

LAW ON GENETICALLY MODIFIED ORGANISMS¹

I. GENERAL PROVISIONS

Scope of Regulation Article 1

This Law shall govern the procedure for issuing approvals for use in closed systems, for deliberate release into the environment, for placing on the market or for transit of genetically modified organisms and products containing genetically modified organisms, conditions for use in closed systems and for deliberate release into the environment of genetically modified organisms, handling, packaging and transport of genetically modified organisms and products containing genetically modified organisms, as well as other issues of importance for genetically modified organisms and products containing genetically modified organisms.

Ban on trade Article 2

No genetically modified organisms or product containing genetically modified organisms can be traded or grown for commercial use at the territory of the Republic of Serbia.

Article 3

Agriculture products of non-animal origin are not considered genetically modified organism if contain up to 0.9% threshold of genetically modified organism and impurities of genetically modified organisms.

Seed and reproductive material are not considered genetically modified organisms if contain up to 0.1% threshold of genetically modified organisms and impurities of genetically modified organisms.

Definitions of Terms Article 4

Terms as used in this Law shall have the following meaning:

- 1) *genetic material* shall mean part of a plant, animal, fungus, microorganism, virus or viroid containing hereditary information;
- 2) a *genetically modified organism* shall mean an organism whose genetic material has been modified through methods of modern biotechnology;
- 3) an *incident* shall mean any event leading to uncontrolled release of a genetically modified organism into the environment, resulting from use in closed systems, deliberate release

¹ Law on Genetically Modified Organisms was adopted by the National Parliament of the Republic of Serbia on May 29, 2009 and published in the Official Gazette of the Republic of Serbia No. 41/09.

- into the environment or placing on the market of a genetically modified organism that may represent an immediate or delayed hazard for the human life and health and the environment;
- 4) *user* shall mean a legal person, entrepreneur or natural person using genetically modified organism or product containing genetically modified organism in closed systems and on the occasion of deliberate release into the environment ;
 - 5) *methods of modern biotechnology* shall mean *in vitro* techniques of nucleic acids, including recombinant deoxyribonucleic acid (DNA) and direct introduction of nucleic acids into cells or organelles and cell fusion beyond the taxonomic level of family overcoming natural reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection (classical methods);
 - 6) *living modified organism* shall mean any genetically modified organism or product containing genetically modified organism capable of reproduction and transfer of genetic material, including a sterile organism capable of growth;
 - 7) *monitoring* shall mean planned and systematic monitoring and supervision of genetically modified organisms, their use in closed systems, monitoring of the procedure of deliberate release into the environment and monitoring and supervising the environment where a genetically modified organism was deliberately released, as well as potential harmful effects on the environment and human health;
 - 8) *deliberate release into the environment* shall mean:
 - contained release of a genetically modified organism for the purpose of carrying out experiments, demonstration experiments and development of new varieties;
 - 9) *unintended release into the environment* shall mean accidental release of a living modified organism into the environment due to an unforeseen event, accident, improper handling, storing, etc.;
 - 10) *authorized laboratory* shall mean a legal person carrying out testing of genetically modified organisms and products containing genetically modified organisms;
 - 11) *product containing genetically modified organism* shall mean any product consisting of, or containing, or derived from one or several genetically modified organisms, regardless of the degree of processing;
 - 12) *risk assessment* shall mean a scientific assessment carried out under the “case by case” procedure involving identification of potential harmful effects of genetically modified organisms or products containing genetically modified organisms for human health and the environment which may arise during use in closed systems, deliberate release into the environment, placing on the market or transit. In risk assessment the precaution principle must be obeyed;
 - 13) *handling* shall mean final processing, reprocessing and storing of genetically modified organisms or products containing genetically modified organisms;
 - 14) *developer/developer* shall mean a legal person, entrepreneur or natural person creating a genetically modified organism or product containing genetically modified organism;
 - 15) *use in closed systems* shall mean any operation whereby genetically modified organisms or products containing genetically modified organisms are grown, reproduced, stored, transported, disposed of, destroyed or in any other manner used in the area separated by physical barriers, or where a combination of physical, chemical or biological barriers prevents the contact of genetically modified organisms with the outside world and their effect on the environment.

