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LAW ON GENETICALLY MODIFIED ORGANISMS

I. GENERAL PROVISIONS

Subject-matter of the Law
Article 1

This Law regulates the requirements for use of genetically modified organisms (hereinafter referred to as: the GMOs) and products that contain, are composed of, or are derived from the GMOs, their use in closed systems and intentional introduction in the environment, as well as placing on the market, handling, transportation, packing, transit through the territory of Montenegro, labeling, processing and measures for prevention

6) **GMO product**

Against a first-instance decision of a responsible authority referred to in Article 10 paragraph 1 item 3 of this Law, an appeal may be filed with the ministry responsible for health.

Against a first-instance decision of a responsible authority referred to in Article 10 paragraph 1 item 6 of this Law, an appeal may be filed with the ministry responsible for environment protection.

Transparency Principle
Article 9

General public shall have the right to be informed about GMOs management and included in the decision making process in accordance with the law.

III. RESPONSIBILITIES IN THE IMPLEMENTATION OF THE LAW

1. Responsible Authorities
Article 10

The state administration activities in the field of GMOs shall be performed by:

- ministry responsible for agriculture (hereinafter referred to as: the Ministry of Agriculture);
- ministry responsible for environmental protection (hereinafter referred to as: the Ministry of Environmental Protection);
- ministry responsible for health (hereinafter referred to as: the Ministry of Health)
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within the first-instance proceedings, establish and maintain cooperation with international organizations and responsible authorities of other countries within the scope of its responsibilities in the GMO area, adopt regulations for implementation of this Law, and perform other activities in accordance with this Law.

In performing activities referred to in Article 10 paragraph 1 item 3 of this Law, the Ministry of Health shall determine the fulfillment of prescribed requirements and issue and withdraw approvals, that is consents for performing activity to operators in transactions including food from GMOs and products containing, consisting of or deriving from GMOs of plant origin following the primary production, combined food and other food, as well as separately declared packaged food of animal origin and combined food in retail sale, establish and maintain cooperation with the National Council for Biological Safety, decide on appeals against the decisions issued within the first-instance proceedings, perform control and inspection supervision, and perform other activities in accordance with this Law.

Administrative authority responsible for veterinary matters referred to in Article 10 paragraph 1 item 4 of this Law shall conduct administrative and related expert activities in the area of food and feed containing, consisting of or deriving from GMOs, hold consultations with the applicant regarding confidential data and adopt conclusions about data considered confidential in accordance with this Law, establish and maintain cooperation with the National Council for Biological Safety, assess the additional data,

intentional introduction into the environment, hold consultations with the applicant regarding confidential data and adopt conclusions about data considered confidential, establish and maintain cooperation with the National Council for Biological Safety, assess the additional data, organize and conduct the public hearings in the procedure of deciding on applications, review potential risks from introduction of GMOs into the environment, issue approvals to GMO business operators for introduction into the environment, prepare expert basis for the audit plan, monitoring plan and plan for crisis management in the area of introduction of GMOs into the environment, conduct monitoring and perform other activities in accordance with this Law.

Article 12

The responsible administration authority referred to in Article 10 paragraphs 4, 5 and 6 of this Law, in the absence of scientific information and knowledge about possible extent of adverse effects on human health, biological diversity and the environment, or, if there are new scientific information that a product may cause adverse effects for human health, biological diversity and the environment, may temporarily restrict or prohibit importation, use and placing on the market or introduction into the environment of GMOs or products containing, consisting of or deriving from GMOs.

Regulations Adopted by the Ministry of Environment Protection
Article 14

The Ministry of Environment Protection shall adopt regulations governing in detail:

- requirements, manner and procedure for introduction of GMOs into the environment;
- requirements with regard to capacities of persons for intentional introduction into the environment, detailed content of technical dossier and requirements with regard to content and scope of risk assessment for intentional introduction of GMOs into the environment, methodology for preparing risk assessment and requirements to be met when preparing risk assessment;
- form, content, manner of keeping registers;
- other regulations for implementation of this Law.

