

UNOFFICIAL TRANSLATION

MINISTRY OF ENVIRONMENT AND PHYSICAL PLANNING

LAW ON GENETICALLY MODIFIED ORGANISMS

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Law on Genetically Modified Organisms
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I GENERAL PROVISIONS

Article 1

Subject Matter of Regulation

(1) This Law regulates the management of genetically modified organisms and combination of genetically modified organisms, and products containing genetically modified organisms and/or consisting of or derived from a combination of genetically modified organisms, including therein genetically modified organisms as a product, measures for prevention and reduction of possible adverse effects on human health and on the environment as a consequence of the contained use of genetically modified organisms, deliberate release into the environment of genetically modified organisms or placing on the market of products containing genetically modified organisms and/or consisting of or derived from a combination of genetically modified organisms, including therein genetically modified organisms as a product, as well as transboundary movement of genetically modified organisms and of products containing genetically modified organisms and/or consisting of or derived from a combination of genetically modified organisms, including therein genetically modified organisms as a product.

(2) Provisions of this Law shall apply to genetically modified organisms and combination of genetically modified organisms, and products containing genetically modified organisms and/or consisting of or derived from a combination of genetically modified organisms, including therein genetically modified organisms as a product obtained through techniques of genetic modification laid down in Article 4 of this Law.

Article 2

Objectives of this Law

The objectives of this Law are as under:

- to provide a high level of protection of human health and of the environment in the management of genetically modified organisms and combination of genetically modified organisms, and products containing genetically modified organisms and/or consisting of or derived from a combination of genetically modified organisms, including therein genetically modified organisms as a product;
- to define measures that provide monitoring and labelling of genetically modified organisms and combination of genetically modified organisms in all stages of their deliberate release into the environment;
- to preserve the biological diversity and to control the risks through deliberate release into the environment of genetically modified organisms and combination of genetically modified organisms; and
- to guarantee an adequate level of protection in the field of safe transport (import, export and transit), handling and use of genetically modified organisms

and combination of genetically modified organisms, and products containing genetically modified organisms and/or consisting of or derived from a combination of genetically modified organisms, including therein genetically modified organisms as a product, especially in transboundary movement.

Article 3

Definitions

Some of the phrases used in this Law have the following meaning:

1. **“living organism”** means any biological entity capable of replication or of transferring genetic material;
2. **“living genetically modified organism”** means any living organism possessing an unusual combination of genetic material obtained by means of biotechnology and is capable of reproduction;
3. **“genetic material”** means a part of plant, animal, fungus, microorganism or virus containing heritable information;
4. **“microorganism”** means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including therein the viruses, viroids, cultures of animal and of plant cells;
5. **“genetic modification”** means deliberate, induced alteration of the heritable genetic material of an organism, in a way that does not occur naturally through the processes of mating and/or natural recombination;
6. **“genetically modified organism”** (hence forward: GMO) means any organism including any microorganism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally through the processes of mating and/or natural recombination. A combination of GMO shall also be regarded as GMO;
7. **“genetically modified microorganism”** (hence forward: GMMO) means any microorganism in which the genetic material has been altered in a way that does not occur naturally through the processes of mating and/or natural recombination;
8. **“contained use of GMO”** means any operation undertaken to alter GMO or to cultivate, keep, utilize, transport, destroy and/or eliminate thus altered GMO or use them in any way, whereby physical barriers or combination of physical barriers are used, including chemical and/or biological barriers, with the purpose of limiting the contact with the population and the environment;
9. **“accident”** means any incident/inconvenience that involves significant and undeliberate release of GMO in the course of their contained use that may pose immediate or delayed hazard to human health and life and to the environment;
10. **“deliberate release into the environment of GMO”** means deliberate introduction into the environment of GMO whereby no special control measures are used to limit their contact with the environment and people and to provide high level of safety for the people and for the environment;
11. **“placing on the market”** means the procedure with which products containing genetically modified organisms and/or consisting of or derived from a combination of genetically modified organisms, including therein genetically modified

organisms as a product, are made available to third parties, whether in return for payment or free of charge;

12. **“genetically modified product”** means preparation consisting of or containing GMO or is a combination of GMO, that has been placed on the market (hence forward: GMO product);
13. **“immediate effect”** means direct or indirect effect on human health or on the environment that can be detected after the release into the environment of GMO or placing on the market thereof;
14. **“cumulative long-term effects”** means the total accumulated effects from the contained use of GMO or from the deliberate release into the environment of GMO on human health, including therein, inter alia, flora, fauna, soil fertility, degradation of organic material in the soil, food chain, biological diversity and animal health.
15. **“level of restriction”** means the sum of safety measures for protection of human health and of the environment with the purpose to reduce to the lowest level possible the contact between people and the environment on the one hand and GMO on the other in the course of contained use;
16. **“user”** means any legal or physical entity responsible for the contained use of GMO;
17. **“notification”** means submission to the competent authority of documents containing the necessary information with the purpose of approval of activities laid down in this Law;
18. **“notifier”** means the person submitting the notification;
19. **“environmental risk assessment”** means the evaluation of direct or indirect, immediate or delayed risks to human health and to the environment that may be caused by the deliberate release into the environment of GMO, contained use of GMO or placing on the market of GMO products;
20. **“monitoring of the situation”** means systematic monitoring and supervision of GMO in the course of contained use of GMO, deliberate release into the environment of GMO and/or placing on the market of GMO products, as well as evaluation of possible adverse effects on human health and on the environment;
21. **“transboundary movement of GMO and GMO products”** means import, export or transit of GMO or GMO products from one country to another country or countries;
22. **“case-by-case environmental risk assessment”** means the evaluation of direct or indirect, immediate or delayed risks to human health and to the environment that is carried out before the deliberate release into the environment of GMO whereby the potential cumulative risk arising from the interaction with other GMO released into the environment is taken into consideration;
23. **“Secretariat to the Protocol”** means the Secretariat established under the Cartagena Protocol on Biosafety;
24. **“competent authority”** means the civil service body competent to execute the operations relating to the environment;
25. **“Biosafety Clearing-House”** means the mechanism for exchange of information and experiences relating to GMO established under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity; and

26. **“competent authorities”** means the civil service bodies that take part in the decision making procedure for approval of activities relating to the management of GMO and GMO products laid down in this or other Laws.

Article 4

Techniques of Genetic Modification

(1) Genetic modification shall be carried out by means of genetic modification techniques:

1. recombinant nucleic acid techniques involving vector systems (in vitro creation of new combinations of genetic material by the insertion of nucleic acid molecules into a virus, bacterial plasmid or another vector system and their incorporation into the host organism in which they do not naturally occur, but in which they are capable of continued propagation);
2. techniques involving the direct introduction of an in vitro prepared heritable material into the organism, including the techniques of micro-injection, macro-injection and micro-encapsulation; and
3. cell fusion or hybridization techniques, where live cells with new combination of heritable material are formed through the fusion of two or more cells in a way that does not occur naturally.

(2) Following operations shall not be regarded as genetic modification, on the condition that they do not involve recombinant nucleic acid molecules or GMO as a starting material created by techniques other than those referred to in paragraph (1) of this Article:

1. in vitro fertilization;
2. natural processes, such as: conjugation (fusion of two cells), transduction (the process whereby DNA is transferred from one unicellular microorganism to another by using a virus), and transformation;
3. poliploidy induction; and
4. tissue culture.

Article 5

Exemptions from the Application of this Law and Application of other Laws and Regulations

(1) Provisions of this Law shall not apply to GMO obtained through techniques of genetic modification referred to in Article 4 paragraph (1) of this Law and/or when using recombinant nucleic acids created by:

- mutagenesis;
- cell fusion, including therein protoplast fusion, of prokaryotic species that can exchange the heritable material through known physiological processes;
- cell fusion, including therein protoplast fusion, of cells of any eukaryotic species, including therein the production of hybridomas and plant cell fusion;
- creation and use of somatic, animal hybrid cells (i.e. production of monoclonal antibodies); and

- autocloning, or deletion of a sequence from a nucleic acid of a cell in the organism, with subsequent insertion of that sequence (or part of the sequence) into cells of organisms of the same species or cells of phylogenetically close species that can exchange the heritable material also by natural, physiological processes, whereby thus created organism (microorganism) is of proven safety, without adverse effects to human health and to the environment.

(2) Transportation of GMO by rail, road, air, and waterway shall be carried out in accordance with the international agreements on transport of hazardous substances ratified by the Republic of Macedonia.

(3) Provisions of this Law relating to placing on the market of GMO and GMO products and transboundary movement of GMO and of GMO products, shall not apply to:

- pharmaceutical products used in human and veterinary medicine, containing GMO or consisting of GMO, or of combination of GMO; and
- food and food ingredients used for production, manufacture, processing and preparation of food used for human consumption, containing and/or consisting of GMO, or a combination of GMO, placing on the market, import and export.

(4) The Law on General Administrative Procedure shall apply to the procedures laid down in this Law unless they are otherwise regulated by this Law.

II PRINCIPLE OF PROTECTION OF THE ENVIRONMENT

Article 6

Principle of Integrity

Foundations and objectives of the policy on management of GMO and GMO products, as well as measures for prevention and reduction of possible adverse effects on human health and on the environment shall have to be integrated in all strategic, planning and program documents in the fields of finances, education, health, research and development adopted by the competent national authorities.

Article 7

Principle of Precaution

GMO and GMO products may be used in a contained manner, deliberately released and placed on the market in accordance with the provisions of this Law. Competent authorities, in accordance with precautionary principle, shall have to provide for the undertaking of adequate measures so as to avoid the possible adverse effects on human health and on the environment that may arise from the contained use of GMO, deliberate release of GMO or placing on the market of GMO products.

Article 8

Principle of Liability and the Perpetrator-Pays Principle

(1) The entity executing operations relating to contained use of GMO, deliberate release into the environment of GMO and placing on the market of GMO products shall be

obliged to compensate for the costs for removal of the hazard and the costs for sanitation of the consequences from the adverse effects from the management of GMO.

(2) Legal or physical entity executing operations relating to contained use of GMO, deliberate release into the environment of GMO and placing on the market of GMO products shall be obliged to pay compensation proportionate to the damage inflicted in accordance with the general provisions on damage compensation.

Article 9

Principle of Risk Assessment

(1) Risk assessment of the potential adverse effects on human health and on the environment that may arise from gene transfer from GMO into other organisms is carried out on case by case basis in accordance with provisions of this Law taking into consideration the nature of the organism in which the insertion is taking place and the environment receiving it.

(2) During the risk assessment of GMO containing genes that show resistance to antibiotics and are used for medical treatment of people or for veterinary treatment of animals special attention shall be paid to identification and exclusion of GMO that may pose undesired effects on human health and on the environment.

III GENERAL OBLIGATIONS

Article 10

Compulsory Measures of Protection

(1) If it is not possible to determine the legal or physical entity executing operations relating to contained use of GMO, deliberate release into the environment of GMO and/or placing on the market of GMO products, the competent authorities of Article 3 paragraph (1) point 26, in accordance with their competences, shall be obliged to undertake all the necessary measures for prevention or removal of the adverse effects in accordance with this and other Laws.

(2) If the legal or physical entity of paragraph (1) of this Article is identified afterwards, this entity shall be obliged to compensate the costs that have arisen from undertaking the measures for prevention and/or removal of the adverse effects of paragraph (1) of this Article.

Article 11

Access to Information

Civil service bodies possessing information about GMO and GMO products shall be obliged to make this information available to the public, and inform the public about their impact on human health and on the environment, of the damages inflicted and the measures undertaken for the removal of the adverse effects, in accordance with the provisions of this Law and the Law on Environment.

Article 12

Consultation of and Information to the Public

(1) The civil service body competent to execute the operations relating to the environment, with regards to the notifications for obtaining consent for contained use of GMO, notifications for obtaining consent for deliberate release into the environment of GMO, and notification for obtaining consent for placing on the market of GMO products, shall be obliged, within five days of receipt of the complete notification, to publish a summary thereof on its internet site and in two daily newspapers available on the entire territory of the Republic of Macedonia on the account of the user i.e. the notifier.

(2) The published summary of paragraph (1) of this Article shall also include information about the location where the data from the notification can be accessed.

(3) The public and civil associations may submit their opinion about the notification of paragraph (1) of this Article to the civil service body competent to execute the operations relating to the environment within 30 days of the publication.

(4) The civil service body competent to execute the operations relating to the environment shall be obliged to provide access to the public and to the civil associations to the data from the notification, including the emergency response plan, risk assessment on the environment, information related to the risk assessment, assessment report on GMO products, the opinion received by the Scientific Committee on GMO, the opinions received from other competent authorities, as well as other information accompanying the notification.

(5) The layout and the contents of the form of the published summary of paragraph (1) of this Article shall be proscribed by the Minister who runs the civil service body competent to execute the operations relating to the environment.

(6) The manner and the procedure for participation of the public in granting consents for contained use of GMO, for deliberate release into the environment of GMO, for placing on the market of GMO products, as well as other information related to the use of GMO, shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment.

(7) When granting the consent for contained use of GMO, consent for deliberate release into the environment of GMO and/or consent for placing on the market of GMO products, the civil service body competent to execute the operations relating to the environment shall take into consideration the timely submitted opinions and comments.

(8) When granting the consents of paragraph (7) of this Article the time period fixed for granting the consents shall not take into account the time periods required to consult the public of paragraph (3) of this Article.

