

LAW ON PLANT PROTECTION PRODUCTS*

I BASIC PROVISIONS

Article 1

This Law shall govern manner of classification, registration, trade and use of plant protection products and active substances, maximum permitted level of residues of plant protection products, manner of keeping registers and records, information exchange and other issues relevant for plant protection products.

This Law shall also govern the manner of registration of plant protection products containing, consisting of or obtained from genetically modified organisms provided that introduction of these organisms into the environment is allowed only based on assessment of risk to the environment, in accordance with law governing genetically modified organisms.

Plant protection products and active substances found to be hazardous to human life and health and the environment, shall be classified, marked and packed in accordance with the law governing chemicals.

Classification and marking of waste, handling of waste from plant protection products and packaging shall be conducted in accordance with the law governing waste.

Article 2

Certain terms used in this Law shall have the following meaning:

1. **Plant protection products** shall mean active substances and preparations that contain one or more active substances in a form in which they are delivered to the end user, and are intended for:
 - protection of plants or plant products from harmful organisms or for preventing influence of such organisms unless such substances or preparations are intended for other purposes, in accordance with this Law;
 - exercising influence on life processes of plants, except nutrition (growth control and the like);
 - conservation of plant products, unless otherwise regulated by separate regulations;
 - destruction of unfavorable plants;
 - destruction of parts of plants or preventing of unfavorable plants growth;
2. **Residue of plant protection products** shall mean one or more substances present on plants or plant products, or in plants or plant products, food, feed or in the environment, and which are the consequence of use of plant protection products including their metabolites and products resulting from their dissolution or reaction;
3. **Substances** shall mean chemical elements and their compounds which naturally occur or are obtained in the process of production, including all impurities which are the inevitable result of the production process;
4. **Active substances** shall mean substances or micro-organisms, including viruses, which have general or specific influence:

* The Law is published in the "Official Gazette of Montenegro", No. 51/08 dated August 22, 2008.

- against harmful organism or
 - on plants, parts of plants or plant products;
5. **Preparations** shall mean mixtures or solutions made of two or more substances out of which at least one is an active substance and are used as plant protection products;
 6. **Plants** shall mean live plants and live parts of plants including fresh fruits and seed;
 7. **Plant products** shall mean products of plant origin, unprocessed or simply processed (grinning, drying or pressing), excluding plants from item 6 of this Article;
 8. **Harmful organisms** shall mean organisms of plants or animals, as well as viruses, bacteria, mycoplasma and other pathogenic organisms that are harmful to plants and plant products;
 9. **Animals** shall mean animal species usually fed, bred or consumed by man;
 10. **Trade** shall mean placing on the market plant protection products, including purchase of plant protection products (charged or free of charge), other than storage for the purpose of shipping from the customs territory of Montenegro or storage for the purpose of management;
 11. **Environment** shall mean water, air, fauna, flora and their mutual relations as well as their relations with living organisms;
 12. **Integral plant protection** shall mean a rational use of combination of biological, biotechnological, chemical and other measures for plants growing, where use of plant protection products is limited to a specified minimum necessary to keep population of harmful organisms under the level that would cause economically unacceptable damage or loss;
 13. **IUPAC** shall mean International Union of Pure and Applied Chemistry;
 14. **T+** shall mean the mark used to identify plant protection products according to the level of danger;
 15. **EPPO** shall mean European and Mediterranean Plant Protection Organization;
 16. **ADI** shall mean the acceptable daily intake.

II TRADE IN PLANT PROTECTION PRODUCTS

Article 3

Plant protection products may not be placed on the market nor used in the territory of Montenegro unless they are registered in accordance with this Law, except for scientific and research purposes.

Notwithstanding paragraph 1 of this Article, plant protection products that are not registered may be produced, stored or shipped only if they are intended for use in another country and if they were registered in another country.

Article 4

Plant protection products may be placed on the market only if they are registered, classified, packed or marked and if they are accompanied by a declaration and instruction for use, in accordance with regulations governing dangerous substances, chemicals and in accordance with this Law.

Registered plant protection products shall be classified according to their intended use.

List of classified plant protection products referred to in paragraph 2 of this Article shall be determined by the ministry responsible for agriculture (hereinafter referred to as: the Ministry).

Plant protection products may not be placed on the market if their validity has expired.

Article 5

Packing of plant protection products must contain the following:

- 1) trade name or mark of plant protection products;
- 2) name and corporate domicile, or name, surname and address of the holder of decision on registration (hereinafter referred to as: registration holder) and registration number of plant protection product, name and address of the person responsible for final packing and marking if different;
- 3) quantity and name of the active substance in accordance with regulations governing chemicals, and if the name is not regulated by these regulations, then its ISO general name shall be stated; if such name is also missing, the active substance shall be marked with chemical mark in accordance with rules of IUPAC;
- 4) net quantity of plant protection products expressed in the measurement units;
- 5) number of series or other data for its identification;
- 6) data on the first aid (symptoms and signs of poisoning and the like);
- 7) warning about risk to humans, animals and the environment in line with the prescribed marks;
- 8) preventive measures for protection of humans, animals and the environment in line with the prescribed marks;
- 9) type of plant protection product with respect to its effect (for example insecticide, growth regulator, weed eradicators etc);
- 10) type of preparation (for example retting powder, emulsion concentrate etc.);
- 11) use for which the plant protection product is registered and specific agricultural, health and ecological conditions under which plant protection product may or may not be used;
- 12) instructions for use and dosage expressed in measurement units for each use, in accordance with the decision on registration;
- 13) whether certain time span is needed between each use and:
 - seeding or planting of agricultural crops that need to be protected,
 - seeding or planting of late agricultural crops,
 - access of people and animals,
 - harvest or vintage,
 - use or consumption;
- 14) information on possible phyto-toxicity, sensitivity of certain varieties and any direct or indirect negative by-products on plants or plant products with time intervals which shall be monitored between the application and seeding or planting:
 - of agricultural crops in question or
 - the subsequent agricultural crops;
- 15) if the instructions referred to in paragraph 2 of this Article are provided separately, the text „Read the enclosed instructions before use“;
- 16) instructions for safe keeping of plant protection products and package;
- 17) validity expiration date, which is valid in case of normal storage conditions, where validity of plant protection products is limited to less than two years.

