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 and elimination of adverse effects.

Definitions
Article 2

Specific terms used in this Law shall have the following meanings:

1) **Genetic material** is a part of plant, animal, fungi and microorganism, that contains genetic (hereditary) information;
2) **Microorganism** is a microbiological entity, cellular or not, that is capable of reproduction or of transferring genetic material, including viruses, viroids, animal and plant cells in the culture;
3) **Genetic modification** is intentional modification of genetic material of an organism in the manner different from natural recombination and mutation induction, namely introduction of foreign genetic material into the genetic material of organism or removal of part of the genetic material of organism;
4) **Organism** is any biological unit capable of replication or of transferring genetic material;
5) **Genetically modified organism (GMO)** is an organism, other than human being, whose genetic material has been altered in the manner not occurring naturally (mating or recombination), but through:
    a) Techniques of recombinant nucleic acid that include creation of new combinations of genetic material by introduction of the molecules of nucleic acid, regardless of the method, outside the organism into a virus, bacterial plasmid or other vector, or their introduction into the organism of the host in which they do not appear naturally but in which they are capable of continuous replication;
    b) Techniques of direct introduction into the organism of hereditary material which was prepared outside that organism, including microinjection, macroinjection, and microencapsulation;
    c) Fusion of cells (including fusion of protoplasts) or hybridization techniques where live cells with new combinations of genetic material are created by fusion of two or more cells using methods not appearing naturally;
6) **GMO product** is any product containing, composed of or derived from one or more GMOs, regardless of the degree of its processing, intended for placing on the market;
7) **Biological diversity** is a totality of all living organisms which are integral parts of ecologic systems, and includes diversity within species, between species, as well as diversity between ecologic systems;
8) **Genetic diversity** is a totality of genes of all living organisms, their diversity between units, populations, species and higher taxonomic categories;
9) **Closed system** is a laboratory, production plant or other space that is isolated from the environment, that is space isolated with physical obstacles or a combination of physical and chemical and/or biological obstacles, which prevent contact of GMOs with outside environment or their influence on it;
10) **Intentional introduction of GMOs into the environment** is intentional introduction into the environment of GMOs or a combination of GMOs without using special measures of prevention for limiting GMOs for the purpose of contact with the general population and the environment and for maintaining high level of protection of the general population and the environment, excluding placing on the market;

11) **Placing on the market GMOs** is placement of GMOs and products containing, consisting of or deriving from GMOs, at disposal of third persons, with or without compensation;
12) **Transit** is transport through the territory of Montenegro of GMOs destined for a user in other country;
13) **Risk assessment** with regard to the GMOs or products containing, consisting of or deriving from GMOs, is a scientifically based assessment and identification of possible adverse effects (direct and indirect, short-term and long-term) on the biological diversity, environment and human health, which may arise when using GMOs or products containing, consisting of or deriving from GMOs in closed systems, intentionally introducing them into the environment or placing on the market;
14) **Incident** is any event including significant and unintentional release of GMOs into the environment during controlled use, which could represent direct or delayed threat to human life and health and the environment;
15) **Authorized laboratory** is a legal person that performs testing and control of GMOs or products containing, consisting of or deriving from GMOs;
16) **GMO business operator** is a company, other legal person, entrepreneur or natural person that uses, intentionally introduces into the environment or in the closed systems, places on the market, transits the GMOs or products containing, consisting of or deriving from GMOs;
17) **Creator** is a legal or natural person that has created GMOs or products containing, consisting of or deriving from GMOs;
18) **Consumer** is a person that uses a product for consumption or immediate utilization, rather than for a business operation or activity;
19) **Applicant** is a legal or natural person that intends to use GMOs in closed systems, intentionally introduce GMOs into the environment, place on the market, transport or transit the GMOs or products containing, consisting of or deriving from GMOs;
20) **Monitoring of GMOs** is planned and systematic monitoring and surveillance of GMOs in closed systems, during intentional introduction of GMOs in the environment, and placing on the market of GMOs or products containing, consisting of or deriving from GMOs, as well as any potential adverse effects in accordance with regulations;
21) **Unique code** is an alphanumeric code composed of nine letters and numbers, that is provided for every GMO which has been approved for placing on the market, that is for culturing for commercial purposes and use for human or animal consumption;
22) **Traceability** is a possibility of tracing GMOs and products containing, consisting of or deriving from GMOs at all stages of production and distribution;
23) **Contained use of GMOs** is use where a GMO is cultured, replicated, stored, transported, destroyed, disposed of or used in any other manner in a closed system.

Exemptions
Article 3

This Law shall not apply to the products containing, consisting of or deriving from GMOs, if intended for medical and cosmetic purposes.

In vitro fertilization, natural processes such as conjugation, transduction, transformation, polyploidy induction, shall not be considered genetic modifications referred to in Article 2, item 6 of this Law, under the condition that they not include use of recombinant molecules of nucleic acid or genetically modified organisms obtained by methods other than methods to which this Law does not apply.

