LAW ON GENETICALLY MODIFIED ORGANISMS

CONSOLIDATED TEXT [1]

Macedonian text
Закон за генетски модифицирани организми

I. GENERAL PROVISIONS

Article 1

Subject to regulation

(1) This Law shall regulate the management of genetically modified organisms and combination of genetically modified organisms and the products which contain genetically modified organisms and/or are composed of, or originate from combination of genetically modified organisms including as well genetically modified organisms as a product, the measures for prevention and decrease of possible negative influences on human health and environment, as a result from limited use of genetically modified organisms, the deliberate release of genetically modified organisms in the environment or placing of products on the market which contain genetically modified organisms and/or are composed of, or originate from combination of genetically modified organisms including as well genetically modified organisms as a product, as well as the transboundary movement of genetically modified organisms and products which contain genetically modified organisms and/or are composed of, or originate from combination of genetically modified organisms including as well genetically modified organisms as a product.

(2) The provisions referred to in this Law shall apply to genetically modified organisms and combination of genetically modified organisms and products which contain genetically modified organisms and/or are composed of, or originate from combination of genetically modified organisms including genetically modified organisms as a product obtained through genetic modification techniques determined in Article 4 of this Law.

Article 2

Aim of the Law

The aims of this Law shall be to:
- provide a high degree of protection of human health and environment during the process of management of genetically modified organisms and combination of generically modified organisms and the products which contain genetically modified organisms and/or are composed of, or originate from a combination of genetically modified organisms including genetically modified organisms as a product,
- define measures that provide monitoring and marking of genetically modified organisms and combination of genetically modified organisms within all the phases of their deliberate release in the environment,
- preserve the biodiversity and risk control through deliberate release of genetically modified organisms and combination of genetically modified

organisms in the environment and
- guarantee proper level of protection in the field of safe trade (import, export and transit), handle and use the genetically modified organisms and a combination of genetically modified organisms and products which contain genetically modified organisms and/or are composed of, or originate from a combination of genetically modified organisms including genetically modified organisms as a product, particularly regarding the transboundary movement.

Article 3

Definitions

The terms referred to in this Law shall have the following meaning:

1. **Live organism** is any biological entity capable of replication or transfer of genetic material;

2. **Genetically modified live organism** is any live organism possessing unusual combination of genetic material derived from application of biotechnology and being capable of reproduction;

3. **Genetic material** is part of a plant, animal, fungus, microorganism or virus containing inheritable information;

4. **Microorganism** is any microbiological entity, consisted of cells or not, capable of replication or transmission of genetic material, including the viruses, viroids, the cultures of animal and plant cells;

5. **Genetic modification** is intentional, induced alteration of the inheritable genetic material in the organism, in a manner not naturally occurring during the processes of reproduction and/or natural recombination;

6. **Genetically modified organism** (hereinafter: GMO) is any organism including any microorganism, with the exception of the human beings, possessing genetic material altered in a manner not naturally occurring during the processes of reproduction and/or natural recombination. Combination of GMO is as well considered to be GMO;

7. **Genetically modified microorganism** (hereinafter: GMMO) is any organism whose genetic material is altered in a manner not naturally occurring within the processes of reproduction and/or natural recombination;

8. **Limited application of GMO** is any activity by which GMO are altered or the already altered GMO are being cultivated, preserved, applied, transported, destroyed and/or removed or used in any way, during which processes physical or a combination of physical barriers including chemical and/or biological barriers are being used for the purpose of limiting the contact with the population and the environment;

9. **Accident** is any type of incident/misfortune including significant and non-deliberate release of GMO during their limited application, which may be considered as direct or differed life threat and danger for the human health as well as for the environment;

10. **Deliberate release of GMO in the environment** is deliberate release of GMO in the environment without using special controlling measures for the purpose of limiting their contact with the environment and people, and as well for the purpose of enabling high level of safety for the people and environment;

11. **Placing on the market** is a procedure that makes the products which contain genetically modified organisms and/or are composed of, or originate from a combination of genetically modified organisms, including as well genetically modified organisms as a product available for a third

party, with or without compensation;

12. **Genetically modified product** is any preparation composed of, or containing GMO or being a combination of GMO, placed on the market (hereinafter: GMO product);

13. **Direct effects** are direct or indirect effects on human health or environment noticed after the emission of GMO in the environment or their placement on the market;

14. **Cumulative long-term effects** are the complete accumulated effects from the limited application of GMO or the deliberate release of GMO in the environment on human health, including, among other the flora, fauna, soil fertility, decomposition of the organic materials in the soil, food chain, biodiversity and animals' health;

15. **Level of limitation** is a set of human health and environmental protection safety measures aiming at decreasing the contact between people and environment on one side and GMO on the other side, during the time of limited application, to the lowest possible level;

16. **User** is any legal entity or natural person responsible for the limited application of GMO;

17. **Notification** is submission of documents to the competent body containing necessary information for the purpose of approving activities determined by this Law;

18. **Notifier** is the person that submits a notification;

19. **Environmental risk assessment** is an assessment of the direct or indirect, current or later risks to human health and environment, possibly caused by deliberate release of GMO in the environment, limited application of GMO or placing of GMO product on the market;

20. **Monitoring of the condition** is systematic following and supervision of GMO during the limited application of GMO, deliberate release in the environment and/or placing of the GMO products on the market, as well as assessment of the possible harmful consequences on human health and environment;

21. **Transboundary movement of GMO and GMO products** is import, export or transit of GMO or GMO products from one country into another country or countries;

22. **Case by case environmental risk assessment** is assessment of the direct or indirect, current or deferred risks to human health and environment being carried out before the GMO are deliberately released in the environment, thus taking into consideration the potential cumulative risk possible to result from interaction with other GMO emitted in the environment;

23. **Secretariat of the Protocol** is the secretariat established in accordance with the Cartagena Protocol on Biosafety to the Convention on Biodiversity;

24. **Competent body** is the state administration body competent for issues in the field of environment;

25. **Biosafety Clearing-House** is a mechanism for exchange of information and experiences related to GMO established by the Cartagena Protocol on Biosafety to the Convention on Biodiversity and

26. **Competent bodies** are the state administration bodies participating in the decision making procedure regarding the approval of the activities related to GMO and GMO products management determined by this or other law.

Article 4

Techniques of genetic modifications

(1) Genetic modification shall be performed by implementation of the following techniques for genetic modification:
1) techniques for recombination of nucleic acids by applying vector systems (in vitro creation of new combinations of genetic material by inserting nucleic acid molecules in a virus, bacteria plasmid or other vector system and their embedding in the host organism where they do not naturally appear, but are capable of continuous reproduction in the same organism);
2) techniques enabling direct insertion of in vitro prepared inheritable material into the organism, including techniques of microinjecting, macroinjecting and microencapsulating and
3) cell fusion or techniques of hybridization during which live cells with new combination of inheritable material are formed by fusion of two or more cells in a manner not naturally occurring.

(2) The following activities shall not be considered to be genetic modification, provided that they do not include re-combinable nucleic molecules or GMO as initial material, created by some of the techniques referred to in paragraph (1) of this Article:
1) in vitro fertilization;
2) natural processes, such as: conjugation (joining of two cells), transduction (process for transferring DNA from one cell microorganisms to another by a virus) and transformation;
3) polyploid induction and
4) tissue culture.

Article 5

Exceptions to the application of the Law and application of other laws and regulations

(1) The provisions of this Law shall not be applied to GMO obtained through techniques of genetic modification referred to in Article 4 paragraph (1) of this Law and/or through the use of recombined nucleic acids created through:
- mutagenesis,
- cell fusion, including as well the protoplast fusion, prokaryotic types able to exchange the inheritable material through already known physiological processes,
- cell fusion, including as well protoplast fusion of cells composed of any eukaryotic types, including the receiving from hybridomas and floral cell fusion,
- creation and application of somatic, animal hybrid cells (i.e. production of monoclonal anti-bodies) and
- self-cloning or removal of a sequence of nucleic acids from cell of an organism, by continuous insertion of that sequence (or part of a sequence) into cells of the same type of organisms or cells with close phylogenic species capable of exchanging the inheritable material through natural, physiological processes, while the created organism (microorganism) has proved safety, with no negative effects on human health and the environment.

(2) The transport of GMO by rail, air, inland and water shall be conducted in accordance with the international agreements on transport of dangerous substances ratified by the Republic of Macedonia.

(3) The provisions of this Law referring to placing of GMO and GMO products on the market, transboundary movement of GMO and GMO products, shall not apply to:
- pharmacist products used in human and veterinary medicine, although containing GMO, or are composed of them or of GMO combinations and

- food and nutrition used for production, procession, re-procession and preparation of food intended for human use, although containing and/or are composed of GMO, or GMO combination, for placement on the market, import and export.

(4) The Law on General Administrative Procedure shall be applied to the procedures laid down by this Law unless otherwise regulated by this Law.

II. PRINCIPLES OF ENVIRONMENTAL PROTECTION

Article 6

Principle of integrity

The basis and goals of the GMO and GMO products management policy, as well as the measures for prevention and decrease of the possible negative influences of human health and environment have to be integrated into all the strategic, plan and program documents in the field of finances, education, health, research work and development adopted by the competent state bodies.

Article 7

Principle of precaution

GMO and GMO products can be limitedly applied, deliberately released and placed on the market in accordance with the provisions of this Law. The competent bodies, in accordance with the principle of precaution, need to provide for taking proper measures for the purpose of avoiding the possible negative effects on human health and environment, being a probable result from the limited application of GMO, its deliberate release or placement of GMO products on the market.

Article 8

Principle of liability and polluter pays

(1) The entity performing activities with limited application of GMO, its deliberate release in the environment and placement of GMO products on the market shall be obliged to cover the costs for hazard removal, the costs for rehabilitation of consequences caused by the harmful effects of the GMO management.

(2) The legal entity or natural person performing activities with limited application of GMO, its deliberate release in the environment and placement of GMO products on the market shall be obliged to pay compensation proper to the caused damage in accordance with the general rules on damage compensation.

Article 9

Principle of risk assessment

(1) Risk assessment of the potential negative effects on human health and environment possible to appear as a result from gene transfer from GMO into other organisms shall be performed case by case and in accordance with this Law, while taking into consideration the nature of the organism being subjected to insertion, as well as the environment accepting it.

(2) During the risk assessment of GMO which contain genes demonstrating resistance to antibiotics, while at the same time are being used for medical treatments of people or veterinary treatment of animals, attention shall be

especially paid to identification and exclusion of those GMO being able to manifest negative effects on human health and environment.

III. GENERAL OBLIGATIONS

Article 10

Compulsory protection measures

(1) Provided that it is not possible to determine the legal entity or natural person performing the activities of limited application of GMO, its deliberate release in the environment and/or placement of GMO products on the market, the competent bodies referred to in Article 3 paragraph (1) point 26 of this Law, in accordance with their competencies, shall be obliged to undertake all the necessary measures for prevention or removal of the harmful consequences in accordance with this or other Law.

(2) If the legal entity or natural person referred to in paragraph (1) of this Article is subsequently determined, it shall be obliged to compensate for the costs incurred in undertaking the measures for prevention and/or removal of the harmful consequences referred to in paragraph (1) of this Article.

Article 11

Access to information

The state administration bodies possessing information on GMO and GMO products shall be obliged to enable insight of the public, as well as to inform the public of their negative influence on human health and environment, the caused damages and undertaken activities for removal of the harmful consequences in accordance with the provisions of this Law and the Law on Environment.

Article 12

Public consultations and notifications

(1) The state administration body competent for performing activities in the field of environment shall be obliged, within five days after receiving the complete notification, to announce short contents of the notification on receiving a license for limited application of GMO, the notification on receiving a license for deliberate release of GMO in the environment, and the notification on receiving a license for releasing GMO products on the market on its web site and in two newspapers available throughout the territory of the Republic of Macedonia, on account of the user, that is the notifier.

(2) Data regarding the place where insight in the notification data is enabled shall be indicated in the announcement referred to in paragraph (1) of this Article.

(3) The public and the citizens' associations can submit their opinion on the notifications referred to in paragraph (1) of this Law to the state administration body competent for performing activities in the field of environment within 30 days from the day of publication.

(4) The state administration body competent for performing activities within the field of environment shall be obliged to enable the public and the citizens' associations to insight into the notification data, including the emergency cases plan, the report on GMO product assessment, the opinion received from the Scientific Committee on GMO, opinions received by other competent bodies, as well as other information following the notification.