Information referred to in items 12, 13 and 14 of this Article may be stated in the separate instructions accompanying the package if the available space on the package is not sufficient for specifying such information.

Separate instructions referred to in paragraph 2 of this Article shall be considered as marking in the sense of this Law.

Package of the plant protection products may not include marks “non-toxic“, “harmless“ or similar marks, other than marks and information confirming that plant protection products may be used when bees or other species, which do not belong to the target group, are active or when agricultural crops and weed blossom, if the decision on registration refers to the use during the period when bees are active or other organisms and that it represents minimal threat to them.

Information on the package of plant protection products on the territory of Montenegro must be written clearly and legibly in Montenegrin language and in a manner disabling their deletion or removal.

Notwithstanding paragraph 1, items 7 and 8 of this Article, the additional marks and information shall be added on the package for the human, animal and environment protection purposes.

Manner of packing, content of information and marks on the package, instructions for use, content of declaration as well as standard terms used to warn to specific threats and security measures for plant protection products shall be prescribed by the Ministry.

Article 6

Trade in plant protection products may be performed by a company, other legal person and entrepreneur registered for performing of these activities in the Central Register of the Commercial Court (hereinafter referred to as: the CRCC) with corporate domicile in Montenegro and which is entered in the Register for Wholesale Trade in Plant Protection Products and the Register for Retail Trade in Plant Protection Products (hereinafter referred to as: the Register).

Wholesale and retail trade in plant protection products may be performed by a company, other legal person and entrepreneur, if:

- it has a full time employed person responsible for purchase, trade, storage, keeping and issuing plant protection products that has completed specialist studies, that is has faculty of agriculture degree (department – plant protection), or specialist studies or faculty of agriculture degree (department – plant production) with completed specialist course in plant protection products;
- it has appropriate equipment and facilities for storage or sale of plant production products.

Administration authority responsible for plant protection products (hereinafter referred to as: the administration body) shall determine the fulfillment of requirements referred to in paragraphs 1 and 2 of this Article in a decision.

The Ministry shall decide on the appeal against the decision referred to paragraph 3 of this Article, as well as other individual acts adopted by the administration body.

Entry in the Register shall be conducted based on the application.

Register shall be kept by the administration body.

Data from the Register shall be public.

Program of the specialist course referred to in paragraph 2 of this Article shall be specified by the Ministry, in cooperation with scientific and educational institution in the area of plant protection.

Scientific and education institution referred to in paragraph 8 of this Article shall organize specialist course in plant protection products and issue a certificate on attended specialist course.

Details with regard to equipment, facilities referred to in paragraph 2 of this Article and plant protection products which may be placed on the market, form, content and manner of keeping the Register, content of application for entry in the Register referred to in paragraph 5 of this Article and documentation to be submitted with the application shall be prescribed by the Ministry.

Article 7

Company, other legal person and entrepreneur engaged in trade in plant protection products shall keep records of the quantity of:

- 1) purchased plant protection products;
- 2) sold plant protection products containing:
 - data on the user or registered producer of plants referred to in Article 8 paragraph 1 of this Law (name and address or name and corporate domicile of the producer, data on the entry in the register of plant producers, name of the plant protection product and active substance, date of sale);
 - data on the producer of plants for its own needs (name, address, personal identification number, name of the plant protection product, date of sale);
- 3) stored plant protection products;
- 4) plant protection products withdrawn from circulation.

Data from the records referred to in paragraph 1 of this Article shall be submitted to the administration body not later than March 31 of the current year for the previous year, and in shorter periods at the request of the administration body.

Company, other legal person and entrepreneur referred to in Article 11 paragraph 2 of this Law shall, apart from records referred to in paragraph 1 of this Article, keep records of use of plant protection products, and shall submit data to the administration body not later than March 31 of the current year for the previous year, and in shorter periods at the request of the administration body.

Company, other legal person and entrepreneur engaged in trade in registered plant protection products, which have been classified on the basis of danger marks, according to regulations

governing chemicals, as plant protection products with mark T+, shall apart from records referred to in paragraph 2 of this Article keep records containing:

- data on plant protection product (trade name, intended use, expiration date);
- data of sale and delivery of plant protection product;
- quantity of sold or delivered plant protection product;
- data on the buyer or user (for legal persons: name, corporate domicile and identification number, and for natural persons: name and surname, address and personal identification number);
- signature of deliverer and receiver.

Company, other legal person and entrepreneur engaged in trade in plant protection products shall retain data referred to in paragraph 4 of this Article for the period of at least five years from the day of entry in records.

Content of records and data, manner of keeping records and submitting data shall be prescribed by the Ministry.

Article 8

Producers may place on the market plant protection products only if they are entered in the Register of Plant Producers, which is kept by the local administration authority responsible for agriculture.

Entry in the Register of Plant Producers shall be conducted based on the application.

The local administration authority referred to in paragraph 1 of this Article shall submit data from the Register of Plant Producers upon request of the Ministry.

Plant protection producers referred to in paragraph 1 of this Article that use plant protection products shall keep records of use of products, properly store plant protection products and handle waste from plant protection products in accordance with law governing waste.

The Ministry shall prescribe the contents, form and manner of keeping the Register of Plants Producers referred to in paragraph 1 of this Article, content of application for entry in the Register with the required documentation, content and manner of keeping records of use plant protection products.

Article 9

Plant protection products must be used in accordance with the decision on registration of plant protection products and instructions for use and declaration, and prescribed concentrations respecting the principles of good agricultural practice for plant protection products, integral plant protection and environment protection must be prepared.

Principles of good agricultural practice and integral plant protection referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

Use of plant protection products from airplane shall not be allowed.

Notwithstanding paragraph 3 of this Article, use of plant protection products from airplane shall be allowed (in forests and on big areas under mono-crops) with consent of the administrative body.

Conditions for use of plant protection products from airplane shall be prescribed by the Ministry.

Plant protection products shall not be used in a manner that would cause pollution of housing, commercial and other facilities where people and animals live, as well as pollution of waters and surrounding land.

Advertising, announcing, providing recommendations and advice shall only be allowed for registered plant protection products, for the purposes set in the decision on registration in accordance with the declaration and instruction for use.

Article 10

Residue of plant protection products may not be of higher level than the one prescribed.