Application of Other Laws
Article 4

Unless otherwise prescribed by this Law, the provisions of the law governing general administrative procedure shall apply to the procedures conducted in accordance with the provisions of this Law.

Unless otherwise prescribed by this Law, the provisions of the law governing food safety shall apply mutatis mutandis to the food or feed containing, consisting of or deriving from GMOs.

Right to Appeal
Article 5

Against a first-instance decision of responsible authorities referred to in Article 10 paragraph 1 items 4 and 5 of this Law, an appeal may be filed with the ministry responsible for agriculture and veterinary medicine.

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.

II. PRINCIPLES OF GMO MANAGEMENT

Principle of Integrity
Article 6

The basis and objectives of GMO management policy, as well as measures for prevention of adverse effects of the products containing, consisting of or deriving from GMOs on the human health and the environment shall be incorporated in the strategic, planning, and program documents in fields of development, finance, education, information and promotion of scientific and research activities.

Precautionary Principle
Article 7

GMOs may be used in closed systems, intentionally introduced into the environment and placed on the market and into use in accordance with this Law.

According to the precautionary principle, the responsible authorities shall ensure that appropriate measures are undertaken to avoid any adverse effects on health and the environment that may be caused by intentional introduction in the closed systems, the environment or placing on the market of products containing, consisting of or deriving from GMOs.

Principle of Risk Assessment
Article 8

Assessment of the risk from potential negative effects on human health and the environment that may arise because of the transfer of GMO genes into other organisms shall be conducted on case to case basis, in accordance with this Law and taking into account the nature of the organism into which they are being introduced, that is the nature of the environment into which they are being introduced.

When conducting the assessment of risk from GMOs, the GMOs containing genes resistant to antibiotics for human or veterinary consumption, and which may cause adverse effects on human health and the environment, shall be separately identified and excluded.

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)
- administrative authority responsible for veterinary matters;
- administrative authority responsible for phytosanitary matters; and
- administrative authority responsible for environmental protection.

Performance of certain activities of public interest that fall within the responsibility of state administration authorities referred to in paragraph 1 of this Article may be conferred to authorized legal persons, in accordance with the law.

Responsibilities
Article 11

In performing activities referred to in Article 10 paragraph 1 item 1 of this Law, the Ministry of Agriculture shall adopt the annual audit plan, monitoring plan, crisis management plan for the case of incidents arising in connection with the GMO operations, establish and maintain cooperation with the National Council for Biological Safety, issue authorizations for testing laboratories, decide on appeals against the decisions issued within the first-instance proceedings, issue approvals for use of GMOs for experimental purposes, establish and maintain cooperation with international organizations and responsible authorities of other countries within the scope of its responsibilities in the GMO area, notify regulations and measures adopted for the implementation of this Law, 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 2 of this Law, the Ministry of Environmental Protection shall adopt the annual audit plan, monitoring plan and crisis management plan for the case of incidents arising in connection with the introduction of GMOs into the environment, establish and maintain cooperation with the National Council for Biological Safety, decide on appeals against the decisions issued 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, organize and administer public hearings in the procedure of deciding on applications for performing operations with food and feed containing, consisting of or deriving from GMOs, prepare expert basis for the audit plan, monitoring plan and plan for crisis management in the area of GMO circulation, perform control and inspection supervision, and perform other activities in accordance with this Law.

Administrative authority responsible for phytosanitary matters referred to in Article 10 paragraph 1 item 5

of this Law shall perform administrative and related expert activities in the area of reproductive GMO of plant material or products containing, consisting of or deriving from GMOs intended for placing on the market, shall decide on the applications for use in closed systems, 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, classify level of risk of a closed system, issue approvals to GMO business operators for placing on the market of GMOs or products containing, consisting of or deriving from GMOs, prepare expert basis for the audit plan, monitoring plan and plan for crisis management in the area of use of GMOs in closed systems, and conduct monitoring and perform other activities in accordance with this Law.

Administrative authority responsible for environment protection referred to in Article 10, paragraph 1, item 6 of this Law shall perform administrative and related expert activities in the area of intentional introduction into the environment of GMOs or products containing, consisting of or deriving from GMOs, decide on the applications for 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 Agriculture
Article 13

The Ministry of Agriculture shall adopt regulations governing:

- requirements for obtaining the authorization for laboratories that perform testing and control of GMOs or products containing, consisting of or deriving from GMOs;
- content of the application for obtaining approval for performing experiments, manner and conditions for performing experiments and monitoring of use of GMOs for experimental purposes;
- detailed criteria for classification, requirements for facilities and risk level in closed systems;
- requirements, content and scope of risk assessment with regard to the use of GMOs in the closed systems;
- detailed content of the application, technical documentation and monitoring requirements for placing on the market GMOs or products containing, consisting of or deriving from GMOs;
- manner of labeling products containing, consisting of or deriving from GMOs;
- requirements with regard to handling, packaging and transportation of GMOs;
- form, content, manner of keeping registers;
- form, content, manner of keeping registers of closed systems and procedure for entry therein;
- other regulations for implementation of this Law.

