

Republic of Macedonia

MINISTRY OF AGRICULTURE, FORESTRY AND WATER ECONOMY

LAW ON PLANT PROTECTION PRODUCTS

I. GENERAL PROVISIONS

Content

Article 1

(1) This Law regulates the authorization, placing on the market, use and control of plant protection products; placing on the market and control of active substances, considered as products; maximum residue levels; equipment for use of products; exchange of information related to products, production of products, register of legal and civil entities involved in production and placing products on the market; requirements for authorizations of the organs responsible for the implementation, monitoring and control of this Law.

(2) Production of products, placing on the market for the needs of production of products, good laboratory practice (GLP), the Rotterdam Convention on the prior informed consent procedure (PIC) for certain hazardous substances and pesticides in international trade, classification, packaging and labeling of the products, besides the provisions of this Law are also regulated by the provisions on hazardous substances and preparations.

(3) Wastes of products, and the packages of the used products, and the state of release of products into environment, if not regulated by this Law, are being regulated by the provisions on environment protection.

(4) The transport of active materials and plant protection products is regulated by the provisions for transport of hazardous materials.

Definitions

Article 2

For application of this Law, the terms used shall have the following meaning:

1. Plant Protection Products shall mean active substances and preparations, containing one or more active substances, prepared in a form in which they are delivered to the user, intended for:

- 1.1 protections of plants or plant products against all harmful organisms or preventing the action of such organisms in so far as such substances or preparations are not otherwise defined below;
- 1.2 influencing the life processes of plants, other than as a nutrient (eg. plant growth regulators);
- 1.3 preserving plant products, to which extent such substances or products are not covered by other legal act;
- 1.4 destroying undesired plants; and
- 1.5 destroying parts of plants, delaying or preventing undesired growth of plants.

2. "Residues":

- 2.1. "Residues of Plant Protection Products" shall mean one or more substances present in or on plants, or in or on products of plant origin, edible products of animal origin, or in the environment and resulting from the use of plant protection products, including their metabolites and products resulting from their degradation or reaction; and
 - 2.2 "Maximum residue level" shall mean the maximum residue level obtained in supervised trials of a product performed according to good plant protection practice.
-

3. **"Substances"** shall mean chemical elements and their compounds, as they occur by nature or manufacture, including any impurity inevitably resulting from the manufacturing process;
 4. **"Active Substances"** shall mean substances or microorganisms including viruses, having general or specific action:
 - 4.1. against harmful organisms; or
 - 4.2. on plants, parts of plants, or plant products;
 5. **"Preparations"** shall mean mixtures or solutions composed of two or more substances, of which at least one is an active substance, intended for use as plant protection product;
 6. **"Plants"** shall mean live plants and live parts of plants, including fresh fruit and seeds;
 7. **"Plant Products"** shall mean products in the unprocessed state or having undergone only simple preparation such as milling, drying, pressing or extraction, but excluding plants themselves as defined item (1), point 6 of this article;
 8. **"Harmful Organisms"** shall mean pests of plants or plant products belonging to the animal or plant kingdom, and also viruses, bacteria, phytoplasmas, fungus and other pathogens;
 9. **"Animals"** shall mean species fed, kept or consumed by man;
 10. **"Placing on the Market"** shall mean any supply, whether in return for payment or free of charge, other than for storage followed by consignment from the territory of Republic of Macedonia, or by safe extermination. The import of a plant protection product in the territory of Republic of Macedonia shall be deemed to placing on the market;
 11. **"Authorization"** shall mean the administrative act (Decision) of the Fytosanitary Directorate to authorize the placing on the market and use of a plant protection product in the territory of Republic of Macedonia, following an application submitted by an applicant;
 12. **"License"** shall mean the administrative act (Decision) of the Fytosanitary Directorate to authorize the import and experimental research of products and auxiliary plant protection products in the territory of Republic of Macedonia, following an application submitted by an applicant;
 13. **"Environment"** shall mean water, air, land, wild species of fauna and flora, and any interrelationship between them, as well as their relationship with other living organisms;
 14. **"Integrated Plant Protection"** shall mean rational application of a combination of biological, biotechnological, chemical, agro-technical or selective plant-breeding measures, whereby the use of chemical products is limited to the strict minimum necessary to maintain the pest population at levels below those causing economically unacceptable damage or loss (threshold of harm);
 15. **"Good Agricultural Practice"** shall mean performing agricultural activities in a manner, which enables good management of agricultural lands, and propagating materials, respecting the natural properties of the agricultural area. Good agricultural practice covers optimal combination of agro-technical measures in order to preserve the natural fertility of the agricultural lands and in order to prevent burdening the environment, exaggerated use of mineral or organic fertilizers and products, and to leave the lowest possible residue level in/on plants and plant products intended to be used as foodstuffs;
 16. **"A product is identical"** if compared to the authorized product in relation to: formulation, content of active substance, including impurities and other components in the active substance, is identical (with permitted derogations in co-formulations and their mutual relations, except if the differences are important from the point of view of safety and efficacy of the authorized product), and if physico-chemical properties of the preparation are identical, as well as labels, packing and package, except the trademark of the preparation;
 17. **"Auxiliary Plant Protection Products"** shall mean substances of natural, synthetic or microbial origin formulated as placed on the market and intended for plant protection without it being necessary
-

to carry out the full evaluation procedures for plant protection products (including pheromones, attractants, repellants, etc.);

18. **“Bio-agents”** shall mean products containing micro-organisms from nature, living organisms, parasites, parasitoids, predators prepared in a form for use against harmful organisms on plants and plant products, not harmful to human and animals;

19. **“List of active substances”** includes active substances which are authorised for use in plant protection products on the territory of the European Union (hereinafter EU) with defined conditions and decision for the use published in Annex 1 from the Regulation 91/414 (hereinafter list Annex 1);

20. **National List of Active substances** shall mean the list of active substances authorised for use in products and used as plant protection products in the territory of Republic of Macedonia by the Minister of Agriculture, Forestry and Water economy under this Law (hereinafter National List); National List of Active substances is consisted of Old Active Substances, New Active Substances, and those Active Substances that are in procedure of listing into the Annex 1.

21. **“Old Active Substances”** shall mean active substances, placed on the market prior to 26 July 1993 in the EU Member States;

22. **“New Active Substances”** shall mean active substances, placed on the market after 26 July 1993 in the EU Member States;

23. **“Production”** shall mean formulating of each formulation of plant protection products packed in appropriately prescribed packages for plant protection products;

24. **“Equipment for Use of Products”** shall mean machines and equipment for use and application of products, including their component parts which impact on the precision of application;

25. **“Parallel Product”** shall mean identical product with the referent one authorised in Republic of Macedonia by the same producer;

26. **“Very toxic substances and products”** shall mean substances and products which in small dosage cause death or acute and chronic health damages to the people when swallowed, inhaled or absorbed through the skin (T+) i.e. group of poisons, in respect of the Law for chemicals.

27. **“Batch”** shall mean each production (formulation) series on plant protection products;

28. **“The Competent Authority”** shall mean the Phytosanitary Directorate as competent authority for authorization, performance of administrative tasks in the field of placing of plant protection products on the market and equipment for application of products, for implementation and enforcement of this Law, and coordination of all relevant activities for providing all necessary contacts with EU Member States, European Commission, European Food Safety Authority and third countries.

29. **“Uniform principles”** shall mean the Uniform Principles for evaluation and authorization of plant protection products adopted under EU Regulations.

30. **“Inspection supervision”** shall mean the process of checking that all natural and legal entities and other entities comply with the provisions of this Law.

II. AUTHORIZATION OF PLANT PROTECTION PRODUCTS

General

Article 3

(1) Plant Protection Product (hereinafter the Product) may not be produced, placed on the market and used on the territory of the Republic of Macedonia unless authorized in accordance with this Law.

(2) The product may be imported, and placed on the market on the territory of Republic of Macedonia, only by a holder of an authorization in accordance with Article 8 of this Law, of appropriately by the holder of permission in accordance with emergency provisions in accordance with the Article 15 of this Law, permission for mutual recognition in accordance with the Article 16, permission for research and development Article 22, or permission for import of parallel products in accordance with the Article 28 of this Law.

(3) A product which is not authorised for placing on the market and for use in Republic of Macedonia, may be manufactured, stored or transported within/through the territory of the Republic of Macedonia provided the product is intended for use in another country under condition that:

1) the product is duly authorized in that other importing country, and

2) the inspection requirements laid down by the importing country for placing of product on the market and its use to be met.

(4) The product may be properly used, only in accordance with the conditions determined by the authorization, according to its declaration, instructions, and according to the principles of good plant protection practice and, where possible, of the principles of integrated plant protection.

(5) The active substance may not be placed on the market if:

1) it is not classified, packaged, declared and labelled according to the requirements referred to in the decision, and in compliance with this Law, and its provision, and EU Regulations, and

2) the dossier on the active substance has not been submitted according to Article 4 of this Law with the declaration that the active substance is intended to be used determined with Article 2, item 1 of this Law. This requirement does not apply to the active substances which are intended to be used according to Article 22 and Article 23 of this Law.

(6) The product may be imported and exported only on border passes assigned by the Government of Republic of Macedonia proposed by Ministry of Agriculture, Forestry and Water economy.

Application for Authorisation of Article 4

(1) The application for authorization of plant protection products shall be submitted to the Phytosanitary Directorate (hereinafter the Directorate) by a legal entity intending to place the product on the market (hereinafter applicant).

(2) The applicant may be a producer or legal entity authorized by him. If the applicant does not have registered headquarters in the Republic of Macedonia, he must authorize a legal entity who has permanent residence within the territory of the Republic of Macedonia (hereinafter Authorised Representative). The authorized representative shall act on behalf of the applicant on the basis of authorization and contract for representation with the manufacturer, under which the responsibility for any kind of damage of the manufacturer is determined and assured within the territory of Republic of Macedonia. The official authorization of, and the contract for representation, shall be a component part of the application.

(3) The application for authorization shall be submitted in the Macedonian language.

(4) The applicant is obliged, together with the application, to submit:

1) For each active substance contained in the product, the dossier on the active substance which fulfils the requirements referred to in Article 6 of this Law, and which contains documentation and data for:

- 1.1. Identity of the active substance, including the manufacturer;
- 1.2. Identity of the manufacturer;
- 1.3. Physical and chemical properties;
- 1.4. Additional information on the active substance (use, manner of handling, storage, safety measures etc.);
- 1.5. Analytical methods;
- 1.6. Toxicological and metabolic studies;
- 1.7. Residues of active substance in/on plants or plant products, food and feed;
- 1.8. Outcome and behaviour of active substance in the environment;
- 1.9. Eco-toxicological studies;
- 1.10. Summary and evaluation of indents 1.6, 1.7, 1.8 and 1.9 of this paragraph;
- 1.11. Proposals including justification for proposed classification and labelling in accordance with the acts for classification, packaging and labelling of dangerous substances enacted in accordance with the EU Regulations (symbols, signs of danger, safety phrases) and Article 25 of this Law;
- 1.12. Dossier referred to in item 2 of this Article for each representative product for plant protection;
- 1.13. Other data, estimated as necessary during the authorization procedure. and

2) The dossier on the product which meets the requirements set out by Article 7 of this Law and which contains data and documentation for:

- 2.1. Identity of the product;
 - 2.2. Identity of the manufacturer;
 - 2.3. Physical, chemical and technical properties of the product;
 - 2.4. Data for use of the product;
 - 2.5. Additional information for the product;
 - 2.6. Analytical methods;
 - 2.7. Efficacy data;
 - 2.8. Toxicological studies;
 - 2.9. Residues in/on the treated plants or plant products, food and feed;
 - 2.10. Outcome and behaviour of the product in the environment after the use;
 - 2.11. Eco-toxicological studies;
-

2.12. Summary and evaluation of indent 2.7, 2.8, 2.9, 2.10 and 2.11 of this paragraph;

2.13 Proposals including justification for the classification and the labelling proposed in accordance with the EU Regulations (symbols, risk, danger signs and risk phrases); and

2.14. Other data, estimated as necessary during the authorization procedure.

(5) The data referred to in paragraph (4) item 1 point 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8 and 1.9 of this Article The Directorate shall submit to the authorized experts of the corresponding fields from Article 6 paragraph (4) of this Law on the request of the applicant of authorization.

(6) The Summary and the evaluation of the documents and the data are submitted to the Directorate by the authorized experts.

(7) The applicant is not obliged to provide the dossier referred to in paragraph (4) item 1 point of this Article, if the active substances are already included in the list of Annex 1 of active substances or in the National List, except the data and documentations by which the active substances are identified. The Directorate shall determine whether it is in compliance with the conditions for its inclusion in the list of Annex 1 and in the National List and whether the active substances do not substantially differ in the purity degree and in the impurity nature from the composition of the active substances, which are referred to in the dossier on the active substances on the basis of which they have been included in the List of Active Substances.

(8) The applicant is also obliged to provide, free of charge, the necessary quantities of samples of the product, active substance, or other ingredients of the product, including the package according to the requirements of the Directorate, within a period and place determined by it. In the application, methods applied to specification of the content and quantity of active substances in the product shall be included, and, where appropriate, toxicologically and eco-toxicologically relevant impurities and co-formulants.

(9) The processing of application procedures and more detailed documentary and data requirements from paragraph (4) items 1 and 2 of this Article shall be laid down by the Minister of Agriculture, Forestry and Water Economy in agreement with the Minister of Health, the Minister of Environment and Physical Planning, and the Minister of Science and Education.

Dossiers

Article 5

(1) The Directorate shall compile and keep a separate dossier for each application according to requirements under paragraph (4) of Article 4 of this Law and include:

1) Reports (Summary), decisions which are accepted in the procedure by the EU Member States in relation to the product, and

2) Evidence of evaluation of the documentation contained in the application, documents referred to in Article 13 paragraph (4) of this Law, and other necessary documents.