Exemptions from Application Article 5

The provisions of this Law shall not apply to the product containing genetically modified organism (hereinafter referred to as: the GMO product) which is not a living modified organism (hereinafter referred to as: the LMO) and is not used as food, feed, medicine or auxiliary medicine.

The provisions of this Law shall not apply to genetically modified microorganisms and to GMO products which are not LMOs, if they are intended for medical use and if their use is governed entirely by other regulations.

Expert Council for Biological Safety Article 6

For the purposes of examining professional issues and providing expert opinion referring to genetically modified organisms (hereinafter referred to as: GMOs), the minister responsible for agriculture (hereinafter referred to as: the Minister), in accordance with regulations governing state administration, shall issue a decision to establish a special working group – the Expert Council for Biological Safety (hereinafter referred to as: the Expert Council).

Activities of the Expert Council Article 7

The Expert Council shall:

- 1) assess the accuracy of data in the application submitted in order to obtain approval for use in closed systems, for deliberate release into the environment, based on the accompanying documents, whereby the data from global practices is used;
- 2) carry out risk assessment for deliberate release into the environment,
- 3) provide expert opinion to the ministry responsible for agriculture (hereinafter referred to as: the Ministry) on fulfillment of the requirements for granting the license for use in closed systems;
- 4) provide expert opinion to the Ministry on fulfillment of the requirements for granting the approval for deliberate release into the environment,
- 5) examine the results of deliberate release into the environment;
- 6) examine proposals for amending regulations on GMOs;
- 7) examine other expert opinions concerning GMOs and GMO products.

The Expert Council shall operate under the “case by case” procedure, and in its activities it shall be guided by data based on scientific knowledge and observe the precautionary principle.

The Expert Council shall issue the Rules of Procedure.

Conflict of Interest
Article 8

The Expert Council member who is family-related, or business and/or financially-related to the applicant may not participate in the decision making process in the course of Expert Council providing its opinion.

II. PROCEDURE FOR ISSUING APPROVAL

Approval
Article 9

The approval shall be issued for use in closed systems, for deliberate release into the environment, of GMOs and GMO products.

Application
Article 10

The procedure for issuing approval for use in closed systems, for deliberate release into the environment shall be initiated based on the application submitted by the developer/developer, user or their authorized representative in the Republic of Serbia (hereinafter referred to as: the applicant).

The application shall contain:

- 1) GMO description;
- 2) business name, corporate domicile and address of the legal person or entrepreneur, name, domicile and personal identification number of the natural person, or the name and address of their authorized representative;
- 3) location where GMO is released into the environment;
- 4) plan and methods of supervision of GMOs and GMO products, as well as plan of measures in case of an incident;
- 5) risk assessment with regard to human health and the environment.

The application shall also be submitted in case a GMO results from cross-breeding of two or more GMOs by applying traditional methods.

The application shall be submitted to the Ministry, and the approval in the form of a decision shall be issued by the Minister.

The Minister shall prescribe the contents and form of the application for use in closed systems, for deliberate release into the environment, of GMOs and GMO products, as well as the manner of protection of confidential data in the application.

Correcting Deficiencies in the Application
Article 11

If the application does not contain the data referred to in Article 10 of this Law, the Ministry shall

inform the applicant to correct the identified deficiencies within the period of 30 days.

If the applicant fails to correct the deficiencies within the specified period, the application shall be refused.

Confidential Data Article 12

The applicant may identify certain data in the application as confidential.

The confidential data shall be kept by all persons with access to confidential data for the period of 10 years from the date of the application submission.

The confidential data shall not be deemed to be data referred to in Article 10, paragraph 2, items 1) to 5) of this Law, nor the data already available to the public.

It shall be prohibited to use the data from one application on the experiments undertaken for risk assessment purposes in other applications without the written approval of the data owner within the period of 10 years from the day the experiment was carried out.

The data identified as confidential shall remain confidential when the applicant withdraws the application.

The Minister shall determine the list of persons with access to confidential data and prescribe the manner of treating, keeping and exchange of data between the persons granted access to confidential data.

Authorized Laboratory Article 13

The testing of GMOs and GMO products for the purposes of identifying and quantifying the genetic modification shall be carried out by the laboratory authorized by the Ministry.