Article 13

Reporting

(1) Competent authorities involved in the procedure for granting the consents that allow the use of GMO or GMO products under this or another Law shall once a year submit report to the civil service body competent to execute the operations relating to the environment and to the Commission for Management of GMO.

(2) The report of paragraph (1) of this Article shall include the information about the number of granted consents relating to GMO and GMO products, the number of rejected notification relating to GMO and GMO products, as well as the reasons for rejections thereof.

(3) Authorities of paragraph (1) of this Article shall be obliged to submit the last year's report no later than 30 January of the current year.

IV CONTAINED USE OF GMO

Article 14

Classes

(1) The civil service body competent to execute the operations relating to the environment shall be obliged to undertake all the necessary measures so as to avoid the negative impact on human health and on the environment that may result from the contained use of GMO.

(2) Contained use of GMO may be carried out by a legal or physical entity, scientific and research institution and/or higher education institution as long as they have received consent for contained use of GMO in accordance with Articles 16, 18 and 19 of this Law.

(3) The user shall be obliged to carry out a risk assessment from the contained use of GMO on human health and on the environment that may be caused by the contained use of GMO, in accordance with Article 15 of this Law.

(4) Based on the assessment of paragraph (3) of this Article, the contained use of GMO shall be classified in four classes to which procedures defined in Article 15 of this Law shall apply, as follows:

- class 1, operations of insignificant risk, for which level one safety is adequate for protection of human health and of the environment;
- class 2, operations of low risk, for which level two safety is adequate for protection of human health and of the environment;
- class 3, operations of moderate risk, for which level three safety is adequate for protection of human health and of the environment; and
- class 4, operations of high risk, for which level four safety is adequate for protection of human health and of the environment.

(5) Based on the classification of paragraph (4) of this Article minimum requirements and necessary measures shall be defined to be undertaken for each class of contained use of GMO separately in accordance with the provision of Article 15 paragraph (9) of this Law.

Article 15

Risk Assessment

(1) Before starting the contained use of GMO, as well as during the contained use of GMO, the user shall be obliged to provide risk assessment of the planned and the applied use of GMO.

(2) Based on the analysis of the characteristics of GMO, the risk assessment shall necessarily define the possible adverse effects on human health and on the environment, risk level and the necessary limitations, safety measures for protection of human health and of the environment, as well as measures necessary for the management of wastes, drainage and wastewaters which result from the contained use.

(3) Limitations and safety measures shall be defined adequately, so as to make sure that the exposure to GMO at work place and in the environment is reduced to the minimum reasonable level with the purpose of providing the highest level of safety.

(4) Based on the risk assessment the user shall classify the contained use in one of the classes referred to in Article 14 paragraph (4) of this Law.

(5) If the user is not certain where to classify the contained use, the contained use shall be classified in the class of stricter protection measures in agreement with the civil service body competent to execute the operations relating to the environment.

(6) The user shall be obliged to provide risk assessment for all operations relating to the use of GMO.

(7) During the application of the contained use of GMO, the user shall obligatorily make revisions of the risk assessment, limitations and safety measures, at least once a year, whereby he shall in particular verify whether:

- the class defined is adequate to the risk from the use of GMO;
- limitations and safety measures applied are adequate to the risk from the use of GMO; and
- there is a credible reason to doubt that the risk assessment is no longer adequate, taking into consideration the new scientific accomplishments and knowledge.

(8) The user shall be obliged to inform the civil service body competent to execute the operations relating to the environment about every change of the risks relating to class 2, 3 and 4.

(9) The methodology and the elements of the assessment, the parameters, the minimum criteria and requirements that have to be taken into consideration when carrying out the assessment, the assessment procedure, as well as the limitations and safety measures, including therein other technical conditions for each class separately, if this is necessary to provide protection of human health and of the environment, in accordance with the species of the organism, the environment and facilities where the GMO is intended to be used, shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment in agreement with the Minister who runs the civil service body competent to execute the operations relating to health and the Minister who runs the civil service body competent to execute the operations relating to agriculture and forestry.

Article 16

Notification for Facility

(1) Contained use of GMO shall be carried out in a closed facility or in a separate facility (hence forward: facility) that fulfils the conditions prescribed for the class where the operations are executed, in accordance with Article 14 of this Law.

(2) Before starting to use the facility for contained use of GMO, the user shall submit to the civil service body competent to execute the operations relating to the environment a notification with the necessary information.

(3) The civil service body competent to execute the operations relating to the environment shall grant a consent for use of the facility within 90 days of receipt of the complete notification, upon previously received opinion by the Scientific Committee on GMO of Article 64 of this Law.

(4) If the civil service body competent to execute the operations relating to the environment finds out that the notification does not include all the necessary requirements, it shall ask the user to complement the notification within a defined period of time not exceeding 30 days.

(5) The time period of paragraph (3) of this Article shall not take into account the additionally given period of time of paragraph (4) of this Article.

(6) Upon complementing the notification, the civil service body competent to execute the operations relating to the environment shall circulate the notification to the Scientific Committee on GMO.

(7) The Scientific Committee on GMO shall be obliged to submit their opinion to the civil service body competent to execute the operations relating to the environment within 30 days of receipt of notification.

(8) Upon receipt of the opinion of paragraph (7) of this Article, the civil service body competent to execute the operations relating to the environment, within the time period of paragraph (3) of this Article, shall grant a consent for use of the facility or shall take a decision to reject the notification.

(9) Consent for use of the facility as well as the facility where the contained use of GMO will be carried out shall be recorded in the register of GMO.

(10) If after the submission of the notification of paragraph (1) of this Article new information becomes available to the user that can seriously affect the human health and/or environment, or classify the contained use of GMO in a new class, the user shall be obliged immediately, and within 24 hours the latest, to inform thereof the civil service body competent to execute the operations relating to the environment.

(11) The layout and the contents of the form of notification for contained use of GMO, as well as the information that the user has to provide when submitting the notification of paragraph (2) of this Article when the notification is submitted for the facility where GMO will be used for the first time and separately for each class of contained use of GMO, shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment.

(12) The standards that have to be fulfilled for the facility for contained use of GMO, depending on the risk level, shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment in agreement with the Minister who runs the civil service body competent to execute the operations relating to agriculture and forestry and Minister who runs the civil service body competent to execute the operations relating to health, for each class of contained use of GMO, whereby the species of the organism will obligatorily be taken into consideration and the environment where the organism is intended to be released.

(13) The user shall be obliged to keep the information from the risk assessment and from the notification as information of permanent value and submit it to the competent authorities upon request.

(14) The user shall be obliged to compensate the real costs made to the civil service body competent to execute the operations relating to the environment, including therein the costs for the work of the Scientific Committee on GMO in the procedure of granting consent of Article 16, 18 and 19 of this Law.

(15) The amount of costs of paragraph (14) of this Article shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment.

(16) The user shall be obliged to pay in the costs of paragraph (15) of this Article to the bank account of the civil service body competent to execute the operations relating to the environment within eight days from the day of submission of notification, based on a decision for the costs made.

(17) The user has the right to file a complaint for a lawsuit in administrative dispute before the court of jurisdiction against the consent or the decision of paragraph (8) of this Article.

Article 17

Class 1 of Contained Use of GMO

(1) Contained use of GMO class 1 may start without additional notification if it takes place in facilities that have previously been granted consent in accordance with Article 16 of this Law, and the user shall inform in writing the civil service body competent to execute the operations relating to the environment thereof.

(2) The user shall be obliged to carry out a risk assessment in accordance with Article 15 of this Law and keep the data relating to it.

(3) Upon request by the civil service body competent to execute the operations relating to the environment the user shall be obliged to submit the data of paragraph (2) of this Article.

Article 18

Class 2 of Contained Use of GMO

(1) Notification for contained use of GMO class 2 that will take place in facilities that have been granted consent in accordance with Article 16 of this Law shall be submitted to the civil service body competent to execute the operations relating to the environment in accordance with Article 16 paragraph (10) of this Law.

(2) The civil service body competent to execute the operations relating to the environment shall be obliged to grant consent for contained use of GMO class 2 within 45 days of receipt of complete notification.

(3) Upon completion of the notification, the civil service body competent to execute the operations relating to the environment shall circulate the notification to the Scientific Committee on GMO of Article 64 of this Law, who shall then be obliged to submit their written opinion within 21 days of receipt of notification.

(4) If the civil service body competent to execute the operations relating to the environment finds out that the notification fails to contain the requirements of Article 16 of this Law or finds out that additional information is required to be able to take a decision about the notification, it shall ask the user to complement the notification within a defined period of time that cannot be shorter than seven days nor exceed 30 days.

(5) The time period of paragraph (2) of this Article shall not take into account the additionally given time period of paragraph (4) of this Article.

(6) If the facility to be used has previously been granted consent for contained use of GMO for class 2 or higher class, and all requirements specified in the notification and relating to the contained use of GMO have been fulfilled, the contained use of GMO class 2 may start immediately after the submission of notification.

(7) If the facility to be used has previously not been granted consent for contained use of GMO for class 2 or higher class, contained use of GMO class 2 may start only after the time period of paragraph (2) of this Article, in case the civil service body competent to execute the operations relating to the environment has not requested additional information in accordance with paragraph (4) of this Article.

(8) In case of paragraph (7) of this Article contained use of GMO class 2 may start even sooner based on a written approval by the civil service body competent to execute the operations relating to the environment.

(9) Upon receipt of the opinion of paragraph (3) of this Article, the civil service body competent to execute the operations relating to the environment, within the defined time period of paragraph (2) of this Article, shall grant consent for contained use of GMO class 2 or takes a decision to reject the notification.

(10) The user has the right to file a complaint for a lawsuit in administrative dispute before the court of jurisdiction against the consent or the decision of paragraph (9) of this Article.

Article 19

Class 3 and 4 of Contained Use of GMO

(1) Notifications for contained use of GMO class 3 or class 4 that will take place in facilities that have been granted consent in accordance with Article 16 of this Law, shall be submitted to the civil service body competent to execute the operations relating to the environment in accordance with Article 16 paragraph (10) of this Law.

(2) The civil service body competent to execute the operations relating to the environment shall be obliged to grant consent for contained use of GMO class 3 or class 4 within 90 days of receipt of the complete notification.

(3) Upon completion of notification, the civil service body competent to execute the operations relating to the environment shall circulate the notification to the Scientific Committee on GMO, who shall then be obliged to submit their written opinion within 30 days of receipt of notification.

(4) If the civil service body competent to execute the operations relating to the environment finds out that the notification fails to contain the requirements prescribed in accordance with Article 16 of this Law or finds out that additional information is required for taking the decision about the notification, it shall ask the user to complement the notification within a defined period of time that cannot be shorter than seven days nor exceed 45 days.

(5) The time period of paragraph (3) of this Article shall not take into account the additionally given time period of paragraph (4) of this Article.

(6) If the facility to be used has previously been granted consent for contained use of GMO for class 3 or higher class, and all requirements specified in the consent and relating to the contained use of GMO have been fulfilled, contained use of GMO class 3 or class 4 may start within 45 days of the receipt of the notification only based on a written approval given by the civil service body competent to execute the operations relating to the environment.

(7) Upon receipt of the opinion of paragraph (3) of this Article, the civil service body competent to execute the operations relating to the environment, within the time period of paragraph (2) of this Article, shall grant consent for contained use of GMO class 3 or class 4 or for class 3 and class 4 or shall take a decision to reject the notification.

(8) The user has the right to file a complaint for a lawsuit in administrative dispute before the court of jurisdiction against the consent or the decision of paragraph (7) of this Article.

Article 20

Emergency Response Plan

(1) Annexed to the notification for contained use of GMO, the user shall be obliged to enclose an emergency response plan, which will in particular include:

- risk assessment for the environment and for human health and possible consequence in case of accident;
- protection measures to be undertaken, in particular the equipment for protection, the alarming system and measures for prevention or reduction of consequences of accident;
- procedures and efficiency assessment plan for limitations and safety measures;
- procedures and efficiency assessment plan for the equipment for protection, the alarming system and measures for prevention or reduction of consequences in case of accident;
- description of instructions to be submitted to the people who operate the contained use of GMO;
- declaration for measures for removal of the risk and for immediate and delayed consequences from the accident;
- declaration for the people and competent authorities that will be involved in the undertaking of the measures laid down in the plan; and
- method and volume of information provision and warning the competent authorities, bodies, services and the population in case of accident.

(2) In the procedure of approving the notification, the civil service body competent for the execution of the operations relating to the environment shall circulate the emergency response plan to the Scientific Committee on GMO of Article 64 of this Law.

(3) The civil service body competent to execute the operations relating to the environment shall be obliged to make the emergency response plan available to the authorities of another country that may be concerned with the contained use of GMO, in accordance with principal of reciprocity or as part of bilateral agreements ratified by the Republic of Macedonia.

(4) The user shall at least once a year revise the adequacy of the emergency response plan and shall accordingly make amendments and/or complements if necessary. The user shall be obliged to submit all the amendments and complements in the emergency response plan to the civil service body competent to execute the operations relating to the environment for approval.

Article 21

Confidentiality of Data

(1) In the notification for contained use of GMO the user can indicate which data represent confidential trade or industrial information, data protected as intellectual property and/or protected in accordance under the law, with adequate justification.

(2) The civil service body competent to execute the operations relating to the environment, based on consultations with the user, shall within 15 days of receipt of notification take decision which data are to be considered confidential and not become the subject of public access.