(2) The Directorate for official purposes, on request of the competent bodies, EU countries and the European Commission, shall make the evidence accessible for evaluation from indent (1) item 2 of this Article, and provide the necessary information related to the application. Also, on their request, the Directorate may confirm that the dossier has been provided in accordance with paragraph (4) from

Article 4 of this Law during the application of the applicant, and shall where requested ensure that applicants provide a copy of the technical documentation laid down in Article 19 of this Law.

Article 6

Evaluation of Active Substances

(1) The evaluation of the active substance is conducted on the basis of the dossier for active substance from Article 4 of this Law which shall contain the information and documents for at least one product that contains this active substance except the active substances included in the Annex 1.

(2) The procedure and evaluation of the active substances which are intended for production of products or for use for plant protection in order to determine whether they meet the requirements for inclusion in the national list of active substances under Article 18 paragraph (2) of this Law, shall be carried out by:

1) The Directorate as the competent body entitled for receiving the applications, checking documentation, evaluating of the dossier, organizing official tests, and contacting competent organs and bodies for evaluation of active substances with the European Commission and with competent bodies of the EU Member States for questions related to evaluation of the active substances;

2) Ministry of Health, from the aspect of human health protection toxicological evaluation and classification of active substances and

3) Ministry of Environment and Physical Planning, for outcome and behaviour of the active substance in the environment, and outcome and behaviour of the product in the environment after its use;

(3) If during the evaluation of the dossier referred to in paragraph (1) of this Article, it is shown that additional information is necessary, the Directorate may ask the applicant or his authorised representative to submit such information, especially when an unfavourable decision is predicted.

(4) Properly qualified experts or legal entities in which qualified experts are employed authorized by the Minister of Agriculture, Forestry and Water economy shall have the responsibility for the evaluation of active substances and the product.

(5) The Expert or legal entities from paragraph (4) of this Article according to their field of activity shall be proposed by the Minister of Agriculture, Forestry and Water Economy in agreement with the Minister of Health and the Minister of Environment and Physical Planning.

(6) The procedure for processing the documents for evaluation of active substance, procedure for evaluation of active substances, and requirements for their inclusion in the national list of active substances shall be laid down by the Minister of Agriculture, Forestry and Water Economy in agreement with the Minister of Health, Minister of Environment and Physical Planning in accordance with the uniform principles.

Authorization Procedures for Plant Protection Products

Article 7

(1) The Directorate shall accept the application for product authorization if:

1) The active substance in the product is included in the list of Annex 1 or national list of active substances and conditions laid down in provisions of the Article 6, paragraph (6) of this Law are fulfilled;

2) In the current scientific and technological knowledge it is determined that on the evaluation of the dossier referred to in Article 4 paragraph (4) item 2 of this Law that when used in accordance with Article 3 paragraph (4) of this Law, and considering all regular conditions under which it may be used, and to the consequences of its use:

2.1 it is sufficiently effective;

2.2 it has no unacceptable effect on plants or plant products;

2.3 it does not cause suffering and pain to vertebrates that are to be controlled;

2.4 has no harmful influence on human or animal health, indirectly or directly (through drinking water or feed), or on groundwater;

2.5 have no unacceptable influence on the environment, having particular regard to:

- its final outcome and behaviour in the environment, particularly contamination of water, including drinking water and groundwater,
- its impact on species for which it is not intended;

3) The nature and content of the active substances and, where appropriate, any toxicologically or eco-toxicologically significant impurities and co-formulants may be determined by prescribed methods, or by using methods given in the application in accordance with Article 4 paragraph (4) item 2 indent 2.5 of this Law;

4) Its residues resulting from authorised manners of application which are toxicologically or eco-toxicologically significant may be determined by appropriate methods in general use;

5) Its physical and chemical properties are determined and considered as acceptable for the purposes of the appropriate use and storage of the product;

6) Provisional maximum residue levels (hereinafter MRL) in agricultural products have been established. In case where a EU MRLs has been already established, the Directorate shall ensure opinion issued by the Expert Commission of the Article 24 of this Law that determined EU MRLs satisfy the requirements in Republic of Macedonia; and

7) Provisional MRL with prescribed expiry dates are not exceeded.

(2) As an attachment of the application, the applicant shall include other documents referred to in paragraph (4) of this Article;

(3) The Directorate may interrupt the procedure for product authorisation, if despite submitting a written request to the applicant, the applicant will not provide the necessary documents for granting a decision in the prescribed time period.

(4) Detailed documentation necessary for evaluation and drafting of evaluation report, and the procedure for products evaluation from paragraph (1) of this Article for granting a decision for product authorisation, shall be laid down by the Minister of Agriculture, Forestry and Water Economy in agreement with the Minister of Health and Minister for Environment and Physical Planning.

(5) Because of compliance with the requirements referred to in paragraph (1) of this Article, the Directorate may require all tests and analyses submitted to be officially recognized and carried out under conditions in agriculture, plant health and environment, including climatic conditions, which exist in Republic of Macedonia, relevant for plant protection products use.

(6) Regardless of paragraph (1) and (5) of this Article, the may require the tests and analyses to be carried out by a legal or physical entity from Article 23 of this Law in Republic of Macedonia for the following purpose:

- 1) conditions that are not comparable in agriculture, plant protection, conditions in the environment or climatic conditions;
 - 2) specific ecological sensitivity in certain areas; or
 - 3) different dietary habits of the population.
-

(7) Also, additional conditions in relation to the product use may be determined.

Granting Product Authorization

Article 8

(1) Confirmation on the application for authorisation for completeness shall be done by the Directorate within a period not longer than 2 months from the day of submission.

(2) Unless the competent authority within a period determined in paragraph (1) of this Article does not confirm the completeness of the application it shall be considered that the application is complete.

(3) The Directorate shall evaluate the submitted application for authorisation and shall grant authorisation for the product on the basis of a check of compliance of the information included in the application, and in the dossier in accordance with Article 4 paragraph (4) indents 1 and 2 of this Law, requirements defined in Article 7 of this Law and the opinion of the Expert Commission of the Article 24 of this Law within the deadline of:

- 18 months in case of application for authorisation of a product containing an active substance included in the list of Annex 1, or a new active substance in complying with the requirements of inclusion in the list,
- 12 months in the case of application for authorisation of a product containing an old active substance, not included in the list of Annex 1, or in the case of extension or amendment of product authorisation, and
- 2 months in the case of application for amendment of product authorisation not requiring assessment with regard to the requirements for the product defined in Article 4, 6 and 7 of this Law.

(4) Unless the competent authority within a period determined in paragraph (3) item 1, 2 and 3 of this Article does not grant an authorization of the product it shall be considered that the authorization is granted.

(5) The Directorate in granting authorisation shall determine the following conditions for:

- 1) declaration (labelling) of product package; and
- 2) placing on the market and product usage, including necessary limits if they are defined for prevention of undesirable effects on the human and animal health and undesirable effects on the environment, or it is necessary to ensure fulfilment of the requirements in compliance with Article 7 paragraph (1) item 2 indents 2.1, 2.2, 2.3, 2.4 and 2.5 of this Law.

(6) The Directorate in granting authorization may determine that the product may only be used by the specific categories of workers to be specified by the Directorate.

(7) Appeal may be submitted for authorization from paragraph (3) to the Minister of Agriculture Forestry and Water economy.

(8) Appeal does not delay the enforcement of the Decision.

Period of Product Authorization Validity, Extension and Revision

Article 9

(1) Regardless of the application of paragraph (4) from this Article and Article 10 of this Law, the authorisation shall be valid for ten years after its entry into force.

(2) The validity period of the authorization may be prolonged if the holder of the decision requests from the Directorate an extension of the validity period not later than six months before the day of the termination of the decision on the authorization. The extension shall be granted if it is ascertained that the conditions referred to Article 7 paragraph (1) of this Law and in the decision are still met.

(3) The validity period of the authorization may be extended for a maximum period of 5 years, which may be repeated.

(4) The authorization may be revised at any time, if there are indications that any requirements referred to in paragraph (1) of Article 7 of this Law are no longer met. In that case the Directorate shall require the applicant or to whom the authorisation for extension in the field of application was granted, in compliance with Article 14 of this Law, to submit additional information necessary for the revision. Where necessary, the decision on an extension may be delayed for a period necessary for completion of the revision and to ensure additional information.

Withdrawal of Authorization

Article 10

(1) Regardless of the decision on an application issued according to Article 16, the Directorate shall repeal the decision for products authorisation if the Directorate is provided with information and confirmation that:

- 1) the requirements in the decision for authorisation, ascertained according to this Law, are not met or are no longer met;
- 2) the decision on the authorization was issued on the basis of false or misleading data;
- 3) the authorisation validity period has expired and has not been extended according to Article 9 of this Law;
- 4) the producer has requested withdrawal, giving reasons; and
- 5) there has been a decision of the European Commission for non-inclusion or exclusion of the active substances contained in the product from the list of Annex 1.

(2) The reasons for withdrawal may include:

- 1) a deviation in the characteristics of the product from the characteristics ascertained during the authorization process, so that the product fails to satisfy the requirements for authorisation and such deviations have not been corrected by the producer within a time period specified; and
- 2) suspicion that the product may cause or is causing harmful consequences for the environment.

(3) The Directorate shall immediately inform the holder of the authorization, and ascertain the grace period for disposal, storage, placing on the market, and use of existing stocks of the product for which the withdrawal of its authorization applies.

(4) Appeal may be submitted against the Decision from paragraph (1) of this Article to the Minister of Agriculture Forestry and Water economy.

(5) Appeal does not delay the enforcement of the Decision.

(6) If the holder of the authorization, before the expiry date of validity, voluntarily decides that this product shall no longer be placed on the market, and no longer used, he shall inform the Directorate at least 6 months before termination of placing the product on the market, and to submit justification with the application.

Review and Modification of the Authorization

Article 11

(1) The Directorate may review and subsequently modify the authorization on its own initiative if it ascertains that it is necessary, based on new scientific and technical knowledge, to change the manner of use and proposed quantity of the product.

(2) The Directorate shall modify the authorization of the product if it is necessary for implementation of the Regulation of the European Commission in relation to the restriction of the use of the active substances contained in the product, or change of its classification and labelling.

(3) The authorization may be modified at request of the holder of the authorization, but only if it is ascertained that the requirements for paragraph (1) of Article 7 are still met.

(4) The Directorate may ask for additional data, documents and samples necessary for evaluation of the justification for modifying the authorization.

(5) An appeal against any authorization made under these paragraphs (1) and (2) of this Article may be submitted to the Minister of Agriculture Forestry and Water economy.

(6) Appeal does not delay the enforcement of the Authorization.

Product Authorization for a Provisional Period

Article 12

(1) By way of derogation from Article 7, the Directorate may authorise a product containing new active substances which are still not included in the list of Annex 1 for a provisional period not exceeding three years (from the decision issued by European Commission for completeness of the documentation) if it is ascertained that the documentation is complete and meets the requirements necessary for authorisation from an aspect of the proposed use with Article 7 paragraph (1) items 2, 3, 4, 5, 6, and 7 of his Law.

(2) The applicant shall submit a statement for completeness of the documentation, and documentation on both the active substance or substances and the product in accordance with Article 4 of this Law.

(3) Following the scientific evaluation of the data for active substance or substances and product, and if from the evaluation of the European Commission it is subsequently ascertained that this active substance does not meet the requirements for inclusion in the list of Annex 1, the Directorate shall repeal the authorization for a provisional period.

(4) An appeal against any decision made under these paragraphs (1) and (2) of this Article may be submitted to the Minister of Agriculture Forestry and Water economy.

(5) Appeal does not delay the enforcement of the Decision.

(6) The validity of the authorization for a provisional period may be extended, by repeating the validity until the day when the decision of the European Commission in relation to the inclusion or non-inclusion of this active substance in the list of Annex 1 comes into force.

Transitional Measures and Derogations

Article 13

(1) The Directorate may authorise placing on the market of plant protection products containing active substances not included in the list of Annex 1 which have been present on the market before July 1993, according to the procedure laid down in paragraph (4) of this Article, including the requirements for general data for product authorisation with old active substances.

(2) The decisions from paragraph (1) of this Article shall be issued, withdrawn or modified in accordance with the decisions of the European Commission.

(3) If the revision by European Commission is ongoing of products containing active substances referred to in paragraph (1) of this Article, and before termination of the revision, the authorisations will be issued according to the requirements ascertained in Article 7 paragraph (1) items 2, 3, 4, 5, 6 and 7 of this Law and according to provisions in paragraph (4) of this Article.

(4) Necessary data, documents and procedures for products authorisation from paragraph (1) and (2) of this Article shall be prescribed by the Minister for Agriculture, Forestry and Water Economy in accordance with appropriate EC Regulations.

(5) The existing decisions for product authorisations containing active substances not included in the list of Annex 1 are in force until such time as it will be decided for inclusion or non-inclusion in Annex 1 of the European Commission or appropriately by additional decisions.

(6) For the extension of an authorisation for active substances which is not included in the list of Annex 1 and which is not under revision in the European Commission when the procedure for extension of the validity of the registration is ongoing, the authorisation will be extended according to the rules referred in paragraph (4) of this Article.

(7) After inclusion in the list of active substances or non-inclusion, and for active substances that are already included or excluded from the list of Annex 1, the Directorate will make re-registration to all valid authorisation according to the EU Regulations within 12 months of the enforcement of this Law.

(8) Quantities of plant protection products for the products which contain active substances included in the list of Annex 1 and that are not from the registered manufacturer who applied and to whom an authorisation from the Directorate has been granted can place them on the market within a period of 24 months from the start of application of this Law. Withdrawal of the products from the market after the expiry of the mentioned time period will on the on the side of the owner of the authorization.

(9) The needed data, documents and procedure for re-registration of the products from the paragraph (7) of this Article prescribes the Minister of Agriculture Forestry and Water economy in accordance with the relevant EU Regulation.