Where it is determined that the residue of plant protection products is above the maximum prescribed level of residue of plant protection products (hereinafter referred to as: the MRL - Maximum Residue Levels), such plants, plant products, food or feed should be destroyed or their use for nutrition of humans or animals prevented.

MRL on plants or plant products or in plants or plant products, food or feed as well as plants and plant products and food and feed for which MRL is determined, measures and procedures to be undertaken when exceeding of MRL is found using laboratory methods, monitoring and other measures and procedures of responsible authorities shall be prescribed by the ministry responsible for health, in cooperation with the Ministry.

Sampling methods for determination of residue of plant protection products shall be prescribed by the ministry responsible for health, in cooperation with the Ministry.

Article 11

Registered plant protection products which are according to the level of danger marked with T+ shall not be intended for general use and may not be placed in free circulation.

Trade in products referred to in paragraph 1 of this Article may be performed only by the company, other legal person and entrepreneur with a full time employed person holding university degree with relevant course for work with chemicals that are very hazardous to life and health of humans and the environment, and if it has the relevant equipment and premises as well as license to perform activity of trade and use of very hazardous chemicals in accordance with law on chemicals issued by the administration body.

Requirements for employees, premises and equipment referred to in paragraph 2 of this Article shall be prescribed by the ministry responsible for chemicals, in cooperation with the Ministry.

Article 12

The Ministry shall prohibit use of plant protection product in the whole territory of Montenegro or its part or restrict trade where in implementation of the prescribed measures and procedures in the area of environment protection and new scientific and technical information there is evidence that the registered plant protection product is dangerous for humans, animals or the environment.

The Ministry shall restrict or prohibit trade and use of plant protection products containing active substances the trade in which is restricted or prohibited.

Article 13

Application for registration of plant protection product shall be submitted by the producer or legal or natural person that acts on behalf of and for the account of the producer, has corporate domicile in Montenegro and is responsible for first placing of plant protection product on the market.

Content of the application referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

III REGISTRATION OF PLANT PROTECTION PRODUCTS

1. Registration procedure

Article 14

Application for registration of plant protection products shall be submitted to the administration body with accompanying documentation:

- 1) for evaluation of active substances in plant protection products referred to in Article 15 paragraph 2 of this Law, except in the case referred to in Article 16 paragraph 2 of this Law;
- 2) for evaluation of plant protection product referred to in Article 16 paragraph 3 of this Law and other documentation, samples and data needed to meet the requirements for registration, upon request of the administration body.

Evaluation of documentation referred to in paragraph 1 of this Article shall be conducted by the administration body, which may as needed include other legal or natural persons for the evaluation of documentation (hereinafter referred to as: the evaluator).

Manner of work of evaluators, procedure of evaluation of active substances and plant protection products, as well as expert profile of engaged evaluators shall be prescribed by the Ministry, with consent of the ministry responsible for health.

The administration body shall adopt decision on registration of plant protection product on the basis of the proposal of evaluator and the opinion of the Commission for Plant Protection Products referred to in Article 20 of this Law.

In the procedure of registration of plant protection products containing active substances included in the List of Permitted Active Substances referred to in Article 30 paragraph 1 of this Law, uniform principles for evaluation of plant protection products prescribed by the Ministry in cooperation with the ministry responsible for health shall apply.

Article 15

The applicant shall submit with the application for evaluation of active substance the documentation for evaluation of active substance.

Documentation and content of documentation required for evaluation of active substance referred to in paragraph 1 of this Article and the manner of handling documentation shall be prescribed by the Ministry.

Article 16

The applicant shall submit with the application for registration of plant protection products the prescribed documentation for evaluation of active substance and plant protection products.

Should plant protection products contain active substance that is already on the List of Active Substances referred to in Article 30 of this Law, the active substance should not be re-evaluated if the level of purity and type of impurities does not differ significantly from the composition stated in documentation for inclusion of active substance on the List. With the application for registration of plant protection products a proof on congruence of the active substance with the short overview or excerpt from the documentation must be submitted.

Content of documentation referred to in paragraph 1 of this Article and manner of handling documentation shall be prescribed by the Ministry.

Article 17

In the procedure of preparation of documentation referred to in Article 16, paragraph 1 of this Law, international documentation on experiments on animals shall also be recognized, if experiments were conducted in accordance with principles of good laboratory practice.

In order to prevent repetition of experiments on vertebrates, the applicant must before conducting the experiment submit the application to the administration body for submitting the name and address or name and corporate domicile of the decision holder, for the purpose of establishing if identical plant protection product has already been registered.

Applicant shall submit with the application referred to in paragraph 2 of this Article a proof that domestic or foreign producer intends to register plant protection product and that they dispose of prescribed documentation.

When the administration body determines that the applicant is applying for registration of plant protection product identical with already registered plant protection product by the third person, the administration body shall deliver to the applicant name and address of the decision holder and shall inform the decision holder accordingly.

Applicant and the decision holder should reach an agreement on joint use of data in order to prevent repetition of experiments on vertebrates.

Experiments on animals are conducted on the basis of the approval of the administration authority responsible for veterinary matters.

Article 18

Administration body may not use in the procedure of registration of plant protection products for the benefit of other applicants:

1) data from documentation on the active substance submitted with the application for registration except:

- if the applicant submits the approval from the first applicant or decision holder;
- if at least 10 years from the first introduction of the active substance on the List has passed;
- if 5 years have passed from the registration of plant protection products based on received additional data needed for first introduction of the active substance on the List, unless this five-year period expires before a ten-year period referred to in indents 2 and 3 of this item, which is the base for change of conditions for introduction of the active substance or for extension of introduction of the active substance on the List;

2) data from documentation on plant protection products submitted with application for registration unless:

- another applicant agrees to use such data with the first applicant or with the person that holds decision on plant protection products registration and provides adequate evidence thereof;
- ten years have passed from the first registration of the plant protection product.

