



*Crna Gora*

*Ministarstvo poljoprivrede, šumarstva i vodoprivrede*

**DRAFT**

**LAW ON PLANT PROTECTION PRODUCT**



Requirement for WTO accession and harmonization with EU  
legislation

Podgorica, December 2007

## DRAFT

# LAW ON PLANT PROTECTION PRODUCT

## I BASIC PROVISION

### Contents

#### Article 1

This Law regulates classification, registration, trade, use of plant protection product in their final form and active matters, as well as maximal level of residues of plant protection product, technical requirements for devices for using of plant protection product, keeping registers and records, information and data exchange and other issues relevant for plant protection.

This Law also regulates the registration of plant protection product which contains, consists of or comes into existence from genetically modified organisms provided that introduction of these organisms into the living environment is allowed only based on living environment risk assessment, in accordance with regulations that govern genetically modified organisms.

Plant protection products and active matters in their final form, found to be hazardous to human life and health as well as living environment, shall be classified, marked and packed in accordance with regulations that govern chemicals.

Classification and identification of disposal, plant protection product disposal and package management shall be conducted in accordance with regulations governing disposal.

### Terms

#### Article 2

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

1. **Plant protection products** are active matters and products that contain one or more active matters in a form in which they are delivered to the final user, and are intended for:
  - protection of plants or plant products from all harmful organisms or for impediment of influence of such organisms unless such matters or products are otherwise defined by this Law ;
  - exercising influence on life processes of plants, except nutrition (for example growth control);
  - conservation of plant products, unless such matters and products are subject to regulations that govern preserving agents;
  - destruction of unfavourable plants; or
  - destruction of parts of plants or impediment of unfavourable plants growth.
2. **Residue of plant protection products** refers to one or more matters present on plants or plant products, in plants or plant products, food or feed or anywhere in living environment, which are the consequence of use of plant protection products including their metabolites and products that come into existence as a result of their dissolution or reaction;

3. **Matters** are chemical elements and their compounds which naturally arise or get generated in the process of production, including all impurities which are the inevitable result of the production process;
4. **Active matters** are matters or micro-organisms, including viruses, which have general or specific influence :
  - against harmful organism or
  - on plants, parts of plants or plant products;
5. **Products** are mixtures or solutions made of two or more matters out of which at least one is an active matter and are intended for use as plant protection products;
6. **Plants** are live plants and live parts of plants including fresh fruits and seed;
7. **Plant products** are products of plant origin, unprocessed or simply processed (grinning, drying or pressing ), excluding plants from Item 6 of this Article;
8. **Harmful organisms** are organisms belonging to plants or animals and pathogenic organisms which are harmful to plants and plant products;
9. **Animals** are animal species usually fed, bred or consumed by man;
10. **Trade** is any procurement of plant protection product, charged or free of charge, as well as import, other than storage for the purpose of shipping from the customs zone of Montenegro, or storage for the purpose of management;
11. **Registration of plant protection product** is a prescribed administrative procedure through which the state administration body authorized for operations of plant protection performs plant protection product registration, that is, approves trading in plant protection products in the territory of Montenegro;
12. **Living environment** is water, air, fauna, flora and their mutual relations as well as their relations with living environment;
13. **Integral plant protection** is a rational use of combination of biological, biotechnological, chemical and measures for plants growing, where use of plant protection products is limited to a certain minimum necessary to keep population of harmful organisms under the level that would cause economically unacceptable damage or loss;
14. **IUPAC (International Union of Pure and Applied Chemistry)** is the International union for pure and applied chemistry;
15. **T+** is the identification used to identify plant protection products according to the level of damage;
16. **EPPO (European and Mediterranean Plant Protection Organization)** is the European and international organization for plant protection;
17. **ADI (acceptably daily intake)** is the allowed daily intake.

## II TRADING IN PLANT PROTECTION PRODUCTS

### Article 3

Plant protection products may not be subject to trading neither be used in the territory of Montenegro unless they are registered in line with this Law, except for scientific and research purposes in line with Article 31 of this Law.

In exception to Paragraph 1 of this Article, plant protection products that are not registered but intended for use in another country may be produced, stored or shipped provided that:

- plant protection products were registered in another state and

- inspection check requirements prescribed by this Law are fulfilled.

## **Trading in plant protection products**

### **Article 4**

Plant protection products may be traded in if they are registered, classified, packed or identified and followed by a declaration and instruction for use in accordance with regulations which govern dangerous matters, chemicals and in line with this Law.

Plant protection products may not be traded in if their validity date is expired.

## **Package and plant protection products identification**

### **Article 5**

Packing of plant protection products must meet the requirements of identification in line with this Law and regulations adopted based on this Law, with the following expressed in a readable and inerasable manner:

- 1) trade name or identification of plant protection products;
- 2) name and address of holder of registration and registration number of plant protection product and, if different, name and address of the person responsible for final packing and identification, or final identification of the product on the market;
- 3) quantity and name of the active matter in line with regulations governing chemicals; if the name is not regulated by these regulations, then its ISO general name should be stated; if this name is also missing, then chemical symbol should be used for the active matter in accordance with regulations of IUPAC;
- 4) net quantity of plant protection products expressed in the prescribed measurement units;
- 5) number of series or any other data of its identification;
- 6) data referring to first aid: symptoms and signs of poisoning etc;
- 7) warning about any special risk to people, animals and living environment in line with the prescribed identification;
- 8) preventive measures for protection of people, animals and living environment in line with the prescribed identification;
- 9) type of plant protection products with respect to its effect (for example insecticide, growth regulator, weed eradicators etc);
- 10) type of products (for example retting powder, emulsion concentrate etc.);
- 11) use for which the plant protection product is registered and all specific agricultural, health and ecological conditions under which plant protection products may or may not be used;

- 12) instructions for use and dosage expressed in measurement units for each use, prescribed by the registration conditions;
- 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) details about possible phyto-toxicity, sensitivity of certain sorts and any other direct or indirect negative by-products on plants or plant products with time intervals which will be monitored between the application and seeding or planting:
  - of those agricultural crops
  - next to plant/seed agricultural crops;
- 15) If the instructions manual from Paragraph 2 of this Article is provided separately, the sentence „Read the instructions before use“;
- 16) Instructions for safe keeping of plant protection products and package; and
- 17) Validity expiration date, which is valid in case of normal storage, where validity of plant protection products is limited to less than two years.