Extension of Use

Article 14

(1) The bodies of the State Administration, scientific and research institutions in the area of agriculture and forestry, professional users of products or their associations (hereinafter the proposers) may ask for an extension of the field of use of a product which is authorized in the Republic of Macedonia for purposes other than those proposed in the original application.

(2) The Directorate shall permit this extension of use when it is of public interest, and if:

- 1) the documentation and information necessary for the decision on the authorization of the extended field of product use has been submitted by the proposer;
- 2) the fulfilment of the requirements referred to in Article 7 paragraph (1) point 2, indents 2.1, 2.2, 2.3, 2.4 and 2.5 of this Law has been satisfied by the documentary evidence;
- 3) the intended use-extension is of a minor nature; and
- 4) the users are fully and exactly informed by the Directorate for the extension of the field of use in relation to the instructions for use, through additional data in the product labelling approved by the Directorate.

Emergency exceptional Permissions

Article 15

(1) By derogation of Article 7 of this Law Government of Republic of Macedonia by proposal of the Minister for Agriculture, Forestry and Water Economy, may authorise for a period not exceeding 120 days the placing on the market and use of products for a limited and controlled use, if such a measure appears necessary because of an unforeseeable danger which can not be controlled by other means, and on the opinion of the Experts Commission for plant protection products from Article 24 of this Law.

(2) The procedure for granting permission may be initiated by official body – The Directorate by its own initiative or at the request of the consumer, producer, or agricultural associations.

(3) On granting permission the EU Member States and the Commission shall be immediately informed.

Mutual Recognition of Authorization

Article 16

(1) At the request of the applicant, who shall substantiate the claim to comparability with documentary evidence, the Directorate to which an application is made for the authorisation of product already authorized in an EU Member State may:

- 1) refrain from requiring the repetition of tests and analyses already carried out in connection with the authorization of the product in that EU Member State and to the extent that agricultural, forestry, plant health and environment including climatic conditions relevant for the use of the product, are comparable with the conditions in the Republic of Macedonia, and
 - 2) issue the decision for authorisation for placing on the market in Republic of Macedonia if the product contains only active substances included in the list of Annex 1 and the authorisation in EU Member State is issued in compliance with the uniform principles of EU Regulations and it is in compliance with the requirements set out by this Law and by its secondary legislation.
-

(2) With the decision on the recognition of the authorization may be set out special conditions resulting from application of other measures, relating to the conditions for placing of the product on the market and its use, intended for protection of the health of concerned distributors, users and workers.

(3) Authorization may be subject to limitations on the uses of the product use resulting from the differences from the dietary point of view and which are necessary to avoid the exposure of the consumers of the treated products from risks of food contamination which exceed the acceptable daily intake of the residues concerned.

(4) Authorization may be subject to modification, in agreement with the applicant, with modified conditions for use, in order to render all non-comparable conditions in agriculture, plant health or environment including the climatic conditions which are important in the sense of comparability, but under prediction that such modifications are irrelevant in relation to the main product intended.

(5) The Directorate shall inform the applicant of cases where they have required repetition of a test and of cases where they have refused to authorise a product already authorised in another EU Member State, in respect of which the applicant had claimed that the agricultural, plant health and environmental conditions, including the climatic conditions relevant to use of the product in the regions where the test was carried out, or for which authorisation was granted, were comparable to those in Republic of Macedonia.

(6) The Directorate grants the authorization of a product for placing on the market or rejects it in the Republic of Macedonia in accordance with an opinion of the Expert Commission from Article 24 of this Law.

(7) In cases when the Directorate refuses to recognise comparability and accept tests and analyses or to authorise the placing on the market of a product on the territory of Republic of Macedonia, the decision as to whether or not comparability exists and if the decision is negative, it shall also specify the conditions of use under which non-comparability may be deemed irrelevant. In the procedure account shall be taken of the serious ecological crises that may arise in certain regions in Republic of Macedonia.

(8) The Directorate shall without delay inform the applicant of such a refusal and provide the reasons for it.

(9) The Directorate may grant product authorisations of products which have been already authorised in the EU Member States having comparable agricultural, health and natural circumstances in which the active substance is included in the list of Annex 1 and under which an uniform principles for granting authorisation have been applied by EU Member Countries;

(10) If the Directorate has valid reasons to consider that a product which it has authorized or is obliged to authorize according to this Article, constitutes a risk to human or animal health or the environment, it may provisionally restrict or prohibit its use and/or placing on the market in the territory of Republic of Macedonia. It shall immediately so inform the producer and the European Commission and give reasons for its decision.

Information on Possible Harmful Effects

Article 17

(1) The holder of an authorization or those to whom an extension of the field of product use has been granted in accordance with Article 14, must immediately notify the Directorate of all new information on potential dangerous effects of any product, or of residues of an active substance on human or animal health or on groundwater, or their potentially dangerous effects on the environment.

(2) The Directorate shall immediately forward the information from paragraph (1) to the all interested parties, EU Member States and to the European Commission.

Exchange and Publishing of Information

Article 18

(1) The Directorate at the end of each quarter shall inform the European Commission of any products authorized or withdrawn, indicating at least:

- 1) the name or business name of the holder of the decision of the authorization;
- 2) the trade name of the product;
- 3) the type of preparation;
- 4) the name and content of each active substance contained in the product;
- 5) the use for which the product is intended;
- 6) provisionally established maximum residue levels for new active substances;
- 7) the dossier necessary for the evaluation of the established maximum residue levels;
- 8) the relevant reasons for withdrawal of the authorization.

(2) The Directorate shall draw up, annually, national lists of the products authorized in the Republic of Macedonia, and active substances and shall publish these lists in Official Gazette of Republic of Macedonia.

(3) The Directorate shall also forward the list of authorised products from the paragraph (1) of this Article to the European Commission, European and Mediterranean Plant Protection Organization (EPPO) and other relevant regional and international institutions.

(4) The list of Annex 1 of the European Commission and its amendments shall also be published in the Official Gazette by the Minister of Agriculture, Forestry and Water economy.

Requirements in Relation to Data and Data Protection

Article 19

(1) By derogation of Article 16 of this law the applicants for product authorisations together with the application shall submit a dossier for the active substance and a dossier for product according to Article 4 item 1 and 2 of this Law.

(2) By way of derogation from paragraph (1) and without prejudice to the provisions of paragraph (3) and (4) of this Article the applicant is not obliged to submit information required under paragraph (1) of this Article for active substance, except for that identifying the active substance if the active substance is already included in the list of active substances, taking into account the conditions for inclusion in the list and does not differ significantly in degree of purity and nature of impurities, from the content recorded in the dossier accompanying the original application.

(3) In the procedure for evaluation of the dossier of the active substance, the Directorate and scientific institutions and natural and legal entities involved in the procedure in writing shall confirm that they will not use the information laid down in Article 4 paragraph (4) item 1 of this Law and also the dossier shall not be used for the benefit of other applicants:

- 1) unless the first applicant notifies in writing that he has agreed with the new applicant upon the use of this dossier;
-

2) for a period of ten years from first inclusion of the active substance in the list of active substances in case of authorisation of a new active substance;

3) for a period of ten years from the date of the authorisation of the product with particular active substance, in case of old active substance; or

4) for a period of five years from the date of authorisation of the product, following receipt of further information necessary for first inclusion in the list of active substances, which has been taken either to vary the conditions for, or to maintain, the inclusion of an active substance in the list of active substances, unless the five-year period expires before period of 10 years specified under indent 2 and 3 of this paragraph, in which case the period of 5 years shall be extended so as to expire on the same date as those periods. This is referred in case of amendments of conditions for inclusion of active substance in the list or its extension for inclusion for a period of five years.

(4) In granting authorisation, the Directorate and scientific institutions and other legal and physical entities involved in the procedure will confirm in writing that they will not make use of the information referred to Article 4 paragraph (4) item 2 of this Law, and the product dossier to the benefit of other applicants:

1) unless the first applicant in a written statement has agreed the use of the dossier for the new applicants;

2) for a period of 10 years from the first authorization of the product in any State, the inclusion in the list of active substances of any active substance from the active substances contained in the product preceded this authorization; and

3) for a period of 10 years from the entering into force of the decision about the first authorisation of the product, if that authorisation preceded inclusion of any of the active substances contained in the product in the list of active substances.

(5) During the examination of an application for authorisation, the Directorate shall inform the European Commission of cases when the active substance was produced by manufacturers or a manufacturing process which was different from those determined in the dossier on which the active substance was included for the first time in the list of active substances.

(6) The Directorate shall forward to the European Commission all information in relation to identity and impurity of the active substance.

(7) By derogation from paragraph (1) of this Article for old active substances for which the Directorate uses the provisions from this Law in relation to data if the active substances are not included in the list of Annex 1.

Confidentiality of Data

Article 20

(1) The Directorate must ensure that all information submitted by an applicant involving industrial and commercial secrets is treated as confidential, for any applicant wishing to have:

1) an active substance included in the National list of active substances, and

2) for authorization of products, if the applicant so requests and if the Directorate accepts that the applicant's request is warranted.

Non confidential information is the following:

- 1) The name and content of the active substance and the name of the product;
- 2) The names of other active substances which are regarded as dangerous substances and preparations, under the rules for classification, labelling and packaging of dangerous substances and preparations;
- 3) Physico-chemical data concerning the active substance and product;
- 4) Any way of rendering the active substance or products harmless;
- 5) The summary of the results of the tests to establish the substance or product efficacy and harmlessness to humans, animals, plants and the environment;
- 6) Recommended methods and precautions to reduce handling, storage, transport, fire or other hazards;
- 7) Methods of analysis prescribed in article 4 paragraph (4) item 1 indent 4 and item 1.4 and indent 2 item 2.5 of this Law;
- 8) Methods of disposal of the product and of its packaging;
- 9) Decontamination procedures which have to be followed in case of accidental spillage or leakage of the product; and
- 10) First aid and medical treatment to be given in case of injury to persons' health.

(2) If the applicant subsequently discloses that the information previously confidential is no longer confidential, he is obliged to immediately inform the Directorate accordingly.

Preventing Duplication of Tests on Vertebrates

Article 21

(1) If the active substance is included in the list of Annex 1, the legal entity who intends to submit a request for authorization of a product (hereinafter applicant), prior to carrying out experiments on vertebrates, shall request from the Directorate information:

- 1) whether the product for which an application is to be made is the same as the product already authorized in the Republic of Macedonia or in an EU Member State; and
- 2) name and address of the holder or holders of the authorization of the same product,

in addition, at the same time in the written statement confirms his intention to submit a request for authorization and that he has access to the data required under paragraph (4) of Article 4 of this Law.

The Directorate, after confirming the request aimed to prevent duplication of tests on vertebrates, shall provide to the potential applicant the address of the holders of the authorization and at the same time shall inform the holder of the authorization of the address of the potential applicant for authorization of the same product.

(2) The holder of the authorization and the potential applicant shall take all the necessary steps to reach agreement for sharing the dossier, to avoid the duplications of testing on vertebrate animals.

(3) The Directorate shall request, in writing, a document that will confirm that the holder of the authorization and the potential applicant have reached agreement to share the dossier. If no agreement has been reached then the Directorate shall determine the balance of interest of the parties concerned.

Permission for Research and Development

Article 22

(1) Any experiment or test for research or development, involving release into the environment of unauthorized product and product which is used in a way other than the way for which it has been authorised, may only be carried out based on authorisation before starting the experiments and tests for trial purposes and under controlled conditions and for limited quantities and areas granted by the Directorate. With the authorization is determined the quantity, conditions under which experiments or tests may be carried out, areas and legal and physical entity who will carry out the research.

(2) The physical or legal entities, which intend to carry out experiments or tests according to paragraph (1) of this Article, shall submit a request for authorization to the Directorate and a dossier containing all the available data to permit an assessment to be made of possible effects on human and animal health or the possible impact on the environment.

(3) If it is obvious that the proposed experiments and tests referred to in paragraph (1) of this Article will have harmful effects on human or animal health or to have unacceptable adverse influence on the environment, then the Directorate shall consider whether to prohibit them or permit them under such conditions as it considers necessary to prevent those consequences.

(4) An appeal against the paragraphs (1) and (3) of this Article may be submitted to the Minister of Agriculture Forestry and Water economy.

(5) Appeal does not delay the enforcement of the Decision.

(6) The provisions under paragraph (1), (2) and (3) of this Article shall not apply to experiments or tests whose purpose is genetically modified organisms (GMOs).

(7) For the purposes of this Article and the enforcement of this Law, 'genetically modified organism' shall mean an organism in which the genetic material has been altered in a manner that does not occur naturally by the process of mating and/or natural recombination, with the exception of human beings.

(8) The conditions under which the experiments or tests must be carried out under paragraphs (1) and (2) of this Article, conditions concerning premises and personnel and other conditions for natural and legal entities, are prescribed by the Minister for Agriculture, Forestry and Water Economy in accordance with the Minister of Environment and Physical Planning.

Officially Recognized Tests

Article 23

(1) Scientific institutions and other legal or civil persons to whom the Directorate on the basis of their application satisfy the requirements under paragraph 3 of this Article and the aptitude for carrying out tests (hereinafter "authorized entities") have the right to carry out efficacy tests of the products in accordance with Article 7, paragraphs (5) and (6) of this Law within the territory of the Republic of Macedonia.

(2) The Directorate is responsible in co-operation with the official authorised entities,

- 1) to stipulate the scope of the product testing;
 - 2) to require information for the preparation of the product testing and on its course as well as the submission of documents on the fulfilment of the conditions for the product testing; and
 - 3) to carry out control over the product testing.
-

(3) The Minister for Agriculture, Forestry and Water Economy will prescribe the manner and procedure under which the official tests from paragraph (1) of this Article should be carried out, conditions regarding premises and personnel, professional qualification of the authorized entities that will carry out the officially recognised tests.