(5) The form and content of the announcement form referred to in paragraph (1) of this Article shall be prescribed by the minister heading the state administration body competent for performing activities in the field of environment.

(6) The manner and procedure for public participation in issuing licenses for limited application of GMO, its deliberate release in the environment, placement of GMO products on the market as well as other information related to GMO application shall be prescribed by the minister heading the state administration body competent for performing activities in the field of environment.

(7) In the process of issuing a license for limited application of GMO, license for deliberate release of GMO in the environment and/or license for releasing GMO products on the market, the state administration body shall take into consideration only promptly submitted opinions and comments.

(8) In the process of issuing the licenses referred to in paragraph (7) of this Article, the time necessary for the public consultation referred to in paragraph (3) of this Article shall not be calculated into the deadline determined for license issuance.

Article 13

Submission of reports

(1) The competent bodies included in the procedure for issuing licenses approving the use of GMO or GMO products in accordance with this or other Law, once a year, shall submit a report to the state administration body competent for performing activities in the field of environment, as well as to the Commission for GMO Management.

(2) The report referred to in paragraph (1) of this Article shall contain data regarding the number of issued licenses related to GMO and GMO products, the number of rejected notifications on GMO and GMO products, as well as the reasons for their rejection.

(3) The bodies referred to in paragraph (1) of this Article shall be obliged to submit the report for the previous year by January, 30 in the current year at latest.

IV. LIMITED APPLICATION OF GMO

Article 14

Classes

(1) The state administration body competent for performing activities in the field of environment shall be obliged to provide all the necessary measures to avoid the negative influence on human health and environment possible to result from the limited application of GMO.

(2) The limited application of GMO can be performed by a legal entity or natural person, scientific and research institution and/or higher education institution in case of previously received license for limited application of GMO in accordance with Articles 16, 18 and 19 of this Law.

(3) The user shall be obliged to make a risk assessment on the limited application of GMO on human health and environment possible to be affected by the limited application of GMO, in accordance with Article 15 of this Law.

(4) Based on the assessment referred to in paragraph (3) of this Article, the limited application of GMO shall be classified within four classes being subject to the procedures defined in Article 15 of this Law, as follows:

- class 1, activities with non-significant risk, for which the safety level 1 is proper to protect human health and environment;
- class 2, low-risk activities, for which the safety level 2 is proper to protect human health and environment;
- class 3, temperate-risk activities, for which the safety level 3 is proper to protect human health and environment;
- class 4, high-risk activities, for which the safety level 4 is proper to protect human health and environment.

(5) The minimal requirements and the necessary measures to be undertaken for each class of limited application of GMO separately shall be determined on the basis of the classification referred to in paragraph (4) of this Article.

Article 15

Risk assessment

(1) Before initiating the limited application of GMO, as well as during the implementation of the limited application of GMO, the user shall be obliged to provide risk assessment of the planned and implemented application of GMO.

(2) On the basis of the analysis of GMO characteristics, the possible negative effects on human health and environment, the level of risk and the necessary limitations, the safety measures to protect human health and environment, as well as the measures for waste, secretion and wastewater management being a result from the limited application shall be necessary to be determined in the risk assessment.

(3) The limitations and safety measures shall be appropriately determined for the purpose of providing the lowest reasonable level of GMO exposure on the work place and in the environment and the highest level of safety.

(4) The user, on the basis of the risk assessment, shall classify the limited application in one of the classes referred to in Article 14 paragraph (4) of this Law.

(5) In case the user is not sure in which class the limited application should be classified, the limited application shall be classified in the class with stricter protective measures in concurrence with the state administration body competent for performing activities in the field of environment.

(6) The user shall be obliged to provide a risk assessment of all the activities related to GMO application.

(7) During the implementation of the limited application of GMO, the user shall be obliged to revise the risk assessment, limitations and safety measures, at least once a year especially assessing if:
- the determined class is proper to the risk of GMO application,
- the limitations and safety measures being implemented are in accordance with the risk of GMO application and
- there is a justified suspicion that the risk assessment is not longer being appropriate bearing in mind the new scientific achievements and knowledge.

(8) The user shall be obliged to inform the state administration body competent for performing activities in the field of environment, about every risk change in reference to classes 2, 3 and 4.

(9) The methodology and the elements of the assessment, the parameters, the minimum criteria and the requirements to be taken into consideration while making the assessment, the assessment procedure as well as the limitations and safety measures, including furthermore other technical conditions if necessary for providing protection of human health

and environment, according to the type of organism, environment and place intended for GMO application, shall be prescribed by the minister heading the state administration body competent for performing activities in the field of environment in concurrence with the state administration body competent for performing activities in the field of agriculture and forestry.

Article 16

Notifications about a place

(1) Limited application of GMO shall be performed in closed or separated place (hereinafter: place) meeting the prescribed conditions for the class within which the activities are being performed, in accordance with Article 14 of this Law.

(2) The user shall submit a notification containing the necessary information to the state administration body competent for issues in the field of environment, before initiating the use of the place for limited application of GMO.

(3) The state administration body competent for issues in the field of environment shall issue a license for using a place within 90 days after receiving the complete notification, upon prior opinion received by the Scientific Committee on GMO referred to in Article 64 of this Law.

(4) In case the state administration body competent for issues in the field of environment confirms that the notification does not contain the necessary requirements, shall require from the user to supplement the notification in a determined deadline not longer than 30 days.

(5) The additionally determined deadline referred to in paragraph (4) of this Article shall not be calculated into the deadline referred to in paragraph (3) of this Article.

(6) After completing the notification, the state administration body competent for issues in the field of environment shall submit the notification to the Scientific Committee on GMO.

(7) The Scientific Committee on GMO shall be obliged to submit its opinion to the state administration body competent for performing activities in the field of environment within 30 days after the day of receiving the notification.

(8) After receiving the opinion referred to in paragraph (7) of this Article, the state administration body competent for performing activities in the field of environment, within the deadline referred to in paragraph (3) of this Article, shall issue a license for using a place or, on the basis of decisions, shall reject the notification.

(9) The license for using a place as well as the place where limited application of GMO shall be performed shall be inscribed in the GMO register.

(10) If after the submission of the notification referred to in paragraph (1) of this Article, new information possible to be of great significance for the influence on human health and/or environment, or information that include GMO application in another class, are available to the user, the user shall be obliged immediately, within 24 hours the latest, to notify the state administration body competent for performing activities in the field of environment.

(11) The minister heading the state administration body competent for performing activities in the field of environment shall prescribe the content and the form of the notification on limited application of GMO form, as well as the information necessary to be submitted when submitting the notification referred to in paragraph (2) of this Article, when the

notification is being submitted for a place where GMO shall be applied for the first time, and separately for each class of limited application of GMO.

(12) The standards to be fulfilled in the place for limited application of GMO, depending on the risk degree shall be prescribed by the minister heading the state administration body competent for performing activities in the field of environment in concurrence with the minister heading the state administration body competent for performing activities in the field of agriculture and forestry and the minister heading the state administration body competent for performing activities in the field of health, for each class of limited application of GMO compulsory taking into consideration the type of organism and the environment where the organism is intended to be released.

(13) The user shall be obliged to preserve the data from the risk assessment and the notification as data with permanent value and to deliver them to the competent bodies upon request.

(14) The user shall be obliged to cover the actual costs incurred by the state administration body competent for performing activities in the field of environment, as well as the costs for the work of the Scientific Committee on GMO in the procedure of issuing the licenses referred to in Articles 16, 18 and 19 of this Law.

(15) The amount of the costs referred to in paragraph (14) of this Article shall be prescribed by the minister heading the state administration body competent for performing activities in the field of environment.

(16) The user shall pay in the costs referred to in paragraph (15) of this Article at the account of the state administration body competent for performing activities in the field of environment, on the basis of a decision on the actual costs, within eight days after the day of submitting the notification.

(17) The user shall have the right to file a lawsuit regarding the license, that is the decision referred to in paragraph (8) of this Article for initiating an administrative dispute procedure with the competent court.

Article 17

Limited application of GMO, Class 1

(1) The limited application of GMO Class 1 can be initiated without supplementary notification if it has been performed in places with previously issued license in accordance with Article 16 of this Law, for which purpose the user shall inform the state administration body competent for performing activities in the field of environment in writing.

(2) The user shall be obliged to assess the risk in accordance with Article 15 of this Law, as well as to preserve the data thereof.

(3) Upon request of the state administration body competent for performing activities in the field of environment, the user shall be obliged to submit the data referred to in paragraph (2) of this Article.

Article 18

Limited application of GMO, Class 2

(1) In accordance with Article 16 paragraph (10) of this Law, the notification for limited application of GMO, Class 2, to be performed in places granted a license in accordance with Article 16 of this Law, shall be submitted to the state administration body competent for performing activities in the field of environment.

(2) The state administration body competent for performing activities in

the field of environment shall be obliged to issue a license for limited application of GMO, Class 2, within 45 days after receiving the complete notification.

(3) After completing the notification, the state administration body competent for performing activities in the field of environment shall submit the notification to the Scientific Committee for GMO referred to in Article 64 of this Law, being obliged to submit an opinion in writing within 21 days after receiving the notification.

(4) If the state administration body competent for performing activities in the field of environment confirms that the notification lacks the requirements referred to in Article 16 of this Law, or confirms that additional information are necessary for the purpose of making a decision on the notification, it shall require from the user to supplement the notification within a deadline not shorter than seven days nor longer than 30 days.

(5) The additionally determined deadline referred to in paragraph (4) of this Article shall not be calculated in the deadline referred to in paragraph (2) of this Article.

(6) In case a license has previously been issued for using a place for class 2 or higher class of limited application of GMO and each requirement from the notification related to GMO limited application has been fulfilled, the limited application of GMO class 2 can begin immediately upon the submission of the notification.

(7) In case a license for using the place has not been previously issued for class 2 or higher class of limited application of GMO, the limited application of GMO class 2 can commence upon the expiry of the deadline referred to in paragraph (2) of this Article if the state administration body competent for performing activities in the field of environment has not requested for additional information in accordance with paragraph (4) of this Article.

(8) In terms of paragraph (7) of this Article, the limited application of GMO, class 2 can be initiated even earlier, based on a written approval by the state administration body competent for performing activities in the field of environment.

(9) After receiving the opinion referred to in paragraph (3) of this Article, the state administration body competent for performing activities in the field of environment shall issue a license for limited application of GMO, class 2 or shall reject the notification on a basis of a decision, within the deadline referred to in paragraph (2) of this Article.

(10) The user shall have the right to file a lawsuit regarding the license, that is the decision referred to in paragraph (9) of this Article for initiating an administrative dispute procedure with the competent court.

Article 19

Limited application of GMO, class 3 and 4

(1) The notification about the limited application of GMO, class 3 and class 4 to be performed in a place with previously issued license in accordance with Article 16 of this Law, shall be submitted to the state administration body competent for performing activities in the field of environment in accordance with Article 16 paragraph (10) of this Law.

(2) Within 90 days after receiving the complete notification, the state administration body competent for performing activities in the field of environment shall be obliged to issue a license for limited application of GMO, class 3 or class 4.

(3) After completing the notification, the state administrative body competent for performing activities in the field of environment shall submit

the notification to the Scientific Committee on GMO obliged to submit opinion in writing within 30 days after receiving the notification.

(4) If the state administration body competent for performing activities in the field of environment confirms that the notification does not contain the requirements prescribed in accordance with Article 16 of this Law or confirms that additional information are necessary for the purpose of making a decision on the notification, it shall require from the user to supplement the notification within a deadline not shorter than seven days nor longer than 45 days.

(5) The additionally determined deadline referred to in paragraph (4) of this Article shall not be calculated in the deadline referred to in paragraph (3) of this Article.

(6) In case a license has been previously issued for using a place for class 3 or higher class of limited application of GMO and each requirement from the notification related to GMO limited application has been fulfilled, the limited application of GMO class 3 or class 4 shall begin within a period of 45 days after the submission of the notification and solely on the basis of a written approval issued by the state administration body competent for performing activities in the field of environment.

(7) After receiving the opinion referred to in paragraph (3) of this Article, the state administration body competent for performing activities in the field of environment shall issue a license for limited application of GMO, class 3 or class 4, or class 3 and class 4, or shall reject the notification on the basis of a decision, within the deadline referred to in paragraph (2) of this Article.