Article 19

The administration body shall protect secrecy of the data that the applicant referred to in Article 15 and 16 of this Law defines as confidential, except for data that are not considered a secret in particular:

- the name and content of active substances and plant protection products, lowest purity of technical active substance that needs to be provided by the producer;
- the name of other substances which are classified as dangerous in accordance with regulations on classification, marking and packing of dangerous substances;
- physical – chemical data on active substances and plant protection products;
- manner of preventing harmful influences of active substances or plant protection products;
- short overview of the results of testing in order to determine influence and harmlessness of substance or plant protection product on humans, animals and the environment;
- recommended procedures and security measures for reduction of risk at the event of handling, storage, transport, fire and other dangers;
- determining the content of active substances, impurities and other elements in active substances and residue of plant protection products;
- methods of disposal of waste and package of plant protection products;
- decontamination procedures in the case of dissemination or discharge;
- data on first aid and medical treatment in case of harmful influence on humans.

If the applicant subsequently publishes that it does not consider information or part of information referred to in paragraph 1 of this Article confidential, it shall inform the administration body thereof.

Article 20

Commission for plant protection products (hereinafter to as: the Commission) shall be established for the purpose of giving opinion and providing expert assistance in the procedure of registration or recognition of plant protection products, establishing validity date of registration and extension of registration, comparability of circumstances in agricultural production, protection of plants, environment or climatic conditions, issuance of license for research and development, issuance of emergency license, license for extending the use of plant protection products (small crops and small intended purposes), monitoring plant protection products and residue of plant protection products, enhancing the good agricultural practice for plant protection products and integral plant protection.

The Ministry shall establish the Commission referred to in paragraph 1 of this Article from ranks of distinguished public scientists and experts for plant protection, health protection of plants, veterinary matters, environment protection, chemistry, biochemistry, toxicology and other experts of significance for the area of plant protection products.

The Commission shall have seven members.

The work of the Commission shall be public.

The Commission shall adopt the rulebook on its operation.

The Commission members shall receive compensation for their work in the amount determined by the Ministry.

Article 21

Decision holder or person referred to in Article 33 of this Law that was approved the expanded use of registered plant protection product shall immediately inform the administration body of data on possible harmful effect of plant protection products or residue of plant protection products on health of humans, animals, surface and underground waters and environment in general, including new information on possible limitations of crop rotation.

Obligation referred to in paragraph 1 of this Article relates also to the user of plant protection products if it becomes aware that plant protection products have harmful effect on health of humans, animals, surface and underground water and the environment.

2. TYPES OF REGISTRATION

Article 22

Administration body shall issue decision on plant protection product registration if the following requirements are met:

- that active substance or active substances contained in plant protection product are included in the List referred to in Article 30 of this Law, on the basis of documentation referred to in Article 15 paragraph 2 and Article 16 paragraph 3 of this Law;
- that the plant protection product is in line with regulation governing uniform principles for evaluation of plant protection product referred to in Article 14 paragraph 5 of this Law;
- that plant protection product meets requirements referred to in paragraph 2 items 1 to 5 of this Article.

Notwithstanding paragraph 1 of this Article, plant protection product may be registered on the basis of documentation referred to in Article 15 paragraph 2 and Article 16 paragraph 3 of this Law, if the procedure for introduction on the List of Active Substances contained in that product is underway and if the following requirements are met:

- 1) that in line with scientific and technical development and based on evaluation of plant protection product it was determined that, with proper use, the plant protection product:
 - is efficient;
 - has no unacceptable effect on plants or plant products;
 - does not cause unnecessary suffering of harmful rodents that are being suppressed;
 - does not have harmful effect on health of humans or animals, directly or indirectly (for example through drinking water, food or feed), on surface or underground waters;
 - does not have unacceptable effect on the environment taking into account behavior of plant protection product in the environment, especially on pollution of surface and underground waters including drinking water, and effect on organisms to which the use refers to;
 - does not deposit in soil and in food chain;
- 2) that it is possible to determine the content of active substances, toxicological and ecotoxicological impurities and ingredients in technically active substance and preparation based on methods or international standards;
- 3) that it is possible to determine using relevant methods residue of plant protection products which can affect health of humans and the environment, and are the consequence of proper manner of use;
- 4) that the established physical – chemical properties are considered acceptable in conditions of adequate use and storage of plant protection product;
- 5) that documentation contains the proposed MRL in food and proposed waiting periods for the requested use.

Results of biological testing in the territory of Montenegro on the basis of methods prescribed by the Ministry shall also be submitted along with documentation referred to in Article 15 paragraph 2 and Article 16 paragraph 3 of this Law at the request of the administration body.

Methods referred to in paragraph 3 of this Article shall be applied in adequate conditions of agricultural production, protection of plants and the environment that correspond to circumstances in which plant protection products shall be used in the territory of Montenegro (EPPO methods).

Plant protection product intended for application in agriculture may also be registered, based on the application, for application on non-agricultural areas if the prescribed requirements referred to in paragraph 2 items 1 to 5 of this Article are met.

The applicant referred to in paragraph 5 of this Article shall submit documentation referred to in Article 15 paragraph 2 and Article 16 paragraph 3 of this Law.

Article 23

Applicant may request the recognition of registration for plant protection product which contains active substance or active substances included in the List referred to in Article 30 of this Law, based on registration conducted in another country, if that plant protection product was registered in accordance with uniform principles for evaluation of plant protection products referred to in Article 14 paragraph 5 of this Law and if for the proposed application of product in the territory of Montenegro, conditions in agricultural production, protection of plants and the environment, including climate conditions relevant for application of the product, are comparable with circumstances in other countries belonging to the same climate zone.

In cases referred to in paragraph 1 of this Article, in the territory of Montenegro it is not necessary to recheck the requirements referred to in Article 22 of this Law.

The following data shall be submitted with the request for recognition of registration: on identity of active substance, plant protection product, proof and report on registration of plant protection product in another country, that are translated into Montenegrin language and certified copy of the original and short overview referred to in Article 16 paragraph 2 of this Law.

Administration body may reject application referred to in paragraph 1 of this Article due to incomparability of circumstances of agricultural production, protection of plants, environment or climatic conditions, based on the opinion of the Commission. The administration body may request that testing is performed in Montenegro and may determine additional conditions for application of plant protection product due to:

- special ecological sensitivity in certain areas (limestone areas);
- difference in alimentary habits of population;
- resistance phenomena.