(3) The notifier cannot request that the following data be considered confidential:

- general characteristics of GMO;
- the name and the address of the notifier;
- location of the facility where the contained use of GMO will take place;
- class of contained use;
- limitations and safety measures;
- information about possible adverse and other effects on the environment and on human health; and
- other information necessary for the risk assessment, especially of the hazard on human health and on the environment.

(4) The civil service body competent to execute the operations relating to the environment and the members of the Scientific Committee on GMO must not reveal to third parties the data considered confidential in accordance with paragraph (2) of this Article.

(5) The data considered confidential shall remain permanently confidential even upon withdrawal of the notification by the notifier, regardless of the reasons for the withdrawal thereof.

Article 22

Additional Requirements

(1) In the course of implementation of the procedures of Articles 16, 17, 18 and 19 of this Law, the civil service body competent to execute the operations relating to the environment and the Scientific Committee on GMO of Article 64 of this Law shall be obliged to verify the credibility of the information contained in the notification, its precision and completeness, the accuracy of the risk assessment and class of contained use of GMO, the adequacy of the limitations and safety measures, as well as the proposed measures for waste management and measures foreseen by the emergency response plan.

(2) In the course of implementation of the procedures of Articles 16, 17, 18 and 19 of this Law, the civil service body competent to execute the operations relating to the environment may ask the user:

- to submit additional information;
- to modify the conditions for carrying out the proposed contained use of GMO;
- to change the class for contained use of GMO;
- to limit the time fixed for the contained use of GMO; and/or
- to subject the contained use of GMO to specific conditions.

(3) In the cases of paragraph (1) indents 1, 2 and 3 of this Article the civil service body competent to execute the operations relating to the environment may ask that the proposed contained use not be started, and/or if it is ongoing, be restricted and/or be temporarily stopped until the civil service body competent to execute the operations relating to the environment grants consent based on the additional information submitted or on the modified conditions for carrying out the contained use of GMO.

(4) If the user fails to comply in accordance with the requirements of paragraph (3) of this Article, the civil service body competent to execute the operations relating to the environment shall take a decision to reject the notification.

(5) The user has the right to file a complaint for a lawsuit in administrative dispute before the court of jurisdiction against the decision of paragraph (4) of this Article.

(6) The time period required for granting consent in accordance with Articles 16, 17, 18 and 19 of this Law shall not take into account the time period required to complement the notification.

Article 23

New Information

(1) If the user acquires new information or changes the contained use of GMO in a way that may inflict significant consequences on the risk of contained use of GMO or changes the class of contained use of GMO, the user shall then be obliged immediately, and within 24 hours the latest, to inform the civil service body competent to execute the operations relating to the environment, and ask, in accordance with Article 16, 17, 18 and 19 of this Law, that the notification be modified.

(2) If the civil service body competent to execute the operations relating to the environment receives new information that may inflict significant consequences on the risk level and/or change of class of contained use of GMO, the civil service body competent to execute the operations relating to the environment may ask the user to modify the conditions for contained use of GMO, or to temporarily stop or restrict the contained use of GMO.

(3) In the cases of paragraph (1) and (2) of this Article, the civil service body competent to execute the operations relating to the environment shall be obliged to ask the user to temporarily stop or restrict the contained use of GMO until a consent is granted upon new notification and/or to modify the conditions for contained use of GMO.

(4) If, based on the new information about contained use of GMO or on the modifications in operations that can significantly influence the risk level, the civil service body competent to execute the operations relating to the environment decides that the contained use GMO can no longer be carried out, it shall take a decision to prohibit the contained use GMO.

(5) The user has the right to file a complaint for a lawsuit in administrative dispute before the court of jurisdiction against the decision of paragraph (4) of this Article.

Article 24

Accidents

(1) In case of accident during the contained use of GMO the user shall be obliged immediately, and within 24 hours the latest, to inform the civil service body competent to execute the operations relating to the environment about:

- the circumstances under which the accident has occurred;
- the species and the quantity of GMO involved in the accident;
- the measures undertaken and their efficiency; and
- other information necessary for the assessment of consequences from the accident and their impact on human health and on the environment.

(2) When the information is submitted in accordance with paragraph (1) of this Article, the civil service body competent to execute the operations relating to the environment shall be obliged to:

- undertake or order the undertaking of all necessary measures, and if there is transboundary impact to immediately inform the state concerned; and
- collect all the necessary information required for a complete analysis of the accident and if adequate propose measures for limitation of the effects from the accident and for evasion of similar accidents in the future.

(3) The operations of paragraph (2) of this Article shall be executed by the civil service body competent to execute the operations relating to the environment on the expense of the user who was responsible for the contained use of GMO where the accident had occurred.

Article 25

Transboundary Impact

(1) The civil service body competent to execute the operations relating to environment in case of transboundary impacts from contained use of GMO shall be obliged to:

- carry out consultations with the concerned country(ies) and in case of accident based on emergency response plan of Article 20 of this Law; and
- inform the country(ies) about the accident occurred, providing details about the circumstances under which the accident had occurred, the species and the quantity of GMO, the measures undertaken and their efficiency, and analysis of the accident, including recommendations for limitation of the effects and evasion of similar accidents in the future.

(2) The civil service body competent to execute the operations relating to environment shall prepare a report on the measures undertaken and their efficiency within three months of the start of the operations prescribed by the emergency response plan.

(3) The civil service body competent to execute the operations relating to the environment shall submit the report of paragraph (2) of this Article to the Government of the Republic of Macedonia for approval and without delay shall inform the public about it in accordance with Article 12 of this Law.

(4) The civil service body competent to execute the operations relating to environment shall keep a register of accidents related to contained use of GMO.

V DELIBERATE RELEASE INTO THE ENVIRONMENT OF GMO AND PLACING ON THE MARKET OF GMO PRODUCTS

Article 26

General Obligations

(1) Every legal or physical entity before carrying out deliberate release into the environment of GMO (hence forward: deliberate release of GMO), as well as placing on the market of GMO products shall be obliged to submit notification to the civil service body competent to execute the operations relating to the environment.

(2) Every legal or physical entity before submitting the notification of paragraph (1) of this Article must carry out a risk assessment on the environment in accordance with provisions of this chapter.

(3) The risk assessment of paragraph (2) of this Article shall in particular contain:

- general information about the notifier and the scientists who made the risk assessment;
- information about GMO, their characteristics, characteristics of the donor, the recipient and the parent organism, characteristics of the vector, and the modified organism;
- information about the conditions for the release and the environment where the release takes place;
- information about the interaction between the GMO and the environment; and
- other information necessary for the risk assessment on the environment.

(4) The approval of the risk assessment on human health and on the environment is carried out following the principle of risk assessment, in accordance with provisions of this chapter.

(5) More details about the contents, quantity and methodology of the risk assessment on the environment, adequate to the character of the GMO and the environment, shall be prescribed by the Government of the Republic of Macedonia on a proposal by the Minister who runs the civil service body competent to execute the operations relating to the environment.

Article 27

Definition of Placing on the Market of GMO Products

(1) Placing on the market of GMO products shall not include the placing on the market of:

- GMO approved for contained use in accordance with Chapter IV of this Law;
- GMO made available, with the exception of GMO of indent (1) of this paragraph, that are used exclusively for operations where adequately strict control measures are undertaken so as to limit their contact with the population and with the environment and to provide a higher level of safety, approved in accordance with the provisions of 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) GMO of paragraph (1) of this Article shall be labeled and packaged in accordance with the consent which approves the use thereof, whereby the information that GMO is contained therein shall obligatorily be placed on the package or on the accompanying

documentation, and as a minimum the following shall obligatorily be indicated: "This product contains genetically modified organisms".

Article 28

Additional Information

(1) In the procedures of granting consent for deliberate release of GMO and consent for placing on the market of GMO products the civil service body competent to execute the operations relating to the environment may ask the notifier to submit additional information within a defined time period, whereby the reasons for the request for the additional information shall obligatorily be stated.

(2) If the notifier fails to complement the notification within the defined time period, the civil service body competent to execute the operations relating to the environment shall discontinue the procedure for granting consent of paragraph (1) of this Article.

Article 29

Prohibitions

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

(2) The GMO that are prohibited for deliberate release into the environment and/or for placing on the market as GMO products shall be specified by the Government of the Republic of Macedonia on proposal by the Minister who runs the civil service body competent to execute the operations relating to the environment in agreement with the Minister who runs the civil service body competent to execute the operations relating to agriculture and forestry and with the Minister who runs the civil service body competent to execute the operations relating to health.

Article 30

Safeguard Clause

(1) If for a particular GMO or GMO product that has been adequately notified and for which consent has been granted in accordance with the provisions of this Law the received new or additional information provide credible reason to consider it a risk on human health and on the environment, the Minister who runs the civil service body competent to execute the operations relating to the environment in agreement with Minister who runs the civil service body competent to execute the operations relating to agriculture and forestry and with the Minister who runs the civil service body competent to execute the operations relating to health shall temporarily restrict or prohibit the use and/or sales of that GMO or GMO product on the territory of the Republic of Macedonia.

(2) In the cases of paragraph (1) of this Article if a more serious risk on human health and on the environment is inflicted, the civil service body competent to execute the operations relating to the environment in cooperation with the civil service body competent to execute the operations relating to agriculture and forestry and the civil service body competent to execute the operations relating to health shall undertake emergency measures for withdrawal of GMO or GMO product from the market and shall inform the public thereof in accordance with Article 12 of this Law.

Article 31

Area for GMO and Protected Zones

(1) Areas of land where genetically modified reproductive material cannot be released shall be defined by the Government of the Republic of Macedonia on proposal by the Minister who runs the civil service body competent to execute the operations relating to the environment, after having obtained the opinion by the Minister who runs the civil service body competent to execute the operations relating to agriculture and forestry.

(2) It shall not be allowed to release GMO in nature, in particular in protected areas and areas of ecological network, ecologically clean areas, areas designated for production of organic products, areas designated for ecological tourism, as well as areas declared as protected zones under the law.

(3) Protected zones are the surrounding areas that prevent the spread of GMO into areas that are not allowed for the deliberate release into the environment of GMO of paragraph (2) of this Article.

(4) The size of the protected zones of paragraph (3) of this Article for particular species of genetically modified reproductive material shall be defined by the Government of the Republic of Macedonia on proposal by Minister who runs the civil service body competent to execute the operations relating to the environment defined in agreement with the Minister who runs the operations relating to agriculture and forestry.

Article 32

Joint Cooperation

(1) The civil service bodies, public institutions, scientific and research institutions, educational institutions, the Commission on Management of GMO of Article 62 of this Law, the Scientific Committee on GMO of Article 64 of this Law, including therein the Macedonian Academy of Sciences and Arts, relevant scientific and ethic committees operating in the Republic of Macedonia, shall be obliged to cooperate with one another as well as to exchange information relating to the risk assessment of GMO on human health and on the environment, with the purpose of making sure that the use of GMO and GMO products in the Republic of Macedonia is carried out in a way that enables prevention and reduction of the risk on human health and on the environment.

(2) If the civil service body competent to execute the operations relating to the environment in the procedure of granting consent under this Law finds out that it is necessary to make consultations with some of the entities of paragraph (1) of this Article, these entities shall be obliged to give their opinion in the shortest time period possible, not later than 45 days of receipt of such a request.

(3) The entities of paragraph (2) of this Article, who have been consulted in the procedure of granting consent under this Law, shall be obliged to permanently keep and not disclose to third parties the information which have been specified in the notification as confidential.

(4) The civil service body competent to execute the operations relating to the environment, in the procedure of granting consent under this Law, may make consultations with authorities competent to grant consent relating to GMO and GMO products of other countries, as well as with scientific and educational institutions and committees, with the purpose of providing more detailed information about GMO and GMO products, especially if

these have been approved and used in that particular country, and this information may contribute in the decision making relating to GMO and/or GMO product.

(5) The civil service body competent to execute the operations relating to the environment shall be obliged, upon request by the authority of another country, to submit information relating to the use of GMO and GMO product in the Republic of Macedonia in accordance with international agreements ratified by the Republic of Macedonia.

Article 33

Confidentiality of Data

(1) The notifier may, by giving justification thereof, specify in the notification which data represent confidential trade and industrial data, data protected as intellectual property and/or protected under the law.

(2) The notifier can specify as confidential also the data which may hamper his competitiveness, whereby he shall be obliged to provide an adequate justification thereof.

(3) The notifier cannot specify as confidential the following data:

- the name and the address of the notifier and of the producer of GMO;
- description of GMO;
- the purpose of the release of GMO, the area where the release of GMO is taking place and the planned use of GMO;
- the method and the plan for monitoring of GMO and the emergency response plan; and
- any other data necessary for the risk assessment and the risk assessment itself;

(4) The civil service body competent to execute the operations relating to the environment within 15 days of receipt of notification, and after having made consultations with the notifier, shall define which information from the notification shall be protected as confidential and shall take a decision thereof.

(5) Data specified as confidential remain permanently protected even in the case of withdrawal of the notification by the notifier, regardless of the reasons for the withdrawal.

V.1 Deliberate Release into the Environment of GMO or Combination of GMO

Article 34

Deliberate Release of GMO

(1) Every notifier, before carrying out the deliberate release of GMO, must submit notification to the civil service body competent to execute the operations relating to the environment.

(2) Notification of paragraph (1) of this Article shall in particular contain:

1. technical documentation containing the information necessary for the carrying out of the risk assessment from the deliberate release of GMO adequate to the character of the introduced organism and the environment; and

2. risk assessment of Article (36) of this Law together with the information about the methods used and the conclusions deriving thereof.