(8) The user shall have the right to file a lawsuit regarding the license, that is the decision referred to in paragraph (7) of this Article for initiating an administrative dispute procedure with the competent court.

Article 20

Plan for emergency cases

(1) The user shall be obliged to attach a plan for emergency cases to the notification for limited application of GMO, particularly containing:
- environmental and human health risk assessment including the possible consequences in case of an accident,
- protection measures that shall be applied, especially the protection equipment, the alarming system and the measures for prevention or decrease of consequences in case of an accident,
- procedures and plan for appraisal of the efficiency of the limitations and safety measures,
- procedures and plan for appraisal of the efficiency of the protection equipment, alarming system and measures for prevention and decrease of consequences in case of an accident,
- description of the guidelines delivered to individuals dealing with limited application of GMO,
- statement in regard to the measures for risk removal and for direct or deferred consequences of the accident,
- statement in regard to the people and responsible bodies that shall be included in the application of the measures determined within the plan and
- the manner and volume of providing information and warnings to the responsible organs, bodies, services and population in case of an accident.

(2) Within the procedure for approving the notification, the state administration body competent for performing activities in the field of environment shall submit the plan for emergency cases to the Scientific Committee on GMO referred to in Article 64 of this Law.

(3) The state administration body competent for performing activities in the field of environment shall be obliged to make the plan for emergency

cases available to the bodies from another country possible to be affected by the limited application of GMO, in accordance with the principle of reciprocity or in the framework of the bilateral agreements ratified by the Republic of Macedonia.

(4) At least once a year, the user shall control the appropriateness of the plan for emergency cases and in accordance with that, if necessary, shall amend it. The user shall be obliged to submit all the amendments to the plan for emergency cases to the state administration body competent for performing activities in the field of environment for approval.

Article 21

Data confidentiality

(1) In the notification for limited application of GMO, the user may indicate which data are confidential trade or industrial information, data protected as intellectual property and/or are protected in accordance with law, by giving appropriate explanation.

(2) On the basis of consultations with the user, the state administration body competent for performing activities in the field of environment shall decide which data are to be considered confidential and not subjected to public insight, within a deadline of 15 days after receiving the notification.

(3) The notifier shall not require the following data to be considered confidential:
- general characteristics of GMO,
- the name and address of the notifier,
- location of the place where the limited application of GMO shall be performed,
- the class of limited application,
- limitations and safety measures,
- data regarding the possible harmful and other effects on the environment and human health and
- other data necessary for risk assessment, especially the danger to the human health and the environment.

(4) The state administration body competent for performing activities in the field of environment and the members of the Scientific Committee on GMO shall not reveal the data determined as confidential in accordance with paragraph (2) of this Law to third parties.

(5) The data determined as confidential shall remain permanently confidential even after the withdrawal of the notification by the notifier, regardless the reasons of the withdrawal.

Article 22

Additional requirements

(1) During the implementation of the procedures referred to in Article 16, 17, 18 and 19 of this Law, the state administration body competent for performing activities in the field of environment and the Scientific Committee on GMO shall be obliged to control the authenticity of the information contained in the notification, their preciseness and completeness, exactness of the risk assessment and class of limited application of GMO, appropriateness of the limitations and safety measures, as well as the proposed measures for waste management and the measures anticipated within the plan for emergency cases.

(2) During the implementation of the procedures referred to in Articles 16, 17, 18 and 19 of this Law, the state administration body competent for performing activities in the field of environment can require the user to:
- submit additional information,
- change the conditions for performing the proposed limited application of

GMO,
- request for class change of the limited application of GMO,
- limit the time designated for limited application of GMO and/or
- subject the same to certain specific conditions.

(3) In the cases referred to in paragraph (1) lines 1, 2 and 3 of this Article, the state administration body competent for performing activities in the field of environment can request not to begin with the proposed limited application of GMO and/or, if it is being performed, to limit and/or temporarily terminate everything until the state administration body competent for performing activities in the field of environment give approval on the basis of the submitted information or changed conditions for performing limited application of GMO.

(4) If the user does not act in accordance with the requirements referred to in paragraph (3) of this Article, the state administration body competent for performing activities in the field of environment, by decisions, shall reject the notification.

(5) The user shall have the right to file a lawsuit regarding the decision referred to in paragraph (4) of this Article for initiation of an administration dispute procedure with the competent court.

(6) The time period necessary for supplementing the notification shall not be calculated in the time period necessary for issuing the licenses in accordance with Article 16, 17, 18 and 19 of this Law.

Article 23

New information

(1) In case the user comes to new information or change the limited application of GMO in a manner possible to cause significant consequences on the risk of limited application of GMO or change the class of limited application of GMO, it shall be obliged immediately, or within 24 hours at latest, to inform the state administration body competent for performing activities in the field of environment and request for change in the notification in accordance with Articles 16, 17, 18 and 19.

(2) In case the state administration body comes to new information possible to cause significant consequences on the risk level and/or change the class of limited application of GMO, the state administration body competent for performing activities in the field of environment can require the user to change the conditions for limited application of GMO, or to temporarily terminate or limit the limited application of GMO.

(3) In the cases referred to in paragraphs (1) and (2) of this Article, the state administration body competent for performing activities in the field of environment shall be obliged to request the user to temporarily terminate or limit the limited application of GMO until a license is issued for the new notification and/or the conditions for limited application of GMO are changed.

(4) If based on the new information regarding the limited application of GMO or regarding the changes in the activities that may significantly affect the risk level, the state administration body competent for performing activities in the field of environment decides that the limited application of GMO can no longer be performed, it shall prohibit the abovementioned by a decision.

(5) The user shall have the right to file a lawsuit regarding the decision referred to in paragraph (4) of this Article for initiating an administrative dispute procedure with the competent court.

Article 24

Accidents

(1) In case of an accident during the limited application of GMO, the user shall be obliged immediately, or within 24 hours at latest, to inform the state administration body competent for performing activities in the field of environment regarding the:
- circumstances of the accident,
- type and amount of GMO included in the accident,
- undertaken measures and their efficiency and
- other information necessary for evaluation of the consequences of the accident and their influence on human health and environment.

(2) When the information is submitted in accordance with paragraph (1) of this Article, the state administration body competent for performing activities in the field of environment shall be obliged to:
- undertake or order undertaking of the necessary measures, and immediately inform the affected country in case of transboundary influence and
- gather all the information necessary for complete analysis of the accident and if it considers appropriate, to give recommendations for limitation of the effect from the accident and for avoiding similar accidents in future.

(3) The issues referred to in paragraph (2) of this Article shall be performed by the state administration body competent for performing activities in the field of environment on the account of the user responsible for the limited application of GMO where the accident appeared.

Article 25

Transboundary influence

(1) In case of transboundary influence of the limited application of GMO, the state administration body competent for performing activities in the field of environment shall be obliged to:
- carry out consultations with the affected country/ies in case of an accident based on the plan for emergency cases referred to in Article 20 of this Law and
- immediately inform the country/ies for the caused accident giving details on the circumstances of the accident, the type and amount of GMO, undertaken measures and their efficiency and analysis of the accident, including recommendations for limitation of the effects and for avoiding similar accidents in future.

(2) The state administration body competent for performing activities in the field of environment shall prepare a report on the undertaken measures and their efficiency within a period of three months after commencing the activities laid down by the plan for emergency cases.

(3) The state administration body competent for performing activities in the field of environment shall submit the report referred to in paragraph (2) of this Article to the Government of the Republic of Macedonia in order to be adopted, and without any postponements shall inform the public about the report in accordance with Article 12 of this Law.

(4) The state administration body competent for performing activities in the field of environment shall keep a register of accidents related to the limited application of GMO.

V. DELIBERATE RELEASE OF GMO IN THE ENVIRONMENT AND PLACEMENT OF GMO PRODUCTS ON THE MARKET

Article 26

General obligations

(1) Any legal entity and natural person before performing deliberate release of GMO in the environment (hereinafter: deliberate release of GMO) or releasing GMO products on the market shall be obliged to submit a notification to the state administration body competent for performing activities in the field of environment.

(2) Any legal entity and natural person before submitting the notification referred to in paragraph (1) of this Article has to assess the risk to the environment in accordance with the provisions of this Law.

(3) The risk assessment referred to in paragraph (2) of this Article shall particularly contain:
- general information on the notifier and the scientific workers who have performed the risk assessment,
- information on GMO, their characteristics, the characteristics of the donor, receiver and parents organism, characteristics of the vector and the modified organism,
- information on the conditions for emission and for the environment where they shall be emitted,
- information on the mutual influence of GMO and the environment and
- other information necessary for assessment of the risk to the environment.

(4) The approval of the risk assessment over human health and over the environment shall be performed through application of the principles for risk assessment, and in accordance with the provisions of this chapter.

(5) The detailed content, scope and methodology for the assessment of the risk on the environment, appropriate to the character of the inserted GMO and the environment, shall be prescribed by the Government of the Republic of Macedonia upon the proposal of the minister heading the state administration body competent for performing activities in the field of environment.

Article 27

Determination of the placement of GMO products on the market

(1) The following shall not be considered as placement of GMO products on the market:
- the GMO approved for limited application in accordance with Chapter IV of this Law,
- available GMO, with the exception of GMO as referred to in line 1 of this paragraph, exclusively used for activities including appropriate strict control measures, in order to limit their contact with the population and with the environment and in order to provide higher degree of safety approved in accordance with the provisions referred to in Chapter IV of this Law and
- GMO approved for deliberate release in accordance with Articles 34, 35, 36, 37, 38, 39 and 40 of this Law.

(2) The GMO referred to in paragraph (1) of this Article shall be labeled and packed in accordance with the license that approves its use, whereas on the package or the accompanying documentation, it shall be obligatory to give information that it contains GMO, and as minimum it shall be obligatory stated that "This product contains genetically modified organisms".

Article 28

Additional information

(1) During the procedure for receiving a license for deliberate release of GMO and license for placement of GMO products on the market, the state administration body competent for performing activities in the field of environment can require from the notifier to submit additional information within a certain deadline, compulsory stating the reasons for requesting additional information.

(2) In case the notifier does not supplement the notification within the given deadline, the state administration body competent for performing activities in the field of environment shall terminate the procedure on issuing the licenses referred to in paragraph (1) of this Article.

Article 29

Prohibitions

(1) Deliberate release of GMO containing genes that demonstrate antibiotic resistance shall be prohibited.

(2) The GMO that are prohibited for deliberate release in the environment and/or prohibited to be placed as GMO products on the market shall be determined by the Government of the Republic of Macedonia upon the proposal of the minister heading the state administration body competent for performing activities in the field of environment in concurrence with the minister heading the state administration body competent for performing activities in the field of agriculture and forestry, and with the minister heading the state administration body competent for performing activities in the field of health.

Article 30

Protective clause

(1) Provided that, on the basis of newly received or additional information, there are justified reasons for considering certain GMO or GMO product which has been properly notified on and has been previously issued a license for, in accordance with the provisions of this Law, as a risk to human health and environment, the minister heading the state administration body competent for performing activities in the field of environment in concurrence with the minister heading the state administration body competent for performing activities in the field of agriculture and forestry, and the minister heading the state administration body in the field of health shall temporarily limit or prohibit the use and/or sale of certain GMO or GMO products in the territory of the Republic of Macedonia.

(2) If in the cases referred to in paragraph (1) of this Article more serious risk to human health and environment appears, the state administration body competent for performing activities in the field of environment in concurrence with the state administration body competent for performing activities in the field of agriculture and forestry and the state administration body competent for performing activities in the field of health shall undertake emergency measures for withdrawal of GMO or GMO products from the market and shall inform the public in accordance with Article 12 of this Law thereof.

Article 31

GMO areas and protective zones

(1) The areas with surfaces on which emission of genetically modified reproductive material in the environment can not be performed, shall be determined by the Government of the Republic of Macedonia upon the proposal of the minister heading the state administration body competent for performing activities in the field of environment, after previously

obtained opinion by the minister heading the state administration body competent for performing activities in the field of agriculture and forestry.

(2) GMO emission shall not be allowed in the nature, especially in protected areas and areas within the ecological network, ecologically clean areas, as well as areas intended for production of organic products, areas intended for ecotourism, including areas being declared protected zones in accordance with law.

(3) Protective zones refer to the surrounding spaces that prevent the widening of GMO in areas where the deliberate release of GMO in the environment is not allowed, as referred to in paragraph (2) of this Article.