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) propose undertaking of measures for elimination of risks from GMOs;
4) provide opinions on drafts and proposals of laws, other regulations and general acts on GMOs;
5) analyze the situation and propose application of international achievements in the area of GMOs use;
6) establish and maintain cooperation with domestic and international institutions in the area of exchanging scientific and expert information;
7) provide proposals for informing, public participation and education with regard to the GMOs;
8) perform other activities laid down in the act on establishing the NCBS in accordance with this Law.

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.

Data confidentiality referred to in paragraph 1 of this Article shall also be protected by other persons that participate in the operations of the NCBS, that is that take part in the process of considering applications for GMOs management.

Procedures with confidential information, exchange of information between the persons that are allowed access to information shall be conducted in accordance with law.

Conflict of Interest
Article 19

Member of the NCBS that has business, financial or family (spouse, children, parents, brothers and sisters) relations with the applicant shall not participate in the voting process when providing proposals and opinions referred to in Article 16 paragraph 1 of this Law.

Member of the NCBS shall notify the president of any conflict of interest.

3. Authorized Laboratory for GMO Testing and Control

Issuing Authorizations
Article 20

Testing and control of GMOs or products containing, consisting of or deriving from GMOs may be performed only by the authorized laboratory.

Authorization for performance of testing referred to in paragraph 1 of this Article may be obtained only by the accredited laboratory with the capacity of a legal person which holds a certificate for good laboratory practice (hereinafter referred to as: GLP certificate) and fulfils the requirements laid down in the regulation adopted by the Ministry of Agriculture with prior opinion of the Ministry of Environment Protection.

Authorization for performing testing shall be issued by the Ministry of Agriculture with consent of the Ministry of Environment Protection.

Authorized laboratory, after concluding the testing of GMOs or products containing, consisting of or deriving from GMOs, shall submit the report with findings to the responsible state administration authority.

Authorized laboratory and employees of the laboratory shall protect the data designated as confidential, in accordance with the provisions of this Law, as well as the confidentiality of the findings obtained from the testing and control performed at the request of the responsible authority.

IV. GENETICALLY MODIFIED ORGANISMS

Applications and Approvals
Article 21

The use in the closed systems, intentional introduction into the environment, placing on the market and transit of GMOs or products containing, consisting of or deriving from GMOs shall be allowed under the conditions and in the manner specified by this Law.

The procedure for issuing approvals for use in closed systems, intentional introduction into the environment, placing on the market and transit of GMOs or products containing, consisting of or deriving from GMOs, shall be instigated based on the application submitted in written or electronic form.

Applicant shall submit separate application for each GMO obtained by combining two or more GMOs using the classical methods.

The applicant may commence with the use of a closed system, use of GMOs in the closed system, intentional introduction into the environment, placing on the market and trans-boundary movement of GMOs or products containing, consisting of or deriving from GMOs only after having obtained the approval of the responsible administration authority.

Article 22

It shall be prohibited to place on the market or to culture for commercial purposes the GMO in the absence of the experimental data for it and research of direct and indirect effects on the ecosystems that may be affected by its use, and which have been obtained in the experiments conducted on the territory of Montenegro.

The content of the application for obtaining approval to perform experiments, manner and requirements for performing experiments and monitoring the use of GMOs for experimental purposes shall be specified in the regulation of the Ministry of Agriculture after having obtained the opinion of the Ministry of Environment Protection.

Confidential Data
Article 23

The applicant may designate certain data in the application as a business secret, that is as confidential in accordance with the law governing protection of confidential data.

Confidential data referred to in paragraph 1 of this Article shall not be deemed to be:

a) description of genetically modified organism;
b) name and corporate headquarters of the applicant – 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;

c) date of submitting application;
d) location of the closed system, and/or location of introduction into the environment;
e) plans and methods of supervising the GMOs or products containing, consisting of or deriving from GMOs, as well as measures for the case of incident;
f) information required for risk assessment (information on potential adverse and other effects)
g) risk level for the use of GMOs in the closed system; and
h) other data specified by the responsible state administration authority in accordance with the law.

The data that were published may be not be designated as confidential data for the purposes of this Law.

Without written consent of the data owner, it shall be prohibited to use the data on the experiments conducted for risk assessment from one application in other applications, if they are not publicly available.

The responsible administration authority, member of NCBS, and employees of an authorized laboratory shall keep as confidential the data designated in the application as confidential for a period of 10 years after the application was considered, that is approved, rejected or withdrawn.

The responsible state administration authority shall, upon the consultations with the applicant, within 15 days from the day of receipt of the application, specify in a conclusion the data considered confidential.

Testing and Costs
Article 24

The applicant shall, upon request of the responsible administration authority, submit additional data as well as the appropriate quantity of GMO for the approval of which the application has been submitted, for the testing purposes.

