative territory of which borders on the territory where the determination of the prohibition for cultivation of genetically modified crops is intended, as well as the Ministry of Agriculture, the relevant regional environmental board of the State Environment Service, as well as the State Plant Protection Service, which includes the referred to information in the Register of Growers of Genetically Modified Crops.

*[18 June 2009, 1 December 2009; 16 December 2010; 21 June 2012; 18 June 2015]*

### **Section 23. Use of Antibiotic Resistance Marker Genes**

It is prohibited to release deliberately genetically modified organisms containing genes, which code resistance to antibiotics used in medicine or veterinary, if in the risk assessment of potential effect of gene transfer of the particular genetically modified organism, it is determined that they have an adverse effect on human and animal health or the environment.

*[21 June 2012]*

### **Section 24. Obligations of Persons**

A person, who has obtained a permit for deliberate release of genetically modified organisms, has the following obligations:

1) to comply with the conditions of the permit regarding deliberate release of genetically modified organisms;

2) to ensure the implementation of monitoring measures and notification of the competent authorities regarding the results thereof in accordance with the laws and

regulations regarding deliberate release of genetically modified organisms, the procedures for monitoring and issuance of a permit, as well as the procedures for the provision of information regarding the circulation of genetically modified organisms and the public involvement in the decision-making process;

3) to take relevant measures and to suspend deliberate release of genetically modified organisms, as well as to inform thereof the relevant competent authorities and the public if new information has become available, and there is a reason to believe in the existence of a risk to human and animal health or the environment.

[21 June 2012]

## **Section 25. Provision of Monitoring**

In order to ensure the implementation of the monitoring referred to in Section 24, Clause 2 of this Law; a person has the right to make an agreement with the competent authority regarding the adjustment of environmental monitoring to the monitoring referred to in Section 24, Clause 2 of this Law, providing accordingly the financing necessary for the implementation thereof.

## **Section 26. Placing on the Market of such Food and Feed, which Contains Genetically Modified Organisms, Consist of or is Produced From Them**

Placing on the market of such food and feed, which contains genetically modified organisms, consist of or is produced from them, shall comply with Regulation No. 1829/2003 of the European Parliament and of the Council and Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

[18 June 2009]

## **Section 26.<sup>1</sup> Requirements with Respect to Trade of Such Food Products, which Contain Genetically Modified Organisms, Consist of or is Produced from Them**

The food products, the labelling of which in accordance with laws and regulations includes an indication that these food products contain genetically modified organisms, consist of or is produced from them, shall be placed for sale separately from other food products at sales points in such a way as to be easily identifiable.

[18 June 2009]

## **Chapter V**

### **Availability of Information and Public Participation**

## **Section 27. Openness and Availability of Information**

Competent authorities shall provide the public with information regarding the circulation of genetically modified organisms in accordance with the requirements of the laws and regulations governing the circulation of genetically modified organisms.

## **Section 28. Public Involvement in the Decision-making Process**

(1) The public – any natural person, as well as associations and foundations – have the right to submit proposals or express an opinion to the competent authority prior to its issuing a permit for the circulation of genetically modified organisms.

(2) The procedures for the public involvement and organisation of public consultation with regard to the circulation of genetically modified organisms shall be specified by the laws and regulations regarding the deliberate release of genetically modified organisms, the procedures for monitoring and issuance of a permit, as well as the procedures for the provision of information regarding the circulation of genetically modified organisms and the public involvement in the decision-making process.

(3) The competent authority shall involve the public in the decision-making process prior to taking the decision on circulation of genetically modified organisms.

*[21 June 2012]*

### **Section 29. Functions of Local Governments, Associations and Foundations**

*[18 June 2009]*

### **Section 30. Obligation to Provide Information**

(1) A person performing activities with genetically modified organisms shall arrange and keep information regarding the circulation of genetically modified organisms, and present it when requested by the competent authorities.

(2) A person, who performs activities with genetically modified organisms shall, in conformity with the laws and regulations regarding circulation of genetically modified organisms, inform the relevant competent authorities and the public, without delay, regarding the cases when scientifically substantiated opinions regarding the possible adverse effect of genetically modified organisms on human and animal health or the environment have been received, as well as when the harm has already been caused to human and animal health or the environment or there are direct hazards that such harm could be caused, or the negative changes in the environment have been observed in connection with deliberate release of the genetically modified organism.

*[18 June 2009; 21 June 2012]*

### **Section 31. Circulation of Information**

The competent authorities shall ensure the exchange of information with the persons, the Member States of the European Union, the European Commission, the European Food Safety Authority, the European Medicines Agency and other authorities, regarding the circulation of genetically modified organisms.

## **Chapter VI Supervision and Control**

### **Section 32. Supervisory and Control Authorities**

The implementation of the laws and regulations regarding the circulation of genetically modified organisms shall be supervised and controlled by the Food and Veterinary Service, the State Environmental Service, the State Plant Protection Service and the State Labour Inspectorate, in accordance with their competence.

*[21 June 2012]*

### **Section 33. Rights of Supervisory and Control Authorities**

(1) The inspector of the supervisory and control authority has the right:

1) to control and to become acquainted with documents in order to ensure the implementation of the conditions specified in the permit;

2) to take samples for identification of the presence of genetically modified organisms in the food, feed, seeds and plant propagating material, as well as in other environmental sites;

3) if serious threats to human and animal health or the environment are caused, to specify immediately containment or prohibitions, informing the public thereof.