(4) The size of the protective zones referred to in paragraph (3) of this Article, for separate types of genetically modified reproductive material shall be laid down by the Government of the Republic of Macedonia, upon the proposal of the minister heading the state administration body competent for performing activities in the field of environment determined in accordance with the minister heading the issues in the field of agriculture and forestry.

Article 32

Mutual cooperation

(1) The state administration bodies, the public enterprises and institutions, the scientific and research institutions, the education institutions, the Commission on GMO Management as referred to in Article 62 of this Law, the Scientific Committee on GMO referred to in Article 64 of this Law, including as well the Macedonian Academy on Sciences and Arts, the relevant scientific and ethical committees acting on the territory of the Republic of Macedonia shall be obliged to mutual cooperation, as well as to information exchange related to the assessment of the risk from GMO on human health and environment, all for the purpose of applying GMO and GMO products in the Republic of Macedonia in a manner that shall enable prevention and decrease of the risk to human health and environment.

(2) In case the state administration body competent for performing activities in the field of environment considers that consultations with some of the entities referred to in paragraph (1) of this Law are necessary during the procedure for issuing licenses laid down by this Law, they shall be obliged to give their opinion in the shortest possible deadline, which shall not exceed 45 days after the day of receiving the request.

(3) The entities referred to in paragraph (2) of this Article being consulted within the procedure for issuing licenses determined by this Law, shall be obliged to permanently preserve the information stated in the notification as confidential and not reveal them to third parties.

(4) During the procedure for license issuance, the state administration body competent for performing activities in the field of environment can consult bodies from other countries competent for issuing approvals related to GMO and GMO products, as well as scientific and educational institutions and committees for the purpose of providing detailed information on GMO and GMO products, particularly if they are approved and applied in the relevant country, and if those information contribute to making a decision related to GMO and/or a GMO product.

(5) Upon request of a body from another country, the state administration body competent for performing activities in the field of environment shall be obliged to submit information related to the use of GMO and GMO product in the Republic of Macedonia in accordance with the international agreements ratified by the Republic of Macedonia.

Article 33

Data confidentiality

(1) The notifier can, by giving a proper explanation, indicate in the notification which data shall be treated as confidential trade or industrial data, data protected as intellectual property and/or are protected by law.

(2) The notifier can indicate the data possible to ruin its competitiveness to be confidential, for which it shall be obliged to provide proper explanation.

(3) The notifier shall not indicate the following data as confidential:
1) the name and address of the notifier and the producer of GMO;
2) the description of GMO;
3) the intention of emitting GMO, area where GMO is emitted, and planned use of GMO;
4) the method and plan for monitoring of GMO, and the plan for emergency intervention and
5) any data necessary for risk assessment and the very risk assessment itself.

(4) Within 15 days after the day of receiving the notification and after the consultations by which the notifier determines which data from the notification are protected as confidential, the state administration body competent for performing activities in the field of environment shall make a decision.

(5) The data determined as confidential remain permanently protected even in case of withdrawal of the notification by the notifier, regardless the reason for withdrawing.

V.1. DELIBERATE RELEASE OF GMO OR A COMBINATION OF GMO IN THE ENVIRONMENT

Article 34

Deliberate release of GMO

(1) Before performing deliberate release of GMO, each notifier shall submit a notification to the state administration body competent for performing activities in the field of environment.

(2) The notification referred to in paragraph (1) of this Article shall particularly contain:
1) technical documentation containing information necessary for carrying out the risk assessment as a result from the deliberate release of GMO appropriate to the character of the inserted organism and the environment and
2) the risk assessment referred to in Article (36) of this Law including the data for applied methods and conclusions from the assessment.

(3) The technical documentation referred to in paragraph (2) point 1 of this Article shall particularly contain:
- general information, including as well information for the personnel who shall handle GMO, their education and other qualifications,
- information on GMO,
- information on the conditions for emission and for the potential environment that shall be subjected to emission,
- information on the mutual influence of GMO and the environment,
- monitoring plan for the purpose of discovering the effects of GMO on human health and environment,
- information on control together with a control plan, measures of rehabilitation and remediation and waste management plan,
- plan for emergency measures in case of non-deliberate release of GMO in accordance with Article 38 of this Law and

- summary of the technical documentation.

(4) The content of the information referred to in paragraph (3) of this Article shall be in detail prescribed by the minister heading the state administration body competent for performing activities in the field of environment.

(5) The notifier shall be obliged to cover the actual costs incurred by the state administration body competent for performing activities in the field of environment, including the costs for the work of the Scientific Committee on GMO included in the procedure for issuing the license as referred to in Article 36 of this Law.

(6) The amount of the costs referred to in paragraph (5) of this Article shall be prescribed by the minister heading the state administration body competent for performing activities in the field of environment.

(7) The notifier shall pay in the costs referred to in paragraph (5) of this Article at the account of the state administration body competent for performing activities in the field of environment within eight days after the day of submitting the notification, on the basis of a decision for actual costs.

(8) The state administration body competent for performing activities in the field of environment can accept the notifier to submit one notification for emitting the same GMO or GMO combination in the environment in the same area or in different area, but intended for the same purpose.

Article 35

License for deliberate release of GMO

(1) Within 90 days after the day of receiving the complete notification, the state administration body competent for performing activities in the field of environment shall issue a license for deliberate release of GMO in the environment (hereinafter: license for deliberate release of GMO) confirming that the conditions for deliberate release of GMO have been met or shall, by a decision, reject the notification in case the conditions for deliberate release of GMO have not been met.

(2) Within 15 days after the receiving the complete notification, the state administration body competent for performing activities in the field of environment shall be obliged to submit one copy of the complete notification to the Scientific Committee on GMO.

(3) The Scientific Committee on GMO shall be obliged to submit a written opinion regarding the notification to the state administration body competent for performing activities in the field of environment within 45 days after the day of receiving the notification referred to in paragraph (2) of this Article.

(4) In case the Scientific Committee on GMO and the state administration body competent for performing activities in the field of environment consider that the notification is incomplete and that, on the basis of the submitted documentation, it is not possible to determine the influence of the deliberate release of GMO on human health and environment, they can request for additional information from the notifier.

(5) Within the deadline referred to in paragraph (1) of this Article, the following shall not be calculated:
- the time periods while waiting for the additional information by the notifier and/or
- the time period when a public debate or consultations have been performed as in accordance with Article 12 of this Law.

(6) The time period referred to in paragraph (5) line 2 of this Article shall not defer the deadline for issuing the license laid down in paragraph (1) of

this Article for no longer than 30 days.

(7) After receiving the opinion referred to in paragraph (3) of this Article, the state administration body competent for performing activities within the field of environment shall issue a license for deliberate release of GMO within the deadline referred to in paragraph (1) of this Article.

(8) The license for deliberate release of GMO shall be issued for the period requested by the notifier, which shall not exceed more than ten years.

(9) The notifier can start the deliberate release of GMO after receiving the license for deliberate release of GMO and in accordance with the conditions anticipated within the license.

(10) The deliberate release of GMO shall be performed in accordance with the license for deliberate release of GMO.

(11) The material received after the deliberate release of GMO that possesses previously issued license for deliberate release of GMO can be placed on the market, only in case if it possesses a license for placing of GMO product on the market, as in accordance with this Law.

(12) The notifier shall have the right to file a lawsuit for initiating an administrative dispute procedure with the competent court regarding the license for deliberate release of GMO, that is the decision on rejection of the notification for deliberate release of GMO.

(13) The form and content of the license for deliberate release of GMO form shall be prescribed by the state administration body competent for performing activities in the field of environment.

Article 36

Risk assessment

(1) Before the submission of the notification for receiving a license for deliberate release of GMO, the notifier shall be obliged to provide a risk assessment for the planned deliberate release.

(2) Based on the analysis of the GMO characteristics and on their deliberate release in the direct environment, as well as on the basis of the analysis of the characteristics of the environment that shall be exposed to a risk, it is necessary, during the risk assessment, to determine and assess the harmful effects and their possible consequences, the risk level and the measures necessary for their control.

(3) The notifier can refer to data or results from the risk assessment of the notifications previously submitted by other notifiers, provided that the information, data and results are not confidential, as well as to provide written consent for that purpose from the notifier.

(4) The notifier in the cases referred to in paragraph (3) of this Article can provide additional information considered to be relevant in regards to the risk assessment.

(5) The risk assessment shall be performed in accordance with the regulation adopted on the basis of Article 26 paragraph (5) of this Law.

Article 37

Taking actions due to changed and new information

(1) If during the deliberate release of GMO, deliberate or non-deliberate changes possible to influence the level of risk to human health and environment occur, or in case new information appear for those risks after issuing the license for deliberate release of GMO or before its issuance, and during its review by the state administration body competent for

performing activities in the field of environment, without any postponement the notifier shall:
1) undertake all the necessary measures for protection of human health and environment;
2) inform the state administration body competent for performing activities in the field of environment for every change in advance and/or shall inform the body about each unexpected change the notifier finds out or gets new information about and
3) submit a notification for the purpose of revising the conditions listed in the license for deliberate release of GMO.

(2) In case the state administration body competent for performing activities in the field of environment, after issuing the license for deliberate release of GMO, receives new information in regards to the changes referred to in paragraph (1) of this Article, it shall be obliged to immediately request from the notifier to submit notification for the purpose of amending the conditions within the license for deliberate release of GMO.

(3) In the cases referred to in paragraphs (1) and (2) of this Article the state administration body competent for performing activities in the field of environment shall be obliged to assess the information in cooperation with the Scientific Committee on GMO.

(4) In the cases referred to in paragraphs (1) and (2) of this Article, and based on the assessment referred to in paragraph (3) of this Article, the state administration body competent for performing activities in the field of environment, depending on the degree of risk to human health and environment, can require from the notifier to stop or limit the deliberate release of GMO in the environment until the license is amended in accordance with the amended conditions.

(5) If on the bases of the assessment referred to in paragraph (3) of this Article it is confirmed that the new data or changes in the cases referred to in paragraph (1) and (2) of this Article can have significant consequences on the level of risk to human health and environment, which prevents the performance of deliberate release of GMO, the state administration body competent for performing activities in the field of environment shall prohibit the same by a decision.

(6) With regard to the cases referred to in paragraphs (3), (4) and (5) of this Article, the state administration body competent for performing activities in the field of environment shall be obliged to inform the public in a manner determined in Article 12 paragraph (5) of this Article, while in regards to the amendment of the license for deliberate release of GMO, about the stoppage and/or prohibition for deliberate release of GMO.

(7) The provisions of Article 35 shall be applied to the procedure for amending the license referred to in paragraph (1) of this Article.

Article 38

Plan for emergency measures in case of non-deliberate release of GMO

(1) While submitting the notification, the notifier shall be obliged to submit a plan for emergency measures in case of unpredicted spreading of GMO in the environment (hereinafter: plan for emergency measures) to the state administration body competent for performing activities in the field of environment.

(2) The plan for emergency measures shall particularly contain:
1) methods and procedures for control of GMO in case of non-deliberate release of GMO in the environment,
2) methods of decontamination of the areas affected by non-deliberate release of GMO which eradicates or decreases the presence of GMO in

those areas,
3) methods for removal or disinfection of the plants, animals, soil and items exposed during or after the non-deliberate release of GMO,
4) methods for isolating the region affected by non-deliberate release of GMO,
5) plans for protection of human health and environment in case adverse effect appears;
6) methods for assessment of the possible consequences and threat to the environment and human health,
7) measures necessary for protection of the place of non-deliberate release of GMO,
8) measures necessary for prevention of further spreading of GMO.

(3) The notifier shall periodically and at least once a year check the appropriateness of the plan referred to in paragraph (2) of this Article, and in accordance with the necessities, shall change and/or amend the plan. The user shall be obliged to submit all the amendments of the plan for emergency measures to the competent body referred to in paragraph (1) of this Article for approval.

(4) The content of the plan for emergency measures shall be in detail prescribed by the minister heading the state administration body competent for performing activities in the field of environment.

Article 39

Reports

(1) The notifier shall be obliged to submit reports in regard to all the risks to human health and environment possible to result from the deliberate release of GMO to the state administration body competent for performing activities in the field of environment, that is:
- in periods as determined by the license for limited application of GMO,
- within three months after the expiry of the validity period of the license,
- within three months after the completion of the deliberate release of GMO and
- on request of the state administration body competent for performing activities in the field of environment.

(2) If the notifier, by applying the deliberate release of GMO, intends to submit a notification for placing of GMO products on the market in future, it shall be obliged to submit special information related to those products, in accordance with paragraph (1) of this Article, to the state administration body competent for performing activities in the field of environment.