Administration body may, with consent of the applicant referred to in paragraph 1 of this Article in the procedure of recognition of registration, respecting the requirements referred to in Article 22 paragraph 2 item 1 of this Law and based on the opinion of evaluator and the Commission referred to in Article 14 paragraphs 2 and 3 of this Law, amend the proposed use of plant protection product in order to exclude from comparison all incomparable circumstances in agricultural production, protection of plants or the environment, including climatic conditions.

In the procedure of deciding upon application for recognition of plant protection product registration, the requirements defined in regulations of Montenegro on protection at work of persons which come into contact with plant protection product shall apply.

Administration body may, in the procedure of recognition of registration, limit the use of plant protection product due to differences in alimentary habits of population in Montenegro in order to prevent exposure of consumers to residue of plant protection products higher than the acceptable daily intake - ADI.

The Ministry shall prescribe conditions and manner for recognition of registration and evaluation of comparability of circumstances and climatic conditions referred to in paragraphs 4 and 5 of this Article.

Article 24

Administration body shall register the plant protection product for a period not longer than 10 years.

The period referred to in paragraph 1 of this Article may be extended several times, every time for maximum 10 years.

Application for extension of registration shall be submitted to the administration body at least 12 months before the expiration of the period in registration.

If the conditions based on which plant protection product was registered have changed, the administration body shall request complete documentation for evaluation of the product or part of documentation needed for adoption of decision on extension of the period of registration.

The registered plant protection product shall be re-evaluated if it does not meet some of the requirements referred to in Article 22 paragraphs 1 and 2 of this Law.

In the case referred to in paragraph 4 of this Article, the administration body shall require from the decision holder, company, other legal person or entrepreneur that was approved expanding of use of plant protection product referred to in Article 33 of this Law, the documentation and additional data needed for re-evaluation of the plant protection product.

Conditions for extension of registration and re-evaluation of plant protection product shall be prescribed by the Ministry.

Article 25

When plant protection product contains active substance that has not been evaluated and included on the List referred to in Article 30 of this Law for which applicant referred to in Article 13 paragraph 1 of this Law has submitted documentation referred to in Article 15 paragraph 2 and Article 16 paragraph 3 of this Law, and for which it has complete documentation, the administration body may within three years from the day of submitting complete documentation issue a decision on temporary plant protection product registration valid maximum three years, provided that plant protection product meets the requirements referred to in Article 22 paragraph 2 items 1 to 5 of this Law.

Article 26

Decision on registration of plant protection product referred to in Articles 22 to 28 of this Law shall be issued by the administration body not later than 12 months after receiving complete documentation of the applicant.

Notwithstanding paragraph 1 of this Article, the administration body shall issue a decision on change without evaluation of plant protection product in case of a request for amendment of a decision on plant protection product registration due to minor changes which have no effect on health of humans, animals or the environment (change of trade name, name of the present producer or representative, change of composition which is according to international standards considered a minor change without any change of content of the active substance and changes caused by reduction of MRL).

Decision on registration of plant protection product shall refer to the plant protection product and the applicant referred to in Article 13 paragraph 1 of this Law. Decision on registration shall in particular contain plant protection product trade name, name and content of active substances and other dangerous substances in the plant protection product, information on use, intended use and marking of the plant protection product, allowed places for sale, waiting period and MRL.

Content of the decision on plant protection product registration referred to in paragraph 3 of this Article shall be prescribed by the Ministry.

Article 27

When conditions based on which decision on plant protection product registration has been issued change, the administration body shall change, upon application of decision holder or ex officio, the decision on plant protection product registration.

Administration body shall change decision on plant protection product registration ex officio if the manner of use and quantity changes based on scientific and technical information.

Changes in the decision on plant protection product registration referred to in paragraphs 1 and 2 of this Article shall be made only if requirements referred to in Article 22 paragraph 2 item 1 of this Law are met.

Administration body shall change decision on plant protection product registration upon proposal of the decision holder if that plant protection product has been registered under the same or different trade name in another country.

Administration body may request additional data, documents and samples needed to justify change of the decision on plant protection product registration.

3. CESSATION OF VALIDITY OF PLANT PROTECTION PRODUCT REGISTRATION

Article 28

Registration of plant protection products shall cease to be effective:

- 1) with expiration of the period from the decision on plant protection product registration unless the registration is extended;
- 2) with abolishing of decision on registration:
 - at request of a person that holds decision of plant protection product registration;
 - when preconditions for issuing decision on plant protection product registration are not fulfilled or no longer exist;
 - when it was adopted based on false data or misleading facts;
 - when plant protection product ceases to meet the requirements for registration;
 - in cases of prohibition of trade in plant protection product on the entire territory of Montenegro referred to in Article 12 of this Law;
 - when a decision holder does not submit documentation referred to in Article 16 paragraph 3 of this Law within the period referred to in Article 24 paragraph 2 of this Law;
 - when active substance is deleted from the List referred to in Article 30 of this Law;
- 3) with abolishing of decision on temporary registration referred to in Article 25 of this Law in line with the decision of another country on non-inclusion of active substance in the List referred to in Article 30 of this Law.

When decision holder decides to stop trading in the product prior to the expiration of the period in registration, it shall inform the administration body and submit the written explanation before termination of trade in such product.

After expiration of validity of decision on registration referred to in paragraph 1 of this Article, plant protection products may be placed on the market for 18 months after the expiration of registration at the most for the purpose of sale of existing stocks.

Notwithstanding paragraph 3 of this Article, the administration body may, after expiration of the validity of plant protection product registration, order the elimination of stocks of such product in line with regulations governing waste.

Administration body may set the deadline in the decision on abolishing of registration to the decision holder for sale of existing plant protection product stocks or elimination of stocks, in line with regulations governing waste.

Conditions for handling plant protection product stocks referred to in paragraph 5 of this Article shall be prescribed by the Ministry.

4. REGISTER OF PLANT PROTECTION PRODUCTS

Article 29

Administration body shall keep the Register of Plant Protection Products in trade on the territory of Montenegro. Entry in the Register of Plant Protection Products shall be made based on the issued decision on registration.

The administration body shall specify the List of Registered Plant Protection Products.

The List referred to in paragraph 2 of this Article shall be published in the “Official Gazette of Montenegro” once a year.

Manner of keeping and content of the Register of Plant Protection Products and the content of the List referred to in paragraph 2 of this Article shall be prescribed by the Ministry.