(4) The method for these tests has to be carried out in accordance with the standards set out by the European and Mediterranean Plant Protection Organisation (EPPO), good experimental practice (GEP) and appropriate EU regulations.

(5) An appeal against the Decision for rejection of the application for granting permission from paragraphs (1) of this Article may be submitted to the Minister of Agriculture Forestry and Water economy.

(6) Appeal does not delay the enforcement of the Decision.

Article 24

Expert Commission

(1) For confirmation of the expert's activities in the area of product authorisation, an Expert Commission consisting of experts in the field of plant protection, chemistry, eco-toxicology, toxicology and other fields shall be established.

(2) Members of the Commission from paragraph (1) of this Article may not be in any relationship with the applicants or with natural or legal entities, which produce or place on the market products, in the sense of conflict of interests.

(3) The Expert Commission shall be constituted by the Decision of the Minister of Agriculture, Forestry and Water Economy, in agreement with the Minister for Health and the Minister for Environment and Physical Planning.

(4) The Expert Commission is responsible for the opinion given about the dossier.

(5) The expenses for the work of the Commission shall be determined by the Government of Republic of Macedonia on proposal of Minister of Agriculture, Forestry and Water Economy and shall be provided from the budget of Republic of Macedonia for the current year by transfer from the Plant Health Programme.

(6) Minister of Agriculture, Forestry and Water Economy, in agreement with the Minister for Health and the Minister for Environment and Physical Planning shall prescribe the procedures for work of the Commission.

III. HANDLING PRODUCTS

Packaging and declaration of products

Article 25

(1) Packaging and declaration of products must be carried out in accordance with EU Regulations for classification, labelling and packaging of dangerous substances and preparations, this Law and the Law that regulates dangerous substances and preparations and in accordance with the Decision issued by the Directorate.

(2) Each package of the plant protection product must have declaration – note with serial number issued by the Ministry of Agriculture, Forestry and Water economy – Fytosanitary Department.

(3) The products' packaging must show clearly and indelibly in the Macedonian language the following data:

1) The trade name or trade mark of the product;

- 2) The name and address of the holder of the authorization and the authorisation number of the product and if different, the name and address of the person responsible for the final packaging and declaration or for the final declaration of the product intended to be placed on the market;
 - 3) Name and quantity of each active substance expressed as provided for in EU Regulations for classification, declaration and packaging of dangerous substances or, if not included there, in its ISO name;
 - 4) If the ISO name is not available, the active substance shall be designated by its chemical designation, according to IUPAC nomenclature;
 - 5) The net quantity of the product given in legal units of measurements;
 - 6) The formulation batch number or some other means of identifying it;
 - 7) Information for first aid and other information ascertained in the authorisation;
 - 8) The nature of all special risks for humans, animals or the environment, by means of standard phrases selected as appropriate from those set out by the authorisation;
 - 9) Designation of the degree of poison (high toxicity T⁺);
 - 10) Safety precautions for the protection of humans, animals and the environment in the form of standard phrases (S,R-phrases) selected as appropriate from those set out in the authorisation;
 - 11) The type of action of the product (e.g. insecticide, growth regulator, herbicide, etc.);
 - 12) The type of preparation (the product) (e.g. vegetable powder, emulsifiable concentrate);
 - 13) The uses for which the product has been authorized and any specific agricultural, forestry, plant health and environmental conditions under which the product may be used or should not be used, have to be visibly marked;
 - 14) Instruction for use and the dose rate expressed in metric units for each use provided in the authorisation;
 - 15) Where necessary the safety intervals for each use between application and:
 - Sowing or planting of the crops to be protected;
 - Sowing or planting of the succeeding crops in the crop rotation;
 - Access by humans or animals;
 - Harvesting or collecting;
 - Usage or consumption;
 - 16) Particulars of possible phyto-toxicity, varieties susceptibility and any other direct or indirect adverse side-effects on plants or products of plant origin together with the intervals between the product application and sowing or planting of :
 - crops in question;
 - subsequent crops;
-

17) If accompanied by a leaflet, as provided for in paragraph (3) of this Article, the sentence “accompanying instructions must be read before use”;

18) Instruction for safe disposal of the product, or its waste and its package;

19) Date of production and expiry date.

(4) The Directorate may, in the authorisation, permit the requirements in paragraph (3) item 14, 15 and 16 of this Article to be indicated on a separate leaflet accompanying the package if the space available for the package is too small. Such a leaflet shall be regarded as part of the product declaration. The product designated as highly-toxic to be designated for use only by special categories of users in accordance with the Article 35 of this Law, this fact, including the characteristics of these categories, being obligatory to be mentioned on the package.

(5) The package of the product must not show any indications as “non-toxic”, “harmless” or other similar indications. Information for the use of the product when the bees are active or other target species or when the crops are in bloom or other similar phrases for bee protection or other target species may be given in the declaration if the authorisation explicitly refers to use in the bee season and presents minimum dangers for them.

(6) The Directorate, because of the protection of humans, animals or the environment, may require additional phrases to be marked clearly and indelibly on the package. The Directorate shall inform the EU Commission of taking such action.

(7) The terms for issuing, records of issued and manner of placing the declarations – note shall be prescribed by the Minister for Agriculture, Forestry and Water Economy.

(8) Cost for printing and issuing of declarations shall be provided from the budget of Republic of Macedonia for current year with transfer from the Plant protection Programme.

(9) The conditions for packaging of products and their declaration and notification of standard phrases shall be prescribed by the Minister for Agriculture, Forestry and Water Economy in agreement with the Minister of Health and Minister of Environment and Physical Planning.

Production, placing on the market and storage of products

Article 26

(1) Production and placing on the market of the products, and active substances included in the product, may be carried out by a legal entity from Article 4 paragraph (2) and (3) of this Law on products authorised in Republic of Macedonia if the legal entity is registered in the register as legal entity for production, placing on the market as a wholesaler or retailer in specialized stores for plant protection products (hereinafter the register).

(2) The legal entities that produce, store products for the purposes for their placing on the market are obliged to provide conditions for:

- 1) production according to the type of product which is mentioned in the application;
 - 2) the separate storage of products according to their type and those separately from other items and items which are intended to be disposed of as waste and out of reach of items which could affect their characteristics;
 - 3) the separate storage of products after their expiry period or withdrawal of quantities from the market;
 - 4) specialized retailer stores and supply to the users according to good plant protection practice;
-

- 5) provision of persons with appropriate education and professional experience according to the responsible activities as follows:

5.1. production: chemical expert or technician and expert in Plant Protection;

5.2. wholesale and specialized gross stores: (Agriculture pharmacies) Grad. Agro. Eng. (all department of study programs in which subject in the filed of plat protection are included); and

- 6) the fulfilment of technical requirements set out under paragraph (7) of this Article.

(3) Legal entities from paragraph (1) from this Article, at their request to the Directorate, shall be registered in the appropriate register.

(4) The Directorate determines the conditions at legal entities who submitted application for registering into the register by Decision, and manages the register from paragraph (1) of this Article.

(5) An appeal against the Decision from paragraph (4) of this Article may be submitted to the Minister of Agriculture Forestry and Water economy.

(6) Appeal does not delay the enforcement of the Decision.

(7) Conditions for production, storage of products, placing on the market and professional qualification of the persons for placing and managing with the products and register under paragraph (1) of this Article, shall be prescribed by the Minister for Agriculture, Forestry and Water Economy in agreement with the Minister for Health and Minister for Environment and Physical Planning.

Evidence (Records)

Article 27

(1) Legal entities that produce, place on the market and store products are obliged to keep record of the quantities produced, and acceptance and delivery of the products, including products past the expiry date.

(2) Data from paragraph (1) under this Article must be submitted to the Directorate by 31 March of each year at the latest by legal entities.

(3) Legal entities who produce and place on the market products classified in the group of poison (risk) marked with T⁺, beside evidence described under paragraph (1) of this Article are obliged to keep the following records:

- 1) data for trade mark, use and expiry date
- 2) date of sale of products
- 3) quantities of sold products
- 4) for a legal entity, firm, headquarter and tax number
- 5) signatures of delivery and receipt.

(4) The record may be kept in electronic form or in hard copy.

(5) On request from the Directorate legal entities are obliged to show and deliver data under paragraphs (1) and (3) of this Article.

(6) The content and the manner of keeping records from paragraph (1) and (3) of this Article shall be prescribed by the Minister for Agriculture, Forestry and Water Economy.

Imports of Parallel Products

Article 28

(1) The import parallel of product shall mean the import of the product which is identical with the product authorized in the Republic of Macedonia (hereinafter "the reference product").

(2) The parallel product is considered to identical with the reference product of the same producer according to:

- 1) The name of reference and parallel product;
- 2) Title and address of the authorised owners of the reference product;
- 3) Authorisation number (authorization) of the reference product;
- 4) Title and address of the importer of the parallel product;
- 5) Content of the active substance in the product according to the specification valid for the reference product;
- 6) Type of formulation;
- 7) Country of origin of the parallel product;
- 8) Declaration (label) and if necessary sample from the imported product.

(3) The parallel product may only be imported on the basis of the permission issued by the Minister for Agriculture, Forestry and Water Economy on advice from the Directorate to a legal entity for one consignment only upon its application for permission and under the conditions referred to in paragraphs (2) and (6) of this Article.

(4) The following information should be provided in the application:

- 1) description of the pest problems and why the reference product cannot be used;
- 2) area of land to be treated and quantity of parallel product required in the single consignment requested; and
- 3) if possible a sample of the label and other user-oriented information of the product it wishes to use.

(5) The applicant for the permission of the import parallel of product must declare in his application whether he intends to import the parallel product solely for commercial use as stated in his application, and provide evidence for the origin of the parallel product and if possible according to the manufacturer (holder) of the reference product.

(6) The import of the parallel product may be allowed if this product comes from an EU Member State in which it is permitted to be placed on the market, and shall be imported into the Republic of Macedonia in packages and with the declaration, as they are placed on the market for the users by the exporter country in the Macedonian language.

(7) The Minister for Agriculture, Forestry and Water Economy shall prescribe in secondary legislation a template for the application for the permission of the import parallel of product, criteria for the assessment of the parallel product with that of the reference product, and the manner of the declaration (labelling) of the parallel product if it is intended for commercial use.

(8) If amendments in the authorization of the reference product appear which are relevant from the point of view of its efficacy and safety, than the Directorate shall start the procedure for amendment of the permission of the parallel product import in the similar way.

(9) The use of the parallel product must not be different from the conditions of use on the reference product prescribed in the authorisation.

(10) The holder of the authorisation on the reference product is not the participant in the procedure concerning the permission of the parallel product import.

(11) The Minister for Agriculture, Forestry and Water Economy shall issue permission on authorisation on request from paragraph (3) of this Article within 60 days from commencement of the procedure.

(12) If competent authority within the period defined in paragraph (11) of this Article does not issue authorization upon application it will be considered as granted.

(13) Against the decision under paragraph (1) of this Article non-satisfied part has the right to an appeal submitted within 15 days to the Commission that decides on a second instance in administrative procedures in the area of agriculture, forestry and water economy and veterinary of the Government of the Republic of Macedonia

(14) Appeal does not delay the enforcement of the Decision.

(15) The provisions of Article 7 and 8, paragraphs (3), (10), (11), (19), (20), (25) and (27) of this Law shall be applied accordingly.

IV. OTHER PLANT PROTECTION PRODUCTS

Article 29

General

(1) Other products for plant protection including auxiliary plant protection products (hereinafter “auxiliary products”) and bio-agents shall be regulated under this Law. These products for plant protection may be placed on the market and used if they are included by the Directorate into a register of other products for plant protection. Only the legal entity, on the basis of whose application the entry into the register has been made, has the right to place such other products on the market.

(2) The application for the entry into the register shall be submitted to the Directorate by the manufacturer or importer intending to place the other products on the market (hereinafter only “the applicant”). The conditions of Article 4, paragraphs 2 and 3 of this Law apply to the application for inclusion in the register.

(3) The Director of the Directorate shall make Decision, on the basis of the submitted application, on the entry of the other products into the register, if the requirements set out above have been fulfilled, and whether the applicant for the entry has prepared a declaration that this product satisfies the special requirements pursuant to Article 32 of this Law in the case of an auxiliary product, and Article 33 of this Law, in the case of a bio-agent and if the Directorate has not found that this declaration of the applicant is false.

(4) The applicant for the entry of other products into the register is obliged to secure, at his own expense, the examples of the other product or bio-agent whose entry into the register is required.

(5) Requirements for the application for the entry of the other products into the register and content of the register shall be prescribed by the Minister for Agriculture, Forestry and Water Economy.

(6) The Directorate shall make a decision on inclusion of the other product into the register from paragraph (1) within 90 days from commencement of the procedure.

(7) If competent authority within the period defined in paragraph (6) of this Article does not make a Decision for entry of other products in the register it will be considered as positively replied.

(8) If the Directorate finds that the other products do not comply with the requirements defined under paragraph (2) or (3) of this Article it shall issue a Decision for rejection of the application for its entry into the register or it shall decide its entry to be erased from the register if it is already entered in it.

(9) An appeal against the Decisions from paragraph (3) and (8) of this Article may be submitted to the Minister of Agriculture, Forestry and Water economy.

(10) Appeal does not delay the enforcement of the Decision.

(11) The other products intended exclusively for research and development purposes are not subject to entry into the register.

(12) If it is necessary from the point of view of the protection of human and animal health or of the environment or use of the other products, the Directorate may, by the decision,

- 1) restrict the validity of the entry into the register for the certain period,
- 2) restrict the scope of the field of use of other products,
- 3) establish special conditions for the use of the other products, or
- 4) establish the data with which the other products must be marked.