(3) The form, content and manner of submission of the report referred to in paragraph (1) of this Article shall be in detail prescribed by the minister heading the state administration body competent for performing activities in the field of environment.

Article 40

Non-deliberate release of GMO in the environment

(1) In case of non-deliberate release of GMO in the environment, the notifier shall undertake measures in accordance with the plan for emergency measures referred to in Article 38 of this Law and shall immediately inform the state administration body competent for performing activities in the field of environment for:
1) the range of the consequences of non-deliberate release of GMO in the environment and the threat to the environment and human health;
2) the undertaken measures and additional measures supposed to be undertaken for protection of the environment and human health;
3) the undertaken and additional measures supposed to be undertaken for the purpose of decreasing or eliminating the consequences of the non-

deliberate release of GMO in the region exposed to non-deliberate release, 4) the other data relevant for the assessment of the effects on the environment and on the human health caused by the non-deliberate release of GMO.

(2) Based on the notification referred to in paragraph (1) of this Article, the state administration body competent for performing activities in the field of environment, in cooperation with the notifier, shall prepare a program for elimination of the consequences of the non-deliberate release of GMO in the environment.

(3) The program for elimination of the consequences of non-deliberate release of GMO in the environment shall be adopted by the Government of the Republic of Macedonia upon the proposal of the minister heading the state administration body competent for performing activities in the field of environment.

(4) The responsible organs and bodies, the measures for decrease of the consequences and/or prevention of further non-deliberate release of GMO, the deadlines for their preparation and implementation, the manner of covering the costs and the necessary limitations and/or prohibitions in regard to the further deliberate release of GMO, the import, trade or use, shall be laid down within the program referred to in paragraph (2) of this Article.

(5) As for the cases referred to in paragraph (1) of this Article, as well as for the preparation and implementation of the program, the state administration body competent for performing activities in the field of environment shall prepare a report that shall be submitted to the Government of the Republic of Macedonia for adoption and without any postponements shall familiarize the public in accordance with Article 12 of this Law and in accordance with the Law on Environment.

(6) In case the state administration body competent for performing activities in the field of environment assesses that the undertaken activities can have negative influence on human health and environment on a territory of some other country, it shall initiate a procedure for informing the competent bodies from the other country in accordance with the reciprocal principle and with the international conventions and agreements ratified by the Republic of Macedonia.

(7) The manner and procedure of implementing the activities referred to in paragraph (6) of this Article shall be prescribed by the minister heading the state administration body competent for performing activities in the field of environment in concurrence with the minister heading the state administration body competent for performing activities in the field of foreign affairs.

V. 2. PLACEMENT OF GMO PRODUCTS ON THE MARKET

Article 41

Placement of GMO products on the market

(1) Before placing GMO products on the market in the Republic of Macedonia, the notifier shall be obliged to submit a notification to the state administration body competent for performing activities in the field of environment.

(2) The notification referred to in paragraph (1) of this Article shall particularly contain information about:
1) technical documentation necessary for conducting the assessment of the risk coming out of the placing GMO products on the market and containing the information set out in Article 34 paragraph (3) of this Law;

2) GMO products placed on the market;
3) the conditions for placing GMO products on the market including the special conditions for using and handling;
4) the diversity of areas where the GMO product shall be used, that shall as well include information on the data and results received by research and development releases related to the effect of the placed GMO products on the market over the human health and environment;
5) risk assessment referred to in Article 26 paragraph (2) of this Law including data about applied methods and conclusions from the assessment;
6) proposal for the period for which a license for placing of GMO product on the market is required, which shall not exceed more than ten years;
7) plan for monitoring the GMO product with a proposed period when the monitoring shall be carried out, including the period after the expiration of the license for placing of GMO products on the market as well;
8) proposal for labeling and packing the GMO product for which purpose a license for placing of GMO product on the market is requested, including the data in accordance with Article 50 of this Law as well and
9) summary of the submitted technical documentation and summary of the submitted information contained in the notification.

(3) The detailed content of the information referred to in paragraphs (2) points 2, 3, 4, 7 and 8 of this Article shall be prescribed by the minister heading the state administration body competent for performing activities in the field of environment.

(4) The notifier shall be obliged to state the purpose of the GMO product for which a license for placing of GMO products on the market is requested in the notification referred to in paragraph (1) of this Article.

(5) The notifier shall be obliged to submit a new notification in case it intends to use the GMO product for purpose other than the one stated in the notification referred to in paragraph (4) of this Article.

(6) The notifier shall be obliged to cover the actual costs incurred by the state administration body competent for performing activities in the field of environment and by the state administration body competent for performing the activities in the field of agriculture and forestry, as well as the costs for the work of the Scientific Committee on GMO referred to in Article 64 of this Law, during the procedure for issuing the license for placing of GMO products on the market.

(7) The amount of the costs referred to in paragraph (6) of this Article shall be prescribed by the minister heading the state administration body competent for performing activities in the field of environment.

(8) The notifier shall be obliged to pay in the costs referred to in paragraph (6) of this Law at the account of the state administration body competent for performing activities in the field of environment within eight days after the day of submitting the notification, on the basis of a decision on actual costs.

(9) The notifier can place GMO products on the market only after a previously issued license for placing GMO products on the market.

Article 42

Exceptions to the submission of information to the notification

(1) On the basis of the results from the deliberate release of GMO for which a license referred to in Articles 18 and 19 of this Law is received, as well as on the basis of essential and scientifically supported explanation confirming that the placing of GMO on the market and their use as products or in products is not posing a risk to human health and environment, the notifier can require from the state administration body

competent for performing activities in the field of environment not to submit a part of the information or all the information set out by Article 41 paragraph (2) points 3, 7 and 8 of this Law.

(2) The information that can be excluded from the notification in the case referred to in paragraph (1) of this Article shall be in detail prescribed by the minister heading the state administration body competent for performing activities in the field of environment.

(3) The notifier, in the notification, shall submit information about data or results from the deliberate release of the same GMO or a combination of GMO for which the notifier has previously or simultaneously submitted other notification in the Republic of Macedonia or in another country.

(4) The notifier, in the notification, can refer to information, data and/or results from the notifications previously submitted by other notifiers if it considers them as relevant for its notification, provided that those information, data and results are not confidential and/or that the other notifiers have previously given a written consent for their use.

Article 43

Report on GMO product assessment

(1) Within 15 days of the day of receiving the complete notification referred to in Article 41 of this Law, the state administration body competent for performing activities in the field of environment shall submit the same notification to the Scientific Committee on GMO and the state administration body competent for performing activities in the field of agriculture and forestry.

(2) The Scientific Committee on GMO and the state administration body competent for performing activities in the field of agriculture and forestry shall be obliged, within 45 days after receiving the notification referred to in paragraph (1) of this Article, to submit a written opinion for accepting or rejecting the notification to the state administration body competent for performing activities in the field of environment.

(3) Based on the opinions referred to in paragraph (2) of this Article, as well as the opinions received from the public and other relevant bodies, the state administration body competent for performing activities in the field of environment shall be obliged to review the notification and to prepare a report for assessment of the GMO product within 15 days.

(4) The assessment report referred to in paragraph (3) of this Article shall determine whether:
- the GMO product is suitable for placing on the market and under which conditions or
- the GMO product is unsuitable for placing on the market.

(5) The state administration body competent for performing activities in the field of environment shall be obliged to submit the product assessment report to the Scientific Committee on GMO and the state administration body competent for performing activities in the field of agriculture and forestry, obliged furthermore, within eight days, to submit an opinion in writing or, if needed, to request additional information from the state administration body competent for performing activities in the field of environment or the notifier.

(6) After receiving the opinions referred to in paragraph (5) of this Article the state administration body competent for performing activities in the field of environment shall submit the report for GMO product assessment, together with the opinions referred to in paragraph (5) of this Article as well as the information being the base of the report to the notifier for no longer than a period of 90 days after the day of receiving the complete notification.

(7) The following shall not be calculated in the deadline determined in paragraph (6) of this Article:
- the time periods while waiting for submission of additional information by the notifier and/or
- the time period during a public debate or consultations in accordance with Articles 22 and 44 of this Law.

(8) The form and content, and the manner of preparing the report for GMO product assessment referred to in paragraph (3) of this Article shall be in detail prescribed by the minister heading the state administration body competent for performing activities in the field of environment in concurrence with the minister heading the state administration body competent for performing activities in the field of agriculture and forestry.

Article 44

Requests for additional information

(1) The state administration body competent for performing activities in the field of environment shall be obliged, on the same day of submission of the assessment report referred to in Article 43 of this Law to the notifier, to announce an overview of the GMO product assessment report on its website and in two daily newspapers available throughout the territory of the Republic of Macedonia.

(2) The announcement referred to in paragraph (1) of this Article shall be born by the notifier.

(3) Data on the place where insight in the notification data and the GMO product assessment report can be performed shall be stated in the announcement referred to in paragraph (1) of this Article.

(4) The public, the other bodies of the state administration, as well as the scientific and expert institutions can submit their opinion in regard to the GMO product assessment report to the state administration body competent for performing activities in the field of environment within 30 days after the day of announcing. The public, the other bodies of the state administration, as well as the scientific and expert institutions shall have the right to insight in the GMO product assessment report in accordance with Article 12 paragraph (4) of this Law.

(5) The state administration body competent for performing activities in the field of environment can, within a period of 60 days after the submission of the GMO product assessment report to the notifier, request for additional information from the notifier, and also to submit to the notifier the comments and/or explained notes received in accordance with paragraph (4) of this Article, referring to the placement of GMO products on the market.

(6) All the disputable matters related to the GMO product assessment report, as well as any additional information shall be solved and an agreement shall be reached for the abovementioned with the notifier within 105 days after the day of submission of the GMO product assessment report.

(7) The requests for additional information for the purpose of solving the disputable matters in accordance with paragraph (6) of this Law can be submitted within a period of 45 days before the expiration of the deadline referred to in paragraph (6) of this Article at latest.

(8) The time periods while waiting for the submission of additional information by the notifier shall not be calculated in the deadline referred to in paragraph (6) of this Law.

Article 45

Withdrawal of the notification

(1) The notifier can withdraw the notification for receiving a license for placing of GMO products on the market or can inform in writing the state administration body competent for performing activities in the field of environment, that it intends to amend the notification if the GMO product assessment report confirms the product to be suitable for placing on the market but only under specific conditions, and until the moment of license issuance.

(2) If within the determined time period referred to in paragraph (1) of this Article, the notifier informs the state administration body competent for performing activities in the field of environment for the intention to amend the notification, then the state administration body competent for performing activities in the field of environment shall determine a time period for amending the notification.

(3) The time period for amending the notification referred to in paragraph (2) of this Article shall not be calculated in the time period determined for receiving the license.

(4) In case the notifier, within the deadline referred to in paragraph (2) of this Article, does not submit the requested amendments to the notification in writing to the state administration body competent for performing activities in the field of environment, the notification shall be considered as withdrawn.

(5) If during the procedure for receiving license for placing of GMO products on the market the notifier fails to submit the information requested in accordance with the determined deadlines, that is not later than the deadline determined in Article 43 paragraph (6) of this Law in regard to the notification, or within the deadline referred to in Article 44 paragraph (6) of this Law in regard to the GMO product assessment report, the state administration body competent for performing activities in the field of environment, the notification shall be considered withdrawn.

(6) In case the notifier withdraws the notification in accordance with paragraph (1) or paragraph (4) of this Article, as well as in the cases referred to in paragraph (5) of this Law, the state administration body competent for performing activities in the field of environment shall terminate the procedure for issuing a license for placing of GMO products on the market.

Article 46

License for placing of GMO products on the market

(1) The state administration body competent for performing activities in the field of environment, based on the prepared report for product assessment referred to in Article 43 paragraph (4) line 1 of this Law, shall issue a license for placing of GMO product on the market within 30 days, that is:
- after the expiry of the deadline of 60 days as in accordance with Article 44 paragraph (5) of this Law, provided that there are no disputable matters and
- after the expiry of the deadline of 105 days as in accordance with Article 44 paragraph (6) of this Law if the disputable matters have been positively solved and an agreement has been reached.