If it is found in the analysis that a GMO or a product containing, consisting of or deriving from GMO is not permitted, the costs of the analysis and destruction, as well as of temporary disposal and storing, shall be borne by the GMO business operator or authorized representative.

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

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 available data, in accordance with the law.

The responsible administration authority shall organize and conduct public hearing in the duration of at least 45 days from the day the notice referred to in paragraph 1 of this Article has been published.

The decision of the responsible administration authority on the application shall be published in the manner specified in paragraph 1 of this Article and in the Official Gazette of Montenegro.

V. USE OF GMOs IN THE CLOSED SYSTEMS

Levels of Risk Associated with the Use of GMOs
Article 26

The use of GMOs or products containing, consisting of or deriving from GMOs in the closed systems shall be classified in one of the four levels of risk, specifically:

- Level 1 relating to the contained use where the risks are insignificant;
- Level 2 relating to the contained use where the risks are small;
- Level 3 relating to the contained use where the risks are significant;
- Level 4 relating to the contained use where the risks are high.

Operator of the business referred to in paragraph 1 of this Article shall, when using the GMOs or products containing, consisting of or deriving from GMOs in the closed system, ensure compliance with the prescribed physical, chemical and other safety conditions and handling in accordance with the prescribed requirements.

Classification of the levels of risk associated with the use of GMOs in the closed systems shall be conducted by the administration authority responsible for phytosanitary matters, based on the fulfillment of prescribed safety measures and other conditions.

The criteria for classification, requirements for facilities and level of risk referred to in paragraph 3 of this Article shall be defined in more detail in the regulation of the Ministry of Agriculture upon opinion obtained from the Ministry of Environment Protection.

Notification of the Closed System
Article 27

The use of GMOs may be conducted only in a closed system fulfilling the requirements prescribed for the level of risk in which the intended use was classified.

The applicant shall notify the closed system, before the first use, to the administration authority responsible for phytosanitary matters.

The notification of the closed system must include the information on the applicant, the closed system, and the risk level of the intended activities in the closed system, and in particular:

- name and corporate headquarters of the GMO business operator, and name of the person responsible for surveillance and safety;
- evidence on registration in the Central Registry of the Commercial Court (hereinafter referred to as: the CRCC) or other relevant register;
- information on professional qualifications and scientific references of the persons responsible for surveillance and safety;
- address and general description of the facilities and premises, and description of the nature of operations to be performed in the facility;
- risk level associated with the use of GMOs and, for the contained use of GMOs classified in the risk level 1, an excerpt from the risk assessment with regard to the intended use of GMOs and waste treatment.

If, after submitting the application, the applicant becomes aware of new information that may have significant effects on human health, biological diversity and the environment or the classification in a new level of risk, the applicant shall inform the administration authority referred to in paragraph 2 of this Article accordingly and submit a new application.

Following the submittal of application, the administration authority referred to in paragraph 2 of this Article shall test if the closed system meets the prescribed requirements and after having obtained the opinion of NCBS shall enter the closed system in the register of closed systems, if it meets the prescribed requirements, within 60 days from the day of receipt of the application and issue a decision on such entry.

Article 28

Before commencing the use of GMOs in a closed system, the applicant shall prepare the risk assessment for the intended use.

Based on the analysis of GMOs characteristics, intended use and conditions of the environment that may be exposed to threats, the assessment shall identify potential adverse effects, risk level, measures necessary for prevention of incident and other safety measures, as well as measures for treatment of waste and waste waters from the closed system.

Based on the risk assessment, the applicant shall propose the classification of the use of GMOs in closed system in one of the levels of risk referred to in Article 26 paragraph 1 of this Law.

If the applicant is in doubt with regard to the level of risk in which the use of the GMO in the closed system should be classified, the use shall be classified in the level with more strict surveillance measures.

Requirements, content and scope of the risk assessment for the use of GMOs in the closed systems shall be prescribed in more detail in the regulation of the Ministry of Agriculture in cooperation with the Ministry of Environment Protection.

Plan of Measures
Article 29

Before commencement of the use of GMOs or products containing, consisting of or deriving from GMOs in the closed system, the applicant shall prepare a plan of measures for the case of incident.

The applicant shall submit the data on the plan of measures for the case of incident which is approved by the Ministry of Agriculture after having obtained opinion of the Ministry of Environment Protection and the Ministry of Health.

Commencement of Use of Risk Levels 1 and 2
Article 30

For the first and every subsequent contained use of GMOs or products containing, consisting of or deriving from GMOs, classified in risk level 1 or 2, which will take place in the closed system registered for that level of risk, the application shall be submitted to the administration authority responsible for phytosanitary matters.

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 1 or 2, 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 paragraph 1 of this Article.

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 21 day 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 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. information about the surveillance, remedial measures, and measures to be implemented in the case of incident;
  6. summary of the dossier;
- assessment of the risk of GMO to the environment, report on the results obtained, methods used for the assessment and scientific and expert literature that was used.