Separate instructions may include contents of Items 12, 13 and 14 of Paragraph 1 of this Article, enclosed with the package, if the space on the package does not suffice.

Separate instructions from Paragraph 2 of this Article shall be considered a constructive part of identification in the sense of this Law.

Declaration with plant protection products package shall not include “non-toxic“, “harmless“ or similar identifications, but identifications 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 registration explicitly refers to use of plant protection products during bees or other mentioned organisms season and that it represents minimal danger to them.

Identification of plant protection products in the territory of Montenegro must be in Montenegrin language and administration body authorized for plant protection products operations (hereinafter: the administration body) may require to have insight into the model or manner of packing, identification and instructions mentioned in this Article.

In exception to provisions from Paragraph 1, Items 7 and 8 of this Article, the administration body may require additional identifications be additionally added on the package in a readable and inerasable manner, if necessary, due to protection of people, animals and living environment.

More detailed requirements for classification, package, contents of declaration and instructions for use as well as standard expressions used to warn to specific dangers and plant protection products security measures shall be prescribed by the Ministry authorized for the agricultural operations (hereinafter : the Ministry).

## **Conditions for trading in plant protection products**

### **Article 6**

Trading in plant protection products may be performed by a business company, that is, another legal entity and entrepreneur registered to perform these activities, with main offices in Montenegro, registered in the Register for plant protection products wholesale and in the Register for plant protection products retail trade (hereinafter: the Register).

Wholesale and retail trading in plant protection products may be performed by a business company, that is another legal entity and entrepreneur, if the entity herein has a full time employed person with specialist studies, that is, Faculty of Agriculture degree (department – plants protection), that is with specialist studies or the Faculty of Agriculture degree (department – plant production) with completed specialist course in plant protection products, and with equipment and storage and place for sale.

Requirements for equipment and space as well as for a group of plant protection products which may be traded in facilities from Paragraph 2 of this Article shall be prescribed by the Ministry.

Administration body shall determine whether the requirements from Paragraphs 1 and 2 of this Article have been met; in the case the requirements have been met the administration body shall assign the individual registration number.

The Ministry shall decide upon grievances referring to fulfillment of requirements from Paragraph 4 of this Article, and upon other individual acts, adopted by the administration body in accordance with this Law.

Register entry shall be conducted based on the request.

Register is managed by the administration body.

Register data are public.

Contents, form and manner of Register management, as well as the contents of requests for Register entry and documentation needed, shall be prescribed by the Ministry.

Program of the specialist course in plant protection products from Paragraph 2 of this Article shall be adopted by the Ministry at proposal of scientific and educational institution in the area of plants protection.

## **Collecting data and keeping records**

### **Article 7**

Business company, that is another legal entity and entrepreneur dealing with trading in plant protection products must keep records about quantity of:

- provided plant protection products ;
- plant protection products in trade;
- stored plant protection products; and
- plant protection products withdrawn from trade.

Report about the records from Paragraph 1 of this Article shall be submitted to the administration body not later than on March 31 of the current year for the previous year or at request of administration body.

Business company, that is another legal entity and entrepreneur from Article 11 Paragraph 2 of this Law is obliged, apart from keeping records from Paragraph 1 of this Article, to keep records of use of plant protection products, and shall deliver data about use to administration body not later than on March 31 of the current year for the previous year or at request of administration body.

Business company, that is another legal entity and entrepreneur dealing with trading in registered plant protection products which have been classified on the basis of information of hazards and regulations governing chemicals as plant protection products with identification T+, must apart from records mentioned in Paragraph 2 of this Article keep records which includes :

- data on plant protection products (trade name, purpose, deadline);
- data on sale that is delivery of plant protection products ;
- quantity of sold that is delivered plant protection products ;
- legal entities shall state the name of the company, main offices and personal identification number, and physical entities shall state name and surname, address and personal identification number ;
- signature of deliverer and receiver.

Business company, that is another legal entity and entrepreneur dealing with trading in plant protection products must retain data from Paragraph 4 of this Article for the period of at least five years and as requested by administration body shall make them public.

More detailed records and reports, manner of keeping records and reporting shall be prescribed by the Ministry.

## **Sale of plant protection products**

### **Article 8**

Plant protection products may be sold to the producers if they are registered in the Register of Plants Producers managed by the body of local administration authorized for agriculture operations.

The Ministry shall prescribe the contents, form and manner of managing the Register of Plants Producers as well as the contents of requests and documentation for registration.

Body of the local administration authorized for agriculture operations at request of the Ministry shall submit data from the Register of Plant Producers.

Exceptionally, provisions of Paragraph 1 of this Article do not refer to the producers dealing with plant production for personal needs.

Plant protection product users from Paragraph 1 of this Article are obliged to keep records of use of plant protection products in the prescribed manner, to store plant protection products and manage plant protection product disposal in accordance with regulations governing disposal management.

## **Regular use of plant protection products**

### **Article 9**

Plant protection products must be used in accordance with the decision of plant protection products registration, that is, instructions for use and declaration, which

includes preparation of the prescribed concentrations and respecting the principles of good agricultural practice for plant protection products, and, if possible, integral protection of plants and protection of living environment.

Principles of good agricultural practice for plant protection products and integral protection of plants shall be prescribed by the Ministry.

Use of plant protection products from airplane is not allowed.

In exception to Paragraph 3 of this Article, use of plant protection products from airplane shall be allowed (use in forests and on big surfaces in mono-crops) with previous compliance of administrative bodies.

More detailed conditions for use of plant protection products from airplane shall be prescribed by the Ministry.

Use of plant protection products shall not be allowed in a manner that would cause pollution of housing, economic and similar objects where people and animals live as well as pollution of waters and land.

Giving advice and recommendations, publicizing and other types of advertising are allowed only for registered plant protection products, particularly for the purposes set in the decision on registration, in accordance with declaration and instruction for use.

## **Residue of plant protection products**

### **Article 10**

Residue of plant protection products may not be bigger than the prescribed.

When residue of plant protection products is above the maximally prescribed level of residue of plant protection products (hereinafter: MRL - Maximum Residue Levels), such plants, plant products, food or feed should be destroyed or in another way impede their use for nutrition of people or feeding of animals.

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 measured, measures and procedures which need to be undertaken when MRL override is found in laboratory tests, as well as other measures and procedures of authorized bodies, shall be prescribed by the Ministry authorized for health operations, with previously obtained opinion of the Ministry.

Sampling methods for determination of residue of plant protection products shall be prescribed by the ministry authorized for health operations, with previously obtained opinion of the Ministry.