2. National Council for Biological Safety

Establishing and Responsibilities
Article 15

For the purpose of continuous monitoring of the situation and developments in the area of genetic biotechnology with GMOs, and provision of scientific and expert assistance in decision making and drafting of regulations in the area of GMOs and products containing, consisting of or deriving from GMOs, the National Council for Biological Safety (hereinafter referred to as: the NCBS) is hereby established.

In performing activities referred to in paragraph 1 of this Article, the NCBS shall:

1) consider applications and provide opinions about the applications submitted by the creators, GMO business operators or their authorized representatives for the purpose of obtaining approvals for transit, use in the closed systems, intentional introduction into the environment, placing on the market of GMOs or products containing, consisting of or deriving from GMOs;
2) provide opinion about the risks involved in the use in closed systems, intentional introduction into the environment, placing on the market of GMOs or products containing, consisting of or deriving from GMOs;
3)

In performing activities referred to in paragraphs 1 and 2 of this Article, the NCBS shall establish and maintain cooperation with ministries, responsible state authorities and administrative authorities.

NCBS Organization and Method of Operation
Article 16

Members of the NCBS shall be appointed from the ranks of distinguished public, scientific and expert workers who hold PhD degree in the fields of biology, agriculture, medicine, veterinary medicine, microbiology, genetics, ecology, evolutionary biology, population biology, toxicology, alergology, forestry, biochemistry, molecular biology and other relevant scientific fields.

The NCBS shall have a president and 10 members to be appointed for a period of four years.

Members of the NCBS shall be appointed by the Government of Montenegro (hereinafter referred to as: the Government) upon the proposal of responsible state administration authorities.

Ministry of Agriculture shall nominate six members, and the Ministry of Environment Protection shall nominate five members of the NCBS.

Method of operation and organizational structure of the NCBS shall be regulated by the NCBS rules of procedure.

The NCBS shall submit to the Government a report on its operations at least once a year.

Administrative-technical tasks for the needs of the NCBS shall be performed by the Ministry of Agriculture and the Ministry of Environment Protection on a parity basis.

Persons employed with the administration authorities may not be members of the NCBS.

Article 17

Members of the NCBS shall receive compensation for their work.

Funds for operation of the NCBS shall be allocated from the budget of Montenegro on the positions of the Ministry of Agriculture and the Ministry of Environment Protection on a parity basis.

Protection of Confidential Data
Article 18

Members of the NCBS shall, in the course of and after expiry of their respective periods of office, protect the data that are designated as confidential in accordance with this Law.

IV. GENETICALLY MODIFIED ORGANISMS

Applications and Approvals

Public Notice with Regard to the Content of Application and Decision upon Application
Article 25

Following receipt of the application, the responsible state administration authority shall, in at least one daily printed media that is distributed throughout the territory of Montenegro, in electronic media and on the website of the responsible authority, publish a notice containing basic information on the applicant and the subject of application, location and period in which access will be allowed to the availab2(s)1e will 8iiwill ned ando e 8.2(o)e

Notification of the Closed System
Article 27

Based on the risk assessment, the applicant shall propose the classification of the use of

Administration authority referred to in paragraph 1 of this Article shall decide on the application within 45 days after the day of receipt of the application.

Commencement of Use of Risk Level 3 and 4
Article 31

For the first and every subsequent contained use of GMOs or products containing, consisting of or deriving from GMOs, classified in risk level 3 or 4, which will take place in the closed system registered for that level of risk, the application shall be submitted to the administration authority referred to in Article 30 paragraph 1 of this Law.

If the closed system referred to in paragraph 1 of this Article has been entered in the register referred to in Article 27 paragraph 5 of this Law for contained use of GMOs classified in risk level 3 and 4, the use of GMOs or products containing, consisting of or deriving from GMOs may commence only after obtaining an approval of the administration authority referred to in Article 30 paragraph 1 of this Law.

Administration authority referred to in paragraph 1 of this Article shall, without delay, submit to the NCBS a copy of the application and accompanying documentation.

The NCBS shall submit the opinion on the application and accompanying documentation to the administration authority referred to in paragraph 3 of this Article within 45 days after the day of receipt of the copy of application.

Administration authority referred to in paragraph 1 of this Article shall decide on the application within 90 days after the day of receipt of the application.