The authorization shall be granted by the decision of the Minister.

The Minister shall revoke the authorization if it is found that the authorized laboratory fails to meet the prescribed requirements, or that the authorization was granted based on incorrect and false data.

The Minister shall prescribe the requirements that must be fulfilled by the authorized laboratory concerning the facilities, technical equipment and human resources, as well as methods used for testing of GMOs and GMO products.

Testing and Report on Testing Performed Article 14

The applicant shall submit to the authorized laboratory a certain quantity of the material for the

purposes of GMOs and GMO products testing, at the request of the Ministry, during the consideration of the application or following the obtaining of the approval.

The authorized laboratory, on completing the testing referred to in paragraph 1 of this Article, shall prepare the report and submit it to the Ministry.

The authorized laboratory and its employees shall keep the data specified as confidential, as well as the results obtained through testing, in accordance with this Law.

The Minister shall prescribe the manner and deadlines for reporting referred to in paragraph 2 of this Article.

Informing the Public Article 15

Following the receipt of the application, the Ministry shall make available to the public the contents of the application in at least one daily newspaper distributed on the entire territory of the Republic of Serbia, and through electronic media.

The Ministry shall organize and administer the public discussion lasting up to 30 days from the day of making the application contents available to the public.

The opinion of the Expert Council and the final decision with the rationale shall be published by the Ministry in at least one daily newspaper distributed on the entire territory of the Republic of Serbia and through electronic media.

Issuing the Decision Article 16

Based on the opinion of the Expert Council, and taking into account the relevant public comments, as well as the report of the authorized laboratory in case the report was requested, the Minister shall issue the decision approving the use in closed systems, deliberate release into the environment specifying the safety measures and the duration of the approval.

In case the requirements specified by this Law for contained use, deliberate release into the environment have not been met, the Minister shall issue the decision refusing the application of the applicant.

The decision of the Minister referred to in paragraphs 1 and 2 of this Article shall be final.

If the responsible state administration authority, following the issuance of the decision approving deliberate release into the environment, finds that the developer, user or their authorized representative in the Republic of Serbia no longer meets the requirements prescribed for the granting of the approval, it shall order to the persons in question to undertake relevant measures, and, where appropriate, by way of a decision, temporarily or permanently revoke the approval.

The decision of the Minister referred to in paragraph 4 of this Article shall be final.

Renewal of the Approval
Article 17

The applicant shall submit the application for renewal of the approval to the Ministry six months prior to the expiry of the approval.

The application referred to in paragraph 1 of this Article shall contain:

- 1) a copy of the approval subject to the renewal request;
- 2) report on the monitoring results;
- 3) new information related to the assessment of risk for human health and the environment;

By the time of issuance of the new decision, the applicant may continue with the use in closed systems, deliberate release into the environment.

The Minister shall prescribe the contents of the application for renewal of approval for use in closed systems, for deliberate release into the environment.

Article 18

If this Law does not regulate the procedure of approval issuance, the provisions of the law governing general administrative procedure shall apply *mutatis mutandis*.

III. REQUIREMENTS FOR USE IN CLOSED SYSTEMS AND FOR DELIBERATE
RELEASE INTO THE ENVIRONMENT OF GMOs

1. Requirements for Use in Closed Systems

License
Article 19

The approval for the use of GMOs in closed systems shall be issued to the legal person in the form of a license.

The license referred to in paragraph 1 of this Article shall be issued for one or several levels of risk.

The legal person must establish an expert body for the assessment of the risk for the use in closed systems and meet the requirements regarding the human resources, facilities and technical equipment prescribed by this Law and regulations adopted on the basis of this Law.

The Minister shall prescribe the requirements for the work of the expert bodies related to risk assessment, as well as the requirements that must be met by legal persons with regard to human resources, facilities and technical equipment.

Risk Level Classification Article 20

The use in closed systems shall be classified into four levels of risk:

- 1) use with negligible risk – level one;
- 2) use with minor risk – level two;
- 3) use with significant risk – level three;
- 4) use with high risk – level four.

Classification into certain risk levels shall be carried out on the basis of the undertaken safety measures in line with the requirements prescribed by this Law and the regulations adopted on the basis of this Law.