(3) Technical documentation of paragraph (2) point 1 of this Article shall in particular contain:

- general information, including information about the personnel handling the GMO and their education and other qualifications;
- information about the GMO;
- information about the conditions for the release and the potential environment where the release is taking place;
- information about the interaction between GMO and the environment;
- monitoring plan with the purpose of detecting the effects of GMO on human health and on the environment;
- information about control together with the control plan, measures for sanitation and remediation, waste management plan;
- emergency response plan in case of undeliberate release of GMO in accordance with Article 38 of this Law; and
- summary of the technical documentation.

(4) The contents of the information of paragraph (3) of this Article shall more closely be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment.

(5) The notifier shall be obliged to compensate the real costs made to the civil service body competent to execute the operations relating to the environment, including therein the costs for the work of the Scientific Committee on GMO in the procedure of granting consent of Article 36 of this Law.

(6) The amount of the costs of paragraph (5) of this Article shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment.

(7) The notifier shall be obliged to pay in the costs of paragraph (5) of this Article to the bank account of the civil service body competent to execute the operations relating to the environment within eight days from the day of submission of the notification, based on a decision for the costs made.

(8) The civil service body competent to execute the operations relating to the environment may accept that the notifier submits one notification for release into the environment of the same GMO or combination of GMO in the same area or in a different area, but intended for the same purpose.

Article 35

Consent for Deliberate Release of GMO

(1) The civil service body competent to execute the operations relating to the environment, within 90 days of receipt of the complete notification, shall grant consent for deliberate release into the environment of GMO (hence forward: consent for deliberate release of GMO), which confirms that conditions have been met for deliberate release of GMO, or shall take a decision to reject the notification if conditions have not been met for deliberate release of GMO.

(2) The civil service body competent to execute the operations relating to the environment shall be obliged, within 15 days of receipt of the complete notification, to circulate one copy to the Scientific Committee on GMO.

(3) The Scientific Committee on GMO shall be obliged, within 45 days of receipt of the notification of paragraph (2) of this Article, to submit written opinion for notification to the civil service body competent to execute the operations relating to the environment.

(4) If the Scientific Committee on GMO and the civil service body competent to execute the operations relating to the environment consider that the notification is incomplete and based on the submitted documentation it is not possible to determine what the impact can be from the deliberate release of GMO on human health and on the environment, they may ask the notifier to submit additional information.

(5) The time period laid down in paragraph (1) of this Article shall not take into the account:

- the time period when the submission of the additional information by the notifier was taking place; and/or
- the time period when the public debate or consultations in accordance with Article 12 of this Law was taking place.

(6) The time period of paragraph (5) indent 2 of this Article may not prolong the time period for granting consent laid down in paragraph (1) of this Article for more than 30 days.

(7) Upon receipt of the opinion of paragraph (3) of this Article, and within the time period of paragraph (1) of this Article, the civil service body competent to execute the operations relating to the environment shall grant consent for deliberate release of GMO.

(8) The consent for deliberate release of GMO shall be granted for the period requested by the notifier, but not longer than ten years.

(9) The notifier may start the deliberate release of GMO upon receipt of the consent for deliberate release of GMO and under the conditions required in the consent.

(10) Deliberate release of GMO shall be carried out in accordance with the consent for deliberate release of GMO.

(11) The material received from the deliberate release of GMO for which the consent for deliberate release of GMO has been granted may be placed on the market only in the case if consent has been granted for placing on the market of GMO products in accordance with provisions of this Law.

(12) The user has the right to file a complaint for a lawsuit in administrative dispute before the court of jurisdiction against the consent for deliberate release of GMO or the decision for rejection of the notification.

(13) The layout and the contents of the form of the consent for deliberate release of GMO shall be prescribed by the civil service body competent to execute the operations relating to the environment.

Article 36

Risk Assessment

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

(2) Based on the analysis of the characteristics of GMO and of their deliberate release in the nearest environment, as well as based on the analysis of the characteristics of the environment to be exposed to this risk, the risk assessment shall have to evaluate the adverse effects and possible consequences thereof, the risk level and the necessary measures for their control.

(3) The notifier may refer to the data or to the results from risk assessments from notifications that have previously been submitted by other notifiers, on the condition that the information, data and results are not confidential and a written approval has been provided for this from the notifier.

(4) In the case of paragraph (3) of this Article the notifier may also provide additional information that is considered relevant for the risk assessment.

(5) The risk assessment shall be carried out in accordance with the regulation adopted under the Article 26 paragraph (5) of this Law.

Article 37

Handling of Modified and New Information

(1) If, during the carrying out of deliberate release of GMO, intentional or unintentional modifications occur that may have consequences on the risk level on human health and on the environment, or if new information becomes available on such risks after granting consent for deliberate release of GMO or before granting but during the examination thereof by the civil service body competent to execute the operations relating to the environment, the notifier without delay:

1. shall undertake all the necessary measures for protection of human health and of the environment;
2. shall inform the civil service body competent to execute the operations relating to the environment about every modification in advance and/or shall inform about every unexpected modification he finds out about or learns new information about; and
3. shall submit notification with the purpose of revision of the conditions required in the consent for deliberate release of GMO.

(2) If the civil service body competent to execute the operations relating to the environment, after granting the consent for deliberate release of GMO, receives new information for the modifications of paragraph (1) of this Article, it shall be obliged to immediately ask the notifier to submit a notification with the purpose of making modifications in the conditions required in the consent for deliberate release of GMO.

(3) In the cases of paragraph (1) and (2) of this Article the civil service body competent to execute the operations relating to the environment shall be obliged to evaluate the information in cooperation with the Scientific Committee on GMO.

(4) In the cases of paragraphs (1) and (2) of this Article, and based on the assessment of paragraph (3) of this Article, the civil service body competent to execute the operations relating to the environment may, depending on the risk level on human health and on the environment, ask from the notifier to temporarily stop or restrict the deliberate release into the environment of GMO, until the consent is modified under the modified conditions.

(5) If based on the assessment of paragraph (3) of this Article it is found out that the new information or modifications of conditions referred to in paragraphs (1) and (2) of this

Article may inflict significant consequences on the risk level on human health and on the environment, because of which the deliberate release of GMO can no longer be carried out, the civil service body competent to execute the operations relating to the environment shall take a decision to prohibit the deliberate release of GMO.

(6) For the cases of paragraph (3), (4) and (5) of this Article the civil service body competent to execute the operations relating to the environment shall be obliged to inform the public in a way laid down in Article 12 paragraph (5) of this Law about the modification of the consent for deliberate release of GMO, the stopping thereof and/or the prohibition for deliberate release of GMO.

(7) In the procedure of complementing the consent of paragraph (1) provisions of Article 35 of this Law shall apply.

Article 38

Emergency Response Plan in Case of Undeliberate Release of GMO

(1) In the process of submission of the notification the notifier shall be obliged to submit an emergency response plan for the case of unexpected spread of GMO into the environment (hence forward: emergency response plan) to the civil service body competent to execute the operations relating to the environment.

(2) The emergency response plan shall in particular contain:

1. methods and procedures of control of GMO in case of undeliberate release into the environment of GMO;
2. methods for decontamination of the affected areas by the undeliberate release of GMO that eradicate or reduce the presence of GMO in those areas;
3. methods for removal or for disinfection of plants, animals, soil and things that have been affected during or after the undeliberate release of GMO;
4. methods for isolation of the area affected by the undeliberate release of GMO;
5. plans for protection of human health and of the environment in case of the occurrence of the undesired effect;
6. methods for assessment of the possible consequences and threats for the environment and for the human health;
7. measures necessary for the protection of the site of deliberate release of GMO; and
8. measures necessary for prevention of the further spreading of GMO.

(3) The notifier shall periodically verify the adequacy of the plan of paragraph (2) of this Article, but at least once a year, and as needs might be amend and/or complement the plan. The user shall be obliged to submit to the competent authority of paragraph (1) of this Article all the amendments and complements of the emergency response plan for approval.

(4) The contents of the emergency response plan shall in more detail be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment.

Article 39

Reporting

(1) The notifier shall be obliged to submit to the civil service body competent to execute the operations relating to the environment reports on all the risks on human health or on the environment resulting from the deliberate release of GMO, in particular:

- in periods as fixed in the consent for the contained use of GMO;
- within three months upon expiry of the period of validity of the consent;
- within three months upon completion of the deliberate release of GMO; and
- upon request by the civil service body competent to execute the operations relating to the environment.

(2) If the notifier of the deliberate release of GMO intends to submit a future notification for placing on the market of GMO products, he shall then be obliged to submit to the civil service body competent to execute the operations relating to the environment, and in accordance with paragraph (1) of this Article, special information relating to these products.

(3) The layout, the contents and the manner of submission of the report of paragraph (1) of this Article shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment.

Article 40

Undeliberate Release into the Environment of GMO

(1) In case of undeliberate release into the environment of GMO the notifier shall undertake measures in accordance with the emergency response plan of Article 38 of this Law and shall immediately inform the civil service body competent to execute the operations relating to the environment about:

1. the volume of the consequences from the undeliberate release into the environment of GMO and the threat it poses to the environment and to human health;
2. measures undertaken and additional measures to be undertaken for protection of the environment and of human health;
3. measures undertaken and additional measures to be undertaken for reduction or removal of the consequences from the undeliberate release of GMO into the affected area by the undeliberate release; and
4. other information relevant for the assessment of the effects on the environment and on human health caused by the undeliberate release of GMO.

(2) Based on the reporting of paragraph (1) of this Article, the civil service body competent to execute the operations relating to the environment in cooperation with the notifier shall prepare a program for removal of the consequences from the undeliberate release into the environment of GMO.

(3) The program for removal of the consequences from the undeliberate release into the environment of GMO shall be adopted by the Government of the Republic of Macedonia on proposal by the Minister who runs the civil service body competent to execute the operations relating to the environment.

(4) The program of paragraph (2) of this Article shall lay down the responsible authorities and bodies, measures for reduction of consequences and/or prevention of the further undeliberate release of GMO, time period for the preparation and implementation

thereof, manners for compensation of the costs and the necessary limitations and/or prohibitions related to the further deliberate release of GMO, import, trade or use.

(5) A report on the cases of paragraph (1) of this Article and on preparation and implementation of the program shall be prepared by the civil service body competent to execute the operations relating to the environment and submitted to the Government of the Republic of Macedonia for adoption, and the public shall without delay be informed thereof in accordance with Article 12 of this Law and in accordance with the Law on Environment.

(6) If the civil service body competent to execute the operations relating to the environment evaluates that the undertaken operations may have negative consequences on human health and on the environment on the territory of another country, it shall start a procedure to inform the competent authorities of the other country in accordance with principle of reciprocity and international conventions and agreements ratified by the Republic of Macedonia.

(7) The manner and the procedure for execution of the operations of paragraph (6) of this Article shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment in agreement with the Minister who runs the civil service body competent to execute the operations relating to foreign affairs.

V.2 Placing on the Market of GMO Products

Article 41

Placing on the Market of GMO Products

(1) Before placing on the market of GMO products for the first time in the Republic of Macedonia the notifier shall be obliged to submit notification to the civil service body competent to execute the operations relating to the environment.

(2) Notification of paragraph (1) of this Article shall in particular contain information about:

1. technical documentation necessary to carry out the risk assessment from placing on the market of GMO products, containing information in accordance with Article 34 paragraph (3) of this Law;
2. GMO products to be placed on the market;
3. conditions for placing on the market of GMO products together with the special conditions for use and for handling;
4. diversity of the areas where the GMO product will be used, which shall also include information about the data and the results obtained from the scientific and development releases relating to the effects that the placing on the market of GMO products has on human health and on the environment;
5. risk assessment of Article 26 paragraph (2) of this Law together with the data about the used methods and conclusions resulting from the assessment;
6. proposed period of time that the granting of consent for placing on the market of GMO product is requested for, which shall not exceed ten years;
7. plan for monitoring of GMO products with proposed time period during which the monitoring will be carried out, which shall also include period upon completion of the consent for placing on the market of GMO products;

8. proposal for labeling and for packaging of GMO products for which the consent for placing on the market of GMO product is requested for, which contains all the information in accordance with Article 50 of this Law; and
9. summary of the submitted technical documentation and summary of the submitted information contained in the notification.

(3) More details about the contents of the information of paragraph (2) points 2, 3, 4, 7 and 8 of this Article shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment.

(4) In the notification of paragraph (1) of this Article the notifier shall be obliged to state the purpose of the GMO product that the consent for placing on the market of GMO product is requested for.

(5) The notifier shall be obliged to submit a new notification if he has the intention to use the GMO product for other purposes than those referred to in notification in accordance with paragraph (5) of this Article.

(6) The notifier shall be obliged to compensate the real costs made by the civil service body competent to execute the operations relating to the environment and the civil service body competent to execute the operations relating to the agriculture and forestry, including therein the costs for the work of the Scientific Committee on GMO of Article 64 of this Law in the procedure of granting consent for placing on the market of GMO product.

(7) The amount of the costs of paragraph (6) shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment.

(8) The notifier shall be obliged to pay in the costs of paragraph (6) of this Article to the bank account of the civil service body competent to execute the operations relating to the environment within eight days of submission of the notification, based on a decision for the costs made.