VI. INTENTIONAL INTRODUCTION OF GMOs INTO THE ENVIRONMENT

Submitting of Application
Article 32

Before the intentional introduction of GMOs, products containing, consisting of or deriving from GMOs into the environment, the applicant shall obtain the approval of the administration authority responsible for environment protection.

The application for introduction of GMOs into the environment must contain the information on the applicant, in particular:

- name, corporate headquarters for legal person and name of the legal representative, and for natural person name, personal identification number and domicile;
- information on professional qualifications of the person that will perform intentional introduction of GMOs into the environment;
- quantity of GMOs planned to be introduced into the environment;
- warning about the adverse effects of GMOs in the conditions of different methods of use.

The following documentation shall be appended to the application referred to in paragraph 2 of this Article:

- evidence of the registration in the CRCC, or other relevant register;
- technical dossier that contains in particular:
  1. general information about the GMO;
  2. information about the conditions of introduction and the area in which the introduction of the GMO is planned;
  3. information about interaction between the GMO and the environment;
  4. plan of monitoring of effects of the GMO on the environment, biological diversity and human health;
  5.

GMOs into the environment and other requirements to be met in order to reach the decision on the application.

Administration authority referred to in paragraph 1 of this Article shall submit to the NCBS, without delay, a copy of the complete application and accompanying documentation.

The NCBS shall submit to the responsible authority referred to in paragraph 1 of this Article the expert opinion about the analysis of the information provided in the application for introduction of GMOs into the environment within 60 days from the day the copy of the application was received.

If the responsible authority referred to in paragraph 1 of this Article requests the submission of additional data, the request must contain the reasons and deadline for submitting additional data.

The administration authority responsible for environment protection shall decide on the application within 90 days from the day the complete application was received.

By the decision referred to in paragraph 6 of this Article, the introduction of GMOs into the environment may be approved on the location specified in the application or on the other location with the same intended use.

The decision approving the introduction of the GMOs into the environment shall contain in particular main characteristics of the GMOs and the summary of the results of risk assessment, the requirements, manner and procedure for introduction into the environment, deadlines for submittal of reports, period for which it is being issued and, in the explanation, observations with regard to the opinions presented in the public hearing.

The applicant may commence the introduction of GMOs into the environment only after obtaining an approval from the responsible state administration authority.

The administration authority referred to in paragraph 1 of this Article shall enter the applicant that has been approved for intentional introduction of GMOs, products containing, consisting of or deriving from GMOs into the environment, in the register of issued approvals for intentional introduction into the environment and shall issue a decision on entry in the register to the applicant within eight days from the day of such entry.

Article 34

It shall be prohibited to introduce GMOs into the environment in the protected areas, in the areas intended for organic production of agricultural products, and in the areas for development of eco-tourism.

Article 35

When the GMO business operator gains knowledge of the information on the alteration or unintentional change of the introduced GMO which may affect the human health and the environment, it shall without delay:

1) undertake measures necessary for the protection of human life and health and the environment;
2) cancel introduction into the environment;
3) notify the responsible authority of every change in the requirements that are relevant for risk assessment, as well as of any unintentional change or new information;

8. proposal of the product labeling;
9. proposal of the product packing;

The following shall in particular be submitted along with the application referred to in paragraph 1 of this Article:

1. technical documentation;
2. risk assessment;
3. plan of monitoring the intended placing on the market;
4. excerpt from the content of technical documentation.

The applicant shall, for every intended use of the GMO or product containing,

Content of the Approval
Article 42

The approval for placing on the market GMO or product containing, consisting of or deriving from GMOs shall contain in particular:

- name and corporate headquarters of the GMO business operator for the legal person and name of the legal representative, and, for natural person, name, personal identification number and domicile, that is relevant data from the identification document for foreign citizens;
- information about the GMO, namely the product containing, consisting of or deriving from GMOs and a unique code;
- intended use and scope for which the approval is issued, as well as identification of the product with indication of its characteristics;
- period for which the approval is issued;
- conditions for placing on the market, inclusive of specific conditions for use, handling, packing, as well as the conditions for human health and environment protection or specific ecological system or geographic area;
- obligation to control samples and submit the results to the responsible authority;
- instructions for labeling;
- monitoring instructions as well as the obligation of informing the responsible authority about the results of monitoring;
- other requirements to be met by the operator referred to in item 1 of this paragraph when placing on the market or using the product.