(13) The Directorate may control the other products at any time and it may decide its declaration or use to be changed if it is necessary from the point of view of the compliance with the legal acts of the Republic of Macedonia, EU regulations as well as with the respective technical norms or current scientific and technical knowledge.

(14) At the request of the holder of the decision, submitted at least two months before the day when the validity of the decision on the entry of the other products into the register is due to expire, the Directorate may grant an extension of its registration.

(15) In case of auxiliary product or bio-agent contains genetically modified organisms, these products may only be written in the register at the time when the applicant has submitted the positive opinion of the competent authority issued according to the law in force.

(16) The use of other products for experimental purposes is possible if:

- 1) for this use, the Directorate was informed in writing not later than 60 days before its commencement,
- 2) the Directorate has not prohibited the experimental use of the other products, within at least two days before its commencement, or the Directorate has not established special conditions for this use if it is necessary regarding hazards to human and animal health, the environment, plants and plant products.

(17) The notification pursuant to paragraph (16) item 1 of this Article shall contain:

- 1) identification of the notifier (business name, or first and last name and address);
- 2) designation of the location where the experimental use of the other products is to be realized;
- 3) description of the purpose, scope and manner of the experimental use of the other products.
- 4) Articles 25, 26 and 27 shall apply to the use of auxiliary products in a similar way.

(18) Article 28 of this Law shall apply to the import of other products in a similar fashion.

Article 30

Other products for plant protection placed on the market referred in paragraph 1 of Article 29 of this Law must be declared and designated with data prescribed by the Minister for Agriculture, Forestry and Water Economy.

Article 31

The person, to whom permission for entry of other products for plant protection in the register is granted, shall, without delay, notify the Directorate of:

- 1) all new findings on possible and ascertained harmful effects of these products, and
-

- 2) changes to the official permission to place these products on the market which have been made in the EU Member States.

Auxiliary Plant Protection Products

Article 32

(1) The auxiliary product is in compliance with the special requirements pursuant to Article 29, paragraph (3), if:

- 1) it has no harmful effects on plants or plant products coming into contact with it at application;
- 2) it is effective from the point of view of purpose for which it is intended;
- 3) all components from which it is made up are identified;
- 4) its physical, chemical and other properties, which confirm its standard production, are defined;
- 5) it does not increase the risks resulting from the use of the products,
- 6) its use does not cause harmful effects on human and animal health and on the environment, and especially on groundwater; and
- 7) it does not contain substances for which the production, importing and placing on the market are prohibited in Republic of Macedonia.

(2) The Directorate shall state the opinion on the application for the entry of the auxiliary product in the register of other products for plant protection from competent authority in the filed of Health from the point of view of human health protection. If the auxiliary product contains substances which show dangerous properties, it shall be subject to the classification according to rules set down provisions for classification aligned with appropriate rules of classification in the EU. The applicant together with the application shall add the results of this classification for the entry of the auxiliary product into the register.

(3) If the auxiliary product is in the nature of an adjuvant, the Directorate may require the applicant to add to the application data and documents for identifying, and the properties and effects that have to be amended in the product.

Bio-agents

Article 33

(1) The bio-agents shall be registered if they are in compliance with the special requirements pursuant to Article 29, paragraph (3) of this Law, if:

- 1) it is defined by the properties declared by the producer and these properties are proved to remain constant in production;
- 2) it is effective for the purpose, for which it is intended; and
- 3) it does not contain the components which show undesirable effects on human health that cannot be prevented by appropriate personal protective equipment.

(2) The bio-agents must not be used differently from that defined in the registration and data by which they are declared, except in case of approved wider use, use of the product according to Article 14 of this Law or for research and development use according to Article 22 of this Law or for testing according to Article 23 of this Law.

(3) For the use of bio-agents the following must be mentioned in the registration and declaration:

- 1) Not to pass the maximum (the biggest) dose and not to reduce the safety intervals prescribed in the instructions for use;
-

- 2) the use must not be different from the instruction for protection of human and animal health, water, bees, water organisms and soil organisms, on performance of instructions for use, and also on performance of requirements set up by legislation in the corresponding filed; and
- 3) plants in the wider environment, beyond the location where the application took place, must not be damaged.

(4) Uses of the bio-agents must be documented in the same way as is prescribed by the Minister for Agriculture, Forestry and Water Economy.

(5) The evidence and documentation shall be kept at least 5 years.

(6) Users (entrepreneurs) that compile such a dossier are obliged to provide, at the request of the Directorate, names and information for the amount of the bio-agents used in the last calendar year.

Information and documentary requirements

Article 34

Entrepreneurs or their representatives that import products and auxiliary products, or produce them within the territory of the Republic of Macedonia are obliged to:

- 1) inform the Directorate, by 31st March next year of the names, marks and amounts of products and auxiliary products placed on the market in the previous year; and
- 2) on request of the Directorate to submit data for packaging and to give samples of packages and instructions of the products and auxiliary products that are typical for their deliverance as products or other products.

Use of Highly Toxic Substances and Products (T+)

Article 35

(1) Highly toxic substances and products shall mean substances and products which in small dosage cause death or acute and chronic health damages to the people when swallowed, inhaled or absorbed through the skin (T+) i.e. I group of poisons, in respect of the Law for chemicals.

(2) Legal entity that fill certain conditions regarding personnel, organizational, technical and other conditions may use the highly toxic substances and products. The Minister of Agriculture, Forestry and Water Economy shall issue the authorization.

(3) Conditions under paragraph (2) of this Article and the manner for use of highly toxic substances and products shall be prescribed by Minister of Agriculture, Forestry and Water Economy in agreement with the Minister of Environment and Physical Planning and Minister of Health

V. USE

Use of Plant Protection Products

Article 36

(1) The products shall be used as set out in the authorisation under paragraph (4) of Article 3 and Article 8 of this Law and data on which the authorisation or according to a derogation for products that have an extension of the field of use in accordance with Article 14 of this Law, for research and development under Article 22 of this Law or for testing under Article 23 of this Law.

- (2) During any product's use:
- 1) the maximum (the biggest) dose shall not be exceeded;
 - 2) the intervals for application prescribed in the directions for use, shall not be shortened;
 - 3) the provisions from Good Agriculture Practise and if possible Integral protection to be followed;
 - 4) application of the products to be done with machines and apparatus which will provide proper use;
 - 5) the instructions for protection of human and animal health, water, bees, water/aquatic organisms and soil organisms, by reference to the instructions for use, shall not be varied;
 - 6) plants in the wider environment, beyond the location where the application took place, must not be damaged;
 - 7) the products under the authorisation, designated with a standard phrase for specific risk;
 - R 50 'high toxic for aquatic organisms'
 - R 51 'toxic for aquatic organisms'
 - R 52 'harmful for aquatic organisms'
 - R 53 'may cause long term negative effects in the aquatic environment'

can only be applied at distance from a body of water that will exclude the possibility of deposition or to be spread by wind into the water or eventually by rain water.

- 8) Management of the package of the used products, unused products shall to be in accordance with the waste management provisions.

(3) The Directorate shall organize training for the users of plant protection products in accordance with the paragraph (1) item 13 of Article 62 of this Law.

(4) The users of products shall keep records about each treatment of plants and plant products in storage and the records shall contain data on the type and quantity of the product used, date of application, date of harvest, i.e. harvest of plants, for the purpose of control whether prescribed pre-harvest intervals are respected. The records shall be kept for a period not less than 5 years.

(5) The users are obliged to provide the Directorate on request data on the quantity and origin of the products used within the last calendar year.

(6) The prescribed MRLs on plants or plant products must not be exceeded.

(7) In cases where it is established that the foreseen MRLs on plants or plant products are exceeded, such plants or plant products shall be destroyed or in any other manner, their use as a food for humans or feed for animals must be suppressed.

(8) The Minister of Agriculture, Forestry and Water Economy in agreement with the Minister for Environment and Physical Planning shall prescribe the training of the users and destruction of package and management of the products. .

VI. PROTECTION OF BEES AND GAME

Conditions for Use

Article 37

(1) The physical or legal entity that carries out the treatment by products and other products in the open air (hereinafter 'the treatment operator'), shall not apply the products:

- 1) which in accordance with the decision on the authorization are toxic to bees, unless he has available information 48 hours prior use for the bee keepers or bee breeders association and representatives from the local self government competent for undertaking of measures for bee protection and public media, and
-

2) which use in accordance with the conditions of authorization is dangerous, or especially dangerous to terrestrial vertebrates, in the area which constitutes part of a hunting ground, unless this application has been notified to the user i.e. concessionaire of the hunting ground for undertaking preventive measures not later than three days before the beginning of the product application.

(2) The Veterinary Directorate or Phytosanitary Directorate may, at the latest 24 hours before the beginning of the product aerial application and eradication of rodents on an open for which they are notified, determine specific conditions for its application.

(3) The bee keepers shall be obliged to accept common precautions for bee protection, relevant to the local conditions, especially regarding the location of the bee colony site in relation to the stands visited by bees, and to provide information on the main bee flight paths, and on the time of the application of the products dangerous to bees from the breeders and competent authorities.

(4) The users of the hunting ground shall be obliged to accept common precautions relevant to the local conditions, especially regarding the stands visited by the game, the sites destined for game feeding, game species, and to provide information on the time of the application of the products dangerous or especially dangerous to terrestrial vertebrates.

(5) If a beekeeper finds that dead bees have appeared, or if a user of a hunting ground, or a person with fishing rights finds that dead game or fish has appeared as a consequence of product use, he shall inform the Veterinary Directorate. The Veterinary Directorate in cooperation with the Phytosanitary Directorate shall perform a local search; if there is any suspicion that the cause of death is related to the product use, it shall ensure sampling in prescribed ways for analyses by the authorised institution/laboratory, and shall supply information on the results of the search to the beekeeper or users of the hunting ground, or to the person with fishing rights. It shall also transmit the record of the results of the local search, and the results of the sample examination from the Veterinary Directorate, Phytosanitary Directorate and user of a hunting ground or person with fishing rights if they have been affected by consequence of application of the product.

(6) The rights for submitting a claim for damages are in accordance with common legal provisions, provided that the recommended precautions of bee colonies and game are respected.

(7) The aerial application of products toxic to bees is not permissible.

(8) The aerial application of products and other products shall be notified, by the treatment operator or, by another person entrusted by the field user, to the municipality office in the administrative area in which it is to be performed not later than 48 hours before the beginning of the application.

(9) The Minister of Agriculture, Forestry and Water economy shall lay down the requirements which have to be fulfilled in the notifications in accordance with paragraph (1) of this Article, and the general measures for bee protection, and the manner of taking samples for analyses.

VII EQUIPMENT FOR APPLICATION

Machines and Apparatus

Article 38

(1) Machines and apparatus for application of plant protection products may be placed on the market and used provided that by proper use they guarantee adequate application of the products, they are not harmful for the leaving and working environment and humans, and they are certified for harmonization and fulfil the conditions listed in the certificate.

(2) The provisions from paragraph (1) of this Article shall not apply to the following machines and apparatus:

- 1) Hand-driven, or engine propelled or pressurised gas driven, with the fuel capacity up to 20 litres inclusive,
- 2) Designed for the purpose of research, development or testing of the products, with authorisation of the Directorate, and
- 3) Machines other than specified under item 1 and 2 of this paragraph that have been specified by the Minister of Agriculture, Forestry and Water Economy.

(3) The Minister of Agriculture, Forestry and Water Economy shall lay down the information on mechanization and apparatus which shall be marked on the equipment placed on the market.

Register of Equipment

Article 39

(1) Machines and apparatus may only be placed on the market by a legal entity which has permission by virtue of an entry of the equipment for application of plant protection products in the official register (hereinafter “register for equipment”).

(2) The applications for entry of equipment into the official register shall be submitted to the Directorate by the manufacturer or by the importer who intends to place the equipment on the market (hereinafter “Applicant”). The right for applications for entry of equipment into the official register have legal and physical entities with permanent residence in the Republic of Macedonia or foreign legal entity through authorised legal entity permanently residing in the Republic of Macedonia to act on his behalf.

(4) On the basis of the application, the submitted documentation, and data on the compliance of machines and apparatus with prescribed technical and technological requirements, testing of the machines and apparatus the Directorate issues a Decision entry of the equipment into the register and certificate for compliance.

(5) Tests of the technical and technological requirements and testing of the machines and apparatus shall be done by a legal entity selected through tendering procedure, or got an authorization in accordance with Article 50 and Article 55 of this Law by the Minister of Agriculture, Forestry and Water Economy. The legal entity after the executed controls issues a document for operability of the machines and apparatus.

(6) Legal entity that executes the control shall keep record for the tests of the machines and apparatus and to regularly inform the directorate.

(7) The Directorate shall be obliged to consider the application for entry of machines and apparatus in the official register within 90 days from the application and make a decision on entry. The period of validity of the entry shall be a minimum of five years.

(8) If the competent authority within the period determined in paragraph (7) of this Article does not issues a Decision for entry in the register it will be considered as entered.

(9) If the Directorate finds that the equipment does not comply with the requirements defined in the register or if the applicant does not fulfil the requirements of paragraph (4) of this Article above, then the Directorate shall reject the application for entry of the machines and apparatus in the official register, or shall decide to delete entry for the machines and apparatus from the official register if it is already entered.

(10) If necessary for protection of human and animal health or the environment, or with regard to the application of the machines and apparatus, the Directorate may decide to:

- 1) restrict the application of the entry in the official register by limiting the period of entry in the register regardless of paragraph (5) of this Article,
- 2) limit the application area of the machines and apparatus,
- 3) define specific conditions for use of the machines and apparatus, or
- 4) define data to be marked on the machines and apparatus.

(11) Technical and technological requirements, content of the documents for operability of the machines and apparatus shall be prescribed by the Minister of Agriculture, Forestry and Water Economy.