Before issuing approval referred to in paragraph 1 of this Article, the administration authority responsible for environment protection shall obtain consent of the Ministry of Agriculture.

The administration authority referred to in paragraph 1 of this Article may, before issuing an approval, request the applicant to submit additional data.

The applicant may in the application refer to the data or results of intentional introduction of GMOs into the environment from other application that has been submitted to the administration authority responsible for environment protection if such data are not designated as a secret or if it has obtained written consent of the applicant in question.

Requirements related to the professional qualifications of persons for intentional introduction into the environment, detailed content of the technical dossier, content and scope of the risk assessment for intentional introduction of the GMOs into the environment, methodology for preparing the risk assessment and the requirements to be met when preparing the risk assessment shall be specified by the Ministry of Environment Protection upon the opinion of the Ministry of Agriculture.

Article 33

The administration authority responsible for environment protection shall record the application number and date and, upon request, issue to the applicant the certificate acknowledging receipt with the date and number from the records.

The administration authority referred to in paragraph 1 of this Article shall, in accordance with scientific development of biotechnology and other available information, after receiving complete application, evaluate the potential risks of the introduction of the 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;
3) implement more strict measures with the purpose of protecting human health and the environment than those that are identified in the approval.

The applicant shall, in the course of the procedure for approving introduction of GMOs into the environment, without delay notify the responsible authority of any change in the requirements that are relevant for risk assessment, unintentional change or new information and it shall provide for more strict measures with the purpose of protecting human health and the environment, which are indicated in the application.

When administration authority responsible for environment protection gains knowledge of the information referred to in paragraphs 1 and 2 of this Article which may have significant effect on the assessment of risk to human health and the environment, it shall evaluate such information, make them accessible to the general public, and order the applicant to adjust the conditions of intentional introduction of GMOs into the environment or cancel the intentional introduction of GMOs and products containing, consisting of or deriving from GMOs into the environment.

If, in the course of the procedure of introducing GMOs into the environment, the GMO business operator suspects that the level of risk is higher than the one that was estimated, it shall without delay cancel the introduction of GMOs into the environment and notify the administration authority referred to in Article 10 paragraph 1 item 6.

Report on Intentional Introduction of GMOs into the Environment
Article 36

The GMO business operator shall submit to the administration authority responsible for environment protection the report on the progress of intentional introduction of the GMOs into the environment within 60 days from the day of introduction and, within the deadlines specified in the approval, submit interim reports in written or electronic form.

The report referred to in paragraph 1 of this Article shall contain the results of introduction and in particular the observations of significance for potential risk to health and the environment.

Detailed content and form of the report referred to in paragraph 1 of this Article shall be prescribed in the regulation by the Ministry of Environment Protection.

VII. PLACING ON THE MARKET AND TRANSBOUNDARY MOVEMENT

Obtaining the Approval
Article 37

A company, other legal person, entrepreneur or natural person that intends to place on the market for the first time GMO or product containing, consisting of or deriving from GMO shall obtain approval for placing on the market GMO or product containing, consisting of or deriving from GMO.

The person referred to in paragraph 1 of this Article shall, before submitting the application for issuing approval for placing on the market the GMO or product containing, consisting of or deriving from GMO, prepare the assessment of risk that may be caused by the intended placing on the market.

The risk assessment shall, based on the analysis of characteristics of the GMO or product containing, consisting of or deriving from GMO and its use, determine possible adverse effects on the human health and environment, the level of risk as well as the monitoring plan.

The content and scope of risk assessment for placing on the market the GMO or product containing, consisting of or deriving from the GMOs, methodology for preparing the assessment and the requirements to be met by the legal person for preparing risk assessment shall be prescribed in the regulation of the Ministry of Agriculture in agreement with the Ministry of Health.

Risk assessment may be prepared by the legal person authorized by the Ministry of Agriculture with consent of the Ministry of Health.

Application
Article 38

The person referred to in Article 37 paragraph 1 of this Law shall submit the application containing:

1. name and corporate headquarters for the legal person and name of the legal representative, and for natural person name, personal identification number and domicile;
2. proposal of the commercial name of the product;
3. data on the producer, importer or distributor that is, in accordance with regulations, responsible for placing the product on the market;
4. data on the authorized laboratory that shall control the samples;
5. intended use of product;
6. information on the requirements for placing on the market, as well as specific requirements for the use and handling of the product;
7. proposal of the period for which the approval is requested;
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, consisting of or deriving from GMO that is different from the one approved, submit a new application for obtaining approval for placing on the market.

The applicant may in the application refer to the data from other application, provided such data are not designated as a secret or if it has acquired written consent from such applicant.

Detailed content of the application, technical documentation and conditions for monitoring shall be prescribed in the regulation by the Ministry of Agriculture.