Approval and risk assessment for biological diversity, human health and the environment, except for the data designated as confidential, must be made available to the public in accordance with this Law.

Recognition of Validity of Foreign Country's Approval
Article 43

The responsible authority may, in the procedure of issuing approval for placing on the market GMO or product containing, consisting of or deriving from GMO, after obtaining the report of the NCBS and/or the National Council for Food Safety Assessment, issue a decision to the applicant recognizing the validity of the document based on which it was issued the approval for placing the product on the market in other country, provided the document specifies requirements corresponding to the requirements prescribed by this Law.

Decision referred to in paragraph 1 of this Article shall specify the manner of monitoring and the obligation of informing about the results of monitoring.

Notwithstanding paragraph 1 of this Article, the responsible authorities referred to in Article 39, that is Article 40 of this Law may, after obtaining the report from the NCBS or the National Council for Food Safety Assessment, temporarily restrict or prohibit placing on the market of GMO or product containing, consisting of or deriving from

GMOs, if, based on the information on new scientifically based data, it has established that the GMO or product containing, consisting of or deriving from GMO may represent a risk that was not taken into account on issuance of the approval.

c) for products for which there is no list of components, a mark that the product has been obtained from GMOs.

When placing on the market GMOs or products containing, consisting of or deriving from GMOs, the seller shall submit to the GMO business operator the documentation containing information specified in paragraph 1 of this Article.

The person referred to in paragraph 1 of this Article that is placing on the market GMO or products containing, consisting of or deriving from GMOs shall maintain a database and put in place the procedure which will ensure monitoring and identification, in the period of five years from each event of placing on the market, of the person from which the GMO or product containing, consisting of or deriving from GMO has been obtained, and the persons to which such GMOs or GMO products have been made available, with the exception of end consumers.

Trans-boundary Movement
Article 46

Trans-boundary movement of GMOs or products containing, consisting of or deriving from GMOs may be performed only subject to the approval for use in closed systems, for introduction into the environment and placing on the market in accordance with the provisions of this Law.

The Government shall, upon proposal of the responsible state administration authority, temporarily restrict or prohibit importation and use of GMOs or products containing, consisting of or deriving from GMOs in the absence of scientific information and knowledge with respect to the possible extent of adverse effects on human health, biological diversity and the environment, or in case new or additional scientifically based information that the GMO may cause adverse effects to human health, biological diversity and the environment become available.

VIII. RENEWAL OF APPROVALS, LABELING, HANDLING AND PROCEDURE FOR THE CASE OF INCIDENT

Application for Extension of the Approval
Article 47

The GMO business operator, for the purpose of extending the approval for use in closed systems, introduction into the environment and placing on the market of GMO or product containing, consisting of or deriving from GMOs, shall, not later than nine months before expiry of the approval, submit to the responsible authority the application containing in particular:

- a copy of the approval for placing on the market whose extension is requested;
- report on the results of monitoring;
- new information on the level of risk for biological diversity, the environment and human health, that it has available;

- proposal for amendment of the requirements for placing on the market from the current approval and in particular with respect to monitoring and time limit of the approval validity, if necessary.

Approval may be extended for the period of up to five years.

The GMO business operator referred to in paragraph 1 of this Article may extend use in closed systems, introduction into the environment and placing on the market GMO or product containing, consisting of or deriving from GMOs, under the conditions specified in the approval until receipt of the approval in accordance with paragraph 1 of this Article.

The provisions of this Law shall apply to the procedure upon application for extension of the approval.

Labeling
Article 48

The GMO business operator shall label the packaging or packing material and the accompanying documentation of GMOs or products containing, consisting of or deriving from GMOs with a clear and apparent mark.

Packaged GMOs or products referred to in paragraph 1 of this Article shall be labeled with a mark on the packaging or packing material, and the unpackaged product with a mark on the product or by positioning the mark immediately next to the product.