(9) The notifier may place on the market GMO products only after having obtained the consent for placing on the market of GMO product.

Article 42

Exemptions from Submission of Information for the Purpose of Notification

(1) Based on the results from the deliberate release of GMO for which the consent of Article 18 and 19 of this Law has been obtained for, as well as based on a reasoned and scientifically supported justification that confirms that placing on the market of GMO and their use as a product or in a product does not pose a risk on human health and on the environment, the notifier may ask the civil service body competent to execute the operations relating to the environment not to submit part of the information or all the information laid down in Article 41 paragraph (2) point 3, 7 and 8 of this Law.

(2) The information that can be exempted from the notification in case of paragraph (1) of this Article shall be in more detail prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment.

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

(4) In the notification the notifier may also refer to the information, data and/or results of the notifications previously submitted by other notifiers, if he finds them relevant for his notification, on the condition that such information, data and results are not confidential and/or a written approval for their use has been given by the other notifier.

Article 43

Assessment Report on GMO Products

(1) The civil service body competent to execute the operations relating to the environment, within 15 days of receipt of the complete notification of Article 41 of this Law, shall circulate it to the Scientific Committee on GMO as well as to the civil service body competent to execute the operations relating to agriculture and forestry.

(2) The Scientific Committee on GMO and the civil service body competent to execute the operations relating to agriculture and forestry shall be obliged, within 45 days of receipt of the notification of paragraph (1) of this Article, to submit written opinion about the notification to the civil service body competent to execute the operations relating to the environment for approving or rejecting the notification.

(3) Based on the opinions of paragraph (2) of this Article, as well as the opinions received from the public and other relevant authorities, the civil service body competent to execute the operations relating to the environment shall be obliged to consider the notification and within 15 days prepare an assessment report on the GMO product.

(4) The assessment report of paragraph (3) of this Article shall examine whether:

- the GMO product is suitable for placing on the market and the conditions thereof;
or
- the GMO product is unsuitable for placing on the market.

(5) The civil service body competent to execute the operations relating to the environment shall be obliged to circulate the assessment report on product to the Scientific Committee on GMO and to the civil service body competent to execute the operations relating to agriculture and forestry, who shall then be obliged, within eight days, to submit written opinion or, if there is such need, request additional information from the civil service body competent to execute the operations relating to the environment or from the notifier.

(6) Upon receipt of the opinions of paragraph (5) of this Article, the civil service body competent to execute the operations relating to the environment shall in a time period not longer than 90 days of receipt of the complete notification submit to the notifier the assessment report on GMO products, together with the opinions of paragraph (5) of this Article, as well as the information based on which the report has been prepared.

(7) The time period laid down in paragraph (6) of this Article shall not take into account:

- the time periods when the submission of the additional information by the notifier was awaited; and/or
- the time period when the public debate or consultations in accordance with Article 12 and Article 44 of this Law have taken place.

(8) The layout and the contents of the form and the manner of preparation of the assessment report on GMO products of paragraph (3) of this Article shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the

environment in agreement with the Minister who runs the civil service body competent to execute the operations relating to agriculture and forestry.

Article 44

Request for Additional Information

(1) The civil service body competent to execute the operations relating to the environment shall be obliged, on the same day when submitting to the notifier the assessment report of Article (43) of this Law, to publish a summary of the assessment report on GMO products on its internet site and in two daily newspapers available on the entire territory of the Republic of Macedonia.

(2) The publication of the summary of paragraph (1) of this Article shall be at the expense of the notifier.

(3) The published summary of paragraph (1) of this Article shall also include the data about the location where the data on notification and the assessment report on GMO products can be accessed.

(4) The public, the other civil service bodies, as well as the scientific and expert institutions may submit their opinions on the assessment report on GMO products to the civil service body competent to execute the operations relating to the environment within 30 days of publication. The public, the other civil service bodies, as well as the scientific and expert institutions have the right to have access to the assessment report on GMO products in accordance with Article 12 paragraph (4) of this Law.

(5) The civil service body competent to execute the operations relating to the environment may, within 60 days of submission of the assessment report on GMO products to the notifier, request additional information from the notifier, or forward to him the comments and/or the justified remarks received in accordance with paragraph (4) of this Article relating to placing on the market of GMO products.

(6) All outstanding issues relating to the assessment report on GMO products, as well as additional information, shall be resolved and an agreement with the notifier shall be reached within 105 days of submission of the assessment report on GMO products.

(7) The requests for additional information with the purpose of resolving the outstanding issues in accordance with paragraph (6) of this Article may be submitted within 45 days the latest before the expiry of the time period of paragraph (6) of this Article.

(8) The time period laid down in paragraph (6) of this Article shall not take into account the time periods when the submission of the additional information by the notifier was awaited.

Article 45

Withdrawal of Notification

(1) The notifier may withdraw the notification for granting consent for placing on the market of GMO products or inform in writing the civil service body competent to execute the operations relating to the environment about his intention to complement the notification, if the assessment report on GMO products indicates that the product is suitable for placing on the market only under specified conditions, until the moment of granting the consent.

(2) If the notifier within the fixed time period of paragraph (1) of this Article informs in writing the civil service body competent to execute the operations relating to the environment for his intention to complement the notification, the civil service body competent to execute the operations relating to the environment shall specify a time period for complementing the notification.

(3) The time period specified for granting the consent shall not take into account the time period for complementing the notification of paragraph (2) of this Article.

(4) If the notifier in the time period of paragraph (2) of this Article fails to submit in writing the requested complementation of the notification to the civil service body competent to execute the operations relating to the environment, it shall be considered that the notification has been withdrawn.

(5) If in the procedure for obtaining consent for placing on the market of GMO product the notifier fails to submit the requested information in accordance with the fixed period of time, i.e. not later than the time period laid down in Article 43 paragraph (6) of this Law when it refers to the notification, i.e. within the time period laid down in Article 44 paragraph (6) of this Law when it refers to the assessment report on GMO products, the civil service body competent to execute the operations relating to the environment shall consider that the notification has been withdrawn.

(6) If the notifier has withdrawn the notification in accordance with paragraph (1) of this Article or paragraph (4) of this Article, as well as in the cases of paragraph (5) of this Article, the civil service body competent to execute the operations relating to the environment shall take a decision to discontinue the procedure for granting consent for placing on the market of GMO product.

Article 46

Consent for Placing on the Market of GMO Products

(1) The civil service body competent to execute the operations relating to the environment, based on the prepared assessment report on products of Article 43 paragraph (4) indent 1 of this Law, shall grant consent for placing on the market of GMO product within 30 days, as follows:

- upon expiry of the time period of 60 days in accordance with Article 44 paragraph (5) of this Law when there are no outstanding issues,
- upon expiry of the time period of 105 days in accordance with Article 44 paragraph (6) of this Law when there have been outstanding issues, but have been resolved with a positive outcome and an agreement has been reached.

(2) The civil service body competent to execute the operations relating to the environment, based on the prepared assessment report on products of Article 43 paragraph (4) indent 2 of this Law, shall take a decision to reject the notification for obtaining consent for placing on the market of GMO product within 30 days:

- of submission of the assessment report;
- upon expiry of the time period of 60 days in accordance with Article 44 paragraph (5) of this Law; and
- upon expiry of the time period of 105 days in accordance with Article 44 paragraph (6) of this Law, when there have been outstanding issues, but have been resolved with a positive outcome and an agreement has been reached.

(3) The civil service body competent to execute the operations relating to the environment shall be obliged to specify the reasons for rejection of the notification in the decision of paragraph (2) of this Article.

(4) The notifier may place on the marker a GMO product in accordance with conditions required in the consent for placing on the market of GMO products.

(5) Consent for placing on the market of GMO products may be granted for a period of ten years the longest from the date of granting.

(6) The notifier has the right to file a complaint for a lawsuit in administrative dispute before the court of jurisdiction against the conditions required in the consent for placing on the market of GMO product, as well as against the decisions of paragraph (3) of this Article.

(7) The layout and the contents of the form of the consent for placing on the market of GMO products and the other accompanying documentation shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment defined in agreement with the Minister who runs the civil service body competent to execute the operations relating to health and the Minister who runs the civil service body competent to execute the operations relating to agriculture and forestry.

Article 47

Renewal of Consent

(1) Consent for placing on the market of GMO products may be renewed if the notifier, within nine months before the expiry of the time period of its validity, submits notification for renewal of the consent to the civil service body competent to execute the operations relating to the environment.

(2) Notification of paragraph (1) of this Article shall contain:

1. copy of the consent for placing on the market of the GMO product that the renewal is requested for;
2. report on the implementation of the monitoring plan in accordance with Article 49 paragraph (2) point 7 of this Law;
3. the new available information relating to the risks resulting from the use of GMO product on human health and on the environment; and
4. proposal for amending and complementing the conditions required in the consent, and in reference to the placing on the market of the GMO product, in particular with reference to application of the monitoring procedure and/or the time period of validity of the consent, if necessary.

(2) Provisions of Article 41 of this Law shall adequately apply to the procedure for renewal of the consent for placing on the market of GMO products.

(3) The civil service body competent to execute the operations relating to the environment, within three months of submission of the complete notification, shall take a decision on renewal of the consent for placing on the market of GMO product.

(4) Upon submission of the notification for renewal of the consent for placing on the market of GMO product, the notifier may continue to place on the market the GMO product in compliance with the conditions required in the consent, until a final decision has been reached on notification for renewal of the consent.

(5) The consent may be renewed once or several times, if conditions thereof have been met.

Article 48

New Information

(1) If the notifier acquires new information after the notification has been submitted and before the consent for placing on the market of GMO products has been granted, that affects the risk level from placing on the market of the GMO product on human health and on the environment, he shall then be obliged to immediately:

- inform the civil service body competent to execute the operations relating to the environment;
- undertake all the necessary measures for protection of human health and of the environment; and
- complement the notification with the purpose of revising the information and conditions specified in the notification for placing on the market of GMO product.

(2) If the notifier acquires new information after the consent for placing on the market of GMO products has been granted, from the users of GMO products or in any other way, relating to the risk level on human health and on the environment, he shall then be obliged to immediately:

- undertake all the necessary measures for protection of human health and of the environment;
- inform the civil service body competent to execute the operations relating to the environment about the new information; and
- complement the notification with the purpose of revising the information and conditions required in consent for placing on the market of GMO product.

(3) If the civil service body competent to execute the operations relating to the environment acquires new information before the consent for placing on the market of GMO products has been granted, relating to the GMO product intended for the market or about the risk entailed in the use thereof on human health and on the environment, it will obligatorily take this information into consideration when granting the consent.

(4) If the civil service body competent to execute the operations relating to the environment acquires new information after the consent for placing on the market of GMO product has been granted, on its own or receives this information from other authorities, from the users of the product or in another way, relating to the placing on the market of GMO products or about the risk level that the use thereof entails on human health or on the environment, it may temporarily limit or prohibit the use and/or sales of that GMO and/or GMO product.

(5) In the cases of paragraph (4) of this Article the civil service body competent to execute the operations relating to the environment shall be obliged to inform the notifier, to request additional information from him, as well as to oblige him to complement the notification with the purpose of revising the information and the conditions required in the consent for placing on the market of GMO products.

(6) The civil service body competent to execute the operations relating to the environment, in agreement with the civil service body competent to execute the operations relating to agriculture and forestry and the Scientific Committee on GMO of Article 64 of this

Law, shall specify the modified conditions required in the consent for placing on the market of GMO product within three months of receipt of the notification for the modified conditions or annul the consent if, due to the modified conditions, the GMO product can no longer be placed on the market.

(7) In the procedure of complementing the consent of paragraph (1), (2) and (6) provisions of Article 41 of this Law shall apply.

Article 49

Monitoring

(1) The notifier who places on the market a GMO product shall be obliged to monitor its use and the effects of the GMO product on human health and on the environment, in accordance with the monitoring plan of GMO product and conditions required in the consent for placing on the market of GMO product, and to regularly inform thereof the civil service body competent for the execution of the operations relating to the environment.

(2) The civil service body competent to execute the operations relating to the environment may, based on the report on the monitoring results, ask the notifier to amend and/or complement the monitoring plan for the GMO product.

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

Article 50

Labelling and Packaging of GMO Products

(1) The notifier may place on the market only a GMO product that has been packaged, and whose package and declaration contain the information that the product contains and/or consists of GMO or a combination of GMO, as well as other necessary information about the product and instructions for its use, in a way that it has been prescribed under paragraph (3) of this Article and as specified in the consent with which the placing on the market of the GMO product has been approved.

(2) The GMO product and the accompanying documentation shall have to satisfy the conditions for labelling and packaging as required in the consent which approves the placing on the market of GMO products, in all stages of placing on the market

(3) The following information, as a minimum, must be specified on the label and the declaration of the GMO product:

1. commercial name of the product;
2. the words "This product contains genetically modified organism";
3. the name of GMO;
4. the name and the address of the legal or physical entity responsible for placing on the market of GMO products in the Republic of Macedonia, regardless of the fact if this be the producer, importer or distributor; and
5. instructions on how to access information in the register relating to the GMO product with indication of the number of the consent.

(4) By way of derogation of paragraph (3) of this Article it shall not be compulsory to label the products intended for direct processing, and which contain approved GMO in a threshold of maximum 0.9 %, if the accidental and the technically unavoidable trace presence of GMO cannot be excluded.