## **Plant protection products identified with T+**

### **Article 11**

Registered plant protection products which are according to the level of danger identified with T+ are not intended for general use and may not be traded in.

Trading in plant protection products from Paragraph 1 of this Article shall be allowed only to the business company, that is another legal entity and entrepreneur with a full time employed person specialized in work with chemicals that were found hazardous to life and health of people and living environment but meet prescribed requirements



regarding space and equipment, and have permit to perform activities of trading and use of dangerous chemicals in accordance with regulations on chemicals issued by the state administration body authorized for operations with chemicals.

Requirements for specialists, space and equipment met by the business company, that is another legal entity and entrepreneur from Paragraph 2 of this Article shall be prescribed by the state administration body authorized for operations with chemicals with consent of the Ministry.

## **Prohibition, trading restrictions and use of plant protection products**

### **Article 12**

When in application of the prescribed measures and procedures in the area of living environment and new scientific and technical solutions, proofs are found stating that the registered plant protection products are dangerous for people and living environment, the Ministry may restrict or prohibit trading in and use of plant protection products in the whole territory of Montenegro, or its part.

When plant protection products contains certain active matters which cause restricted or prohibited trade in European Union, the Ministry will restrict or prohibit trading that is use of plant protection products which contain those active matters in Montenegro.

## **Applicant for registration of plant protection products**

### **Article 13**

Application for registration of plant protection products shall be submitted by the producer or legal or physical entity that acts on behalf of and for the account of the producer, has main offices in Montenegro and is responsible for initial trading in plant protection products.

Contents of the requests from Paragraph 1 of this Article shall be prescribed by the Ministry.

## **III REGISTRATION OF PLANT PROTECTION PRODUCTS**

### **A. REGISTRATION PROCEDURE**

## **Registration of plant protection products**

### **Article 14**

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

- 1) needed for evaluation of active matters in plant protection products, as stated in Article 15 Paragraph 2 of this Law, except in the case stated in Article 16 Paragraph 2 of this Law;
- 2) needed for evaluation of plant protection products stated in Article 16 Paragraph 3 of this Law and other data, documentation and samples needed to meet the requirements for registration, if required by the administration body.

Evaluation of documentation from Paragraph 1 of this Article shall be conducted by the administration body and when needed other legal and physical entities authorized by the ministry (hereinafter: evaluators).

Requirements for specialist staff, composition and manner of work of evaluators, procedure of evaluation of active matters and plant protection products and manner of adopting proposals of evaluators for registration of plant protection product, shall be prescribed by the Ministry with consent of the state administration bodies authorized for health issues.

On the basis of the proposal of evaluator and the opinion of the Commission for plant protection products from Article 20 of this Law, the administration body shall adopt decision on registration of plant protection products.

At the event of definition of requirements for registration of plant protection products on the basis of active matters included in the Lists from Article 30 Paragraph 1 of this Law, unique principles for evaluation of plant protection products prescribed by the Ministry with consent of the public administration bodies authorized for health issues shall be applied.

Trading in plant protection products on the basis of active matters from Paragraph 2 of Article 30 of this Law shall be conducted based on the decision of administration body.

#### **Documentation for evaluation of active matter**

### **Article 15**

The applicant shall submit with the application for registration of active matter the appropriate documentation for evaluation of active matter.

Documentation and contents of documentation needed for evaluation of active matter from Paragraph 1 of this Article and the manner of documentation management shall be prescribed by the Ministry.

#### **Documentation for evaluation of plant protection products**

### **Article 16**

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

Should plant protection products contain active matter that is already on the List of active matters from Article 30 Paragraph 1, the active matter should not be re-evaluated if the level of purity and type of impurities do not differ significantly from the composition stated in documentation for inclusion of active matters in the List. With the application for registration of plant protection products a proof on congruence of the active matters and the resume must be submitted.

Contents of documentation from Paragraph 1 of this Article and manner of documentation management shall be prescribed by the Ministry.

#### **Prevention of repeating experiments on vertebrates**

### **Article 17**

In the procedure of preparation of documentation from Article 16, Paragraph 1 of this Law, international documentation on experiments on animals shall be recognized, if plant protection products experiments, subject to registration, 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 request to the administration body in order to establish facts whether the identical plant protection product has already been registered, then request the name or title of the company, address or main offices of the holder of decision on plant protection products registration.

Applicant must submit with the request from Paragraph 2 of this Article a proof that domestic or foreign producer intends to register plant protection products and that s/he disposes of prescribed documentation.

When the administration body determines that the applicant is applying for registration of plant protection products identical with already registered plant protection products of another person, the administration body shall deliver to the applicant name and address of the company that holds decision on registration of plant protection products and shall inform person or persons that holds decision on registration of plant protection products about it.

Applicant and the person holding decision on registration of plant protection products should undertake all steps in order to achieve the agreement on joint use of data in order to prevent repetition of experiments on vertebrates.

In order to conduct the experiment on animals, the administration body authorized for the veterinary operations needs to approve it.

## **Data protection**

### **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 matter submitted with the application for registration except:

- if the applicant got the approval of the first applicant or the person that holds decision on plant protection products registration, which can be proved by the adequate document; or
- if at least 10 years as of the first introduction of the active matter to the List has passed; or
- if at least 10 years has passed as of the first registration of the active matter in one of the states of European Union; or
- if 5 years have passed as of registration of plant protection products based on received additional data needed for first introduction of the active matter to the List, unless this five-year period expires before a ten-year period from lines 2 and 3 of this Item, which is the base for change of conditions for introduction of the active matter or for extension of introduction of the active matter to the List;

2. data from documentation of plant protection products submitter with registration request unless:

- another applicant agrees with the first applicant to use such data or with the person that holds decision on plant protection products registration and it can prove with adequate document ; or
- ten years have passed from the first registration of plant protection products.

## **Confidentiality of data**

### **Article 19**

The administration body shall treat data on industrial and trade secrets delivered by the applicant from Article 15 and 16 of this Law as confidential if the applicant requests it and if administration body evaluates that the request is in line with regulations which govern secrecy of data.