The mark referred to in paragraph 2 of this Article must have the following contents:
- „genetically modified organism“, or
- „this product contains a genetically modified organism“, or
- „this product consist of genetically modified organism“, or
- „this product derives from genetically modified organism”.

The mark referred to in paragraph 3 of this Article must also contain the unique identification code.

Detailed manner of labeling GMOs or products containing, consisting of or deriving from GMOs and the accompanying documentation referred to in paragraph 1 of this Article shall be specified in a regulation adopted by the Ministry of Agriculture in cooperation with the Ministry of Environment Protection and the state administration authority responsible for health.

The level of unintentional and technologically unavoidable traces of GMO below which such products must not be labeled shall be specified in the regulation of the Government of Montenegro.

Article 49

It shall be prohibited to place on the market GMOs or products containing, consisting of or deriving from GMOs which are not labeled in accordance with Article 57 paragraph 1 of this Law.

Handling, Packing and Transport of GMOs
Article 50

In every event of handling, transport and packing of GMOs or products containing, consisting of or deriving from GMOs, the accompanying documentation must contain data clearly indicating that the product in question is the GMO intended for:

- use in closed systems: about requirements and manner of handling, storing,

- circumstances of the incident;
- type and quantity of the GMO that was unintentionally introduced into the environment;
- undertaken and required actions and measures to protect human health and the environment, and other information necessary to assess the effects of the incident on human health, biological diversity and the environment.

Liability
Article 54

GMO business operator that performs activities in closed systems, intentionally introduces GMOs into the environment and places on the market GMOs or product containing, consisting of or deriving from GMOs shall compensate the costs of removing the danger and the costs of remedying any consequences of the adverse effects caused by the GMOs management.

Legal or natural person that performs activities in closed systems, intentionally introduces GMOs into the environment or places on the market products containing, consisting of or deriving from GMOs shall compensate for the damage caused by the GMOs management, which shall not exclude its criminal liability.

Detailed procedure for destroying waste shall be specified in the regulation of the Ministry of Environment Protection with consent of the Ministry of Agriculture.

Costs
Article 57

The costs of the responsible state authority, that is responsible administration authority that incurred in the procedure of considering the application and issuing the approval for use in closed systems, intentional introduction into the environment, placing on the market GMOs or products containing, consisting of or deriving from GMOs and the trans-boundary movement shall be borne by the applicant.

Amount of costs referred to in paragraph 1 of this Article shall be prescribed by the regulation of the Government.

IX. GMO REGISTERS

Entry into the Register
Article 58

The responsible authority shall enter in the register the decision issued for registration of the closed system, for use of GMOs in the closed system, for introduction into the environment and placing on the market.

Register of issued approvals for closed systems referred to in Article 27 paragraph 5 of this Law shall be kept by the administration authority responsible for phytosanitary matters.

Register of issued approvals for introduction of GMOs into the environment referred to in Article 33 paragraph 10 of this Law shall be kept by the administration authority responsible for environment protection.

Register of issued approvals for placing on the market GMOs, products containing, consisting of or deriving from GMOs referred to in Article 41 paragraph 3 of this Law shall be kept by the state administration authority responsible for health, administration authority responsible for veterinary matters and administration authority responsible for phytosanitary matters.

It shall be not be allowed to enter in the Register of GMOs and products containing, consisting of or deriving from GMOs data which were designated as business secret, in accordance with this Law, or which enjoy protection in accordance with specific regulations.

Registers of GMOs with data not of confidential nature must be made available to the public.

The form, content and manner of keeping registers referred to in paragraphs 2, 3, 4 of this Article shall be prescribed in the regulation by the responsible state administration authorities.

Removal from the Register
Article 59

The responsible authority shall remove from the register legal person for which it is determined that it fails to meet the prescribed requirements for obtaining decision approving entry in the register of closed systems, for use of GMOs in the closed systems, for introduction into the environment and placing on the market, legal person that ceased to perform its activity and if a protective measure of banning further performing of activity has been ordered.

The responsible authority shall issue a decision on removal from the register in cases referred to in paragraph 1 of this Article.