Records and Informing

Article 40

A legal entity which holds an entry of equipment in the official register shall keep evidence and shall inform in writing the Directorate of:

- 1) equipment purchased and sold,
- 2) data on the persons to whom the equipment have been sold,
- 3) new findings on the potential or actual defects of the equipment, and
- 4) change in the construction of the equipment which might affect the application of products.

Extension of Validity and Control Testing

Article 41

(1) On requests submitted at least two months before expiration of the entry of the machines and apparatus in the official register for equipment, the Directorate shall extend the validation of the entry for 5 years, for which the machines and apparatus shall undergo control testing.

(2) The equipment before entering into the official register (Article 38), and other equipment prescribed with the regulation from Article 38, 2, indent 3.

The control testing is carried out in intervals defined under provisions in paragraph (5) of this Article, or within a period defined for the control testing, if it is find necessary that the defects to be corrected during the control testing of the machines and apparatus. The control testing includes inspection on the functionality of the machines and apparatus for proper application of products in compliance with the technological requirements defined in the paragraph (5) of this Article.

(3) Control testing shall be carried out by a legal entity, which has authorization for public services issues under Article 50 and Article 55 of this Law by the Minister of Agriculture, Forestry and Water Economy. After performing the control testing, the legal entity shall issue a report on the functionality of the mechanization means.

(4) The legal entity carrying out control testing shall keep record of the testing of the equipment and shall regularly inform the Directorate.

(5) The Minister of Agriculture, Forestry and Water Economy shall lay down the technical requirements, the intervals for control testing, the content of the report on the functionality of mechanization and apparatus, template of documents for keeping records and the manner for extension of the validity for the entry in the official register for equipment for application of plant protection products.

Import of Equipment for Application of Products

Article 42

(1) Only machines and apparatus which have a certificate or authorisation from the Directorate may be imported. If it is not otherwise foreseen under international or bilateral agreement, any machines and apparatus without certificate or permission shall not be imported except for re-export or transit.

(2) The Minister of Agriculture, Forestry and Water Economy shall lay down the import requirements.

(3) By derogation of paragraph (1) of this Article, the Minister of Agriculture, Forestry and Water Economy may order that no certificate or permission for specific kinds of equipment or for specific application is needed.

VIII. PUBLIC SERVICES IN THE FIELD OF PRODUCTS AND EQUIPMENT FOR APPLICATION OF PRODUCTS

Public services – Definition

Article 43

Public services in the field of products and equipment for application of products (hereinafter: "public service") shall mean an professional activity in filed of approval and placing on the market and the application of the products as well as professional activities in the filed of equipment for application of the products.

Types of public services

Article 44

Public services in the field of products and equipment may be carried out by:

- 1) public institutions and other legal entities;
- 2) civil persons;
- 3) civil associations; and
- 4) units of the self-government.

Form of Provision of Public Services

Article 45

The entities from Article 44 of this Law in order to be able to conduct public services in the filed of products and equipment should fulfil certain conditions regarding premises and equipment foreseen with this Law.

law with execution of which the executor shall have special obligations in the public interest.

Public services are regulated by the provisions of the Law for Public Institutions, if not stipulated otherwise with this or another Law.

The Minister of Agriculture, Forestry and Water Economy shall lay down the manner of conducting public services in accordance with this Law as appropriate, in compliance with the Minister of Health and the Minister of Environment and Physical Planning, and in compliance with this Law and the Law for Public Institutions.

Persons Performing Public Services

Article 46

(1) Only persons with appropriate professional education - Faculty of Agricultural Sciences and Food, or where appropriate, Faculty of Forestry, department where subjects in the field of plant protection are studied professionally qualified for performing a particular public service or authorization shall have the right to perform public services in the field of products and equipment.

(2) The Minister of Agriculture, Forestry and Water Economy shall lay down the conditions regarding professional qualification, equipment, objects and other requirements, which should be met by a person who shall provide public services in the field of products and equipment.

Professional activities

Article 47

Professional tasks in the field of authorization, placing on the market, and use of products shall include:

- 1) activities in the field of testing and evaluating products in the authorization procedure,
- 2) laboratory testing of products,
- 3) monitoring the residues of products in or on plants or plant products regarding the proper use of the products in primary production.
- 4) professional expertise provided as a support to decision-making of the Directorate,
- 5) performing research and development activities,
- 6) developing and introducing new procedures of good plant protection practice and good agricultural practice,
- 7) introducing European standards in the field of biological tests for the products' efficiency,
- 8) activities related to education of persons responsible for placing the product on the market and users of products,
- 9) collaboration during introduction, development and establishment of information systems,
- 10) professional control of the production, repacking of a product and over the prescribed quality of products, and auxiliary products. and
- 11) other activities in the field of products.

Professional Activities in the Field of Equipment

Article 48

Professional activities in the field of equipment shall cover:

- 1) professional expertise and testing for issuance of licence and certificate,
- 2) activities related to education in the field of equipment,
- 3) collaboration during introduction, development and establishment of information systems,
- 4) performing research and development activities,
- 5) performing other tasks in the field of equipment.

Obligations

Article 49

(1) Obligations of the providers of public services in the field of plant protection products and equipment are as follows:

- 1) permanent and continuous performance of the activity and services in accordance with the contract of the Directorate;
- 2) performing services under specially pre-determined programmes; and
- 3) performing services according to pre-determined prices.

(2) If a provider of public services or the authorized legal person does not provide a public service to a person to whom he is obliged to provide it, or does not provide a service at pre-determined prices and other conditions prescribed, the user of the service may demand that the Directorate make a determination of the user's right to the public service, and to order the provider of public service to provide the public service according to the pre-determined price.

Permissions

Article 50

(1) The Directorate grants permissions for providing public services in the area of products and equipment based on public announcement, which is published in at least two daily newspapers.

The public announcement contains data for:

- 1) The type of the public service for which an permission has been granted;
- 2) Starting date and expiration of the permission;
- 3) Conditions (circumstances) which have to fulfilled by the subject to whom this permission has been granted;
- 4) Mandatory (obliged) data in the application;
- 5) Selection criteria;
- 6) Time period for granting the permission;
- 7) Contact person for providing necessary information in relation to the content of the public announcement;
- 8) Data, place and time of opening of the applications on the public announcement;
- 9) Manner of informing the candidates for the selection made.

(2) The procedure for opening and evaluation of the offers (applications) is determined by the Commission nominated by the Minister for Agriculture, Forestry and Water Economy.

(3) Authorised representatives of the candidates may be present at the opening of the applications.

(4) Applications submitted after the dead line will not be taken into consideration.

(5) Non completed application may be completed in the period of 8 days after they have been notified, in opposite the application will not be taken into consideration for which the applicant will be informed.

(6) The permission for providing public services is granted into form of decision.

(7) Against the decision under paragraph 7 of this Article non-satisfied part has the right to an appeal submitted to the Commission that decides on a second instance in administrative procedures in the area of agriculture, forestry and water economy and veterinary of the Government of the Republic of Macedonia.

Contracts

Article 51

(1) The subjects (applicants) who have received permission for providing public services in the area of products and equipment, they are making contracts with the Ministry of Agriculture, Forestry and Water Economy.

(2) The contract from paragraph (1) of this Article is made in written form and especially contains data for:

- 1) Public services providers and professionals who provides the services;
- 2) The services in the area of products and equipment;
- 3) The region in which the provider of the public service have to provide the services in the area of products and equipment;
- 4) Manner and conditions for conducting the services ascertained in the contract;
- 5) Rights, obligations and responsibilities of the provider of the public services;
- 6) Time and manner of providing the services;
- 7) Starting date and expiration (validity) of the permission;
- 8) Source of financing;
- 9) Control under the providing the services;
- 10) Expiration date of the permission;
- 11) Reasons for breaking the contract;
- 12) Time period for breaking the contract and other.

Financing of Public Service

Article 52

Public services from Article 47 of this Law in the field of products and Article 48 of this Law in the field of equipment shall be financed from:

- 1) payment of the price for services provided;
- 2) budget of the Republic of Macedonia for current year from the Budget of Republic of Macedonia provided with transfer for financing of the Plant Health Program ; and
- 3) donations, loans and other sources.

Prices for Public Services

Article 53

(1) The prices for individual services in the field of products and equipment shall be partly or fully paid by the users of public services, however some services may be free of charge.

(2) The Minister of Agriculture, Forestry and Water Economy shall lay down the price for the services as well as the share that should be paid by the user and criteria for definition of the price of services.

Supervision over Performance of Public Services

Article 54

(1) Supervision of public services shall be carried out by the Directorate excluding the public services in the forestry area which are carried out in compliance to this Law and the provision in the forestry area.

(2) The Directorate may assign tasks of professional supervision concerning performing of the public services from paragraph (1) of this Article to other legal or civil persons that are qualified for that.

(3) The Minister of Agriculture, Forestry and Water Economy shall determine the conditions for professional qualification of the persons referred to in the paragraph (2) of this Article

(4) The Minister of Agriculture, Forestry and Water Economy shall determine by Decision, published in the Official Gazette of the Republic of Macedonia, the private legal entities providers of public services referred to in paragraph 2 of this Article, and shall conclude contracts for mutual relations.

(5) Inspection supervision over public services shall be carried out by phytosanitary inspector.

IX. PUBLIC AUTHORISATIONS

Public authorisations

Article 55

(1) The Minister of Agriculture, Forestry and Water Economy grants public authorisations of legal and physical persons which satisfy the conditions in relation to scientific staff, facilities and technical capacities for the activities (tasks) defined under Article 62 paragraph (1), items 3, 4, 5, 6 and 7 of this Law.

(2) In relation to the scientific staff, they should have employed at least one person with at least bachelor degree in the area of agricultural sciences - plant protection department or specializations in the area of plant protection, and in the area of forestry they should have employed at least one person with at least bachelor degree in the area of forestry sciences and specializations in the area of plant protection, with working experience at least 3 years.

(3) The tasks in the area of plant health in the area of forestry defined under Article 62 paragraph (1), items 3, 4, 5, 6 and 7 of this Law are conducted by persons ascertained by this Law and the regulations which are in force for protection of the forests.

(4) The specific conditions from paragraph (1) of this Article in relation to the facilities and the equipment shall be prescribed by the Minister of Agriculture, Forestry and Water Economy.

(5) The Minister of Agriculture, Forestry and Water Economy with a decision grants an public authorisations for conducting tasks under paragraph (1) and (3) of this Article on the basis of public announcement announced in at least two newspapers.

(6) Against the decision under paragraph (5) of this Article non-satisfied part has the right to an appeal submitted to the Commission that decides on a second instance in administrative procedures in the area of agriculture, forestry and water economy and veterinary of the Government of the Republic of Macedonia.

(7) The holders of the public authorisations are responsible in front of the Ministry of Agriculture, Forestry and Water Economy for conducting the tasks for which a public authorisation has been granted.

(8) If the holder of the authorisation do not fulfil the conditions anymore prescribed with this Law this authorisation shall be withdrawn.

(9) Financial means for conducting the public authorisations are ensured in the Budget of republic of Macedonia for the current year with transfer from the programme for plant health.

(10) The Directorate shall supervise the performance of the public services in accordance with this Law and for the public services in the field of forestry in accordance with this Law and regulations in the in the field of forestry.

(11) The Directorate may assign tasks of professional supervision concerning supervision for performing of the public services from paragraph (1) of this Article to other legal or civil persons that are qualified for that.

(12) The Minister of Agriculture, Forestry and Water Economy shall determine the conditions for professional qualification of the persons referred to in the paragraph (11) of this Article.

(13) The Minister of Agriculture, Forestry and Water Economy shall determine by Decision, published in the Official Gazette of the Republic of Macedonia, the private and legal entities referred to in paragraph (11) of this Article, and shall conclude contracts for mutual relations.

(14) Inspection supervision over public authorizations shall be carried out by phytosanitary inspector.

Advisory Committee

Article 56

(1) For the reasons of advisory, proposing measures concerning country protection from entering and use of certain harmful agent, products and equipment for application an Advisory Committee is established consisted of experts in the field of of plant protection, mechanization, chemistry, eco- toxicology and toxicology.

(2) The Advisory Committee is formed with a Decision by the Minister for Agriculture, Forestry and Water Economy in agreement with the Minister for Health and Minister for Environment and Physical Planning according to their corresponding field of work.

(3) Advisory Committee gives opinion, suggestions and proposes measures in relation to:

- 1) Protection of import, production, placing on the market and use of harmful active substances, plant protection products;
- 2) Equipment for application of the plant protection products;
- 3) risk minimization in relation to the measures for use of plant protection products;
- 4) Research priorities;
- 5) Establishment of international contacts
- 6) other important issues.

(4) The Advisory Committee for its work shall issue reports if is necessary or at request of the Minister for Agriculture, Forestry and Water Economy with a proposed measures for suppressing of certain consequences and regularly at least once in a year at the end of the year.

(5) The Minister for Agriculture, Forestry and Water Economy shall prescribe the manner and the principles for work of the Committee.

(6) The costs for the work of the Committee shall be defined by the Government of Republic of Macedonia on proposal of Minister for Agriculture, Forestry and Water Economy and the funds are provided from the budget of the Republic of Macedonia for current year provided with transfer for financing of the Plant Health Program

X. EXPENSES

Charges

Article 57

(1) The implementation of certain provisions under this Law is conditioned by the following charges to be paid:

- 1) The cost of authorizations of the products shall be paid by the applicant or holder of the registration.
- 2) The cost of issuing a certificate for equipment shall be paid by the manufacturer or importer,
- 3) The cost of inspection of equipment shall be paid by the owner who is using the equipment.
- 4) The cost of analysis of plants and plant products for product residues during the inspection and monitoring shall be paid by the user of the products. If the user is not known, the analysis shall be paid by the owner of the plants or plant products, in cases where the residues of products exceed the prescribed limits for product residues.
- 5) The cost of analysis of soil and other objects during the inspection and monitoring of products or active substances used shall be paid by the land owner, if prohibited or irregular use has been established.
- 6) The cost of analysis of plant and other objects during the inspection of irregular use of products, carried out upon the user's request, shall be paid by the user of products, in cases where the product residues have exceeded the maximum residue levels. If the residues were established on plants to which products have not been applied, such expenses shall be paid by the client who requested such inspections.
- 7) The cost of product examination during the monitoring and inspection shall be paid by the holder of the product's authorization in cases where such a product does not correspond to the conditions determined in the authorization.
- 8) The cost of testing of equipment for application of products during monitoring and inspection shall be paid by the manufacturer or importer, in cases where the equipment does not meet the conditions specified under the certificate.