Confidentiality shall not apply to:

- the name and contents of all active matters and name of plant protection products and lowest purity of technical active matter that needs to be provided by the producer;
- the name of other matters which are classified as dangerous in accordance with regulations on classification, identification and packing of dangerous matters;
- physical – chemical data on active matters and plant protection products ;
- manner of impediment of harmful influences of active matters or plant protection products ;
- resume of the results of testing in order to determine influence and harmlessness of matter or plant protection products on people, animals and living environment;
- recommended procedures and security measures for reduction of risk at the event of handing, storage, transport, fire and other dangers;
- determining the contents of active matters, impurities and other elements in active matters and residue of plant protection products;
- methods of disposal and plant protection products package management;
- actions of decontamination in the case of dissemination or discharge;
- data on first aid and medical treatment in case of harmful influence on people.

If the applicant states latter that s/he does not consider information or part of information from Paragraph 1 of this Article confidential, s/he must inform the administration body about it.

## **Commission**

### **Article 20**

Commission for plant protection products (hereinafter: the Commission) shall be established in order to give opinion on plant protection products in the procedure of plant protection products registration as well as on other operations related to plant protection products.

The Ministry shall appoint members of the Commission from scientists and specialists.

The Commission members shall be paid fee for their work in the amount determined by the Ministry.

## **Reporting on potentially harmful influences of plant protection products**

### **Article 21**

Person that holds decision on plant protection products registration or the person from Article 33 of this Law that was approved the expanded use of registered plant protection products shall immediately inform the administration body about all new data, about possible dangerous influence of any of the plant protection products or residue of plant protection products on health of people, animals, surface and underground waters and living environment in general, including new information on possible limitations of crop rotation.

Duty from Paragraph 1 of this Article refers to the user of plant protection products as well if s/he notices that plant protection products are dangerous for health of people, animals, surface and underground water and living environment.

## **B. TYPES OF REGISTRATION**

### **Terms of registration**

#### **Article 22**

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

- that active matters or active matters in that plant protection product are included in the List from Paragraph 1 Article 31 on the basis of documentation from Article 15 Paragraph 2 and Article 16 Paragraph 3 of this Law;
- that the plant protection product is in line with regulation governing unique principles for evaluation of plant protection product as stated in Article 14 Paragraph 5 of this Law;
- that plant protection product is in line with requirements mentioned in Items 1 – 5 Paragraph 2 of this Article.

In exception to Paragraph 1 of this Article, plant protection product may be registered on the basis of documentation from Article 15 Paragraph 2 and Article 16 Paragraph 3 of this Law, if the procedure to introduce active matters from that plant protection product to the List in EU 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 products it was determined that with regular use of plant protection product :
  - is efficient;
  - there are no unacceptable influences on plants or plant products ;
  - it does not cause unnecessary suffering of harmful rodents that are kept under control;
  - it does not have any harmful influence on health of people or animals, direct or indirect (for example through drinking water, food or feed) or to surface or underground waters;
  - it does not have unacceptable influence on living environment taking into account behaviour of plant protection products in living environment especially on pollution of surface and underground waters including drinking water, and influence on organisms which the use refers to ;
  - it does not deposit in soil and food chain.

- 2) That it is possible to determine the contents of active matters and toxicological and eco-toxicological significant impurities and elements in technically active matter and products with accepted methods of regulated procedure or based on international standards;
- 3) That it is possible to determine with suitable methods on residue of plant protection products which can significantly influence on health of people and living environment, which are the consequence of regular manner of use;
- 4) That established physical – chemical quality is considered acceptable in conditions of adequate use and storage of plant protection products ;
- 5) That documentation contains the proposed MRL in food and waiting periods for the requested use.

With documentation from Article 15 Paragraph 2 and Article 16 Paragraph 3 of this Law, submitted with application for registration, at request of administration body, results of biological researches need to be submitted in the territory of Montenegro on the basis of methods proposed by the Ministry.

Methods are applied in adequate conditions of agricultural production, protection of plants and living environment that suit circumstances in which plant protection products will be used in the territory of Montenegro (EPPO methods).

Plant protection product is intended for application in agriculture and based on the request it may be registered for application in non-agricultural areas if requirements from Items 1 – 5 Paragraph 2 of this Article are met.

Applicant shall submit the documentation from Article 15 Paragraph 2 and Article 16 Paragraph 3 of this Law.

## **Recognition of registration of plant protection products**

### **Article 23**

Applicant may request registration of plant protection products which contains an active matter or active matters included in the List from Article 30 of this Law, based on registration conducted in another country member of the European Union if that plant protection product was registered in accordance with unique principles for evaluation of plant protection products from Article 14 Paragraph 6 of this Law and if in the event of the proposed application of plant protection products in the territory of Montenegro conditions in agricultural production, plant protection and living environment, including climate conditions relevant for application of plant protection products, comparable with situation in other countries members of the same climate zone.

In cases from Paragraph 1 of this Article, in the territory of Montenegro it is not necessary once again to perform tests and analysis from Article 22 of this Law.

With the request for recognition of registration, data about identity of active matters, identity of plant protection products and proof and report on registration of plant protection products in another state should be submitted and translated into Montenegrin by a testified translator as well as a certified copy of the original and resume from Article 16 Paragraph 4 of this Law.

Administration body may reject request from Paragraph 1 of this Article due to incomparability of circumstances of agricultural production, protection plants, living environment or climate conditions, with the opinion of the Commission. Administration

body may request to perform tests, analysis or examinations 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 people;
- resistance phenomena.

Administration body may with consent of the applicant from Paragraph 1 of this Article in the procedure of recognition of registration, respecting the requirements from Article 22 Paragraph 2 Item 1 of this Law and based on the opinion of evaluator from Article 14 Paragraph 2 and 3 of this Law, will change the proposed use of plant protection products in order to exclude from comparison all incomparable circumstances in agricultural production, protection of plants or living environment including climate conditions.

In the procedure of execution of the request for recognition of plant protection product registration, requirements defined by regulations of Montenegro need to be taken into account referring to protection at work of legal and physical entities which come into contact with plant protection products when trading as well as users of plant protection product .

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

## **Validity of registration and its extension**

### **Article 24**

Administration body on the basis of the proposal of evaluator and the Commission from Article 14 Paragraph 4 of this Law shall register validity of plant protection product for a period of time not longer than 10 years.

Validity of plant protection product registration may be extended several times, every time maximum 10 years. Request for extension of validity of registration shall be submitted to the administration body at least 12 months before the expiration of registration validity.

If the conditions based on which plant protection product was registered, administration body will require a complete documentation for evaluation of plant protection product or a part of documentation needed for adoption of decision on extension of registration validity.

The registered plant protection product may be subjected at any time to re-evaluation if plant protection product does not meet any of the requirements from Article 22 Paragraphs 1 and 2 of this Law.