(2) The state administration body competent for performing activities in the field of environment, based on the prepared report for product assessment referred to in Article 43 paragraph (4) line 2 of this Law, shall issue a decision to reject the notification for receiving a license for placing of GMO product on the market within 30 days:
- after the day of submission of the assessment report,
- after 60 days in accordance with Article 44 paragraph (5) of this Law and

- after 105 days in accordance with Article 44 paragraph (6) of this Law in case the disputable matters have not been positively solved and an agreement has not been reached.

(3) The state administration body competent for performing activities in the field of environment shall be obliged to state the reasons for rejecting the notification in the decision referred to in paragraph (2) of this Article.

(4) The notifier can place the GMO product on the market in accordance with the conditions determined within the license for placing GMO products on the market.

(5) The license for placing GMO products on the market can be issued for a period of ten years after the issuance date at most.

(6) The notifier shall have the right to file a lawsuit for initiating an administrative dispute with the competent court against the conditions stated in the license for placing GMO products on the market and against the decision referred to in paragraph (3) of this Article.

(7) The form and content of the Form of the license for placing of GMO products on the market and the other accompanying documentation shall be in detail prescribed by the minister heading the state administration body competent for performing activities in the field of environment in concurrence with the minister heading the state administration body competent for performing activities in the field of health and the minister heading the state administration body competent for performing the activities in the field of agriculture and forestry.

Article 47

Extension of the license

(1) The license for placing of GMO products on the market can be extended in case the notifier, within nine months after the expiration of its validity, submits notification for license extension to the state administration body competent for performing activities in the field of environment.

(2) The notification referred to in paragraph (1) of this Article shall contain:
1) copy of the license for placing of GMO product on the market being subject to validity extension;
2) report on conducting the monitoring plan as in accordance with Article 49 paragraph (2) point 7 of this Law;
3) new available information referring to the risks to the human health and environment resulting from the use of GMO products and
4) draft amendments to the conditions determined by the license, but related to placing of GMO product on the market, especially in regard to the application of the procedure of following and/or the license deadline, if necessary.

(3) The provisions of Article 41 of this Law shall be accordingly applied to the procedure for extension of license for placing of GMO products on the market.

(4) Within three months after the submission of the complete notification, the state administration body competent for performing activities in the field of environment shall decide upon the extension of the license for placing of GMO products on the market.

(5) After submitting the notification on extension of the license for placing of GMO products on the market, the notifier can continue placing the GMO product on the market under the conditions laid down by the license until bringing the final decision upon the notification on license extension.

(6) The license can be extended once or more times, if the conditions for

that purpose are fulfilled.

Article 48

New information

(1) In case the notifier, after submitting the notification but before issuing the license for placing of GMO product on the market, comes to new information affecting the level of risk to human health and environment from placing GMO product on the market, the notifier shall be obliged to immediately:
- inform the state administration body competent for performing activities in the field of environment,
- undertake all the necessary measures for protection of the human health and environment and
- submit amendment to the notification for the purpose of revising the information and conditions stated in the notification for placing of GMO product on the market.

(2) If the notifier, after the issuance of the license for placing of GMO products on the market, comes to new information by the users of GMO products or otherwise, referring to the level of risk to human health and environment, then the notifier shall be obliged to immediately:
- undertake all the necessary measures for protection of human health and environment,
- inform the state administration body competent for performing activities in the field of environment about the new information and
- submit amendments to the notification for the purpose of revising the information and conditions stated in the license for placing GMO product on the market.

(3) In case the state administration body competent for performing activities in the field of environment, before issuing the license for placing of GMO products on the market, comes to new information regarding the GMO product intended for the market or the risk from the use of the said product to human health and environment, then the said body shall obligatory consider this fact in the process of issuing the license.

(4) If after the issuance of the license for placing of GMO product on the market, the state administration body competent for performing activities in the field of environment, comes to new information by itself or receives them through another bodies, users of the product or in another way, which are related to placing of GMO products on the market or refer to the level of risk from the use of the said product to human health or environment, it can temporarily limit or prohibit the use and/or the sale of the referred GMO product and/or a GMO product.

(5) In the cases referred to in paragraph (4) of this Article, the state administration body competent for performing activities in the field of environment shall be obliged to inform the notifier, to request additional information from the notifier, as well as to oblige the notifier to submit amendment to the notification for the purpose of revising the information and conditions listed in the license for placing of GMO product on the market.

(6) The state administration body competent for performing activities in the field of environment, in concurrence with the state administration body competent for performing activities in the field of agriculture and forestry and the Scientific Committee on GMO referred to in Article 64 of this Law shall determine the amended conditions in the license for placing of GMO product on the market within three months after the day of receiving the notification for the amended conditions, or shall annul the license if, as a result from the amended conditions, the GMO product can not be further placed on the market.

(7) The provisions referred to in Article 41 of this Law shall be applied to

the procedure for amending the license referred to in paragraphs (1), (2) and (6) of this Article.

Article 49

Monitoring

(1) The notifier who places a GMO product on the market shall be obliged to monitor its use and the effects the GMO product has on the human health and environment, in accordance with the Monitoring Plan of the GMO products and the conditions determined in the license for placing of GMO product on the market, and shall inform thereof the state administration body competent for performing activities in the field of environment on regular basis.

(2) The state administration body competent for performing activities in the field of environment can, on the basis of the report on the monitoring results, request the notifier to amend the Monitoring Plan of the GMO product.

(3) The data from the monitoring report shall be public, in accordance with the provisions for access to information contained in the Register of GMO referred to in Article 60 of this Law and the Law on Environment.

Article 50

Labeling and packing of the GMO products

(1) The notifier can place on the market only a GMO product which is packed, whose package and declaration contain a listing that the said product contains and/or is consisted of GMO, as well as GMO combination, and other necessary data regarding the product and the manner of its application as prescribed in accordance with paragraph (3) of this Article and as determined in the license approving the placement of the GMO product on the market.

(2) During all the phases of placement, the GMO product as well as the accompanying documentation shall meet all the conditions for labeling and packing as determined in the license for approval of placement of GMO product on the market.

(3) The following information shall as minimum be listed in the label and declaration of the GMO product:
1) trade name of the product;
2) the words “This product contains genetically modified organisms”;
3) the name of the GMO;
4) the name and address of the legal entity and the natural person responsible for placing the GMO products on the market in the Republic of Macedonia, regardless whether it is the producer, importer or distributor and
5) directions for the possible manner of reaching the information from the register where it is possible to request for information about the GMO product with indication of the license number.

(4) As an exception to paragraph (3) of this Article, the labeling of the products intended for direct procession and containing approved GMO of up to 0,9% at the most shall not be obligatory if it is not possible to exclude the accidental and technical unavoidable presence of GMO traces.

VI. TRANSBOUNDARY MOVEMENT OF GMO AND GMO PRODUCTS

Article 51

Import of GMO and GMO products

(1) The import of GMO and GMO products can be performed only on the basis of a previously issued license from the state administration body competent for performing activities in the field of environment, in accordance with the procedure set out in the chapters IV and V of this Law, depending on the intention of GMO application.

(2) During the import, the information for GMO presence shall be obligatory entered in the veterinary or phytosanitary certificate.

Article 52

Export

General provisions

(1) The export of GMO and GMO products shall be performed in accordance with the provisions of this Law.

(2) The export of GMO live organism shall be performed in accordance with the provisions of this Law and the provisions of the Cartagena Protocol on Biosafety to the Convention on Biodiversity (hereinafter: the Protocol) by applying the agreement for early informing of the Protocol.

(3) The approval of the export shall be given by the state administration body competent for performing activities in the field of environment by issuing a license for export of GMO and/or GMO products.

(4) The state administration body competent for performing activities in the field of environment shall issue the license referred to in paragraph (3) of this Article exclusively if the exporter has previously submitted a certificate and/or license for import approved by the competent body from the state performing the import of the exported GMO and/or GMO product from the Republic of Macedonia.

(5) The state administration body competent for performing activities in the field of environment shall be obliged to submit a copy of the license referred to in paragraph (3) of this Article to the Customs Administration of the Republic of Macedonia.

(6) The Customs Administration of the Republic of Macedonia shall not allow export of GMO and/or GMO products from the Republic of Macedonia unless the exporter submits the license referred to in paragraph (3) of this Article together with the accompanying documentation on export.

(7) The form and content of the license form referred to in paragraph (3) of this Article shall be prescribed by the minister heading the state administration body competent for performing activities in the field of environment.

Article 53

Procedure on export notification

(1) The exporter of GMO or GMO products shall be obliged to submit a notification to the state administration body competent for performing activities in the field of environment before exporting the GMO or GMO products.

(2) The state administration body competent for performing activities in the field of environment shall submit the notification referred to in paragraph (1) of this Article to the body of the state importer competent for issuing approvals for import of GMO or GMO products, asking it to submit a certificate for accepting the notification within 30 days after the day of receiving.

(3) In case the state administration body competent for performing activities in the field of environment does not receive the certificate for receiving the notification referred to in paragraph (2) of this Article within 90 days after the day of submitting the notification, then it shall be obliged to submit a written reminder to the body of the other state for the necessity of submitting the certificate.

(4) In case the notification refers to export of GMO live organism, the state administration body competent for performing activities in the field of environment shall submit the written reminder referred to in paragraph (3) of this Article to the Secretariat of the Protocol as well.

(5) The state administration body competent for performing activities in the field of environment shall be obliged to issue the license for export of GMO and GMO product within 30 days after the day the notifier submits the certificate and/or the license approved by the competent body of the country importer which is the target importer of the exported GMO and GMO product.

(6) In case the body competent for issuing approvals for import of GMO and GMO products in another country does not respond to the submitted notification referred to in paragraph (1) of this Article within a deadline of 270 days after the day of submitting the notification, the state administration body competent for performing activities in the field of environment shall be obliged, once again, to address it requiring to respond to the notification within 60 days after the day of receiving the request.

(7) When the notification refers to export of GMO live organism, the state administration body competent for performing activities in the field of environment shall submit the request referred to in paragraph (5) of this Law to the Secretariat of the Protocol as well.

(8) It shall not be considered as approval for receiving license for export of GMO and GMO products if the acceptance of the notification is not confirmed by the body of the importing country competent for issuing approvals for import of GMO and GMO products referred to in paragraph (3) of this Article, as well as when respond shall not be received upon the submitted request referred to in paragraph (6) of this Article.

Article 54

License for export of GMO and GMO products

(1) The importer shall be obliged to attach particularly the following information and data to the notification referred to in Article 53 paragraph (1):
1) name, phone number and address, as well as contact information of the exporter of GMO and GMO product;
2) name, phone number and address, as well as contact information of the person whom the GMO and GMO products are intended for (the importer from the other country);
3) description of GMO and GMO product and its characteristics and the applied techniques of modification, while for GMO live organisms, name and identity, as well as description of the parent organism and the receiver's organism;
4) the planned date of export, if known;
5) the intended use of GMO and GMO product;
6) the amount and/or volume of GMO and GMO product;
7) origin of GMO and GMO product;
8) previous and present report on risk assessment;
9) taxonomic status, name and identity, point of collection or acquisition and characteristics of the donated organism or organisms related to biosafety;
10) proposed methods, measures and manners for secure packing, handling, transport and use, including the labeling, accompanying

documentation, disposition and contingence procedures;
11) legal provisions related to the use and regime of import/export/transit of GMO and GMO products in the importing country;
12) the correspondence or communication with the importer or the body from the country importer competent for issuing approvals on import of GMO and GMO products;
13) statement by the notifier that the submitted information and data together with the notification are true and
14) statement that the notifier shall obey the provisions from the Protocol and that it bounds to undertake all the activities which depend on the notifier, for the purpose of implementing the Protocol.

(2) In case the notification does not contain the required information and data in accordance with paragraph (1) of this Article, the state administration body competent for performing activities in the field of environment shall be obliged to determine a deadline for the notifier during which time the notifier shall be obliged to submit the additional information. The deadline can not be shorter than 30 days.

(3) The time period for supplementing the notification shall not be calculated into the time period referred to in Article 53 paragraph (5) of this Law.

(4) The state administration body competent for performing activities in the field of environment shall issue a certificate about the receipt of the complete documentation to the notifier.

(5) The state administration body competent for performing activities in the field of environment shall issue a license for export of GMO and GMO products with the same validity period as indicated in the certificate and/or license for import approved by the competent body in the importing country of the exported GMO and GMO product.

(6) If the validity period is not indicated at the certificate and/or license for import referred to in paragraph (5) of this Article, the state administration body competent for performing activities in the field of environment shall issue a license for export of GMO and GMO product for the period requested by the notifier, which shall not exceed more than five years.