(2) The Minister of Agriculture, Forestry and Water Economy shall lay down the amount of the charges in the paragraph (1) item 1, 2 and 3 of this Article and is to be considered as an income to the legal entity who was granted a permission i.e. authorization in accordance with the Article 6, Article 50 and Article 55 of this Law.

(3) The charges in paragraph (1), items 4, 5, 6, 7 and 8 of this Article in case the results are as prescribed, real expenses for the procedure are on the expense of the Budget of Republic of Macedonia - Ministry of Agriculture, Forestry and Water Economy.

XI. DATA

Obtaining and Usage of Data

Article 58

(1) For the purpose of handling and maintaining of databases and supervision over the placing products on the market, the Directorate may obtain and use data kept in the framework of the databases prescribed in this Article by the official state services, public institutes and services, holders of licenses and other authorised bodies, specifically the data from:

- 1) databases in the field of dangerous substances and preparations,
- 2) databases for pollution of land and water,
- 3) databases for water and ecologically important areas,
- 4) land cadastre (lot number, boundaries of the lot, surface, owner, and user),
- 5) basic data from the Central population register for the owners and users (ID number, name, surname and address), necessary for maintaining its own databases.

(2) In compliance with its competence, the Directorate shall link its databases with all databases kept by the Ministry of Agriculture, Forestry and Water Economy.

(3) The Directorate may communicate data from its registers and databases to other state services and bodies, and bodies of the units of local community if necessary for carrying out legally defined activities, as well as to public institutes responsible for collecting data on acute toxicities and other effects of active substances, and to other authorized legal entities and those who provide public services if it is necessary for carrying out the activities of the Directorate.

(4) Data being classified as confidential under this Law or which use is limited by other laws (statistic, tax service) shall not be communicated.

(5) Data referred to in paragraph (1) of this Article, defined as personal data, and may be communicated by those maintaining the databases in accordance with the rules for personal data protection.

(6) Those maintaining databases shall communicate data free of charge, and only direct material expenses for additional copies and processes are to be charged.

(7) Databases set up and maintained by the Directorate in accordance with this Law and data that will use from the data holders, shall be financed by the Programme for Plant Protection - budget of the Republic of Macedonia.

(8) The Minister of Agriculture, Forestry and Water Economy shall lay down the manner of links with other databases and the manner of obtaining data from other databases in agreement with the Minister of Health, and the Minister of Environment. and Physical Planning.

International Data Exchange

Article 59

(1) The Directorate shall exchange data at international level on authorized products, on bans, termination or restrictions of use.

(2) Such information shall contain:

- 1) name of the manufacturer, or the holder of the authorization,
- 2) trade mark of the product,
- 3) physical and chemical properties of the product,
- 4) name and content of active substances which the product contains, purpose,
- 5) provisional limits for residues of products in plants if they are not yet determined by EU limits,
- 6) in case of termination of the permit, reasons for termination, and
- 7) required data for evaluating limits for residues of products in plants.

(3) A list of authorized products in the Republic of Macedonia shall be exchanged on an international level on an annual basis, while respecting the rules of the EU member states and the Codex Alimentarius Commission for placing products on the market and use of plant protection products and for pest management of Food and Agriculture Organization of the United Nations (FAO).

XII. RESPONSIBILITIES OF THE STATE AUTHORITY

Ministry

Article 60

The Ministry of Agriculture, Forestry and Water Economy proposes and implements the policy of the Government of Republic of Macedonia in the filed of plant protection products and application equipment.

Minister

Article 61

For the purpose of implementation of this law, the development and protection of the use of products and equipment, the Minister for Agriculture, Forestry and Water Economy conducts the following tasks:

- 1) He may authorise physical persons or legal entities to perform certain professional phytosanitary activities within the area of business of the entities upon their request under provisions defined with this law.
- 2) He may authorise legal entities to carry out research and development of new methods and systems for plant protection and defines the principal tasks of phytosanitary care in the area of research and development,
- 3) He shall appoint an Advisory Committee consisting of high-level professional experts as the body for plant protection in agriculture and forestry, toxicology and protection on the environment, whose task is to propose recommendations.
- 4) He shall appoint the expert commission in accordance wit Article 24 of this Law, and
- 5) Performs other activities defined under this Law.

The Directorate

Article 62

(1) The Directorate has the following tasks and authorities under this Law:

- 1) conducting the procedure for products authorization and auxiliary products, conducting entry in the register of application equipment;
 - 2) preparing secondary legislation and taking care of their implementation, preparing public announcements, make a contract for enabling public service in accordance to this law;
 - 3) monitoring in the area of products use and resistance to them, efficiency and phyto toxicity of the plants or plant products from product use, placing on the market;
 - 4) adopting programmes related to the measures for proper use of products, introducing the principles of good agriculture practice,
 - 5) confirming the draft provisional maximum residue levels (MRL) for plant/crop combination for which there is still no EU MRL on the basis of the good agricultural practice,
 - 6) confirming the draft provisional MRLs for active substances/products combinations of animal origin and for which there are still no EU MRLs on the basis of residues expected in/on the feed and proceeding them to the Veterinary Directorate and the Ministry of Health for further risk assessment,
 - 7) Prescribing an annual program for monitoring and control of used plant protection products over primary production,
 - 8) Prescribing an annual program for quality control and plant protection product declaration,
 - 9) coordination of the work and collaboration in respect of the approval on products and equipment with other competent bodies,
 - 10) confirming the conditions for registration according to paragraph (4) Article 26 of this Act, for registration, evidence and lists,
 - 11) representing the Republic of Macedonia in the international organizations/bodies in the field of plant protection products and their residues,
 - 12) setting up information systems, collecting, processing, mediating and storage of data and management of information systems.
 - 13) organizing education for professional qualifications of the personnel and all stakeholders involved in the process of placing a product on the market and their usage, as well as publishing guidelines.
 - 14) performing other tasks specified by the Ministry of Agriculture, Forestry and Water Economy.
-

15) control over the experts work of the legal entities that carries out production, official test, analyses, placing of products on the gross market and to a physical persons involved in the procedures for evaluation of the active substances and products.

(2) The control under point 14 from paragraph (1) of this Article shall be carried out by the Directorate through Commission consisted of experts and scientific workers in the appropriate areas nominated by the Director of the Directorate.

(3) The Advisory Committee for the carried out control over the experts work shall submit reports to the Directorate for the ascertained situation and irregularities with proposed measures and dead-lines for implementing the measures to eliminate the irregularities.

(4) The Director shall prohibit the placement of a product on the market and the carrying out of the activity when a supervisory report, carried out on the professional work, confirms that:

- 1) the measures have not been undertaken in the specified deadline in the report;
- 2) there is deviation that may cause change of the characteristics of the authorized product compared with the conditions given in the authorization;
- 3) the identified irregularities during the activity are from nature that can cause harmful consequences or danger to human life and health, i.e. to animals, and the environment.

(5) The Directorate also has the right to carry out control on the persons enterpreneurs that perform re-packaging or re-labelling of the product in the territory of Republic of Macedonia.

(6) Against the decision under paragraph (4) and (5) of this Article non-satisfied part has the right to an appeal submitted to the Ministry of Agriculture, Forestry and Water Economy.

(7) An appeal lodged against a Decision for prohibition paragraph (4) and (5) of this Article shall not delay its execution.

(8) The holder of the authorization is obliged, on request of the Directorate, at his expense, to submit samples of the product that are in accordance with the serial numbers of an authorized product that has been placed on the market in the Republic of Macedonia, If the results of the control or examinations of the products are positive the expenses are on account of the Ministry of Agriculture, Forestry and Water Economy

XIII. INSPECTION SUPERVISION

Article 63

(1) The Ministry of Agriculture, Forestry and Water Economy shall carry out the supervision over the implementation of the provisions of this Law and the provisions based on it.

(2) The MAFWE via Phytosanitary Directorate shall carry out the supervision over the implementation of the public authorisations prescribed in this Law.

(3) Inspection supervision over the implementation of this Law and the execution of the measures resulting from this Law by physical and legal entities, institutions and other legal entities shall be carried out by.

- 1) The Directorate through phytosanitary inspectors, and
- 2) the State Agricultural Inspectorate through agricultural inspectors.

(4) Activities under the competences of the phytosanitary inspector, under this Law, supervision of the execution of this Law and secondary legislation deriving from this Law may be carried out by authorized persons by the Minister of Agriculture, Forestry and Water Economy

Inspection supervision and documents for identification

Article 64

The designated inspector must poses documents for identification during the inspection supervision.

Authorising the phytosanitary inspector

Article 65

(1) On the basis of this Law and the provisions based on it, the phytosanitary inspectors have the rights and duties to:

- 1) Prohibit use of products and other products if they are not declared and are not used in accordance to the conditions in the authorisation;
- 2) Prohibit use of products that are harmful to bees if the user and breeder acted in accordance to Article 38 of this Law;
- 3) Order appropriate measures, if by official analysis it is confirmed that MRLs are exceeded in the plants or plant products before their placement on the market;
- 4) Prohibit the official examination and analysis without previous fulfilment of the conditions in the permit for performance, or other conditions laid down in this Law and the provisions based on it;
- 5) Take samples of plants, plant products, mixtures for treatment, products and other necessary samples for verification that the product is used without irregularities and unacceptable MRLs;
- 6) Propose to the Directorate a of the authorization for placing of the product on the market or other products in process of application for authorization or products at the producer of products;
- 7) Prohibit temporary use of products or other products on the field, i.e. batches for which there is suspicion of irregularities until those irregularities are not confirmed by examination;
- 8) Prohibit temporary use of products or other products without declaration;
- 9) Confiscate irregular products or other products in the process application for authorization;
- 10) Confiscate products or other products which do not have declaration from manufacturer or discovers this in the process application for authorization;
- 11) Order withdrawal of irregular product or other products in the process application for authorization and at the manufacturer of products after getting the results from the examination;
- 12) Order withdrawal of irregular product or other products in the process application for authorization and at the manufacturer of products without declaration;
- 13) Take samples of plant protection products, other products and other necessary samples for products examination whether the product complies with the declared properties and action, purity of the active substance in the process application for authorization and at the manufacturer of products.;
- 14) Conduct control during the plant protection product imports and other products at the border post in relation to whether the it poses authorisation, expiry date, declaration, label and package in accordance to this Law;
- 15) Remove from the market equipment for application of products and to order verification of its compliance with a certificate;
- 16) Prohibit the placing on the market of equipment for application of products if it does not have a certificate, or is not in compliance with the certificate;
- 17) Establish whether the providers of public services or those who have public authorization according to this Law fulfill the conditions or act in accordance with this Law, contract or authorization, and order elimination of any deviations;
- 18) Order other measures and determine deadlines for their execution for the purpose of compliance of the actions of the legal entities who produce plant protection products or place the plant protection products on the market in accordance with this Law and the provisions based on it, and

(2) In cases where the provisions of this Law and other laws are contravened, recommend criminal proceeding against legal and civil persons to the competent authorities.

Measures of the phyo-sanitary inspector

Article 66

The agriculture inspector shall by right and obligation, along with the measures referred to in Article 65 of this Law prohibit performance of any activity by a legal entity for a period of 90 days if:

1. produces products, as well as uses premises in which the activity is performed in those cases where there is no permit for that activity, where the conditions for performance of the activities prescribed by this Law are lacking;
2. produces products, as well as uses premises in which the activity is performed in case irregularities have been ascertained regarding the premises, equipment, personnel, or performance of activity which may cause harmful consequences to human and animal health, until elimination of those irregularities in specified time period;
3. in the production of products and other products, uses substances for which a certificate for the prescribed quality has not been previously provided, i.e. uses substances with low quality or falsified substances.
4. official examinations, laboratory analysis of the products and other products are performed in accordance with prescribed conditions, standards and methods of this Law;
5. uses irregular products and other products;
6. places products on the market not in accordance with the determined prices by the Directorate;
7. produces, stores products but the conditions for performance prescribed by this Law are lacking; and
8. does not permit the supervision conducted by the inspector, does not give the necessary data, samples and materials having on disposal, or on other manner disables the inspection supervision.

Authorising the agricultural inspector

Article 67

(1) On the basis of this Law and the provisions based on it, the agriculture inspectors have the rights and duties to:

- 1) Prohibit the placing on the market products and other products as well as prohibit the use of the premises in which the activity is performed in those cases where there is no permit for that activity, under the conditions for performance of the activities prescribed by this Law are lacking;
 - 2) Prohibit the placing on the market products and other products, as well as prohibit the use of the premises in which the activity is performed in case irregularities have been ascertained regarding the premises, equipment, personnel, or performance of activity which may cause harmful consequences to human and animal health, until elimination of those irregularities in specified time period;
 - 3) Prohibit the placing on the market and use of products and other products, in those cases where they are not authorised, banned, or past expiry date, in accordance with the provisions of this Law;
 - 4) Prohibit the placing on the market or use of products in those cases where the products are not in accordance with the authorization in relation to: packaging, declaration, labelling, instructions for use (instruction manual), physical and chemical content, purity of the active substance, etc.;
 - 5) Prohibit temporary placing of products or other products on the market without declaration;
 - 6) Prohibit temporary placing of products or other products on the market, batches for which there is suspicion of irregularities until those irregularities are not confirmed by examination;
 - 7) Confiscates plant protection products or other products on the market without declaration;
 - 8) Confiscates plant protection products or other products placed on the market under conditions, which does not correspond to the conditions prescribed by this Law, and the provisions based on it;
 - 9) Propose to the Directorate a withdrawal of the authorization for use of the product or other products in case of irregularity of placing of the product on the market;
-

10) Confiscate products or other products with past expiry date, not having the original package of the manufacturer and when the instruction manual and the declaration are not in accordance with the authorization for placing products on the market and are not printed in Macedonian language, as well as not properly market in accordance with the degree of toxicity, when there is a irregularity find while placing on the market;

11) Order withdrawal of irregular product or other products in case of irregularity regards to placing the product on the market;

12) Order other measures and determine deadlines for their execution for the purpose of compliance of the actions of the legal and civil persons placing plant protection products on the market with this Law and the provisions based on it.