In the case from Paragraph 4 of this Article, the administration body will require from the person that holds plant protection product registration or from the business company, that is another legal entity and entrepreneur who was allowed to expand use of plant protection product from Article 33 of this Law, documentation and additional data needed for new evaluation of plant protection product.

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

## **Temporary registration**

### **Article 25**

When plant protection products contain new active matter which applicant from Article 13 Paragraph 1 of this Law has submitted documentation from Article 15 Paragraph 2 and Article 16 Paragraph 3 of this Law for, and which European Commission has reached decision for about completeness of documentation, administration body may within three-year time as of the day of adoption of the decision of the European Commission issue a decision on temporary plant protection product registration valid maximum three years provided that plant protection product meets the requirements from Article 22 Paragraph 2 Items 1-5 of this Law.

In case that European Commission extends deadline from Paragraph 1 of this Article by a decision, the administration body may extend validity of temporarily plant protection product registration.

## **Decision on registration of plant protection product**

### **Article 26**

Decision on registration of plant protection product from Articles 22 - 28 of this Law shall be issued by the administration body on the basis of the proposal of evaluator and the opinion of the Commission from Article 14 Paragraph 4 of this Law not later than 12 months after receiving complete documentation of the applicant.

In exception to 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 change or amendment of a decision on plant protection product registration due to minor changes which have no influence on health of people or living 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 contents of the active matter and changes caused by reduction of MRL).

Decision on registration of plant protection product are on the name of plant protection product and the applicant from Article 13 Paragraph 1 of this Law. Plant protection product trade name, name and contents of active matters and other dangerous matters in the plant protection product must be clearly written in the decision as well as information about use, classification and identification of plant protection product, allowed places for sale, waiting period and MRL.

More detailed contents of the decision on plant protection product registration from Paragraph 3 of this Article shall be prescribed by the Ministry.

## **Change of registration decision**

### **Article 27**

When conditions that made grounds for issuing the decision on plant protection product registration, the administration body shall change at the request of the person holding decision on plant protection product registration or ex officio the decision on plant protection product registration.

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



Changes in the decision on plant protection product registration from Paragraph 1 and 2 of this Article may be approved only if requirements from Article 22 Paragraph 2 Item 1 are still met.

Administration body shall change decision on plant protection product registration at proposal of the person that holds decision on plant protection product registration if that plant protection product of that producer was registered in any of the countries members of the European Union under the same or different trade name.

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

## **C. CESSATION OF REGISTRATION VALIDITY**

### **Cessation of registration validity**

#### **Article 28**

Validity of registration shall cease to exist:

1. with expiration of validity from decision on plant protection product registration unless the registration is extended;
2. with cessation of validity 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 do not exist any more;
  - when false data or data about facts which cause delusion were delivered based on which decision on plant protection product registration was issued;
  - when plant protection products ceases to meet the requirements for registration;
  - in cases of prohibition of trading in plant protection products in the whole territory of Montenegro from Article 12 of this Law;
  - when a person that holds decision on plant protection product registration does not submit documentation from Article 16 Paragraph 3 of this Law within the period of time prescribed in Article 24 Paragraph 2 of this Law;
  - when active matter is erased from the List from Article 30 of this Law.
- 6) With expiration of validity of decision on temporary registration from Article 25 of this Law in line with the decision of the European Commission about non-inclusion of active matters in the List.

When person that holds decision of plant protection product registration decides to stop trading in plant protection product prior to expiration of validity of registration, s/he is obliged to inform the administration body about that and to submit in writing the explanation before s/he stops trading in plant protection product.

After expiration of validity of registration from Paragraph 1 of this Article, plant protection product may be traded in not more than 18 months after the expiration of registration for the purpose of sale of existing supplies.

In exception to Paragraph 3 of this Article, administration body may reach decision to eliminate that plant protection product supplies after expiration of plant protection product registration validity in line with regulations governing disposal.

Administration body may set the deadline in its the decision on termination of registration issued to the person that holds decision on plant protection product registration for sale or elimination of existing plant protection product supplies in line with regulations governing disposal.

More detailed requirements on plant protection product disposal management from Paragraph 5 of this Article shall be prescribed by the Ministry.

## **D. PLANT PROTECTION PRODUCT REGISTER**

### **Article 29**

Administration body shall keep the Register of plant protection product in trade in the territory of Montenegro, based on issued decision on registration.

List of plant protection product shall be published in the "Official Gazette of Montenegro" once a year.

Manner of keeping and contents of the Register of plant protection product as well as the contents of the List from Paragraph 2 of this Article shall be prescribed by the Ministry.

### **List of active matters**

### **Article 30**

List of active matters that are positively evaluated in EU will be kept by the administration body and published in the "Official Gazette of Montenegro" once a year.

List of active matters with plant protection product in use in the territory of Montenegro shall be kept by the administration body together with the Register from Article 29 of this Law and published in the "Official Gazette of Montenegro" once a year.

## **E. LICENSES**

### **License for research or development**

### **Article 31**

Research and development analysis which including researches on non-registered plant protection product in living environment shall be allowed only if based on license for research or development.

Administration body shall issue licenses for limited quantity of plant protection product or for limited area of research.

Based on the written request and positive opinion of the evaluator and the Commission, the administration body shall issue license from Paragraph 1 of this Article if the plant protection product is not dangerous to health of people and animals and if it has no negative effect on living environment.

If the administration body finds that researches from the request may have harmful influence on health of people and animals or unacceptably harmful influence on living environment, it may at proposal of the evaluator and the Commission prohibit researches or allow them provided that requirements for prevention of harmful influence are met.

Requirements that the applicant needs to meet, contents of the request, conditions for execution of and duration of research shall be prescribed by the Ministry.

### **Extraordinary license**

#### **Article 32**

In the case of extraordinary circumstances that may be caused by a harmful organism, which may not be either stopped or limited in adequate manner with use of registered plant protection products neither with other measures, or in the case of lack of plant protection product on the market, the administration body may issue extraordinary license for trading and use of non-registered plant protection product within 120 days.

Procedure for issuing extraordinary license shall be initiated ex officio or at request of a party. Administration body shall require a specialist opinion of the evaluator and the Commission in the procedure of issuing extraordinary license.

Administration body shall issue extraordinary license for trading in non-registered plant protection product ex officio or at request of a party even when there are no registered plant protection product 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 use is in line with scientific achievements, good agricultural practice and procedures and standards of the European Union.