(7) The information and data referred to in paragraph (1) of this Article that need to be submitted as attachment to the notification in accordance with the purpose of GMO and GMO product and their characteristics shall be prescribed by the minister heading the state administration body competent for performing activities in the field of environment in concurrence with the state administration body competent for performing activities in the field of agriculture and forestry and the minister heading the state administration body competent for performing activities in the field of health.

Article 55

Extension of the license for export of GMO and GMO products

The license for export of GMO and GMO products can be extended by submitting a new notification in accordance with Articles 53 and 54 of this Law.

Article 56

Export notification

(1) After issuing the license for export of GMO and GMO product, the state administration body competent for performing activities in the field of

environment shall notify in writing the competent body in the other country being the importer of the exported GMO and GMO product.

(2) In case the license refers to GMO live organism, the notification referred to in paragraph (1) of this Article shall be submitted to the Secretariat of the Protocol as well.

Article 57

Transit

(1) The individuals who transport GMO or GMO products through the territory of the Republic of Macedonia shall be obliged to submit a notification on the transit to the state administration body competent for performing activities in the field of environment.

(2) The notification referred to in paragraph (1) of this Article shall be submitted not later than 14 days from the day the transit is to be performed.

(3) The notification referred to in paragraph (1) of this Article, besides the information and data referred to in Article 54 paragraph (1) of this Law shall be obliged to submit the following as well:
1) certificate and/or license for import approved by the competent body of the importing country of the exported GMO and GMO product and
2) certificate for receipt of the notification on transit from the competent bodies of the countries through which GMO and GMO product is supposed to transit for the purpose of reaching the importing country, or a certificate that the transit has been approved.

(4) The state administration body competent for performing activities in the field of environment shall be obliged, within three days after the day of receiving the complete notification referred to in paragraph (1) of this Article, to issue a certificate for a receipt of the notification to the notifier.

(5) The state administration body competent for performing activities in the field of environment shall issue a license for transit of GMO and GMO product through the territory of the Republic of Macedonia not later than three days before the day the transit is to be performed.

(6) The state administration body competent for performing activities in the field of environment shall be obliged to submit a copy of the license referred to in paragraph (5) of this Article to the Customs Administration of the Republic of Macedonia.

(7) The Customs Administration of the Republic of Macedonia shall not allow transit of GMO and GMO product through the territory of the Republic of Macedonia unless the transporters of GMO and GMO product include the license referred to in paragraph (5) of this Article in the other documentation for transit.

(8) The form and content of the license form referred to in paragraph (5) of this Article shall be prescribed by the minister heading the state administration body competent for performing activities in the field of environment.

Article 58

Non-deliberate transboundary movement of GMO

(1) In case of non-deliberate release of GMO and GMO products resulting in non-deliberate transboundary movement of GMO into the territory of another country, the state administration body competent for performing activities in the field of environment shall be obliged immediately, and within 24 hours at latest, to perform the following:
1) to inform the public, the bodies of the involved and/or potentially

involved country, the party countries of the Protocol and the Secretariat of the Protocol, as well as, if appropriate, the relevant international organization, and the Clearing House of Biosafety and
2) to consult the involved and/or potentially involved country for the purpose of enabling determination of appropriate measures for rehabilitation and to plan an appropriate action for prevention of the negative influence on people and environment.

(2) The notifier who is responsible for the non-deliberate release of GMO and GMO products shall be obliged to immediately submit a notification for export, as in accordance with Article 53 and 54 of this Law.

(3) Attached to the notification referred to in paragraph (2) of this Article, all the information which refer to the following shall be submitted as urgent:
1) the assessed amount of non-deliberately released GMO and GMO products and relevant characteristics and/or features of GMO;
2) information about the circumstances and the estimated time of non-deliberate release of GMO;
3) the manner of GMO and GMO product application;
4) the possible negative influences on the preservation and sustainable application of the biodiversity and the environment, while considering the risks to human health and environment;
5) possible measures for risk management and
6) other data relevant for the non-deliberate release of GMO and GMO products.

(4) The notification referred to in paragraph (2) of this Article shall contain also telephone numbers and contact addresses of the responsible individuals within the state administration body competent for performing activities in the field of environment, as well as within the notifier.

VII. REGISTER OF GMO AND SUBMISSION OF REPORTS

Article 59

Register of GMO

(1) The state administration body competent for performing activities in the field of environment shall keep and maintain the Register of GMO. The Register shall be considered as a public document.

(2) The Register of GMO shall contain data of the places where limited application of GMO is performed, as well as other data relevant to the limited application of GMO, deliberate release of GMO in the environment and placement of GMO products on the market.

(3) The data referred to in paragraph (2) of this Article particularly contain:
1) name and address of the legal entities and natural persons responsible for:
1. limited application of GMO,
2. deliberate release of GMO in the environment or
3. placing of GMO products on the market.
2) the licenses issued in accordance with this Law and their amendments;
3) the list of GMO used in the Republic of Macedonia and for which purpose;
4) the addresses and characteristics of the places;
5) limited application of GMO and its classification;
6) deliberate release of GMO in the environment, including the exact description of the area being subject to release;
7) types of GMO products and their placement on the market, including the description of the GMO product and the place where the GMO product

is placed on the market;
8) data of the risk assessment and assessment of the GMO product;
9) data of accidents and the assessment of the consequences;
10) noted experiences and researches in relation to GMO;
11) scientific, technical and legal information related to GMO;
12) data about the GMO trade and issued licenses for trade and
13) other information relevant to GMO.

(4) The state administration body competent for performing activities in the field of environment shall be obliged to regularly update the data contained in the Register of GMO.

(5) Every individual shall have the right to insight in the data from the Register of GMO and to request data in a manner and under conditions determined by law.

(6) The amount of the fee for getting data from the Register of GMO shall be equal to the actual costs incurred for getting the data.

(7) The data determined as confidential in accordance with this Law, as well as the regulations for data protection shall not be entered into the Register of GMO.

(8) The data from the Register of GMO can be used for exchange of information with other countries, as well as with international organizations in the manner determined by this Law and by the international agreements ratified or accessed by the Republic of Macedonia.

(9) The form, content and manner of keeping the Register of GMO shall be in detail prescribed by the minister heading the state administration body competent for performing activities in the field of environment.

Article 60

Biosafety Clearing House

The state administration body competent for performing activities in the field of environment shall set up and maintain the Biosafety Clearing House.

Article 61

Submission of reports

The Government of the Republic of Macedonia upon proposal of the minister heading the state administration body competent for performing activities in the field of environment, determined in accordance with the minister heading the state administration body competent for performing activities in the field of agriculture and forestry and the minister heading the state administration body competent for performing activities in the field of health, shall be obliged, at least once in every three years, to submit a report to the Parliament of the Republic of Macedonia related to the implementation of the deliberate release of GMO and the placement of GMO products on the market, and particularly:
- the influence and efficiency of their application;
- the necessity of additional legal regulation;
- the feasibility of different options for further promotion of the consistency and the efficiency of their application, including the implementation of the procedures for their approval implemented by the state administration bodies;
- the possibility to use the registers of the European Commission on GMO and their application in the Republic of Macedonia;
- the practice and experience in the application of GMO which can be acquired or appears among the state administration bodies in the Republic of Macedonia, including the Commission on GMO Management and the

Scientific Committee on GMO, as well as other scientific and expert bodies;
- social and economical influences from the application of GMO;
- ethical matters that have appeared or have been discussed in relation to the application of GMO;
- list of approved applications of GMO and resume of the data contained in the Register of GMO and
- other relevant matters related to GMO.

VIII. EXPERT BODIES

Article 62

Commission on GMO Management

(1) For the purpose of achieving the goals of this Law, the Government of the Republic of Macedonia on proposal of the minister heading the state administration body competent for performing activities in the field of environment, shall set up a Commission on GMO Management (hereinafter: the Commission).

(2) The Commission shall perform the following activities:
1) to monitor the conditions and development in applying the techniques of genetic modification and GMO management;
2) to take up stances, give opinions and proposals for using the techniques of genetic modification and GMO management, as well as give opinion regarding the social, ethical, technical and technological, medical, scientific and other aspects of GMO management;
3) to advise the Government of the Republic of Macedonia in regard to the application of techniques of genetic modification and GMO management and
4) on annual basis, to submit a report for its work to the Government of the Republic of Macedonia.

Article 63

Composition of the Commission

(1) The Commission referred to in Article 62 of this Law shall be composed of 15 members, including the President of the Commission, with a four-year term of office.

(2) The Commission shall elect the President from among its members with a two-year term of office.

(3) The Commission members shall be elected from among the scientific workers, more precisely one from the field of social sciences, one from the biological sciences, the forestry sciences, the agriculture sciences, biotechnological sciences, medical sciences, veterinary, pharmacist, ethical sciences and the public health, as well as one member of the Scientific Committee referred to in Article 64 of this Law, the citizens' association in the field of environmental and nature protection, the Macedonian Academy of Science and Arts, and the Organization of Consumers' Protection as well as from the Government of the Republic of Macedonia.

(4) The members shall have appropriate university degree and at least seven years of scientific experience in the respective field.

(5) The Commission shall work according to the Rules of Procedure adopted by the Commission.

(6) The Commission shall be an expert, independent and autonomous within the framework of its own scope of work.

(7) The Commission members shall be obliged to perform their activities conscientiously and honestly, for which purpose they shall sign an

agreement.

(8) The expert and administrative-technical work necessary for the work of the Commission shall be performed by the state administration body competent for performing activities in the field of environment.

(9) The Commission members shall have the right to compensation for their work in the Commission.

(10) The amount of the compensation referred to in paragraph (10) of this Article shall be determined by the Government of the Republic of Macedonia.

(11) The amount of the compensation referred to in paragraph (10) of this Article shall be reasonable and in accordance with the significance, scope of work of the members and the complexity of the activities.

Article 64

Scientific Committee on GMO

(1) Upon proposal of the minister heading the state administration body competent for performing activities in the field of environment, and for the purpose of reviewing the matters in the GMO field and for giving opinions and proposals, the Government of the Republic of Macedonia shall set up a Scientific Committee on GMO as an expert advisory body.

(2) The Scientific Committee on GMO referred to in paragraph (1) of this Article shall review and give opinions and proposals in regard to:
- the GMO management,
- preparation of acts for GMO management,
- defining the way of implementation of the risk assessment, the limited application of GMO, the deliberate release of GMO and placement of GMO products on the market,
- the notifications and other documents related to the procedure on issuing the licenses laid down by this Law,
- the requests submitted to the Commission on GMO Management and the state administration bodies and
- the requests submitted to the public, citizens' associations, scientific and expert institutions.

(3) The Scientific Committee on GMO shall, once a year, submit a report on its work for the previous year to the state administration body competent for performing activities in the field of environment and to the Government of the Republic of Macedonia, by January 31 the current year at latest.

(4) The Scientific Committee on GMO shall work in sessions and shall discuss the matters within its competence and shall decide by majority votes of the members.

Article 65

Composition of the Scientific Committee on GMO

(1) The Scientific Committee on GMO shall be consisted of seven members elected from among the distinguished scientific workers and experts with appropriate education and expert development in the field of medicine, biology, agriculture, veterinary, biotechnology, and protection at work, as well forestry, with a four-year mandate.

(2) The Scientific Committee on GMO shall elect the President from among its members with a two-year term of office.

(3) The Scientific Committee on GMO shall work according to the Rules of Procedure adopted by the Committee.

(4) Other experts and scientists in the fields relevant to the discussion can participate in the Scientific Committee on GMO, depending on the nature of the notification being subject to expert opinion.

(5) The expert and administrative-technical activities necessary for the work of the Scientific Committee on GMO shall be performed by the state administration body competent for performing activities in the field of environment.

(6) The members of the Scientific Committee on GMO shall have the right to compensation for their work in the Scientific Committee.

(7) The amount of the compensation for the members referred to paragraph (1) of this Article shall be determined by the minister heading the state administration body competent for performing activities in the field of environment.

(8) The amount of the compensation referred to in paragraph (7) of this Article shall be reasonable and in accordance with the significance, scope of work of the members and the complexity of the activities.

(9) The funds for payment of the compensation referred to in paragraph (6) of this Article shall be provided by the budget of the state administration body competent for performing activities in the field of environment.

Article 66

Data protection

(1) The members of the Commission on GMO Management and the Scientific Committee on GMO during, as well as after the expiry of their mandate, shall be obliged to preserve the confidential data and not to reveal them to third parties in accordance with the provisions of this Law and the regulations for access to classified information.