VI TRANSBOUNDARY MOVEMENT OF GMO AND OF GMO PRODUCTS

Article 51

Import of GMO and GMO Products

(1) Import of GMO or of GMO products may be carried out only with previously granted consent by the civil service body competent to execute the operations relating to the environment in accordance with the procedures laid down in Chapters IV and V of this Law, depending on the intention for which the GMO shall be used.

(2) During import, the information about the presence of GMO shall obligatorily be recorded into the veterinary or phyto-sanitary certificate.

Article 52

Export

General Provisions

(1) Export of GMO and of GMO products shall be carried out in accordance with the provisions of this Law.

(2) Export of living genetically modified organism shall be carried out in accordance with the provisions of this Law and with provisions of the Cartagena Protocol on Biosafety to the Convention on the Biological Diversity (hence forward: the Protocol) by way of implementing the agreement for advanced information from the Protocol.

(3) The approval for the export shall be given by the civil service body competent to execute the operations relating to the environment by means of granting consent for export of GMO and/or GMO products.

(4) The civil service body competent to execute the operations relating to the environment shall grant the consent of paragraph (3) of this Article only if the exporter has previously enclosed an acknowledgement and/or consent for import granted by the competent authority of the country where the import of GMO and/or GMO product from the Republic of Macedonia is taking place.

(5) The civil service body competent to execute the operations relating to the environment shall be obliged to submit a copy of the consent of paragraph (3) of this Article to the Customs Administration of the Republic of Macedonia.

(6) The Customs Administration of the Republic of Macedonia must not allow the export of GMO and/or GMO product from the Republic of Macedonia if the exporter fails to enclose the consent of paragraph (3) of this Article within the accompanying documentation for export.

(7) The layout and the contents of the form of the consent of paragraph (3) of this Article shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment.

Article 53

The Procedure of Notification for Export

(1) The exporter of GMO or GMO products shall be obliged, before carrying out the export, to submit notification for export of GMO or GMO product to the civil service body competent to execute the operations relating to the environment.

(2) The civil service body competent to execute the operations relating to the environment shall submit to the authority competent to grant consent for import of GMO or GMO products of the country importer the notification of paragraph (1) of this Article with the request that this authority returns an acknowledgement of receipt of notification within 30 days of the receipt.

(3) If the civil service body competent to execute the operations relating to the environment fails to receive the acknowledgement of receipt of notification of paragraph (2) of this Article within 90 days of submission of the notification, it shall be obliged to submit a written reminder to the authority of the other country for the need that such an acknowledgement be returned.

(4) In case when the notification is for the export of a living genetically modified organism, the civil service body competent to execute the operations relating to the environment shall submit the written reminder of paragraph (3) of this Article also to the Secretariat of the Protocol.

(5) The civil service body competent to execute the operations relating to the environment shall be obliged to grant consent for export of GMO and GMO product within 30 days of the day when the notifier encloses the acknowledgement and/or the consent for import granted by the competent authority of the country importer where the import of the exported GMO and GMO product is carried out.

(6) If the authority competent to grant consent for import of GMO or GMO products of the other country fails to respond to the submitted notification of paragraph (1) of this Article within 270 days of submission of notification, the civil service body competent to execute the operations relating to the environment shall be obliged once again to address a request for response on the notification within 60 days of receipt of request.

(7) When the notification is for export of living genetically modified organism, the civil service body competent to execute the operations relating to the environment shall submit the request of paragraph (5) of this Article also to the Secretariat of the Protocol.

(8) When the receipt of notification is not acknowledged by the authority competent to grant consent for import of GMO or GMO products of the country importer of paragraph (3) of this Article, or when there is no response received on the submitted request of paragraph (6) of this Article, this shall not be considered as approval for granting consent for export of GMO and GMO products.

Article 54

Consent for Export of GMO and GMO Products

(1) Within the notification of Article 53 paragraph (1) of this Law the exporter shall be obliged to submit in particular the following information and data:

1. name, telephone number and address as well as contact details for the exporter of GMO and GMO product;
2. name, telephone number and address as well as contact details for the person the GMO and GMO product is intended for (importer in the other country);
3. description of GMO and GMO product and its characteristics and the used modification techniques, and for the living genetically modified organism its name and identity, as well as the description of the parent organism and of the recipient;
4. the planned date of export, if known;
5. the intended use of the GMO and of the GMO product;
6. the quantity and/or the volume of GMO and of GMO product;
7. origin of GMO and of GMO product;
8. previous or current risk assessment report;
9. taxonomic status, name and identity, collection point or acquisition and characteristics of the donor organism or the organisms relating to biosafety;
10. proposed methods, measures and manners for safe packaging, handling, transport and use, including therein labelling, accompanying documentation, disposition of and contingency procedures;
11. legal provisions relating to the use and regime of import/export/transit of GMO and GMO products in the country importer;
12. correspondence or communication made with the importer or with the authority in the country importer competent to grant consents for import of GMO or GMO products;
13. declaration by the notifier that the information and data submitted with the notification are true; and
14. declaration that the notifier shall observe the provisions of the Protocol and that he shall oblige himself to undertake all the actions in due to the notifier, for the purpose of implementation of the Protocol.

(2) If the notification fails to contain the required information and data in accordance with paragraph (1) of this Article, the civil service body competent to execute the operations relating to the environment shall be obliged to define a time period for the notifier to submit the complements. The time period may not be shorter than 30 days.

(3) The time period of Article 53 paragraph (5) of this Law shall not take into account the time period for complementing the notification.

(4) The civil service body competent to execute the operations relating to the environment shall issue to the notifier an acknowledgement of receipt of the complete documentation.

(5) The civil service body competent to execute the operations relating to the environment shall grant consent for export of GMO and GMO product with the same expiry date as referred to in the acknowledgement and/or consent for import granted by the competent authority of the country where the import of the exported GMO and GMO product is taking place.

(6) If the expiry date is not specified in the acknowledgement and/or consent for import of paragraph (5) of this Article, the civil service body competent to execute the operations relating to the environment shall grant consent for export of GMO and GMO product with the time period requested by the notifier, but not longer than five years.

(7) The information and data of paragraph (1) of this Article that have to be enclosed with the notification in accordance with the intended use of GMO and GMO product and their characteristics shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment in agreement with the civil service body competent to execute the operations relating to agriculture and forestry and the Minister who runs the civil service body competent to execute the operations relating to health.

Article 55

Renewal of Consent for Export of GMO and GMO Products

Consent for export of GMO and GMO products may be renewed by way of submission of a new notification in accordance with Article 53 and Article 54 of this Law.

Article 56

Notification for Export

(1) The civil service body competent to execute the operations relating to the environment upon granting consent for export of GMO and GMO products shall in writing, by way of notification, inform thereof the competent authority of the other country where the import of the exported GMO and GMO product is taking place.

(2) When the consent is for a living genetically modified organism, notification of paragraph (1) of this Article shall also be submitted to the Secretariat to The Protocol.

Article 57

Transit

(1) Persons who transit GMO or GMO products through the territory of the Republic of Macedonia shall be obliged to submit a notification for transit to the civil service body competent to execute the operations relating to the environment.

(2) Notification of paragraph (1) of this Article shall be submitted not later than 14 days of the day when the transit is to be carried out.

(3) Notification of paragraph (1) of this Article, besides the information and data of Article 54 paragraph (1) of this Law, shall also include:

1. acknowledgement and/or consent for import approved by the competent authority of the country where the import of the exported GMO and GMO product is carried out; and
2. acknowledgement of receipt of the notification for transit by the competent authorities of the countries through which GMO and GMO product will transit with the purpose of reaching the country of import or acknowledgement that the transit has been approved.

(4) The civil service body competent to execute the operations relating to the environment shall be obliged within three days of receipt of the complete notification of

paragraph (1) of this Article to issue to the notifier an acknowledgement of receipt of notification.

(4) The civil service body competent to execute the operations relating to the environment shall grant consent for transit of GMO and GMO product through the territory of the Republic of Macedonia not later than three days before the day when the transit is to be carried out.

(5) The civil service body competent to execute the operations relating to the environment shall be obliged to submit to the Customs Administration of the Republic of Macedonia a copy of the consent of paragraph (4) of this Article.

(6) Customs Administration of the Republic of Macedonia must not allow transit of GMO and GMO products through the territory of the Republic of Macedonia if the transporter of GMO and GMO products fails to enclose the consent of paragraph (4) of this Article as part of the accompanying documentation for transit.

(7) The layout and the contents of the form of the consent of paragraph (4) of this Article shall be prescribed by the Minister who runs the civil service body competent to execute the operations relating to the environment.

Article 58

Undeliberate Transboundary Movement of GMO

(1) In case of undeliberate release of GMO and GMO products that resulted in undeliberate transboundary movement of GMO on the territory of another country, the civil service body competent to execute the operations relating to the environment shall be obliged immediately, and within 24 hours the latest:

1. to inform thereof the public, the authorities of the concerned and/or potentially concerned countries, countries parties in the Protocol and the Secretariat to the Protocol, as well as if adequate, relevant international organizations, as well as the Biosafety Clearing-House; and
2. to consult the concerned and/or potentially concerned countries with the purpose of providing them with an opportunity to undertake adequate measures for sanitation and to plan the proper actions for prevention of the negative impact on people and the environment.

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

(3) The notification of paragraph (2) of this Article shall have enclosed, as urgent, all the information relating to:

1. the assessed quantities of undeliberately released GMO and GMO products and relevant characteristics and/or properties of GMO;
2. information about the circumstances and the assessed time of undeliberate release of GMO;
3. intended use of GMO and GMO product;
4. possible adverse effects on preservation and sustainable use of biological diversity and the environment, whereby taking into consideration the risks on human health;

5. possible measures for risk management; and
6. other information relevant for the undeliberate release of GMO and GMO products.

(4) Notification of paragraph (2) of this Article shall also contain the telephone numbers and contact address of the responsible persons in the civil service body competent to execute the operations relating to the environment and for the notifier.

VII REGISTER OF GMO AND REPORTING

Article 59

Register of GMO

(1) The civil service body competent to execute the operations relating to the environment shall keep and update the Register of GMO. The Register is a public document.

(2) Register of GMO shall contain data on the facilities where the contained use of GMO is carried out, as well as other relevant data for contained use of GMO, deliberate release into the environment of GMO and for placing on the market of GMO products.

(3) Data of paragraph (2) of this Article shall in particular contain:

1. name and the address of the legal and physical entities responsible for:
 - contained use of GMO,
 - deliberate release of GMO into the environment, or
 - placing on the market of GMO products;
2. consents granted in accordance with this Law and modifications thereof;
3. list of GMO used in the Republic of Macedonia and the purpose thereof;
4. the addresses and characteristics of the facilities;
5. contained use of GMO and its classification;
6. deliberate release into the environment of GMO, including therein the exact description of the area where the release is taking place;
7. types of GMO products and their placing on the market, including therein the description of GMO product and the location where the GMO product has been placed on the market;
8. data from the risk assessment and assessment of GMO products;
9. data on accidents occurred and assessment of the consequences inflicted;
10. experiences acquired and research relating to GMO;
11. scientific, technical and legal information relating to GMO;
12. data on the transport of GMO and granted consents for transport; and
13. other information relating to GMO.

(4) The civil service body competent to execute the operations relating to the environment shall be obliged to regularly update and renew the data contained in the Register of GMO.

(5) Everyone has the right to have access to the data in the Register of GMO and to request information there from in a way and on conditions regulated by law.

(6) The amount of compensation for receiving information from the Register of GMO shall be equal to the real costs made for data provision.

(7) The data specified as confidential under this Law and in accordance with regulations on data protection shall not be recorded in the Register of GMO.

(8) Data from the Register of GMO may also be used for the purpose of exchange of information with other countries, as well as with international organizations, in a way that is regulated by this Law and by international agreements ratified by the Republic of Macedonia.

(9) The layout, contents and the manner of keeping the Register of GMO, shall be prescribed more closely by the Minister who runs the civil service body competent to execute the operations relating to the environment.

Article 60

Biosafety Clearing-House

The civil service body competent to execute the operations relating to the environment shall establish and maintain the Biosafety Clearing-House.

Article 61

Reporting

The Government of the Republic of Macedonia on proposal by the Minister who runs the civil service body competent to execute the operations relating to the environment, in agreement with the Minister who runs the civil service body competent to execute the operations relating to agriculture and the Minister who runs the civil service body competent to execute the operations relating to health, shall be obliged at least once in three years to submit a report to the Parliament of the Republic of Macedonia on the implementation of the deliberate release of GMO and placing on the market of GMO products, and in particular on:

- the impact and the efficiency resulting from their use;
- the need for additional legal regulation;
- feasibility of different options for further improvement of the consistency and of the efficiency of their use, including therein the application of procedures for their approval that are implemented by the civil service bodies;
- the possibilities to use the registers of the European Commission on GMO and their application in the Republic of Macedonia;
- the practice and the experiences in the use of GMO that have been acquired or are available with the civil service bodies in the Republic of Macedonia, including therein the Commission on Management of GMO and the Scientific Committee on GMO, as well as other scientific and expert bodies;
- social and economic impacts from the use of GMO;
- ethical issues that have arisen from or are considered in relation to the use of GMO;
- list of approved uses of GMO and summary of the data contained in the Register of GMO; and

- other relevant issues relating to GMO.

VIII EXPERT BODIES

Article 62

Commission on Management of GMO

(1) For the purpose of accomplishment of the objectives of this Law, the Government of the Republic of Macedonia, on proposal by the Minister who runs the civil service body competent to execute the operations relating to the environment, shall establish a Commission on Management of GMO (hence forward: Commission).