Procedure of the Responsible State Administration Authority upon Application
Article 39

The Ministry of Health shall, with respect to GMO food and products containing, consisting of or deriving from the GMOs of plant origin after the primary production, combined and other food, as well as

separately declared packaged food of animal origin and combined food in retail sale, administer public hearing in accordance with Article 25 paragraphs 1 and 2 of this Law and without delay submit the copy of the complete application to the NCBS, and/or the National Council for Food Safety.

The NCBS and the National Council for Food Safety shall submit the expert opinion to the responsible authority referred to in paragraph 1 of this Article within 45 days from the day of receiving the application, at the latest.

If the national council referred to in paragraph 2 of this Article fails to submit the expert opinion within 45 days from the day of submitting the copy of the application, it shall be deemed that the opinion is negative.

The responsible state authority referred to in paragraph 1 of this Article shall prepare and submit to the applicant a report on suitability of the product for placing on the market within 60 days from the day of receiving the complete application, and it shall contain one of the following evaluation:

- suitable for placing on the market;
- suitable for placing on the market under specific additional conditions; or
- unsuitable for placing on the market.

The applicant may, within seven days from the day of receiving the report referred to in paragraph 4 of this Article, if it was assessed that the product is suitable for placing on the market, withdraw the application for obtaining approval for placing on the market GMOs or products containing, consisting of or deriving from GMOs, or inform the responsible state authority referred to in paragraph 1 of this Article that the application will be amended.

If the applicant referred to in paragraph 5 of this Article informs the responsible authority that he intends to amend the application, he shall be designated a deadline for amending the application.

If the applicant fails to inform the responsible authority referred to in paragraph 1 of this Article within the deadline referred to in paragraph 5 of this Article about the intended amendments to the application, the application shall be deemed withdrawn.

The responsible authority shall cancel the procedure for issuing approval if the application is withdrawn in accordance with paragraphs 5 and 7 of this Article.

Procedure of Responsible Administration Authorities upon Application
Article 40

The administration authorities referred to in Article 10 paragraphs 4 and 5 of this Law shall apply procedure prescribed in Article 39 of this Law when deciding on applications for placing on the market GMOs, products containing, consisting of or deriving from GMOs.

Deadline for Issuing Approvals
Article 41

Responsible administration authority referred to in Article 39, that is Article 40, shall decide on application for placing on the market GMO or product containing, consisting of or deriving from GMOs within 105 days from the day of receiving the application.

Approval for placing on the market shall be issued for the period of up to five years with the possibility of extension in accordance with this Law.

The responsible state administration authority shall enter the approval for placing on the market GMOs, products containing, consisting of or deriving from GMOs in the register of issued approvals for placing on the market and it shall issue a decision on entry in the register within 8 days from the day of such entry.

The provisions of the law governing food safety shall apply on the production, health safety, declaration and labeling of food and feed, placing on the market of food and feed that contains or is derived from GMOs.

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.

Measures of Protection in the Case of New Information in Circulation of GMOs
Article 44

If the GMO business operator, after obtaining the approval for placing on the market, doubts or gains knowledge about the existence of higher level of risk than estimated for human health and the environment, it shall without delay undertake measures for protection of human health and the

environment, initiate the procedure for its withdrawal from circulation in cases it is no longer under its control and inform about that the responsible authority that has issued the approval.

In the event referred to in paragraph 1 of this Article, the GMO business operator shall, based on the changed circumstances, submit to the responsible authority a new application.

Any GMO business operator shall submit to the responsible authority new information about risks to human health and the environment, without delay.

If, before or during the procedure of issuing the approval, the responsible authority gains knowledge of new information about the levels of risk that represents the product or its use, it shall take into account such information when deciding on placing on the market.

If the responsible authority gains knowledge about new information after the effective date of the approval, it shall, after obtaining the opinion of the NCBS or the National Council for Food Safety Assessment, issue a decision amending the existing approval, with the consent of the applicant, or cancel the approval, if the applicant does not agree with the amendment of the approval.

Traceability
Article 45

The user or the person placing on the market GMOs or products containing, consisting of or deriving from GMOs shall provide to the person receiving GMOs or GMO products, in accordance with the traceability principle, the following information in the written form:

a) for products containing, consisting of or deriving from GMOs:
   - information that the product or its specific parts contain or consist of GMOs;
   - unique code or codes for GMOs that the product contains or of which it consists of.
b) for products deriving from GMOs:
   - mark of any food ingredient produced from GMOs;
   - mark of any feed components or additives produces from GMOs;
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, transport and use, location where further information can be obtained, including the name, personal identification number and domicile for natural persons, name and corporate headquarters for legal persons and name of the person authorized for representing activities, to which the GMO has been entrusted;
- intentional introduction into the environment: about the identity and characteristics that is properties, and requirements for safe handling, storing, transport and use, as well as the location where further information can be obtained;
- placing on the market – state that it is not intended for intentional introduction into the environment, and the place where further information can be obtained.