The Minister shall prescribe the criteria for risk classification, measures in case of an incident, manner of handling the GMOs at certain risk levels, the manner of disposing of the resulting waste, and other requirements for use in closed systems at a particular level of risk.

Revoking the License Article 21

If the legal person ceases to meet the requirements referred to in Articles 19 and 20 of this Law, its license for use in closed systems may be temporarily revoked.

The Minister shall issue the decision on suspending the license, order the removal of deficiencies and specify the period of 60 days from the day of the submission of the decision for the removal of deficiencies.

The license for use in closed systems shall be permanently revoked if the legal person fails to remove the deficiencies due to which the license has been suspended.

The Minister shall issue a decision permanently revoking the license.

The decision of the Minister shall be final.

2. Requirements for Deliberate Release into the Environment

Cross-Border Movement of LMOs Article 22

For each cross-border movement of LMOs whereby they are deliberately released into the environment for the purposes of performing experiments, demonstration experiments and development of new varieties, all the obligations under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity that refer to the first cross-border movement for the purpose of deliberate release into the environment shall apply.

Monitoring Plan, Plan of Measures in Case of an Incident and Risk Assessment
Article 23

The monitoring plan that is submitted by the applicant along with the application for deliberate release of GMOs into the environment shall also contain the manner of waste disposal.

The Minister shall prescribe the manner of preparing the monitoring plan and methods of monitoring GMOs, the manner of preparing the plan of measures in case of an incident, and the contents of risk assessment for deliberate release into the environment.

Data or Results of Deliberate Release into the Environment of the Other Applicant
Article 24

In the application, the applicant may refer to the data or results of the deliberate release into the environment submitted to the Ministry by a different applicant, provided the applicant has obtained the written consent of the other applicant.

Duty of the Applicant
Article 25

If the data on any modification or unintended modification of the GMO becomes available to the applicant during the time that the Ministry is considering the application or after the issuance of the approval for deliberate release into the environment, and such data may affect the assessed risk for human health and the environment, the applicant shall:

- 1) undertake the necessary measures for the protection of human health and the environment;
- 2) inform the Ministry of the new data that may affect the assessed risk for human health and the environment;
- 3) adjust the measures for case of an incident stated in the application or the approval for the purposes of the protection of human health and the environment.

If the data on any modification or unintended modification of the GMO that may significantly affect the assessment of risk for human health and the environment becomes available to the Ministry, the Ministry shall make such data available to the public and order the developer, user or their authorized representative in the Republic of Serbia to:

- 1) stop the deliberate release into the environment;
- 2) cease the deliberate release into the environment until the conditions for the deliberate release into the environment are adjusted.

Issuing One Approval
Article 26

The applicant may be allowed the deliberate release into the environment on the same location or on different locations for the same purpose by issuing one approval.

Report on the Results of Deliberate Release into the Environment
Article 27

During and on completion of the deliberate release into the environment, within the periods specified in the approval, the developer, user or their authorized representative in the Republic of Serbia shall submit to the Ministry the report on the results of the deliberate release into the environment in a written or electronic form.

The Minister shall prescribe the contents and form of the report on the results of the deliberate release into the environment.

IV. HANDLING, PACKAGING AND TRANSPORT OF GMO AND GMO PRODUCTS

Content of Documentation Accompanying GMOs and GMO Products during Handling, Packaging and Transport Article 28

During handling, packaging and transport, including transit over the whole territory of the Republic of Serbia, the GMOs and GMO products shall be accompanied by the documentation which must contain the data clearly indicating that they are GMOs and GMO products.

For use in closed systems, the documentation must contain the conditions and requirements for safe handling, transport and use, the place for obtaining information, including the name and address of the person or institution that has been consigned the GMO.

For deliberate release into the environment, the documentation must include identity and the appropriate characteristics of the GMOs and GMO products, conditions for safe handling, storage, transport and use, as well as the place for obtaining information.

The Minister shall prescribe the manner of handling, packaging and transport of GMOs and GMO products.

Informing the Ministry Article 29

Legal persons, entrepreneurs and natural persons are obliged to inform the Ministry when transporting genetically modified organisms or products from genetically modified organisms via the whole territory of the Republic of Serbia, in accordance with this law and other regulations.