(2) The Commission shall execute the following operations:

1. monitor the conditions and the development in the field of use of techniques of genetic modification and management of GMO;
2. take positions, give opinions and proposals for the use of techniques of genetic modification and management of GMO, as well as give opinions relating to the social, ethical, technical and technological, health, scientific and other aspects of management of GMO;
3. advise the Government of the Republic of Macedonia with regards to the use of the techniques of genetic modification and management of GMO; and
4. submit once a year report on its work to the Government of the Republic of Macedonia.

Article 63

Composition of the Commission

(1) The Commission of Article 62 of this Law shall be composed of fifteen members including therein the president of the Commission, with a mandate of four years.

(2) The Commission shall elect the president of the Commission from its members with a mandate of two years.

(3) Members of the Commission shall be selected among scientists, each expert in one of the following fields: social and societal sciences, biological sciences, forestry sciences, agricultural sciences, biotechnological sciences, medical sciences, veterinary sciences, pharmaceutical sciences, ethical sciences and from the public health, as well as one representative from the Scientific Committee of Article 64 of this Law, civil associations from the field of protection of the environment and nature, Macedonian Academy of Sciences and Arts, consumers' organization, and from the Government of the Republic of Macedonia.

(4) Members of the Commission shall have completed adequate higher education and shall have at least 7 years of scientific experience in the adequate field.

(5) The Commission operates based on Rules of Procedures adopted by the Commission.

(6) The Commission shall be professional, independent and autonomous in the field of its operation.

(7) Members of the Commission shall be obliged to carry out their work conscientiously and honorably, for which they sign a declaration.

(8) The specialized and administrative-technical activities necessary for the operation of the Commission shall be carried out by civil service body competent to execute the operations relating to the environment.

(9) Members of the Commission shall have the right to compensation for their work in the Commission.

(10) The amount of compensation to the members of paragraph (3) of this Article shall be specified by the Government of the Republic of Macedonia.

(11) The amount of compensation of paragraph (10) of this Article shall be reasonable and proportionate to the relevance, quantity of work by the members, and complexity of the activities.

Article 64

Scientific Committee on GMO

(1) For the purpose of consideration of issues relating to GMO and giving opinions and proposal, the Government of the Republic of Macedonia, on proposal by the Minister who runs the civil service body competent to execute the operations relating to the environment, shall establish the Scientific Committee on GMO as an expert and advisory body.

(2) The Scientific Committee on GMO of paragraph 1 of this Article shall consider and give opinions and proposals in relation to:

- management of GMO;
- preparation of rules for management of GMO;
- definition of the manner of carrying out the risk assessment, contained use of GMO, deliberate release of GMO and placing on the market of GMO products;
- notifications and other documents relating to the procedure for granting consents under this Law;
- the requests submitted by the Commission for Management of GMO and the civil service bodies; and
- requests submitted by the public, civil 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 civil service body competent to execute the operations relating to the environment and to the Government of the Republic of Macedonia by 31 January in the current year the latest.

(4) The Scientific Committee on GMO operates in sessions and discusses the issues of its competence and takes decisions by majority vote of its members.

Article 65

Composition of the Scientific Committee on GMO

(1) The Scientific Committee on GMO shall be composed of members who shall be selected from prominent scientists and experts with adequate education and professional

qualification in the field of medicine, biology, agriculture, veterinary medicine, biotechnology, workplace safety and forestry, with a mandate of four years.

(2) The Scientific Committee on GMO shall elect its President from its members serving a mandate of two years.

(3) The Scientific Committee on GMO works in compliance with Rules of Procedures adopted by the Committee.

(4) Other experts and scientist from the fields of operation relevant for the discussion may be involved in the Scientific Committee on GMO, depending on the nature of the notification for which the expert opinion is given.

(5) The specialized and administrative activities necessary for the operation of the Scientific Committee on GMO shall be carried out by the civil service body competent to execute the operations relating to the environment.

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

(7) The amount of compensation to the members of paragraph (1) of this Article shall be prescribed by the Minister who runs the civil service body competent for the execution of the operations relating to the environment.

(8) The amount of compensation of paragraph (7) of this Article shall be reasonable and proportionate to the relevance, quantity of work by the members, and complexity of the activities.

(9) The funds for payment of the compensations of paragraph (6) of this Article shall be provided from the budget of the civil service body competent to execute the operations relating to the environment.

Article 66

Protection of Data

(1) Members of the Commission on Management of GMO and of the Scientific Committee on GMO shall be obliged in the course of serving their mandate, and upon completion of their mandate, to keep the data confidential and not to disclose them to third parties in accordance with provisions of this Law and regulations on access to classified information.

(2) The obligation of paragraph (1) of this Article shall also apply to external experts who take part in the work of the Scientific Committee on GMO.

IX SUPERVISION OF THE APPLICATION

Article 67

Supervision of the Application

Supervision of the application of this Law and the regulations adopted based on this Law, shall be carried out by the civil service body competent to execute the operations relating to the environment, the civil service body competent to execute the operations

relating to health and the civil service body competent to execute the operations relating to agriculture and forestry, in accordance with the competences of their fields of operation.

Article 68

Inspection Supervision

(1) For the purpose of supervision over the implementation of the measures for protection of human health and of the environment in accordance with the provisions of this Law, the competent authority to supervise:

- the implementation of the contained use of GMO shall be the civil service body competent to execute the operations relating to the environment;
- the implementation of the deliberate release into the environment of GMO shall be the civil service body competent to execute the operations relating to the environment;
- the placing on the market of GMO products shall be the civil service body competent to execute the operations relating to the environment and the civil service body competent to execute the operations relating to agriculture and forestry;
- the packaging of GMO products shall be the civil service body competent to execute the operations relating to the environment and the civil service body competent to execute the operations relating to economy;
- the transit, import and export of GMO shall be the civil service body competent to execute the operations relating to the environment; and
- the implementation of the provisions or of the measures for prevention of possible adverse effects on human health and on the environment and the declared prohibitions shall be the civil service body competent to execute the operations relating to the environment and the civil service body competent to execute the operations relating to health.

(2) The inspection supervision of the implementation of the provisions of this Law and the regulation adopted based on this Law shall be carried out by:

- State Environmental Inspectorate through the state environmental inspector;
- State Sanitary and Health Inspectorate through the state sanitary and health inspector;
- Food Inspectorate through the state food inspector;
- State Agricultural Inspectorate through the state agricultural inspector;
- State Forestry Inspectorate through the state forestry inspector;
- Veterinary Directorate through the state veterinary inspector;
- Phyto-Sanitary Directorate through the state phyto-sanitary inspector; and
- State Market Inspectorate through the state market inspector,

each within their competences under the law.

(3) In carrying out the inspection supervision the state inspectors of paragraph (2) of this Article shall have the right to access facilities, areas and protected zones, as well as the right to carry out an insight into the facilities and areas, to make an insight into the

documentation and to take samples and specimens with the purpose of verifying whether the product or the organism contains GMO.

Article 69

Measures to be Undertaken by the Competent Inspectorates

(1) If the state inspector of Article 68 paragraph (2) of this Law finds out that the failure to fulfill the prescribed conditions in accordance with provisions of this Law poses a hazard or could pose a hazard to human health and to the environment, the inspector may undertake the following measures:

- to prohibit or to order temporary discontinuation of the contained use of GMO;
- to prohibit or to order temporary discontinuation of the deliberate release into the environment of GMO;
- to prohibit or to order temporary discontinuation of the placing on the market of GMO products;
- to order the removal of the defects that have resulted from the operations listed above within a defined time period;
- to order the withdrawal from the market of GMO products permanently or within a defined time period; and
- to order the undertaking of temporary measures for improvement, removal and/or reduction of the consequences from the adverse effects that have occurred in the management of GMO.

(2) If during the inspection the state inspector of Article 68 paragraph (1) of this Law finds out irregularities he shall be obliged to immediately inform the civil service body competent to execute the operations relating to the environment.

(3) The state inspector of Article 68 paragraph (1) of this Law may take a decision to prohibit the transboundary movement of GMO and GMO product, transport of GMO and GMO product, contained use of GMO, deliberate release into the environment of GMO and/or placing on the market of GMO products for the legal or physical entities who do not possess consents laid down in this Law.

(4) The state inspector of Article 68 paragraph (2) of this Law may order the undertaking of measures for protection of the environment and of human health with the purpose of reducing the damage inflicted as the result of carrying out the unauthorized activities or operations.

(5) The state inspector of Article 68 paragraph (2) of this Law shall be obliged to institute legal proceedings before the court of jurisdiction.

(6) In carrying out the inspection supervision the state inspector of Article 68 paragraph (2) of this Law shall adequately apply the provisions of the Law on Environment.

Article 70

Obligations of the Legal and Physical Entities during the Inspection

With the purpose of carrying out the inspection the legal and physical entities shall be obliged to provide to the competent inspector of Article 68 paragraph (2) of this Law access to and insight into the facilities and documentation of the legal or physical entity, to provide

them the requested data, explanations and information, to take measures, to take samples and to collect evidence in accordance with this Law and the Law on Environment.

X VIOLAITION PROVISIONS

Article 71

Violations

(1) A fine in size of € 3,000 to 10,000 in denar value shall be imposed for violations to the legal entity if:

1. before the start of the contained use of GMO, as well as during the implementation of the of contained use of GMO, the user fails to provide risk assessment for the planned and implemented use of GMO (Article 15);
2. during the implementation of the contained use of GMO the user fails to make revisions of the risk assessment, limitations and safety measures, in accordance with Article 15 of this Law;
3. the user fails to inform the civil service body competent to execute the operations relating to the environment in accordance with Article 15 of this Law;
4. the user starts to use the facilities for contained use of GMO before submission of the notification with the necessary information to the civil service body competent to execute the operations relating to the environment. (Article 16);
5. the user fails to keep the data from the risk assessment and notification as data of permanent value and fails to submit them to the competent authority upon its request (Article 16);
6. the user fails to keep the data from the risk assessment (Article 17);
7. the user, upon request by the civil service body competent to execute the operations relating to the environment, fails to submit the requested data in accordance with Article 17 of this Law;
8. the user fails to proceed in accordance with Article 20 of this Law;
9. the user proceeds contrary to the requests by the civil service body competent to execute the operations relating to the environment (Article 22);
10. the user fails to inform the civil service body competent to execute the operations relating to the environment in accordance with Article 23 of this Law;
11. the legal or physical entity carries out deliberate release of GMO containing genes showing resistance to antibiotics contrary to the prohibition referred to in Article 29;
12. the notifier, in the course of procedure, refers to data or to results from the risk assessment of a previous notification submitted by other notifiers, without providing the written approval therefor by the notifier (Article 36);
13. the notifier fails to proceed in accordance with the requests by the civil service body competent to execute the operations relating to the environment (Article 37);

14. the notifier proceeds contrary to the decision by the civil service body competent to execute the operations relating to the environment (Article 37);
15. the notifier fails to proceed in accordance with the requirements of Article 38 of this Law;
16. the notifier continues the placing on the market of GMO products contrary to Article 42; and
17. members of the Commission on Management of GMO and of the Scientific Committee on GMO fail to keep the data confidential in accordance with provisions of this Law and regulations on access to classified information (Article 66).

(2) A fine in size € 1,000 to 2,000 shall be imposed for violations to the responsible person in the legal entity for actions of paragraph (1) of this Article.

(3) If violations of paragraph (1) of this Article pose greater damage on the environment and human health sanction shall be imposed proportionate to the damage inflicted but to a maximum of five times the amount specified in paragraph (1) of this Article.

(4) State inspectors shall be obliged, before instituting the legal proceedings of paragraph (1) of this Article, to offer to the perpetrator a settlement procedure in accordance with this Law and the Law on Environment.

(5) The body competent to carry out the legal proceedings and to impose the fines of this Article is the court of jurisdiction.

Article 72

(1) A fine in size of € 10,000 to 20,000 in denar value shall be imposed for violations to a legal person if:

1. legal or physical entity, scientific and research organizations and/or high education institutions carried out contained use of GMO without having obtained consent for contained use of GMO in accordance with Article 16, 18 and 19 of this Law (Article 14);
2. the user started the contained use of GMO of class 1 without additional notification in facilities which have not been previously granted the consent in accordance with Article 16 of this Law (Article 17);
3. contained use of class 2 is carried out contrary to the provisions of Article 18 of this Law;
4. contained use of class 3 and 4 is carried out contrary to the provisions of Article 19 of this Law;
5. the user carries out the contained use despite the decision for prohibition (Article 23);
6. in case of accident during the contained use of GMO the user fails to inform the civil service body competent to execute the operations relating to the environment (Article 24);
7. legal or physical entity carries out deliberate release of GMO in nature in protected areas and in areas of ecological network, ecologically clean areas, areas for production of organic products, areas for ecological tourism, as well as areas declared as protected zone (Article 31);

8. entities involved in the procedure of granting consent fail to keep or disclose to third parties the information specified in the notification as confidential (Article 32);
9. the notifier starts the deliberate release of GMO without the consent for deliberate release into the environment of GMO (Article 35);
10. the notifier carries out deliberate release of GMO contrary to the conditions required in the consent for deliberate release of GMO and in accordance with conditions required in the consent (Article 35);
11. the material received from the deliberate release of GMO for which the consent for deliberate release of GMO has been granted is placed on the market without prior consent for placing on the market of GMO product (Article 35);
12. the notifier fails to submit report on all the risks to human health or to the environment resulting from the deliberate release of GMO to the civil service body competent to execute the operations relating to the environment in accordance with Article 39 of this Law;
13. the notifier, in case of undeliberate release into the environment of GMO, fails to undertake measures in accordance with the emergency response plan of Article 38 of this Law and fails to inform the civil service body competent to execute the operations relating to the environment in accordance with Article 40 of this Law;
14. the notifier places on the market in the Republic of Macedonia a GMO products without the consent for placing on the market of GMO products (Article 41);
15. the notifier continues to place on the market a GMO product contrary to the conditions required in the consent (Article 41);
16. the notifier who places on the market a GMO product fails to provide monitoring for its use and of the effects of the product on the environment and on human health, in accordance with the monitoring plan of GMO product and conditions required in the consent, and fails to inform thereof the civil service body competent for the execution of the operations relating to environment in accordance with Article 50 of this Law;
17. the notifier places on the market a GMO product contrary to requirements of Article 51 of this Law; and
18. import, export and transit of GMO or of GMO products is carried out contrary to provisions of Chapter VII of this Law (Article 52).