Detailed requirements with respect to handling, packing and transport of GMOs shall be prescribed in the regulation adopted by the Ministry of Agriculture with the opinion of the Ministry of Environment Protection.

Advertising
Article 51

When advertising GMO products, the business operator shall clearly and explicitly state that the product being advertised contains, consists of or derives from GMOs.

Transit
Article 52

Transit of GMOs shall be performed in accordance with regulations governing veterinary matters, plant protection and customs regulations.

Procedure for the Case of Incident
Article 53

In the case of an incident, the GMO business operator shall without delay proceed in accordance with the plan of measures for procedure in the case of incident and shall inform without delay the responsible state administration authority of the incident, and in particular of:

- 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.

Biological Safety
Article 55

For the purpose of protecting the environment and biological diversity, it shall be prohibited to introduce into the environment GMOs contrary to the provisions of this Law.

The responsible state administration authority shall undertake all the necessary measures for preventing or eliminating damage, in accordance with the law, in case the legal or natural person performing activities of use of GMOs in closed systems, intentional introduction into the environment or placing GMOs on the market can not be identified.

In case the legal or natural person referred to in paragraph 2 of this Article is subsequently identified, such person shall compensate the costs arising from undertaking of measures for preventing or eliminating damage referred to in paragraph 2 of this Article and to compensate the damages.

Procedure with the Waste Created by the Use of GMOs
Article 56

The GMO business operator shall destroy the waste containing, consisting of or deriving from GMO in such a manner as to ensure that GMO is no longer capable of replication or of transferring the genetic material to other organisms.

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) control the manner of labeling and advertising of GMO products;
4) 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 veterinary inspector performing inspection supervision at the border crossing or in customs warehouse shall have the power to:

1) following the veterinary inspection of shipments of GMO food and feed and the accompanying documentation, permit importation, transit or storing of food and feed;
2) take samples of GMO food and feed and forward them to the authorized laboratories for laboratory testing or perform necessary testing in the laboratory at the border crossing.

Powers of Phytosanitary Inspector
Article 65

In addition to the powers of inspectors prescribed by the law governing inspection supervision and other laws, the phytosanitary inspector shall, in accordance with Article 62 paragraph 3 of this Law, have in particular the power to:

1) control the introduction of GMOs into the closed system;
2) check the control systems established by the user of the GMO, the records and the results that were obtained;
3) control the method of operation with the GMOs or products containing, consisting of or deriving from GMOs;
4) inspect the facility, surroundings, premises and equipment of the closed system;
5) inspect and take samples of substances used for GMOs, as needed;
6) control the efficiency of the procedures related to the implementation of the Plan of Supervision;
7) control the manner of keeping the prescribed records and maintaining the documentation for the GMOs which may be relevant for the assessment of compliance with this Law and regulations adopted based on this Law;
8) control the labeling of GMOs;
9) inspect the shipments and accompanying documentation for the GMOs and, in particular, to verify that, based on the prescribed requirements, there are not obstacles for their respective importation;
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 supervision and other laws, the inspector for environment protection shall, in accordance with Article 62 paragraph 4 of this Law, have in particular the power to:

1) control the introduction of GMOs into the environment;
2) check the control systems established by the user of the GMO, the records and the results that were obtained;
3) control the method of operation with the GMOs or products containing, consisting of or deriving from GMOs;
4) inspect the facility, surroundings, premises, equipment, and means of transportation;
5) inspect and take samples of substances used for the GMOs, as needed;
6) control the procedure with the waste created by the use of the GMOs;
7) control the efficiency of procedures related to the implementation of the Plan of Supervision;
8) control labeling of GMOs;
9) control the manner of keeping the prescribed records and maintaining the documentation for the GMOs which may be relevant for the assessment of compliance with this Law and regulations adopted based on this Law;
10) take samples of GMOs;
11) implement any other activity necessary to ensure fulfillment of the objectives of this Law.

Administration Supervision
Article 67

In addition to the administration measures and actions prescribed by the law governing inspection supervision and other laws, the phytosanitary inspector shall, in accordance with Article 69 paragraph 1 of this Law, when he establishes that this Law or other regulation has been infringed, have the obligation and power to:

1) prohibit operation of the GMO business operators that do not hold the approval of the responsible authority;
2) prohibit transportation, importation or exportation;
3) prohibit use in closed systems and placing on the market of GMOs or products containing, consisting of or deriving from GMOs;
4) order labeling of GMOs or GMO products;
5) order destruction of unapproved GMOs or products containing, consisting of or deriving from unapproved GMOs;
6) order destruction of the waste created by the use of GMOs in the prescribed manner;
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 business operator that does not hold the approval of the responsible authority;
2) prohibit intentional introduction into the environment of GMOs or products containing, consisting of or deriving from GMOs;
3) order labeling of the GMOs;
4) order destruction of the waste created by the use of the GMOs in the prescribed manner;
5) order destruction of unapproved GMOs or products containing, consisting of or deriving from unapproved GMOs;
6) 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.