Contents of the request and contents of extraordinary permission shall be prescribed by the Ministry.

### **Approval for extension of use – small crops and small purposes**

#### **Article 33**

Business company, that is another legal entity and entrepreneur that professionally deals with agriculture or reforest activities shall submit the request to the administration body for extension of use of already registered plant protection product for other purposes (small crops or small purposes).

Applicant from Paragraph 1 of this Article is obliged to submit with the request data or documentation which explain the request for extension of the area of use of registered plant protection product.

Administration body shall issue the license for extension of use if requirements from Article 22 Paragraph 2 Item 1 Lines 3, 4, and 5 and Item 5 are met, and on the basis of the proposal of the evaluator and the Commission. Information about extension of use shall be stated in the additional instruction for use.

More detailed requirements for issuing license and contents of license from Paragraph 3 of this Article as well as definition of small crops or small purposes shall be prescribed by the Ministry.

## **IV LEGAL ENTITIES AUTHORIZED TO CONDUCT OPERATIOIS IN THE AREA OF PLANT PROTECTION PRODUCTS**

### **Authorized legal entities**

#### **Article 34**

Professional operations and tasks from the area of plant protection products, operations of laboratory analysis for monitoring of residue of plant protection products, which come from this Law and regulations which regulate food safety, shall be performed by the legal entities that fulfill the prescribed conditions in regard to personnel, equipment and devices, that are authorized by the decision of the Ministry (hereinafter: the authorized legal entity).

The Ministry may give powers to the professional services authorized for agriculture operations to perform certain operations from Paragraph 1 of this Article.

Requirements regarding specialist staff, equipment and devices from Paragraph 1 of this Article as well as the operations from Paragraph 2 of this Article shall be prescribed by the Ministry with consent of the public administration body authorized for health issues operations.

### **Article 35**

Operations and tasks performed by the authorized legal entities from Article 34 Paragraph 1 of this Law are particularly the following:

1. support operations to the administration body in the procedure of registration of plant protection product and establishing of MRL;
2. risk assessment related to determination of expert grounds for establishment of MRL in cooperation with other bodies of the state administration authorized for safety of food ;
3. plant protection product laboratory tests;
4. residue of plant protection products analysis;
5. analysis in the program of monitoring of post-registration control of plant protection product;
6. execution of annual programme of monitoring on residue of plant protection products;
7. development of specialist grounds and opinions from the area of plant protection product and residue of plant protection products for the needs of administration bodies decision making;
8. execution of research and development activities in the plant protection product area;
9. development and introduction of new procedure in good agriculture practice and integral protection;
10. introduction of standards in the field of tests of plant protection product biological effects;
11. tasks from the field of records of plant protection product in circulation;
12. participation in establishment and development of information system in the field of plant protection product and residue of plant protection products;
13. tasks related to training of persons responsible for trading in and use of plant protection product;
14. other tasks from the field of plant protection product and residue of plant protection products and devices for use of plant protection product.

Operations and tasks from the area of use of plant protection product executed by the legal entity from Article 34 Paragraph 1 of this Law are particularly the following:

1. development of professional grounds to support administration body decision making in the field of devices for use of plant protection product ;
2. tasks related to professional training in the area of devices for use of plant protection product;
3. participation in introduction, development and setting the information system in the area of devices for use of plant protection products ;
4. conducting research and development activities ;
5. performing other tasks in the area of devices for use of plant protection product.

#### **Article 36**

Financial means for the operations and tasks execution from Article 35 of this Law shall be provided from the Budget of Montenegro except for the operations and task performed at request of legal and physical entities which are paid individually in line with Article 46 of this Law.

### **V SERVICES PROVIDERS**

#### **Prevention and eradication of harmful organisms**

#### **Article 37**

Prevention and eradication of harmful organisms activities in agriculture and forestry with use of plant protection products may be executed by business companies that is other legal entities or entrepreneurs who meet the prescribed requirements (hereinafter: service providers).

Service providers from Paragraph 1 of this Article shall enter the Register of entities who perform operations of prevention and eradication of harmful organisms in agriculture and forestry with use of plant protection products (hereinafter: the Register of service provider).

Administration body shall keep the Register of service providers.

Administration body shall determine in the decision whether the requirements from Paragraph 1 of this Article have been met.

Requirements from Paragraph 1 of this Article, requirements for registration and manner of leading the Register of services provider shall be prescribed by the Ministry with consent of the state administration bodies authorized for health issues operations.

### **VI DEVICES FOR USE OF PLANT PROTECTION PRODUCTS**

#### **Article 38**

Devices which guarantee safe use of plant protection products for humans and living environment supported by the producers' certificate shall solely be used for plant protection products application.

#### **Article 39**

Owner of devices for use of plant protection products is obliged to keep devices technically in working order.

Owner of the device for use plant protection products is obliged to keep technical documentation of the device (certificate of the producer, manual, certificate of repair works conducted etc.).

### **Regular inspection of equipment**

#### **Article 40**

Owner of the equipment for use of plant protection products is obliged to perform regular inspection of technical regularity of devices.

## **VII INTERNATIONAL TRADING**

### **Import of plant protection products**

#### **Article 41**

Plant protection products may be imported only by business companies, that is other legal entities or entrepreneurs, holders of decisions on plant protection product registration or importers authorized by the appropriate document, registered in the Register from Article 6 of this Law. Business companies that is other legal entities or entrepreneurs are obliged in the event of importing plant protection product to report the shipping of plant protection products to the phyto-sanitary inspector at the border crossing in Montenegro.

Surveillance over the import of plant protection products shall be performed by the phyto-sanitary inspector.

Import of plant protection products may be conducted only at border crossings where phyto-sanitary inspection is organized.