Waste Disposal Article 30

The developer, user or their authorized representative in the Republic of Serbia shall destroy the waste containing, consisting of or derived from GMOs, as well as the waste resulting from the use of GMOs in such a manner that the GMOs are no longer capable of reproducing and transferring genetic material to other organisms.

The developer, user or their authorized representative in the Republic of Serbia is obliged to inform the Ministry about the date of when waste was destroyed.

Liability for Damage
Article 31

The developer, user or their authorized representative in the Republic of Serbia shall be liable for damage arising from its direct or indirect activity related to GMOs or GMO products, causing harmful effect for human health and the environment, in accordance with this Law and other regulations.

V. REGISTER OF GMO AND GMO PRODUCTS AND LICENSE REGISTER

1. Register of GMOs and GMO products

Entry in the Register of GMOs and GMO Products
Article 32

GMOs and GMO products for which the approval for deliberate release into the environment, for placing on the market, or for transit have been issued, shall be entered in the Register of GMOs and GMO products (hereinafter referred to as: the Register).

The data from the Register shall be public.

The Register shall be kept by the Ministry in electronic form and it may be linked with the other bases and registers of the Ministry.

The data identified as confidential in accordance with this Law and other regulations may not be entered into the Register.

The Minister shall prescribe more closely the contents and manner of keeping the Register.

Deletion from the Register
Article 33

GMOs and GMO products shall be deleted from the Register if the period specified in the decision for deliberate release into the environment expires.

The Minister shall issue the decision on deletion from the Register.

The decision of the Minister referred to in paragraph 2 of this Article shall be final.

2. Licenses Register

Entry in the Licenses Register
Article 34

Legal persons having obtained the license for use in closed systems shall be entered in the Licenses Register.

The data from the Licenses Register shall be public.

The Licenses Register shall be kept by the Ministry in electronic form and it may be linked with other electronic bases and registers of the Ministry.

The Minister shall prescribe the contents and manner of keeping the Licenses Register.

Deletion from the Licenses Register Article 35

A legal person shall be deleted from the Licenses Register:

- 1) if its license has been permanently revoked;
- 2) if it fails to submit a new application on the expiry of the period referred to in Article 17, paragraph 1 of this Law;
- 3) based on the substantiated request.

Lists to Be Published Article 36

The Minister shall determine the List of GMOs and GMO Products for Which the Approvals for Deliberate Release into the Environment have been issued, and the List of Legal Persons Granted the License for Use in Closed Systems, which are published in the “Official Gazette of the Republic of Serbia”.

VI. SUPERVISION

Article 37

The supervision of the implementation of the provisions of this Law and the regulations adopted based on this Law shall be carried out by the Ministry.

The inspection supervision of the implementation of the provisions of this Law and the regulations adopted based on this Law shall be carried out by the Ministry through phytosanitary and veterinary inspectors.

The supervision of work of the authorized laboratory in performing delegated activities of testing of GMOs and GMO products shall be carried out by the Ministry, in accordance with regulations governing state administration.

Rights and Duties of Phytosanitary Inspectors Article 38

When performing the activities of inspection supervision, phytosanitary inspectors shall have the

right and duty to:

- 1) control the use in closed systems, deliberate release into the environment for which the approval was issued;
- 2) control whether the authorized laboratory meets the requirements for testing GMOs and GMO products;
- 3) control the safety measures on deliberate release into the environment;
- 4) control the implementation of plan of measures and monitoring plan on deliberate release into the environment
- 5) control the manner of keeping records and the documentation accompanying the GMOs and GMO products;
- 6) take samples for testing GMOs and GMO products;
- 7) take samples to check the presence of prohibited GMOs or GMO products;
- 8) check disposal of waste containing, consisting of, derived from or resulting from the use of GMOs.

Measures Ordered by Phytosanitary Inspectors Article 39

When performing the activities referred to in Article 40 of this Law, phytosanitary inspectors may:

- 1) prohibit use in closed systems, deliberate release into the environment of GMOs and GMO products;
- 2) order undertaking of urgent measures for the protection of human health and the environment;
- 3) order the destruction of GMOs and GMO products that have not been approved;
- 4) order the destruction of waste containing, consisting of, derived from, or resulting from the use of GMOs;
- 5) order the undertaking of other measures, based on the authorizations under this Law.