Article 30

The List of Permitted and the List of Prohibited Active Substances shall be specified by the administration body.

The Lists referred to in paragraph 1 of this Article shall be published in the “Official Gazette of Montenegro” once a year.

The content of the Lists referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

5. LICENSES FOR SCIENTIFIC RESEARCH

Article 31

Research for scientific and development purposes of non-registered plant protection product in the environment may be conducted only in controlled conditions and with limited quantities for limited area of research, based on the license of the administration body.

Based on a written application and positive opinion of the evaluator and the Commission, the administration body shall issue license referred to in paragraph 1 of this Article if the plant protection product is not harmful to the health of humans and animals and if there is no adverse effect on the environment.

If the administration body finds that research referred to in paragraph 1 of this Article could have harmful effect on the health of humans and animals or unacceptably harmful effect on the environment, it may, upon proposal of the evaluator and the Commission, prohibit research or allow research provided that requirements for prevention of harmful effect are met.

Conditions referred to in paragraph 1 of this Article, content of the application and license, conditions for conducting research and time limit for research shall be prescribed by the Ministry.

Article 32

In the case of emergency circumstances caused by harmful organism that may not be suppressed or limited by the registered plant protection products or with other measures, or in the case of lack of plant protection products on the market, the administration body may issue emergency license for trade and use of non-registered plant protection product.

Procedure for issuing emergency license shall be initiated ex officio or upon request of the interested party. Administration body shall issue emergency license based on the opinion of the evaluator and the Commission.

Administration body may issue emergency license for trade in non-registered plant protection product ex officio or upon request of the interested party even when there are no registered plant protection products for specific purposes on the market (treatment of certain types of seed, treatment of seed with specific plant protection product and the like), if such request or need is in line with scientific knowledge and good agricultural practice.

Conditions for issuing emergency license, necessary documentation to be submitted with the request, content of the request and emergency license shall be prescribed by the Ministry.

Article 33

Company, other legal person and entrepreneur that are professionally engaged in agriculture or forestry activities shall submit the application to the administration body for extension of use of registered plant protection product for other purposes (small crops or small intended purposes).

Applicant referred to in paragraph 1 of this Article shall submit with the application documentation or data for extension of the area of use of registered plant protection product.

Administration body shall issue license for extension of intended use of registered plant protection product on the basis of the proposal of the evaluator and the Commission, if requirements referred to in Article 22 paragraph 2 item 1 indents 3, 4 and 5 and item 5 of this Law are met. Information on extension of use shall be stated in the additional instruction for use.

Requirements for issuing license and content of license referred to in paragraph 3 of this Article, as well as definition of small crops or small intended purposes shall be prescribed by the Ministry.

IV AUTHORIZED LEGAL PERSONS

Article 34

Expert operations in the area of plant protection products, operations of laboratory analysis for monitoring of residue of plant protection products in accordance with this Law and law governing food safety shall be performed by legal persons meeting the conditions with regard to personnel, premises and equipment that are authorized by the decision of the Ministry (hereinafter referred to as: the authorized legal person).

Article 35

Expert operations performed by the authorized legal persons referred to in Article 34 of this Law shall relate to the following:

- 1) laboratory testing of plant protection products, residue of plant protection products and establishing of MRL;
- 2) risk assessment for MRL;
- 3) monitoring of residue of plant protection products;
- 4) analysis of residue of plant protection products;
- 5) implementation of annual program of monitoring of residue of plant protection products;
- 6) development of expert grounds and opinions from the area of products and residue of plant protection products;
- 7) analysis per program of monitoring of post-registration control of plant protection products;
- 8) conducting research and development activities in the plant protection products area;
- 9) development and introduction of new procedures in good agricultural practice and integral protection;
- 10) testing of biological effect of plant protection products;
- 11) development of expert grounds for use of devices for plant protection products;
- 12) providing of expert assistance in implementation of measures in the area of plant protection products;
- 13) education of persons responsible for trade and use of plant protection products;
- 14) other tasks in accordance with this Law.

Requirements with regard to expert personnel, equipment and devices that must be met by authorized legal persons referred to in Article 34 of this Law shall be prescribed by the Ministry, with consent of the ministry responsible for health.

Article 36

Operations referred to in Article 35 of this Law shall be funded from the Budget of Montenegro except for the operations performed upon request of legal and natural persons.

V PROVISION OF SERVICES

Article 37

Activities of suppression and eradication of harmful organisms in agriculture and forestry with use of plant protection products may be performed by companies, other legal persons or entrepreneurs that meet the prescribed requirements (hereinafter referred to as: the service providers), which are registered for performing such activity in the CRCC and if they meet the requirements referred to in Article 6 paragraph 2 of this Law.

Service providers referred to in paragraph 1 of this Article shall be entered in the Register of Persons That Perform Activities of Suppression and Eradication of Harmful Organisms in

Agriculture and Forestry with Use of Plant Protection Products (hereinafter referred to as: the Register of Service Providers).

Administration body shall keep the Register of Service Providers.

Administration body shall determine in a decision the fulfillment of requirements referred to in paragraph 1 of this Article.

Requirements with regard to premises and equipment and the manner of keeping the Register of Service Providers shall be prescribed by the Ministry, with consent of the ministry responsible for health.

VI DEVICES FOR USE OF PLANT PROTECTION PRODUCTS

Article 38

Only devices that guarantee safe use of plant protection products for humans, animals and the environment and accompanied by the certificate of the producer may be used for application of plant protection products.

Article 39

Owner of devices for use of plant protection products shall keep devices in technically working order.

Article 40

Owner of the device for use of plant protection products shall keep technical documentation on the device (certificate of the producer, manual, evidence of repair works conducted etc.).

VII IMPORTATION

Article 41

Plant protection products registered in Montenegro may be imported by companies, other legal persons or entrepreneurs entered in the Register of Importers.

Persons referred to in paragraph 1 of this Article shall deliver imported plant protection products registered in Montenegro only to persons entered in the Register referred to in Article 6 of this Law.

Entry in the Register of Importers shall be made upon request.

Register of Importers shall be kept by the administration body.

Data from the Register of Importers shall be public.

Content, form and manner of keeping the Register of Importers, as well as the content of the request for entry in the Register of Importers and the necessary documentation shall be prescribed by the Ministry.