(2) A fine in size of € 2,000 to 4,000 shall be imposed for violations to the responsible person in the legal entity for actions of paragraph (1) of this Article.

(3) If the violations of paragraph (1) of this Article cause greater damage on the environment and human health a sanction shall be imposed proportionate to the damage inflicted but to maximum of seven times the amount specified in paragraph (1) of this Article.

(4) State inspectors shall be obliged, before instituting the proceedings for violations of paragraph (1) of this Article, to offer to the perpetrator a settlement procedure in accordance with this Law and the Law on Environment.

(5) Competent authority to implement the legal proceedings and to impose the fines of this Article is the court of jurisdiction.

Article 73

Settlement Procedure and Mediation

(1) For violations of Article 71 of this Law a settlement procedure may be applied.

(2) For violations of Article 72 of this Article a mediation procedure may be applied.

(3) In cases when a settlement agreement has been reached the fine imposed on the perpetrator may be reduced at most by one half of the maximum specified fine for the violation.

(4) The settlement procedure shall be implemented in a way and in a procedure laid down in the Law on Environment.

(5) The mediation procedure shall be implemented in a way and in a procedure laid down in the Law on Environment.

XI FINAL AND TRANSITIONAL PROVISIONS

Article 74

Establishment of Expert Bodies

The Government of The Republic of Macedonia within three months of entry into force of this Law shall establish the Commission on Management of GMO and the Scientific Committee on GMO.

Article 75

Regulations for Implementation of the Law

Regulations specified in this Law shall be adopted within two years of entry into force of this Law.

Article 76

Entry into Force

This Law shall enter into force on the eighth day of publication in the "Official Gazette of the Republic of Macedonia", and shall apply as of 1st September 2008.

EXPLANATION OF THE LAW

1. Evaluation of the situation in the field to be regulated by the Law on Genetically Modified Organisms

Management of genetically modified organisms (GMO) relating to contained use of GMO in closed facilities, deliberate release into the environment, placing of products on the market, and transboundary movement of GMO have so far not been regulated in the Republic of Macedonia. The need for such regulation results above all from the need to control the operations listed above as the uncontrolled execution thereof may significantly impact the human health and the environment.

The Draft-Law on GMO regulates the management of genetically modified organisms and products containing GMO and/or consisting of or derived from a combination of GMO, measures for prevention and reduction of possible adverse effects on the environment and on human health, as a consequence during the contained use of genetically modified organisms, deliberate release into the environment of GMO or placing on the market of GMO products, as well as transboundary movement of GMO and of products containing GMO.

This approach results from the need to implement the obligations assumed by the Republic of Macedonia with regards to the harmonization of the national legislation with the law of the European Union whereby due attention is paid to fulfilling the requirements contained in the law of the European Union.

2. Objectives to be accomplished by way of regulating this field

The draft-law on genetically modified organisms regulates the basic principles for management of genetically modified organisms. The draft-law has been prepared in accordance with the requirements of the EU law which enables the regulation of the management of GMO, with the purpose of setting up a legal framework for regulation of the management of genetically modified organisms cultivated in contained areas as well as their deliberate release into the environment and placing on the market. The requirements of the Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, complemented by the Regulations (EC) No 1829/2003 and 1830/2003/EC as well as Decisions 2002/623/EC and 2002/811/EC and the Directive of the Council of 23 April 1990 on the contained use of genetically modified microorganisms, complemented by the Directive 98/81/EEC complemented by the Regulation (EC) 1882/2003 and Decisions 2001/204/EC and 2005/174/EC are directly transposed in this draft-law.

The draft-law on GMO contains a total of 76 Articles divided in 11 Chapters as under:

- Chapter I. General provisions
- Chapter II. Principles of protection of the environment
- Chapter III. General measures
- Chapter IV. Contained use

- Chapter V. Deliberate release into the environment of GMO and Placing on the market of GMO products
- Chapter VI. Transboundary movement of GMO and of products containing or consisting of GMO
- Chapter VII. Register of GMO
- Chapter VIII. Expert bodies for implementation of the law
- Chapter IX. Supervision of the application
- Chapter X. Violation provisions
- Chapter XI. Final and transitional provisions

Chapters I *General Provisions* and II *Principles of Protection of the Environment*

include: subject matter of regulation, objectives of the law, definition of the terms used in the Law, genetic modification, exemptions from application of the law and principles on which the law is based.

Article 4 specifies the techniques by means of which GMO are created, and also specifies those activities which do not create GMO. Article 5 specifies the exemptions from the application of this Law. Therein techniques are excluded which do not cause the creation of GMO covered by this Law. At the same time, this law, in the part on control of GMO on the market excludes the products intended for human consumption, as well as pharmaceutical products. Transport of GMO shall be carried out in accordance with provisions of international conventions on transport of hazardous substances.

The draft-law regulates the following principles: Principle of integrity; Principle of precaution; Principle of liability and perpetrator pays and Principle of risk assessment.

Chapter III *General Measures* defines the compulsory measures that need to be undertaken for the purpose of prevention or removal of the adverse consequences. Article 10 specifies that if the perpetrator of the damage inflicted with the management of GMO is not found, the civil service bodies are competent to undertake all the measures for the removal thereof and protection of human health and of the environment. Again in this Chapter, Article 11 and 12 define the obligations of the competent body for compulsory inclusion of the public in the procedure of granting the consents resulting from the draft-law. The public has the right to have an insight both in the notifications and in the risk assessments and risk assessment reports relating to the use and approval of GMO. The public must be informed via the internet site of the Ministry of Environment and Physical Planning, as well as through announcements in daily newspapers. Article 13 specifies that all bodies involved in the management of GMO are obliged to submit reports to the Ministry of Environment and Physical Planning for the purpose of all-inclusive database on GMO.

Chapter IV *Contained use of GMO* prescribes the procedure for the contained use of GMO. The Ministry of Environment and Physical Planning together with the other competent bodies shall be obliged to provide all the necessary measures to avoid the adverse effects to human health and to the environment that may occur resulting from the contained use. Entities that have the intention to carry out the contained use shall be obliged to obtain the consent for the facilities where the contained use will be carried out as well as consent for the contained use. The objective of the contained use most frequently represents a pre-research stage in the development of GMO with the purpose of assessing its impact on human health and on the environment, which represent, above all, a scientific activity. In accordance with the Draft-Law four classes for contained use have been specified, the type of the class wherein the contained use will be classified depends on the risk assessment. Depending on the class type conditions are prescribed that have to be fulfilled in the facilities where the contained

use shall be carried out, as well as measures that need to be undertaken. The law gives the legal basis for specifying the manners of contained use of GMO, individual safety measures, rules of management, as well as other conditions for each class separately if necessary for providing the protection of human health and of the environment, in accordance with species of the organism and the environment where it is intended to be released. It is important that the consent for the contained use of GMO may not be granted if a risk assessment has not been carried out. The consent may be granted only if the assessment is positive and all measures have been undertaken with the purpose of limiting the impact on human health and on the environment. The procedure of granting consents, examination of notifications and risk assessment also involve the Scientific Committee on GMO. Every user of GMO shall be obliged to have an emergency response plan which specifies the actions in case of accident. It has to be revised and tested every year. Notification may contain data that can be specified as confidential, with the exemption of data relating to the risk assessment, etc. In this Chapter the Directive of the Council of 23 April 1990 on the contained use of genetically modified microorganisms complemented with the Directive 98/81/EEC complemented with the Regulation (EC) 1882/2003 and the Decision 2001/204/EC and 2005/174/EC is transposed.

Chapter V.1 *Deliberate Release into the Environment of GMO* has the requirements of the Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, complemented with the Regulation (EC) 1829/2003 and 1830/2003/EC as well as the Decision 2002/623/EC and 2002/811/EC which regulates the procedure for deliberate release into the environment of GMO transposed therein, and it also specifies the measures for protection of the environment and human health transposed. Everyone who has the intention to release a GMO in the environment needs to obtain consent for deliberate release, wherein conditions will be defined under which the deliberate release into the environment can be carried out. Deliberate release follows the stage of contained use of GMO. Article 29 specifies the prohibition of GMO which may be introduced in the Republic of Macedonia. GMO that show resistance to antibiotics are prohibited. At the same time, under Article 31 the Government of the Republic of Macedonia specifies the areas where the release of GMO is not allowed. It is not allowed to release GMO in protected areas and in areas of ecological network, ecologically clean areas, areas intended for the production of organic products, areas intended for ecological tourism, as well as areas declared as protected zones. Article 30 gives the safeguard clause which provides that the release of GMO may be discontinued if new data and information detect a risk to human health and to the environment. In this procedure it is also compulsory to carry out the risk assessment. At the same time the notifier shall be obliged to submit reports on all possible risks to human health and to the environment relating to the contained use of GMO.

Chapter V.2 *Placing on the Market of GMO Products* containing GMO and/or consisting of or derived from a combination of GMO regards the regulation of the procedure of granting the consents for placing on the market of GMO products. The procedure for placing on the market of GMO products begins with the notification submitted to the Ministry of Environment and Physical Planning. The notification is compulsorily submitted to the Ministry of Agriculture and Forestry, as well as to the Scientific Committee on GMO. At the same time a risk assessment is obligatorily carried out for the GMO product from the aspect of its impact on the environment and human health. The assessment report and the notification itself are circulated to the public and the expert public. Based on positive assessment consent is granted for placing on the market of GMO products. This also regulates the monitoring of the use and the effects of the product on the environment and on human health as well as manners of labeling and packaging of products containing GMO. GMO products must be designated with the words "This product contains GMO". These products can also be packaged

in accordance with conditions required in the consent, and instructions for handling should be placed on the packaging. In this Chapter the Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms complemented with the Regulation (EC) 1829/2003 and 1830/2003/EC as well as the Decisions 2002/623/EC and 2002/811/EC has been transposed.

Chapter VI *Transboundary Movement of GMO and of Products Containing or Consisting of GMO* prescribes that it is not possible to carry out transboundary movement if previously consents in accordance with this Law have not been granted. For import of GMO and GMO products the procedure is the same as with obtaining the consent for contained use of GMO and obtaining the consent for placing on the market of GMO product. Export of GMO and GMO products is carried out by means of submitting a notification. Export may be granted if the notifier obtains consent for import of the same GMO or GMO product from the authorities of the country where the import is taking place. Transit of GMO or GMO product is allowed only by means of consent, whereby it is necessary to previously obtain consents for import and conformation for transit by the countries where the transit is taking place. This Chapter also regulates the issues resulting from the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

Chapter VII *Register of GMO and Reporting* prescribes the manner in which the register of GMO is kept as well as data contained therein. Register of GMO is a public document that everyone can access and obtain information contained therein. The Ministry of Environment and Physical Planning is responsible for setting up and maintaining the Register of GMO as well as the Clearing-House on Biosafety. Article 61 gives the obligation of the Government of the Republic of Macedonia to submit reports every three years on the management of GMO to the Parliament of the Republic of Macedonia.

Chapter VIII *Expert Bodies* These are established for the purpose of implementing the law. With the purpose of management of GMO in the Republic of Macedonia expert bodies are established for handling the GMO, as follows: Commission on Management of GMO and Scientific Committee on GMO, which are competent for the procedures in the management of genetically modified organisms. The Commission has the role of national advisory body to the Government of the Republic of Macedonia and it comprises of 15 prominent scientists in the field of natural sciences, as well as one representative from the Government. The Scientific Committee is composed of 7 members, experts above all. The main role of the Committee is to give opinions to the Ministry of Environment and Physical Planning with regards to granting consents for the use of GMO and placing on the market of GMO products.

Chapter IX *Supervision of the Application* Competent authorities have been specified to implement this Law as well as the field of operation for the state inspectors for the environment and other competent inspectorates. Ministry of Environment and Physical Planning has the leading role in the supervision, whereas the Ministry of Agriculture, Forestry and Water Economy and Ministry of Health carry out the supervision in accordance with this Law and regulations from their field of operation.

Chapter X *Violation Provisions* This chapter prescribes the size of fines and the type of violations. The fines amount from € 3,000 to 20,000 depending on the weight of the violation. Due to the specificity of the field, the court of jurisdiction is competent to implement the legal proceedings.

Chapter XI *Final and Transitional Provisions* Because of the complexity of this matter, it has been proposed that the application of this law starts on 1st September 2008.