The measures referred to in paragraph 1 of this Article shall be ordered by a decision of the phytosanitary inspector.

Rights and Duties of Veterinary Inspectors Article 40

When performing the activities of inspection supervision, veterinary inspectors shall have the right and duty to:

- 1) take samples for testing GMOs and GMO products;
- 2) take samples to detect the presence of GMOs and GMO products that have not been approved;
- 3) control the manner of keeping records and the documentation accompanying the GMOs and GMO products;
- 4) control disposal of waste containing, consisting of, derived from, or resulting from the use of GMOs.

Measures Ordered by Veterinary Inspectors
Article 41

When performing the activities referred to in Article 40 of this Law, veterinary inspectors may:

- 1) order the destruction of GMOs and GMO products that have not been approved;
- 2) order the destruction of waste containing, consisting of, derived from, or resulting from the use of GMOs;
- 3) order the undertaking of other measures based on the authorizations under this Law.

The measures referred to in paragraph 1 of this Article shall be ordered by a decision from the veterinary inspectors.

Responsibility for Deciding on Appeals
Article 42

The decisions of the phytosanitary and veterinary inspectors may be appealed to the Minister within eight days of the day of delivery of the decision.

The appeal shall not stay the execution of the decision.

Testing and Testing Costs
Article 43

If there is suspicion that GMOs and GMO products are used contrary to the provisions of this Law, the phytosanitary or veterinary inspector shall request the developer, user or their authorized representative in the Republic of Serbia to present the relevant approvals.

If the developer, user or their authorized representative in the Republic of Serbia does not hold the approval, the phytosanitary or veterinary inspector shall prohibit the use in closed systems, deliberate release into the environment of GMOs and GMO products, and deliver the sample of GMOs and GMO products to the authorized laboratory for analysis.

If the analysis demonstrate that the GMO and GMO product have not been approved, the phytosanitary or veterinary inspector shall issue the decision prohibiting use in closed systems, deliberate release into the environment and the GMO and GMO product sample shall be destroyed.

The costs of the analysis and the destruction of the GMO and GMO product shall be borne by the developer, user or their authorized representative in the Republic of Serbia.

The costs of the testing under the inspector's order shall be borne by the applicant.

Funds for Enforcing this Law
Article 44

The applicant shall pay the republic administrative fee for the procedure of considering the application for use in closed systems, for deliberate release into the environment.

The funds referred to in paragraph 1 of this Article shall be revenues of the Budget of the Republic of Serbia.

VII. PENAL PROVISIONS

1. Criminal Offense

Article 45

The person that, contrary to the provisions of this Law, commences the use of GMOs and GMO products in closed systems, deliberate release into the environment, placing on the market or transit, or disposes of them into the environment and thus causes harmful consequences for human health and the environment, shall be punished for a criminal offense by imprisonment of up to three years.

The GMOs and GMO products referred to in paragraph 1 of this Article shall be confiscated and destroyed at the expense of the person having committed the criminal offense.

2. Commercial Offense

Article 46

The legal person shall be fined in the amount from RSD 500,000 to 3,000,000 for a commercial offense if it commences the use of GMOs and GMO products in closed systems, deliberate release into the environment, placing on the market or transit, without obtaining the approval of the Ministry (Article 9).

For a commercial offense referred to in paragraph 1 of this Article, the responsible person within the legal person shall also be fined in the amount from RSD 50,000 to 200,000.

For the actions referred to in paragraph 1 of this Article, in addition to the fine, the protective measure may be ordered prohibiting the legal person to perform certain economic activity, or the protective measure prohibiting the responsible person within the legal person from performing certain duties in the duration from six months to seven years.

The GMOs and GMO products referred to in paragraph 1 of this Article shall be confiscated and destroyed at the expense of the person having committed the commercial offense.