Importers referred to in paragraph 1 of this Article shall declare importation of the shipment of plant protection products to the phytosanitary inspector at the border crossing.

Importation of plant protection products may be conducted only through border crossings where phytosanitary inspection is organized.

VIII RESPONSIBILITY OF ADMINISTRATION BODY

Article 42

Administration body shall perform administrative and related expert tasks related to:

- 1) registration of plant protection products;
- 2) evaluation of active substances and plant protection products and issuing licenses and decisions on plant protection products registration, programs of monitoring post-registration control of plant protection products, and recognition of plant protection products registration;
- 3) keeping registers and records;
- 4) preparation of expert grounds for development of regulations in the area of plant protection products;
- 5) determining the fulfillment of requirements for entry in the registers;
- 6) monitoring the situation in the area of trade in plant protection products and participation in preparation and implementation of measures;
- 7) preparation, coordination and monitoring of the prescribed programs related to measures and proper use of plant protection products (post-registration control of plant protection products), as well as implementation of the program;
- 8) introduction of principles of good agricultural practice and integral plant protection;
- 9) preparation and coordination of activities related to residue of plant protection products and implementation of the program of monitoring of residue of plant protection products in food, on plants or plant products or in plants or plant products;
- 10) preparation of reports, analysis, information and other documents for the bodies and international organizations based on international agreements;
- 11) informing the public and interested parties in the area of plant protection products;
- 12) issuing expert publications in the area of plant protection products;
- 13) establishment of information system in the area of plant protection products, collecting, processing and keeping data in the area of plant protection products;
- 14) cooperation with other institutions in Montenegro and abroad in the area of plant protection products;
- 15) performing other tasks in accordance with the law.

IX INFORMATION AND RECORD KEEPING

Article 43

For the purpose of regulating trade and supervision of trade in plant protection products, the administration body shall collect data and information on plant protection products and residue of plant protection products necessary for preparing and maintenance of database and for record keeping regarding trade in the plant protection products.

Administration body shall collect and use data and information from the prescribed databases and records that are kept by other state administration bodies, agencies, producers of plant protection products and other institutions, in accordance with regulations governing the right to access to information and data protection.

The manner of collecting data and information, keeping database and records referred to in paragraph 1 of this Article and confidentiality protection obligation shall be prescribed by the Ministry.

Article 44

Administration body may exchange, on the international level, information on registered plant protection products, termination of validity of plant protection products registrations, restricted use and other data related to the plant protection products in accordance with regulations and international agreements.

X FEES AND COSTS

Article 45

Fees for covering the costs shall be payable by:

- 1) the applicants in the procedure of plant protection product registration and costs of biological analysis in the procedure of registration and recognition of registration of plant protection product;
- 2) the owners of plants, plant products, food or feed, for determining the presence of residue of plant protection products on plants, plant products, food or feed when residue of plant protection products exceed the prescribed maximum allowed concentration;
- 3) the owners or land users for the analysis of land and other facilities during the use of plant protection products or active substances;
- 4) holders of the decision on registration for laboratory testing of plant protection products if such plant protection product is not in conformity with the decision on registration or declaration;
- 5) importers from which the samples were taken for the laboratory testing of samples of plant protection products on importation.

Fees referred to in paragraph 1 items 2 to 5 of this Article shall be an income of persons that perform activities or provide services for which the fee is payable.

Fees referred to in paragraph 1 item 1 of this Article shall be income of the Budget of Montenegro.

The amount of fees referred to in paragraph 1 item 1 of this Article shall be determined on the basis of the actual costs.

XI INSPECTION SUPERVISION

Article 46

Inspection supervision of the implementation of this Law shall be conducted, within the scope of their responsibilities, by the state administration authority responsible for health through sanitary inspector, administration authority responsible for veterinary matters through veterinary inspector and administration body through phytosanitary inspector, in accordance with the law.

1. Authorization of the phytosanitary inspector

Article 47

In addition to the authorization of the inspector prescribed by the law governing inspection supervision, the phytosanitary inspector shall be authorized to:

- 1) check if the imported plant protection product is entered in the Register of Plant Protection Products, and if decision on registration referred to in Article 29 paragraph 1 of this Law has been issued for such product;
- 2) check documentation accompanying the plant protection product in circulation;
- 3) control keeping of registers and records;
- 4) check the fulfillment of conditions for placing the plant protection products on the market, for packing, marking, performance of trade and use of the plant protection product;
- 5) control the performance of expert operations and tasks of the authorized legal persons and activities performed by the service providers in accordance with this Law;
- 6) establish the identity of an offender, if necessary by photographing or recording, when there is a doubt that the provisions of this Law are not implemented;
- 7) take samples for post-registration control of the plant protection product;
- 8) take samples of plants, plant products, substrates for growth of plants, solutions mixture, the plant protection product or other necessary samples for the purpose of checking the prescribed usage of plant protection product (for example damage to crops, non-compliance with the waiting period and the like);
- 9) temporarily prohibit, until the irregularities are removed, the performance of activity of trade in plant protection products if a company or other legal person or entrepreneur is not entered in the Register referred to in Article 6 of this Law, or if they do not fulfill the prescribed conditions and shall inform the administration body thereof.

2. Administrative measures and actions

Article 48

In addition to the administrative measures and actions prescribed by the law governing inspection supervision, the phytosanitary inspector shall undertake the following administrative measures and actions:

- 1) prohibit the trade in the plant protection product if it is not registered;
- 2) prohibit the importation of the plant protection products to the person that is not entered in the Register referred to in Article 6, paragraph 1 of this Law and shall inform the administration body thereof;
- 3) prohibit the importation of the plant protection product, if such product is not classified, packed and marked or does not have instructions for use;
- 4) prohibit the importation of the plant protection product if the trade in such product is prohibited;
- 5) temporarily prohibit the importation of the plant protection product when the irregularities on the shipment of the plant protection product or on the accompanying documentation have to be corrected;
- 6) prohibit the trade in the banned plant protection products;
- 7) prohibit the trade in the plant protection product if its expiration date has passed;
- 8) prohibit the trade in the plant protection product if the plant protection product is not classified and in conformity with the decision on registration (packaging, declarations, marks, instructions for use, physical and chemical characteristics etc.);
- 9) prohibit trade in the plant protection product if it is established, during the post-registration control, that the plant protection product is defective;
- 10) prohibit the user to incorrectly use plant protection product;
- 11) prohibit the trade and usage of device for the use of the plant protection products if such device has not been issued a certificate, or is not in the working order;
- 12) prohibit harvesting or gathering of fruits or order their destruction due to incorrect use of the plant protection products or prohibit the use of plant protection product in the quantity and for the purpose contrary to this Law;
- 13) undertake other actions and procedures necessary for the implementation of this Law and regulations adopted based on this Law, for which it is authorized pursuant to the special law.