(2) If serious threats to human and animal health or the environment are caused or the requirements of the laws and regulations governing the circulation of genetically modified organisms have been violated, the following bodies have the right to specify restrictions or prohibitions for the circulation of genetically modified organisms:

1) the Food and Veterinary Service – regarding the contained use of genetically modified micro-organisms and deliberate release of genetically modified organisms;

2) the State Labour Inspectorate – regarding the contained use of genetically modified micro-organisms;

3) the State Environmental Service – regarding the release into the environment of genetically modified organisms for experiments and the cultivation of genetically modified crops;

4) the State Plant Protection Service – regarding the cultivation of genetically modified crops.

(3) The State Plant Protection Service has the right:

1) to cancel the registration with the Register of Growers of Genetically Modified Crops, if the requirements of the laws and regulations regarding the cultivation and co-existence of genetically modified crops have been violated;

2) in accordance with the laws and regulations regarding the co-existence of genetically modified crops take a decision that sowings or plantations should be destroyed using mechanical or chemical methods within a specific time period. A decision of an inspector of the State Plant Protection Service to destroy sowings or plantations may be contested by submitting a respective submission to the director of the State Plant Protection Service. The decision of the director of the State Plant Protection Service may be appeal to the court. Contesting and appeal of a decision shall not suspend its operation;

3) to destroy sowings and plantations by force, if the decision referred to in Clause 2 of this Paragraph has not been executed within a specific time period.

(4) [25 September 2014]

[18 June 2009; 21 June 2012; 25 September 2014]

## **Section 34. Action in Emergency Situations**

(1) The Food and Veterinary Service shall develop and the Director-General thereof shall approve the plan for action in emergency situations, shall be liable for action in emergency situations and shall comply with the requirements of the laws and regulations governing the civil protection and those of the laws and regulations governing the circulation of genetically modified organisms.

(2) In emergency situations the Director-General of the Food and Veterinary Service shall:

1) ensure and co-ordinate the implementation of the plan of emergency situations;

2) ensure the circulation of information in accordance with the laws and regulations regarding food circulation and the circulation of genetically modified organisms;

3) perform the emergency situation analysis and in accordance with the laws and regulations regarding the circulation of genetically modified organisms prepare recommendations for the avoidance of similar situations.

## **Chapter VII Liability and Legal Protection**

### **Section 35. Liability**

- (1) The persons which have violated the laws and regulations governing the circulation of genetically modified organisms shall be held liable according to the laws and regulations.
- (2) Subjecting to liability shall not release the persons referred to in Paragraph one of this Section from the duty to compensate the damage to human and animal health and the environment.
- (3) The liability regarding the damage to human and animal health resulting from the circulation of genetically modified organisms, as well as regarding the environmental damage or imminent threat of damage, is prescribed by the Environmental Protection Law and other laws and regulations.

### **Section 36. Legal Protection in the Field of Biotechnology**

The extent of rights and exceptions related to biotechnological inventions, as well as the legal protection of such inventions shall be prescribed by the Patent Law.

#### **Transitional provisions**

1. The Cabinet shall issue the Cabinet regulations referred to in Section 5, Paragraph one of this Law by 1 December 2008.
2. Until the day of coming into force of the new Cabinet regulations, but not later than until 1 December 2008, Cabinet Regulation No. 333 of 20 April 2004, *Regulations Regarding the Contained Use and Deliberate Release into the Environment and Placing on the Market of Genetically Modified Organisms, as well as Procedures for the Monitoring Thereof*, shall be applied, insofar as they comply with this Law.
3. Section 5, Clause 5 of this Law comes into force concurrently with the relevant amendments in the Law On Taxes and Fees.
4. Until the day of coming into force of the Cabinet regulation referred to in Section 5, Paragraph one, Clause 4 of this Law governing the requirements for co-existence, as well as the procedures for supervision and control of genetically modified crops, but not later than until 1 July 2010, the Cabinet Regulation No. 30 of 15 January 2008, *Regulations Regarding the Requirements for Co-existence of Genetically Modified Crops, as well as the Procedures for Supervision and Control*, shall be applied, insofar as they comply with this Law.  
*[18 June 2009]*
5. Until 1 July 2013 the Cabinet shall issue the Cabinet regulations referred to in Section 5, Paragraph one, Clause 4 of this Regulation.  
*[21 June 2012]*
6. Amendments to Section 5, Paragraph one, Clause 5 of this Law in relation to determination of fee for the preparation of an opinion on risk assessment of genetically modified organisms shall come into force concurrently with respective amendments to the Law On Taxes and Fees.  
*[25 September 2014 / The abovementioned amendment will be included in the wording of the Law on the day of coming into force of respective amendments to the Law On Taxes and Fees]*

7. The Cabinet shall make amendments to Cabinet Regulation No. 457 of 26 May 2009, Regulations Regarding Deliberate Release of Genetically Modified Organisms, by 30 September 2015.

[18 June 2015]

### **Informative Reference to European Union Directives**

[21 June 2012; 18 June 2015]

This Law contains legal norms arising from:

1) 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;

2) Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast) (Text with EEA relevance);

3) Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

This Law has been adopted by the *Saeima* on 15 November 2007.

President

V. Zatlers

Rīga, 5 December 2007