3. Misdemeanors Committed by Legal Persons

Article 47

A legal person shall be fined in the amount from RSD 200,000 to 1,000,000 for a misdemeanor:

- 1) if it fails to keep confidential data for the period of 10 years after the date of the submission of the application (Article 12, paragraph 2);
- 2) if it uses the data from one application on the experiments performed for risk assessment in other applications without the written approval of the owner of the data within the period of 10 years from the date the experiment was performed (Article 12, paragraph 4);
- 3) if it carries out the testing of GMOs and GMO products without the authorization of the Ministry (Article 13);
- 4) if it fails to prepare the report following the completed testing of the GMOs and GMO products and to submit it to the Ministry (Article 14, paragraph 2);
- 5) if it fails to submit the application for approval renewal within the prescribed period, and continues operation (Article 17, paragraph 1);
- 6) if it engages in use in closed systems without having the license for a certain degree of risk (Article 19);
- 7) if it fails to notify the Ministry of the data on any change or unintentional modification of the GMO while the Ministry is considering the application or after issuing the approval for deliberate release into the environment (Article 24, paragraph 1);
- 8) if it fails to submit to the Ministry the report on the results of the deliberate release into the environment (Article 25, paragraph 1);
- 9) if the documentation accompanying GMOs and GMO products in handling, packaging and transport does not contain the data referred to in Article 28 of this Law;
- 10) if it fails to destroy the waste containing, consisting of or derived from GMOs and the waste resulting from the use of GMOs (Article 30).

For a misdemeanor referred to in paragraph 1 of this Article the responsible person within a legal person shall also be fined in the amount from RSD 10,000 to 50,000.

4. Misdemeanors Committed by Entrepreneurs Article 48

An entrepreneur shall be fined for a misdemeanor in the amount from RSD 250,000 to 500,000:

- 1) if it fails to keep confidential data for the period of 10 years after the date of the submission of application (Article 12, paragraph 2);
- 2) if it uses the data from one application on the experiments performed for risk assessment in other applications without the written approval of the data owner within the period of 10 years from the date when the experiment was performed (Article 12, paragraph 4);
- 3) if it fails to submit the application for approval renewal within the prescribed period, and continues operation (Article 17, paragraph 1);
- 4) if it engages in use in closed systems without having the license for a particular degree of risk (Article 19);
- 5) if it fails to notify the Ministry of the data on any change or unintentional modification of the GMO while the Ministry is considering the application or after issuing the approval (Article 25, paragraph 1);
- 6) if it fails to submit to the Ministry the report on the results of the deliberate release into the environment (Article 27, paragraph 1);
- 7) if the documentation accompanying GMOs and GMO products in handling, packaging and

- transport fails to contain the data referred to in Article 28 of this Law;
- 8) if it fails to destroy the waste containing, consisting of or derived from GMOs and the waste resulting from the use of GMOs (Article 30).

5. Misdemeanors Committed by Natural Persons Article 49

A natural person shall be fined for a misdemeanor in the amount from RSD 30,000 to 50,000:

- 1) if it engages in deliberate release into the environment without obtaining approval (Article 9);
- 2) if it fails to observe the plan of measures in case of an incident (Article 10);
- 3) if the documentation accompanying GMOs and GMO products in handling, packaging and transport fails to contain the data referred to in Article 28 of this Law;
- 4) if it fails to destroy the waste containing, consisting of derived from GMOs and the waste resulting from the use of GMOs (Article 30).

VIII. TRANSITIONAL AND FINAL PROVISIONS

Deadline for Aligning Business Operations Article 50

The developer, user or their authorized representative in the Republic of Serbia shall align its business operations with the provisions of this Law within six months from the day this Law comes into force at the latest.

Adoption of By-laws Article 51

By-laws prescribed by this Law shall be adopted within six months from the day this Law comes into force.

Until the adoption of by-laws referred to in paragraph 1 of this Article, the by-laws adopted based on the Law on Genetically Modified Organisms (“Official Gazette of FRY”, no. 21/01 and “Official Gazette of RS”, no. 101/05-other law) shall apply, unless they are contrary to this Law.

Cessation of Effect of the Previous Law Article 52

On the day this Law comes into force, the Law on Genetically Modified Organisms (“Official Gazette of FRY”, no. 21/01 and “Official Gazette of RS”, no. 101/05-other law) shall cease to apply.

Coming into Force of the Law Article 53

This Law shall come into force on the eighth day from the day of its publication in the “Official Gazette of the Republic of Serbia”.