(2) The obligation referred to in paragraph (1) of this Law shall refer to external experts participating in the work of the Scientific Committee on GMO as well.

IX. SUPERVISION OVER THE IMPLEMENTATION

Article 67

Supervision over the implementation

Supervision over the implementation of this Law and the regulations adopted on the basis of this Law, shall be performed by the state administration body competent for performing activities in the field of environment, the state administration body competent for performing activities in the field of health and the state administration body competent for performing activities in the field of agriculture and forestry in accordance with the competences within their field.

Article 68

Inspection supervision

(1) During the supervision over the implementation of the measures for human health and environmental protection, in accordance with the provisions of this Law, the competent bodies for supervision over:
- implementation of the limited application of GMO shall be the state administration body competent for performing activities in the field of environment,
- implementation of deliberate release of GMO in the environment shall be

the state administration body competent for performing activities in the field of environment,
- placement of GMO products on the market shall be the state administration body competent for performing activities in the field of environment and the state administration body competent for performing activities in the field of agriculture and forestry,
- packing the GMO products shall be the state administration body competent for performing activities in the field of environment and the state administration body competent for performing activities in the field of economics,
- transit, import and export of GMO shall be the state administration body competent for performing activities in the field of environment and
- implementation of the provisions or measures for prevention against the possible negative effects on human health and environment and the imposed prohibitions shall be the state administration body competent for performing activities in the field of environment and the state administration body competent for performing activities in the field of health.

(2) Inspection supervision over the implementation of the provisions of this Law and the regulations adopted on the basis of this Law shall be performed by:
- State Environment Inspectorate through the state environmental inspector,
- State Sanitary and Health Inspectorate through the state sanitary and health inspector,
- Food Directorate through the state food inspector,
- State Agriculture Inspectorate through the state agriculture inspector,
- State Forestry Inspectorate through the state forestry inspector,
- Veterinary Directorate through the state veterinary inspector,
- Phytosanitary Directorate through the state phytosanitary inspector and
- State Market Inspectorate through the state market inspector, each within the framework of his/her competencies determined by law.

(3) During the inspection supervision, the state inspectorates referred to in paragraph (2) of this Article shall have the right to access places, areas and protected areas, as well as to insight in the places and areas, in the documentation, and to take samples for the purpose of determining whether the product or organism contains GMO.

Article 69

Measures undertaken by competent inspectorates

(1) If the state inspector referred to in paragraph (2) of this Law determines that, due to a failure at fulfilling the prescribed conditions in accordance with the provisions of this Law, a danger to human health and environment has occurred or may occur, the inspector can undertake the following measures:
- prohibit or order temporary termination of the limited application of GMO,
- prohibit or order termination of the deliberate release of GMO in the environment,
- prohibit or order temporary termination of placement of GMO products on the market,
- order removal of faults resulting from the abovementioned activities in a certain time period,
- order permanent or temporary withdrawal from the market of GMO products and
- order undertaking of temporary measures for improvement, removal and/or decrease of the consequences of the harmful effects caused by the GMO management.

(2) During the supervision, the state inspector referred to Article 68 paragraph (1) of this Law shall be obliged to immediately inform the state

administration body competent for performing activities in the field of environment in case he/she determines irregularities.

(3) The legal entities and natural persons which do not possess license as determined by this Law, by a decision, can be prohibited the transboundary trade of GMO and GMO product, the transport of GMO and GMO product, the limited application of GMO, the deliberate release of GMO in the environment and/or placement of GMO products on the market by the state inspector referred to in Article 68 paragraph (1) of this Law.

(4) The state inspector referred to in Article 68 paragraph (2) of this Law can order emergency measures for the purpose of protecting the environment and human health in order to decrease the damage caused by performing non-allowed activities.

(5) The state inspector referred to in Article 68 paragraph (2) of this Law shall be obliged to initiate a misdemeanor procedure with the competent court.

(6) While performing the supervision, the state inspector referred to in Article 68 paragraph (2) of this Law shall appropriately apply the provisions of the Law on Environment.

(7) In the course of conducting the supervision, in addition to the provisions of this Law, the provisions of the Law on Inspection shall apply.

Article 70

Obligations of the legal entities and natural persons during supervision

For the purpose of enabling the inspection supervision, the legal entities and natural persons shall be obliged to provide the competent inspector referred to in Article 68 paragraph (2) of this Law right to access and insight in the places and documentation of the legal entity and natural person, to submit all the requested data, explanations and announcements, to perform measurements and take samples as well as to collect evidence as in accordance with this Law and the Law on Environment.

X. MISDEMEANOR PROCEDURES

Article 71

Misdemeanors

(1) Fine in the amount of Euro 3.000 to 10.000 in Denar counter-value shall be imposed for a misdemeanor to the legal entity if:
1) before initiating the limited application of GMO, as well as during the conducting the limited application of GMO, the user fails to provide risk assessment of the planned and the limited application of GMO (Article 15);
2) during the limited application of GMO, the user fails to perform a revision of the risk assessment, limitations and safety measures, in accordance with Article 15 of this Law;
3) the user fails to inform the state administration body competent for performing activities in the field of environment in accordance with Article 15 of this Law;
4) the user starts using the places for limited application of GMO before submitting the notification with the necessary information to the state administration body competent for performing activities in the field of environment (Article 16);
5) the user fails to preserve the data of the risk assessment as data of permanent value and fails to deliver them to the state administration body competent for performing activities in the field of environment upon its

request (Article 16);
6) the user does not preserve the risk assessment data (Article 17);
7) upon request of the state administration body competent for performing activities in the field of environment, the user does not submit the requested data as in accordance with Article 17 of this Law;
8) does not act in accordance with Article 20 of this Law;
9) the user acts opposite to the requests from the state administration body competent for performing activities in the field of environment (Article 22);
10) the user fails to inform the state administration body competent for performing activities in the field of environment in accordance with Article 23;
11) the legal entity or the natural person performs deliberate release of GMO containing genes that demonstrate resistance to antibiotics opposite to the prohibition referred to in Article 29 of this Law;
12) during the procedure, the notifier refers to the data or results from the risk assessment of the notifications previously submitted by other notifiers without previously providing a written consent from the notifier (Article 36);
13) the notifier fails to act in accordance with the requirements of the state administration body competent for performing activities in the field of environment (Article 37);
14) the notifier acts opposite to the decision of the state administration body competent for performing activities in the field of environment (Article 37);
15) fails to act in accordance with the requirements referred to in Article 38 of this Law;
16) the notifier continues releasing GMO products opposite to Article 42 of this Law and
17) the members of the Commission on GMO Management and the Scientific Committee on GMO fail to preserve the confidential data as in accordance with the provisions of this Law and the regulations for access to classified information (Article 66).

(2) Fine in the amount of Euro 1.000 to 2.000 in Denar counter-value shall be imposed for a misdemeanor to the responsible person within the legal entity for the actions referred to in paragraph (1) of this Article.

(3) In case the misdemeanors referred to in paragraph (1) of this Article cause greater damage to the environment and human health, sanction shall be imposed proportionally to the caused damage, but five times higher that the amount determined in paragraph (1) of this Article at the most.

(4) The state inspector shall be obliged to offer the perpetrator a settlement procedure as in accordance with this Law and the Law on Environment, before initiating a misdemeanor procedure for the misdemeanors referred to in paragraph (1) of this Article.

(5) Competent body for conducting the misdemeanor procedure as well as for pronouncing the misdemeanors referred to in this Article shall be the competent court.

Article 72

(1) Fine in the amount of Euro 10.000 to 20.000 in Denar counter-value shall be imposed for a misdemeanor to a legal entity if:
1) legal entity, natural person, scientific and research organization, and/or higher education institution performs limited application of GMO without being granted a license for limited application of GMO in accordance with Articles 16, 18 and 19 of this Law (Article 14);
2) the user initiates limited application of GMO class 1 without additional notification, in places without previously issued license in accordance with Article 16 of this Law (Article 17);
3) the limited application class 2 is performed opposite to the provisions referred to in Article 18 of this Law;

4) the limited application class 3 and 4 is performed opposite to the provisions referred to in Article 19 of this Law;
5) the user performs limited application even besides the decision for prohibition (Article 23);
6) in case of an accident during the limited application of GMO, the user fails to inform the state administration body competent for performing activities in the field of environment (Article 24);
7) the legal entity or natural person performs deliberate release of GMO in the nature, that is in protected areas or areas in the ecological network, ecologically clean areas, areas intended for production of organic products, areas intended for ecotourism, as well as areas declared protected zones (Article 31);
8) the entities included in the procedure for issuing licenses fail to preserve the information determined in the notification as confidential and reveal them to third parties (Article 32);
9) the notifier initiates deliberate release of GMO without a license for deliberate release of GMO in the environment (Article 35);
10) the notifier performs deliberate release of GMO opposite to the conditions anticipated within the license for deliberate release of GMO and in accordance with the conditions anticipated in the license (Article 35);
11) the material received by deliberate release of GMO with a license for deliberate release of GMO is placed on the market, without previously granted license for placing of GMO product on the market (Article 35);
12) the notifier fails to submit a report regarding all the risks to human health or environment deriving from the deliberate release of GMO to the state administration body competent for performing activities in the field of environment in accordance with Article 39 of this Law;
13) the notifier in case of non-deliberate release of GMO in the environment does not undertake measures in accordance with the plan for emergency measures referred to in Article 38 of this Article and fails to inform the state administration body competent for performing activities in the field of environment in accordance with Article 40;
14) the notifier places GMO products on the market in the Republic of Macedonia without a license for placing of GMO products on the market;
15) the notifier continues placing the GMO product on the market opposite to the conditions defined within the license (Article 41);
16) the notifier who places GMO product on the market, fails to provide monitoring of its application and the effects the product causes in the environment or on human health, in accordance with the Plan for Monitoring the GMO product and the conditions prescribed in the license and fails to inform the state administration body competent for performing activities in the field of environment regarding the abovementioned, as in accordance with Article 50 of this Law;
17) the notifier places the GMO product on the market opposite to the requirements referred to in Article 51 of this Law and
18) the import, export and transit of GMO or GMO products are performed contrary to the provisions of Chapter VII of this Law (Article 52).

(2) Fine in the amount of Euro 2.000 to 4.000 in Denar counter-value shall be imposed for a misdemeanor to the responsible person within the legal entity for the actions referred to in paragraph (1) of this Article.

(3) In case the misdemeanors referred to in paragraph (1) of this Article cause greater damage to the environment and human health, a sanction shall be imposed appropriate to the caused damage, but seven times higher than the amount determined in paragraph (1) of this Article at most.

(4) The state inspector shall be obliged to offer the perpetuator a mediation procedure as in accordance with this Law and the Law on Environment, before initiating a misdemeanor procedure for the misdemeanors referred to in paragraph (1) of this Article.

(5) Competent body for conducting the misdemeanor procedure as well as for pronouncing the misdemeanors referred to in this Article shall be the competent court.

Article 73

Settlement and mediation procedure

(1) Settlement procedure can be initiated for the misdemeanors referred to in Article 71 of this Law.

(2) Mediation procedure can be initiated for the misdemeanors referred to in Article 72 of this Law.

(3) If consent has been reached for the settlement, the fine of the perpetrator can be decreased for up to a half of the maximum prescribed fine for the misdemeanor the most.

(4) The settlement procedure shall be performed in a manner and in a procedure determined by the Law on Environment.

(5) The mediation procedure shall be performed in a manner and in a procedure determined by the Law on Environment.

XI. TRANSITIONAL AND FINAL PROVISIONS

Article 74

Establishment of expert bodies

The Government of the Republic of Macedonia, within three months after the day this Law enters into force, shall establish a Commission on GMO Management and a Scientific Committee on GMO.

Article 75

Regulations for Law implementation

The regulations anticipated in this Law shall be adopted within two years after the day this Law enters into force.

Article 76

Entry into force

This Law shall enter into force on the eight day of its publication in the "Official Gazette of the Republic of Macedonia", and shall be applied as of September 1, 2008.

PROVISION OF ANOTHER LAW:
Law on Genetically Modified Organisms ("Official Gazette of the Republic of Macedonia" no. 163/2013):
Article 2
This Law shall enter into force on the eight day as of the day of its publication in the "Official Gazette of the Republic of Macedonia" and shall start to apply as of 1 May 2014.