3. Authorization of the sanitary and veterinary inspector

Article 49

In addition to the authorization of the inspector prescribed by the law governing inspection supervision, the sanitary and veterinary inspector shall be authorized to:

- 1) take samples for determining the residue of plant protection product, in accordance with the responsibilities prescribed by the Law on Food Safety;
- 2) specify appropriate measures if it establishes that the MRL was exceeded;
- 3) temporarily prohibit the trade in food, feed, plant or plant products from which the samples for the establishment of the residue of plant protection products were taken, until the results of analysis are obtained.

Article 50

Responsible inspector referred to in Article 46 of this Law may temporarily, until the decision has been adopted, deprive documentation, items and products which may be used as evidence in the court procedure.

The receipt shall be issued regarding the temporary deprivation referred to in paragraph 1 of this Article.

Article 51

Responsible inspector referred to in Article 46 of this Law shall, within the scope of its responsibility, deliver to the authorized legal persons referred to in Article 34, paragraph 1 of this Law for analysis the samples taken in the inspection supervision.

Article 52

Professional training program for the inspectors in the field of plant protection products shall be adopted by the Ministry upon proposal of scientific and educational institution in the field of plant protection.

XII PENAL PROVISIONS

Article 53

A body, company, other legal person or entrepreneur shall be fined for the offence in the amount ranging from 100-fold to 300-fold the amount of minimum monthly salary in Montenegro, if:

- 1) on the territory of Montenegro, it places on the market and use the plant protection product which is not registered, or decision on registration has not been issued for such product (Article 3, paragraph 1);
- 2) it places on the market plants, and it has not been entered in the Register of Plant Producers (Article 8, paragraph 1);
- 3) it does not keep records on use of products, properly stores plant protection products and does not handle the waste of plant protection products in accordance with the law (Article 8, paragraph 4);
- 4) it does not use plant protection products in the manner prescribed in Article 9 paragraph 1 of this Law;
- 5) it uses plant protection products from the airplane (Article 9, paragraph 3);
- 6) it uses plant protection products contrary to the provisions of Article 9, paragraph 4 of this Law;
- 7) it provides advice, recommendations, performs announcements and other types of advertising contrary to the provisions of Article 9, paragraph 7 of this Law;
- 8) an applicant, before conducting an experiment, does not submit the request to the administration body for establishing facts whether identical plant protection product has already been registered, and other data regarding the registration of such product (Article 17, paragraph 2);
- 9) the decision holder, the person referred to in Article 33 of this Law or the user of the plant protection product fails to inform the administration body about all new data,

- possible harmful effect of any plant protection product or the residue of plant protection product on health of humans and animals (Article 21);
- 10) it amends the decision on registration of the plant protection product and the conditions referred to in Article 22 paragraph 2 item 1 of this Law have not been met (Article 27 paragraph 3);
 - 11) it performs research of unregistered plant protection product without a license or contrary to the conditions from the license (Article 31, paragraphs 1 and 3);
 - 12) it issues emergency license for trade and use of unregistered plant protection product contrary to the provisions of Article 32 of this Law;
 - 13) it uses already registered plant protection product for other (expanded) purposes without a license for expanded use or contrary to the license for expanded use of such product (Article 33, paragraph 1);
 - 14) it performs expert operations and tasks from the field of the plant protection products and laboratory analysis activities for the monitoring of residue in accordance with this Law and regulations governing food safety, and it does not meet requirements regarding the personnel, equipment and devices (Article 34);
 - 15) it utilizes devices that do not guarantee safe use of the plant protection product and environment protection (Article 38);
 - 16) it keeps devices in the out of working order and does not keep technical documentation about the device (Article 39).

For the offence referred to in paragraph 1 of this Article, a natural person and responsible person within a legal person shall be fined in the amount equal to 20-fold the amount of minimum monthly salary in Montenegro.

Article 54

A body, company, other legal person or entrepreneur shall be fined for the offence in the amount ranging from 100-fold to 250-fold the amount of minimum monthly salary in Montenegro, if:

- 1) it places on the market plant protection products whose expiration date has passed (Article 4, paragraph 4);
- 2) it does not keep records on plant protection products, does not submit report from the records to the administration body and does not keep data for the prescribed time limits (Article 7, paragraphs 1, 2, 3, 4 and 5);
- 3) it does not destroy or prevent the use of plants, plant products or food when it is established that the residue of plant protection products on or in such products and food have exceeded the prescribed level (Article 10, paragraph 2);
- 4) it performs suppression and eradication of harmful organisms, and it is not entered in the Register of Service Providers (Article 37, paragraph 2);
- 5) it does not keep technical documentation on devices (Article 40);
- 6) it imports plant protection products and is not entered in the Register, or does not declare the shipment to the phytosanitary inspector on importation (Article 41 paragraphs 1 and 7).

For the offence referred to in paragraph 1 of this Article, a responsible person within a legal person shall be fined in the amount equal to 20-fold the amount of minimum monthly salary in Montenegro.

For the offence referred to in paragraph 1 of this Article, a natural person shall be fined in the amount ranging from 10-fold to 20-fold the amount of minimum monthly salary in Montenegro.

XIV TRANSITIONAL AND FINAL PROVISIONS

Article 55

By-laws for the implementation of this Law shall be adopted within two years from the day this Law comes into force.

Article 56

Until the adoption of bylaws on the basis of authorization from this Law, the bylaws adopted on the basis of the Law on Plant Protection (“Official Gazette FRY”, No. 24/98) shall apply, if they are not contrary to the provisions of this Law.

Article 57

Provisions of the Law on Plant Protection (“Official Gazette FRY”, No. 24/98) related to the plant protection products shall not apply from the day this Law comes into force.

Article 58

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