XI. PENAL PROVISIONS

Article 69

The company, other legal person and entrepreneur shall be fined for misdemeanor in the amount ranging from one hundred times to three hundred times the amount of lowest price of labor in Montenegro if it:

1. commences the use of the closed system, use of GMO in the closed system, intentional introduction into the environment, placing on the market and trans-boundary movement of GMOs or products containing, consisting of or deriving from GMOs, without obtaining the approval of the responsible administration authority (Article 21 paragraph 4);
2. places on the market or cultures for commercial purposes the GMOs for which there are no experimental data and research on direct and indirect effects on the ecosystems that may be affected by its use, and which were obtained in the experiments conducted on the territory of Montenegro (Article 22);
3. uses the GMO in the closed system that does not comply with prescribed requirements for the levels of risk in which the intended use of the GMO has been classified (Article 27 paragraph 1);
4. the applicant fails to register the closed system before the first use (Article 27 paragraph 2);

5. fails, if after submittal of application new information become available that can significantly effect human health, biological diversity and the environment or the classification into the new level of risk, to notify the responsible authority about it and to submit the new application (Article 27 paragraph 4);
6. before commencing the use of the GMO in the closed system, the applicant fails to prepare the risk assessment for the intended use (Article 28);
7. before commencing the use of the GMO in the closed system, the applicant fails to prepare the plan of measures for the case of incident (Article 29 paragraph 1);
8. the applicant fails to submit the data on the plan of measures for the case of incident to the Ministry of Health, Ministry of Agriculture, Ministry of Environment Protection (Article 29 paragraph 2);
9. GMO business operator fails to submit the application for the first and every subsequent use of the GMO classified in the level of risk 1 and 2, which will take place in the closed system registered for such (Article 30 paragraph 1);
10. GMO business operator fails to submit the application to the responsible authority for the use of a GMO classified in the level of risk 3 or 4, which will take place in the closed system registered for such (Article 31 paragraph 1);
11. engages in the contained use of level 3 or 4 without previously obtaining the approval from the responsible authority (Article 31 paragraph 2);
12. GMO business operator fails to submit the application for intentional introduction of GMO into the environment to the responsible administration authority (Article 32);
13. the applicant commences introduction into the environment without approval from the responsible state administration authority (Article 33 paragraph 9);
14. introduces the GMOs into the environment in the protected areas, in the areas intended for organic production of agricultural products, for development of eco-tourism (Article 34 paragraph 1);
15. with respect to any change or unintentional alteration of the introduced GMO which may have effect on the assessed risk to human health and the environment, after the approval has been issued by the Ministry for Environment Protection, it fails to undertake measures necessary for the protection of human life and health and the environment, and fails to notify the responsible authority of any change as well as of unintentional alteration or new information that is available, and fails to change the criteria, for the purpose of protecting human health and the environment, as specified in the application (Article 35);
16. fails to submit the report in the course of and at the end of the intentional introduction of the GMOs into the environment, in the intervals specified in the approval of the responsible authority (Article 36 paragraph 1);
17. fails to submit to the responsible state administration authority the application for obtaining the approval for placing on the market GMO or product containing, consisting of or deriving from GMO, which it intends to place on the market for the first time (Article 37 paragraph 1);
18. fails to submit new application for obtaining the approval for placing on the market for every intended use of the GMOs or products containing, consisting of or deriving from GMOs that differs from the one that was approved (Article 38 paragraph 3);
19. fails to without delay undertake measures for the protection of human health and the environment, and inform about that the responsible authority that has issued the approval (Article 44 paragraph 1);
20. places on the market GMOs or products containing, consisting of or deriving from GMOs, which are not labeled in accordance with the law (Article 49);
21. advertises products contrary to the provisions of Article 51;
22. in the case of incident, the GMO business operator fails to without delay proceed in accordance with the plan of measures for procedure in the case of an incident, and fails to without delay inform the responsible state administration authority of the incident **(**Article 53);

For the misdemeanor referred to in paragraph 1 of this Article, natural person and the responsible person in the company or in other legal person shall be fined in the amount ranging from ten times to twenty times the amount of lowest price of labor in Montenegro.

Article 70

A legal or natural person that performs activities in the closed systems, activities of intentional introduction of GMOs into the environment and placing on the market the products containing, consisting of or deriving from GMOs, shall pay the compensation proportionate to the damage caused by the GMOs management in accordance with the law, which shall not exclude its criminal liability.

XII. TRANSITIONAL AND FINAL PROVISIONS

Article 71

The phytosanitary control in the area of GMOs shall be performed by the Ministry of Agriculture until the establishment of the administration authority responsible for the activities of phytosanitary control.

The activities of environment protection in the area of GMOs shall be performed by the Ministry of Environment Protection until the establishment of the administration authority responsible for environment protection.

Article 72

The regulations based on the authorizations from this Law shall be adopted within two years from the day this Law comes into force.

Article 73

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“.