The decision on removing legal person from the register shall contain in particular:

- name and corporate domicile of the legal person;
- first name and last name of the natural person;
- control number.

Article 60

Administration authority responsible for veterinary matters, phytosanitary matters and environment protection shall publish in the „Official Gazette of Montenegro“ the list of GMOs or products containing, consisting of or deriving from GMOs for which they have issued a decision approving intentional introduction into the environment for commercial purposes or placing on the market.

X. INSPECTION SUPERVISION

Article 61

Inspection supervision over the implementation of this Law and regulations adopted based on this Law shall be conducted by the Ministry of Health through the sanitary inspector, administration authority responsible for veterinary matters through the veterinary inspector, administration authority responsible for phytosanitary matters through the phytosanitary inspector and the administration authority responsible for environment protection through inspector for environment protection.

Powers of Inspectors
Article 62

Sanitary inspector shall perform supervision of safety of food of GMO of plant origin after the primary production, combined and other food in the production, international trade, wholesale and retail sale as well as separately declared packaged food of animal origin in retail sale.

Veterinary inspector shall perform supervision of safety of food of GMO of animal origin, combined food and feed in the production, international trade, wholesale and retail sale of meat, fish and other aquaculture products.

Phytosanitary inspector shall perform supervision over the implementation of the prescribed measures for use of GMOs, safety of GMO food of plant origin at the primary production stage.

Inspector for environment protection shall perform supervision over the implementation of the prescribed measures with regard to the introduction of GMOs into the environment.

Inspection controls shall be implemented using the control methods and techniques such as supervision and sampling appropriate to the subject of control.

Powers of Sanitary Inspector
Article 63

In addition to the powers of inspectors prescribed by the law governing inspection supervision, the sanitary inspector shall, in accordance with Article 62 paragraph 1 of this Law, have in particular the power to:

1) inspect and take samples of raw material and substances used for preparation and production of GMO food, if needed;
2) inspect and take samples of semi-processed GMO products, if needed;
3) inspect and take samples of processed GMO products, if needed;
4) control labeling and advertising of GMO products;
5) undertake any other activity necessary to ensure the fulfillment of objectives of this Law.

In addition to the powers referred to in paragraph 1 of this Article, the sanitary inspector performing inspection supervision in customs warehouses and in free customs zones shall have the power to:

1) following the inspection of GMO food shipments and accompanying documentation, permit importation or storing by an act determining for each shipment separately that there are no barriers for their respective importation based on the prescribed requirements;
2) take samples of GMO food and forward them to the authorized laboratories for laboratory testing.

Powers of Veterinary Inspector
Article 64

In addition to the powers of inspectors prescribed by the law governing inspection supervision, the veterinary inspector shall, in accordance with Article 62 paragraph 2 of this Law, have in particular the power to:

1) inspect and take samples of raw material and substances used for preparation and production of food and feed from GMO, if needed;
2) inspect and take samples of semi-processed GMO products, if needed;
3)

10) take samples of GMOs;
11) implement any other activity necessary to ensure the fulfillment of the objectives of this Law.

Powers of Inspector for Environment Protection
Article 66

In addition to the powers of inspectors prescribed by the law governing inspection

7) undertake other measures in accordance with the law.

The costs resulting from the implementation of the measure shall be borne by the GMO business operator.

Article 68

In addition to the administration measures and actions prescribed by the law governing inspection supervision, the inspector for environment protection shall, in accordance with Article 69 paragraph 2 of this Law, when he establishes that this Law or other regulation has been infringed, have the obligation and power to:

1) prohibit introduction into the environment to the GMO businebeovefr95

4. the applicant fails to register the closed system before the first use (Article 27 paragraph 2);
5.

or deriving from GMOs that differs from the one that was approved (Article 38 paragraph 3);

19.

Until the adoption of regulations based on the authorization from this Law, the regulations adopted based on the Law on the GMOs („Official Gazette of FRY“, No. 53/91) shall apply if they are not contrary to this Law.

Article 74

The provisions of the Law on the GMOs („Official Gazette of FRY“, No. 53/91) shall cease to apply on the day this Law comes into force.

Article 75

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