## **VIII ADMINISTRATION BODY**

#### **Article 42**

Administration body according to this Law shall perform administrative and related specialist jobs which refer to:

1. coordination of operations related to registration of plant protection products;
2. running operations of registration and evaluation of active matters and plant protection products and issuing licenses and decisions on plant protection product registration, monitoring programs of post-registration control of plant protection products, that is recognizing plant protection product registration;
3. keeping registers and records;
4. preparation of grounds for development of regulations and conducting other administrative operations and their enforcement;
5. determining whether the requirements are met and entering the Register from Article 6 of this Law;
6. monitoring the situation in the area of trading in plant protection products and participation in preparation of measures;

7. preparation, coordination and monitoring of the prescribed programmes related to measures and regular use of plant protection products (post-registration control of plant protection products) as well as conducting the programme;
8. introduction of principles of good agricultural practice and integral protection of plants;
9. preparation and coordination of operations related to residue of plant protection products and conducting the program of monitoring on 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 whom Montenegro is obliged to submit the reports to in accordance with regulations and based on international agreements;
11. informing the public and interested persons about operations in the area of plant protection products;
12. issuing publications in the area of plant protection products;
13. establishment and development of information – communication system in the area of plant protection products, collecting, processing, mediating and managing data in the area of plant protection products and information system management;
14. conducting professional education advancing and advanced trainings for employees in the area of plant protection products;
15. cooperation with other bodies in Montenegro and abroad in the area of plant protection products;
16. performing other tasks in the area of plant protection products.

## **IX ACQUISITION OF DATA AND INFORMATION AND RECORD KEEPING**

### **Acquisition and use of data and information**

#### **Article 43**

In order to organize trading and trading supervision of plant protection products administration body acquires data and information, regarding the plant protection products and residue of plant protection products, which are necessary for database establishment and maintenance and for record keeping regarding the trade of the plant protection products.

Administration body acquires and uses data and information which are, within the prescribed databases and records, kept by other state administration bodies, agencies, manufacturers of plant protection products and other institutions in accordance with the regulations which define the right on data access and data protection.

The manner of data and information acquisition, database keeping and records from paragraph 1 of this Article and confidentiality protection obligation are defined by the Ministry.

### **International exchange of information**

#### **Article 44**

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

#### **X FEES**

#### **Article 45**

Fees shall be paid for:

1. the procedure of registration of plant protection products and for issuance of decision on plant protection products registration and issuance of license for the applicant;
2. the analysis of the presence of residue on plant protection products during the inspection supervision by the owner of plants, plant products, food or feed, when the plant protection products residues are exceeding the prescribed maximum allowable concentration;
3. the ground and other objects analysis during the inspection supervision of the use of the plant protection products and active substances by the owner or land user if it is established that the prohibited plant protection product was used or if it is established that the plant protection product was incorrectly used;
4. the laboratory analysis of the plant protection products during the protection supervision by the entity that holds the plant protection product registration if such plant protection product is not in accordance with registration or declaration.
5. the laboratory analysis of the plant protection products samples during import by the importer from whom the samples were taken.

Fees from paragraph 1 items 2 – 5 of this Article are the income of people who perform duties and offer services for which the fee is paid.

Fees from paragraph 1 item 1 of this Article are the income of administration body.

The amount of the fees from paragraph 1 of this Article is defined by the Ministry.

## **XI INSPECTION SUPERVISION**

### **Article 46**

Inspection supervision over the enforcement of this law shall be conducted, within the scope of their competences, by the state administration body which is competent for health operations through sanitary inspector, by the administration body which is competent for veterinary operations through veterinary inspector and by the administration body through phytosanitary inspector, in accordance with the Law.

### **Authorities of the phytosanitary inspector**

#### **Article 47**

Apart from the authorities of the inspector prescribed by the Law which regulates inspection supervision, the phytosanitary inspector shall have the following authorities:

1. To check whether the imported plant protection product is entered into the plant protection product Register, i.e. to check if such product has a decision on registration from Article 29 paragraph 1 of this Law;
2. To check documentation which accompanies the plant protection product in transit;
3. To control register and record keeping;



4. To check the fulfillment of conditions for putting the plant protection product into trade, for packing, identification, performance of trade and the use of the plant protection product;
5. To control the performance of professional activities and tasks of the authorized legal entities and activities which are performed by the service providers in accordance with this Law;
6. To establish the identity of an offender, by photographing or recording if necessary, when there is a suspicion that the provisions of this Law are not applied;
7. To take samples for post registration control of the plant protection products;
8. To take samples of plants, plant products, substrates for growth of plants, solutions mixture, the plant protection products or other necessary samples in order to control the prescribed plant protection product usage (for instance, damage to crops, non compliance with the waiting period etc.);
9. To temporarily prohibit, until the irregularities are not removed, the performance of activities of the plant protection product trading if a company or other legal entity or entrepreneur is not entered into the Register from Article 6 of this Law, or if they do not fulfill the required conditions and the inspector informs administration body about it.

## **1. Administrative measures and actions**

### **Article 48**

Apart from administrative measures and actions prescribed by the Law which regulates inspection supervision, phytosanitary inspector shall undertake the following administrative measures and actions:

1. Prohibit the trading of the plant protection product if it is not registered;
2. Prohibit the import of the plant protection products to an entity which is not entered into the Register from Article 6, item 1 of this Law and the inspector informs administration body about it;
3. Prohibit the import of the plant protection products, if such product is not categorized, packed and labelled or does not have instruction for use;
4. Prohibit the import of the plant protection products if the trading of such product is prohibited;
5. Temporarily prohibit the import of the plant protection products, when the irregularities on the plant protection products package or accompanying documentation have to be corrected;
6. Prohibit the trading of the prohibited plant protection products;
7. Prohibit the trading of the plant protection product if it is out of date;

8. Prohibit the trading of the plant protection product if it is not categorized and in accordance with the decision on registration (packaging, declarations labels, instructions for use, physical and chemical characteristic etc.);
9. Prohibit the trading of the plant protection product if it is established, during the post registration control, that the plant protection product is defective;
10. Prohibit to the user the incorrect use of the plant protection products;
11. Prohibit the trading and the utilization of the devices for the use of the plant protection product if such devices do not have certificate, or it is not in 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 selling of the plant protection products in the quantity and for the purpose which are not in accordance with the provisions of Article 8 of this Law;
13. Undertake other actions and procedures necessary for the enforcement of this Law and regulations based on this Law, for which he/she obtains authorization through the special law.

#### **Authorizations of the sanitary and veterinary inspector**

##### **Article 49**

Apart from authorizations of the inspector prescribed by the Law which regulates inspection supervision, sanitary and veterinary inspector shall have the following authorizations:

1. To take samples for the establishment of the residue of plant protection products, in accordance with the competencies prescribed by the Food Safety Law;
2. To define appropriate measures if he/she establishes that the maximum residue level was exceeded;
3. To temporarily prohibit the trading of food, feed, plant and plant products, from which the samples for the establishment of the residue of plant protection products were taken, until the analysis results are not obtained.

##### **Article 50**

Competent inspector from Article 46 of this Law may temporarily, until the decision is made, confiscate documentation, objects and products which may be used as evidence during the court procedure.