(2) In cases where the provisions of this Law are contravened, recommend criminal proceeding against legal and civil persons to the competent authorities.

Measures of the agricultural inspector

Article 68

The agriculture inspector shall by right and obligation, along with the measures referred to in Article 67 of this Law prohibit performance of any activity by a legal entity for a period of 90 days if:

- 1) places products and other products on the market, as well as uses premises in which the activity is performed in those cases where there is no permit for that activity, where the conditions for performance of the activities prescribed by this Law are lacking;
- 2) places products on the market, as well as uses storage premises in which the activity is performed in case irregularities have been ascertained regarding the premises, equipment, personnel, or performance of activity which may cause harmful consequences to human and animal health, until elimination of those irregularities in specified time period;
- 3) places on the market irregular products and other products.
- 4) does not permits the supervision conducted by the inspector or does not gives the necessary data, samples and materials having on disposal or on other manner disables the inspection supervision

Article 69

(1) The permit for performing an activity shall be withdrawn from the legal entity in cases where the administrative measures of Article 65, 66, 67 and 68 of this Law have been started for a second time with effective decision of the competent inspector.

(2) The decision for withdrawal of the permit for execution of certain activities shall be made by the Director of the Directorate.

(3) An appeal or complaint may be lodged against a decision referred to in paragraph (2) from this Article to the Minister for Agriculture, Forestry and Water Economy.

(4) The legal entity from whom the permit was withdrawn shall be deleted from the Register.

Article 70

(1) The competent inspector may decide whether product or other products, which he has banned from being placed on the market, are to be impounded at the place of the legal or physical entity where they were found or whether they are to be confiscated.

(2) Products from paragraph (1) of this Article shall be kept separately, packed and labeled.

(3) In addition to a report of samples taken and the written decision for the measure taken, the competent inspector shall enclose a list of prohibited products referred to in paragraph (1) of this Article.

Article 71

(1) By a decision, the competent inspector under Article 65, 66, 67 and 68 shall determine the measures for which he is authorised to take, in accordance with the rules for general administrative procedure and this Law.

(2) An appeal against such a decision referred to in paragraph (1) of this Article within 15 days from the day of the receipt of the Decision to the Minister for Agriculture, Forestry and Water Economy.

(3) An appeal against such a decision shall not delay its execution.

Article 72

(1) A product and/or other products shall be withdrawn from use and placing on the market if it is determined that it is used and placed on the market against this Law and the provisions based on it.

(2) In cases where the authorization for the product or other products has been issued already, the Directorate shall withdraw the authorization for placing on the market.

(3) This decision for withdrawal of the product from the market shall be published in the "Official Gazette of Republic of Macedonia".

Article 73

(1) The designated inspector is obliged to order a removal of a forbidden product or other products when:

- 1) It is confirmed that it is not in accordance with the prescribed conditions from the authorization on the basis of laboratory testing-analysis (physical-chemical, clearance of the active substance, deviation of the content of the active substance, and analyses of MRLs), or on the basis of the effective decision for prohibition of their use, and
- 2) The owner does not deny that they are not irregular.

(2) In a case where the owner denies the irregularity or irregularities, a superior analysis shall be performed, and when the results from the report of the superior analysis confirm the previous analysis results, a measure for removal shall be performed, without agreement of the owner.

(3) The owner is obliged to store forbidden product or other products for removal in the place and time determined by the decision of the competent inspector.

(4) In case the product is in the list of dangerous wastes, removal of the forbidden product or other products is done in accordance with the Law for waste management.

Article 74

(1) The expenses for examination and withdrawal, removal of the product or other products, as well as the expenses related to the implementation of the decisions referred to in Article 72 and 73 of this Law, shall be covered by the legal and civil persons who have produced the product, or imported it, i.e. placed it on the market.

(2) In a case where that the examination shows the products and/or other product not to be irregular, the expenses shall be covered by the Ministry of Agriculture, Forestry and Water Economy.

(3) Legal entity authorized for examination of the product or other product, shall cover the expenses for withdrawal of the product from the market, in a case where an incorrect report for the regularity of the product has been submitted, on the basis of which the product or other products were withdrawn.

IVX. OFFENCES AND PENALTIES

Bodies

Article 75

(1) Bodies for conducting offence procedures in accordance with Article 77, 78, 79 and 80 of this Law, are the Phytosanitary Directorate and State Agriculture Inspectorate.

(2) Procedure for the three-member Committee conducts the Phytosanitary Directorate consisted of official personnel authorized by Minister of Agriculture, Forestry and Water Economy.

(3) Procedure for the three-member Committee conducts the State Agriculture Inspectorate consisted of official personnel authorized by Minister of Agriculture, Forestry and Water Economy.

Offences by Legal Entities

Article 76

(1) A legal entity shall be fined with a monetary fine of 2.500 to 5.000 euros in MKD, on conviction of an offence if:

- 1) places a product on the market or other products that imitate authorized products and other products (paragraph (1) and (2), Article 3);
- 2) As holder of the authorization he does not take into consideration the conditions for declaration, packaging, placing on the market and application (paragraph (3) of Article 8);
- 3) places a product on the market and other products and uses product and other products with an expired date of use (Article 25 paragraph (3) indent 19);
- 4) places a product on the market and uses products and other products without declaration (paragraph (2) Article 25);
- 5) He produces, places a product on the market and uses products and active substances within the territory of the Republic of Macedonia, which are not authorized or for which no authorizations have been issued (paragraph (1) and (2) of Article 3 and paragraph (1) of Article 26);
- 6) He does not keep records and do not provide data to the Directorate (paragraph (1) and (2) from Article 27);
- 7) He gives incorrect data or false documents in the procedure for product authorization, or in the procedure for professional supervision and inspection supervision, (Article 4, 9, 10, 11, 15, 16, and 29);
- 8) He does not inform the Phytosanitary Directorate with all new data on possible dangerous (harmful) effects of products or their residues and does not inform (Article 34);
- 9) He do not poses authorisation for products use classified as highly toxic product T⁺ (Article 35);
- 10) He provides public services or uses public authorisation contrary to agreement (Article 50 and 55);

(2) A person responsible for a legal entity shall be fined with a monetary fine of 1.000 to 2.000 euro in MKD, for committing an offence according to paragraph (1) of this Article.

(3) Apart the fine, under paragraph (1) of this Article the legal entity shall be sentenced offence sanction temporary prohibition for production and placing the products on the market in the period of 6 months up to 1 year.

(4) A person responsible for a legal entity apart the fine under paragraph (2) of this Article, shall be sentenced offence sanction temporary prohibition for execution of the function in the period of 1 up to 2 years.

Article 77

(1) A legal entity shall be fined on the spot with monetary fine of 2.000 to 4.000 euro in MKD if:

- 1) He uses products in contrary to the authorisation for extended use (Article 14);
- 2) He places on the market or uses unauthorized products in relation to an exceptional permit (Article 15);
- 3) He gives confidential data in contrary to paragraph (3) and (4) of Article 19 of this Law;
- 4) He is conducting tests of products in contrary to the authorisation issued for research and development purposes (Article 22);
- 5) Declares, announces or gives instructions in relation to the products and other products in contrary to Article 25 of this Law;
- 6) He produces and stores products for the purpose of placing them on the market in contrary to the paragraph (2) Article 26 of this Law;
- 7) He do not allow to the inspector to conduct uninterrupted inspection in accordance to this Law or he is suppressing him in this action, offences (attacks) him or he do not want to show him the necessary documents, data or facilities (Article 27);
- 8) Inappropriate use of products (paragraph (2) and (6) of Article 36);
- 9) He uses product harmful to bees and terrestrial vertebrates (Article 37);
- 10) He does not meet the conditions predicted for professional qualification or the conditions in relation to the equipment (Article 26, 45 and 55);
- 11) He places on the market equipment which do not meets the conditions prescribed in the certificate (paragraph (1), Article 37);
- 12) He uses equipment that has not been subjected to control testing (paragraph (2), Article 41);
- 13) He imports without permission or certificate (paragraph (1) Article 42);
- 14) He provides wrong report for the regularity of the product on the basis of which the product or other products are withdrawn of the market (Article 74).

(2) A person responsible for a legal entity shall be fined with a monetary fine of 900 to 1.800 euro in MKD, for an offence committed according to paragraph 1 of this Article.

Penalties on the spot

Article 78

(1) A person responsible for a legal entity shall be fined on the spot with a monetary fine of 600 euro in MKD, for an offence if:

- 1) He places on the market or uses unauthorized products in relation to an exceptional permit (Article 15);
- 2) He places on the market and uses products contrary to the ban or restriction by the Directorate (paragraph (3), Article 8 and paragraph (2) and (3), Article 16);
- 3) He places on the market a product without declaration, package or label, including instructions manual (Article 25);
- 4) he does not use the product in prescribed manner (Article 36);
- 5) he does not keep record (paragraph (4) Article 36 and Article 40);
- 6) he places on the market equipment without certificate and is not registered I the register for equipment (Article 38 and 39);

Penalties for civil persons

Article 70

A civil person shall be fined on the spot with a monetary fine of 500 to 1000 euro in MKD, if:

- 1) He uses products in contrary to the authorisation for extended use (Article 14);
- 2) He uses unauthorized products in relation to an exceptional permit (Article 15);
- 3) He does not inform the Directorate of dangerous (harmful) effects of the products (Article 17);
- 4) He gives confidential data (paragraph (3) and (4) Article 19);
- 5) He do not allow to the inspector to conduct uninterrupted inspection in accordance to this Law or he is suppressing him in this action, offences (attacks) him or he do not want to show him the necessary documents, data or records (Article 27);
- 6) he uses bio-agents contrary to designated authorization (paragraph (2) Article 33);
- 7) he uses products contrary to prescribed manner (Article 36);
- 8) he uses products contrary to the prohibition or restriction (Article 37);
- 9) performs aerial application of products toxic for bees (paragraph (7) Article 37);

Penalties on the spot

Article 80

(1) A civil person shall be fined on the spot with a monetary fine of 200 euro in MKD, if:

- 1) Places on the market products without being registered for such activity (paragraph (1) of Article 26);
- 2) It uses himself highly toxic products (Article 35);
- 3) He uses equipment has not been subjected to control testing (paragraph (2) and (3) of Article 41).

VX. TRANSITIONAL AND FINAL PROVISIONS

Control of Trade Across the State Border

Article 81

Following the full accession of the Republic of Macedonia to the European Union, the tasks of control of trade across the state border with the EU Member States shall be transferred to internal trade, the monitoring of which shall be performed by the competent phytosanitary inspector.

Applicant for Authorization Registration of the Products

Article 82

Following the full accession of the Republic of Macedonia to the European Union, a legal entity with permanent residence or headquarters in any EU Member State may submit an application for authorization of products, which he intends, to place on the market and use in the territory of the Republic of Macedonia.

Conditions for Performing Trade of Products following the Entry in the European Union

Article 83

Following the full of accession of the Republic of Macedonia to the European Union, a legal or civil person with permanent residence or headquarters in any EU Member State may be involved in placing a product and equipment for its application on the market, within the territory of the Republic of Macedonia, as long as the prescribed conditions under this Law are met.

Article 84

The provisions under item 2 paragraph (3) Article 3 of this Law shall apply until the full of accession of the Republic of Macedonia to the European Union.

Ongoing Procedure for Product Authorization

Article 85

The procedure for authorization of products or other products initiated prior to the entering into force of this Law shall be continued in accordance with the provisions that were valid to day of enactment of this Law in accordance with the provisions of this Law only in case they are more favorable to the applicant for authorization.

Provisions based on this Law and Timeframe for preparation of new provisions

Article 86

(1) The secondary legislation prescribed under this Law shall be issued within two years following the entering into force of this Law.

(2) The provisions of the Decision of determination of Border Passes on which import, export and transit of plants, plant products and plant protection products will be conducted (“Official Gazette of Republic of Macedonia” no 34/2000) shall apply up to the entering into force of the provision under item 5 paragraph (1) Article 61 of this Law for determination of border passes on which export and import of plant protection products will be conducted as well as the manner of control.

(3) Employed Agriculture engineers and shall be retired in period of a 5 years, with long years of experience can place products and other products on gross market and in specialized stores (agriculture pharmacies).

Provisions, which shall be applied

Article 87

Until adoption of provisions based on this Law, the current provisions shall remain in force.

Provisions, which shall cease to Apply

Article 88

On the day of entering into force of this Law, the Law on Plant Protection shall cease to apply (“Official Gazette of Republic of Macedonia” No.25/98 and 6/2000), except the provisions concerning agriculture tillage for seed production, forest plants, for forest seed production, facilities for seedlings production for perennial agriculture and forest plants and trade with seed and seedlings.

Entering into Force of this Law

Article 89

This Law shall enter into force on the 8th day of its publication in the Official Gazette of the Republic of Macedonia and shall be applied from January 1st 2008, except he provisions under Articles 38, 39, 40, 41 and 42 of this Law that shall be applied from January 1st 2009. .