The receipt is issued after the temporary confiscation from paragraph 1 of this Article is performed.

##### **Article 51**

Competent inspector from Article 46 of this Law, within the scope of its competence, shall deliver to the analysis the samples taken during the inspection supervision to the authorized legal entities from Article 34, paragraph 1 of this Law.

##### **Article 52**

Professional training programme for the inspectors from the field of plant protection products is determined by the Ministry on suggestion of scientific and educational institution from the field of plant protection.

## **XII PENALTY PROVISIONS**

### **Article 53**

Entity, company or other legal entity or entrepreneur shall be fined from hundredfold to three hundredfold amount of the minimum work price in Montenegro for an offence if:

1. they, on the territory of Montenegro, put into trade and use the plant protection product which is not registered, or does not have decision on registration (Article 3, paragraph 1);
2. they sell the plant protection product to the purchaser that is not entered into the Register of plant manufacturers (Article 8, paragraph 1);
3. they do not use the plant protection product in the manner prescribed by Article 1, paragraph 1 of this Law;
4. they use the plant protection product from an airplane (Article 9, paragraph 3);
5. they use the plant protection product contrary to the provisions of Article 9, paragraph 4 of this Law;
6. they provide advice, recommendations, performs announcements and other types of advertising contrary to the provisions of Article 9, paragraph 7 from this Law;
7. an applicant, before the performance of an experiment, does not submit the request to the administration body in order to establish facts whether this identical plant protection product is already registered, and other data regarding the registration of such product (Article 17, paragraph 2);
8. the entity that holds decision on registration, the entity from Article 33 of this Law or the user of the plant protection product fails to inform the administration body about all his/her new data, possible harmful influence of any such plant protection product or the residue of plant protection products on health of people and animals;
9. they make changes in the decision on registration of the plant protection product and fails to fulfill conditions from Article 22 paragraph 2 item 1 of this Law;
10. they perform researching of unregistered plant protection product without license or contrary to the conditions from the license (Article 31, paragraph 1 and 3);
11. they use special license for trading and use of unregistered plant protection product during the period longer than 120 days (Article 32, paragraph 1);

12. they use already registered plant protection product for other (expanded) purposes without license for such expanded purposes or contrary to the license for the expansion of the use of such product (Article 33, paragraph 1);
13. they perform technical activities and tasks from the field of the plant protection product and operations of laboratory analysis for the monitoring of residues in accordance with this Law and regulations which define the food safety and do meet requirements regarding the personnel, equipment and devices (Article 34, paragraph 1);
14. the owner utilizes devices for the use of the plant protection products which do not guarantee safe use of the plant protection product and environment protection (Article 38, paragraph 1);
15. the owner of the device for the use of the plant protection product keeps this devices out of working order and does not possess technical documentation about the device (Article 39);

Physical entity or responsible person in the legal subject shall be fined to the level of twenty fold amount of the minimal work price in Montenegro for the offence from paragraph 1 of this Article.

#### **Article 54**

Body, company or other legal entity or entrepreneur shall be fined from hundredfold to two hundred fifty fold amount of the minimum work price in Montenegro for an offence if:

1. they put into trade the plant protection products which are out of date (Article 4, paragraph 2);
2. they do not keep records about the plant protection products, do not submit reports from the records to the administration body and do not keep data during the defined period of time (Article 7, paragraphs 1, 2, 3, 4 and 5);
3. they do 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 are exceeding the prescribed level (Article 10, paragraph 2);
4. they perform suppression and extermination of harmful organisms, but they are not entered into the Register of service provider (Article 37, paragraph 2);
5. they do not keep records and data in accordance with Article 39, paragraph 2 of this Law;
6. they import the plant protection products, but they are not entered into the Register, or if they do not, while importing, declare the package to the phytosanitary inspector.

Responsible person in the legal subject shall be fined to the level of twenty fold amount of the minimal work price in Montenegro for the offence from paragraph 1 of this Article.

Physical entity shall be fined from tenfold to twenty fold amount of the minimal work price in Montenegro for the offence from paragraph 1 of this Article.

#### **XIV TRANSITIONAL AND FINAL PROVISIONS**

##### **Article 55**

Old active substances are active substances which are not on the List and which were registered and put into trade before July 26<sup>th</sup> 1993 in any EU country and which are on the active substances list from the Overview of the plant protection products in agriculture and forestry from 2004.

New active substances are active substances which are not on the List and which were registered and put into trade after July 26<sup>th</sup> 1993 in any EU country.

Active substances list contains active substances which may be used in the plant protection products in Montenegro. The List is harmonized with the positive list of active substances allowed for the use in the plant protection products in the EU.

##### **Plant protection products trade supervision over the state border**

##### **Article 56**

After Montenegro's attainment of the fully-fledged membership in the EU, the operations of supervision over the plant protection products trade over the state border with the EU countries shall be considered as internal trade.

##### **Applicant for plant protection products registration**

##### **Article 57**

After Montenegro's attainment of the fully-fledged membership in the EU, request for the plant protection products registration, which are intended for the trade on the territory of Montenegro, may be submitted by both legal and physical entity with the residence in any EU country.

##### **Conditions for the performance of the plant protection products trade after Montenegro's attainment of the fully-fledged membership in the EU**

##### **Article 58**

After Montenegro's attainment of the fully-fledged membership in the EU, performance of trade of plant protection products and devices for the use of the plant protection products on the territory of Montenegro may be done by legal and physical entity with the residence in any EU country, if they meet the requirements prescribed by this Law.

##### **Regulations adopted on basis of this Law and time-limit for their creation**

##### **Article 59**

Bylaws, on the basis of authorization from this Law, shall be adopted within the period of three years after the day of its entering into force.

Apart from bylaws from paragraph 1 of this Article, the Ministry can also adopt other bylaws which are necessary for the implementation of the EU directives and decisions from the field of the plant protection products.

##### **Article 60**

Until the bylaws, on the basis of authorization from this Law, are not adopted, the bylaws adopted on the basis of the Plant Protection Law ("Official Gazette FRY", No. 24/98) shall be applied, if they are not against the provisions of this Law.

##### **Article 61**

Provisions of the Plant Protection Law (Official Gazette FRY, No. 24/98), which are related to the plant protection products shall not be applied when this Law enters into force.

##### **Entering into force**

**Article 62**

This Law shall enter into force eight days after the day of its publication in the "Official Gazette of Montenegro".