

Plant Protection Act

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Text in Bulgarian: ЗАКОН за защита на растенията

Chapter One GENERAL DISPOSITIONS

Section I Subject

Article 1. This act regulates the public relations pertaining to:

1. the phyto-sanitary measures under the International Plant Protection Convention approved by the Conference of the International Food and Agriculture Organization - November 1997 (ratified by law - SG, No. 32 of 2005) (SG, No. 75 of 2005);

2. the protection of the plants and plant products from economically important pests;

3. the monitoring, surveillance, diagnostics, forecasting and signalization in plant protection;

4. the integrated production of plants and plant products and the control over the integrated production;

5. the phyto-sanitary control over the plants and plant products and the protection measures against the introduction into the country of quarantine pests of plants and plant products and the protection measures against their spread within the country according to the requirements of Directive 2000/29/EC of the Council of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plant and plants products and against their spread within the Community;

6. measures for application of Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the Placing on the Market of Plant Protection Products and Repealing Council Directives 79/117/EEC and 91/414/EEC (Official Journal, L 309/1 of 24 November 2009), hereinafter referred to as "Regulation (EC) No. 1107/2009";

7. the requirements to the plant protection products for the purpose of protection of the health of people and animals and environmental protection, their use according to the requirements of Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 Establishing a Framework for Community Action to Achieve Sustainable Use of Pesticides (OJ, L 309/71 of 24 November 2009), hereinafter referred to as "Directive 2009/128/EC", and the control over the production, placing on the market, trade, re-packaging

and use thereof;

8. requirements for rendering specialized plant protection services and the follow-up control thereof;

9. the measures for implementation of Regulation (EC) No. 2003/2003 of the European Parliament and the Council of October 13 relating to Fertilizers, hereinafter referred to as "Regulation (EC) No. 2003/2003";

10. the requirements to the fertilizers, soil ameliorators, biologically-active substances and nutrient substrates and the control in the process of the production, placing on the market and use thereof.

Section II

Organization of the activities

Article 2. The Minister of Agriculture and Foodstuffs shall conduct the state policy in the field of plant protection.

Article 3. (1) The Bulgarian Food Safety Agency (BFSA) shall perform:

1. monitoring, surveillance, diagnostics, forecasting and signalization in the field of plant protection;

2. control over the integrated production of plants and plant products;

3. phyto-sanitary control over plants, plant products and other articles, by virtue of which quarantine pests may be transmitted and disseminated;

4. biological testing of plant protection products and mixtures thereof;

5. authorization of plant protection products and registration of fertilizers, soil ameliorators, biologically-active substances and nutrient substrates for placing on the market and use;

6. control over the persons who trade in and re-package plant protection products and who perform biological testing and specialized plant protection services;

7. control over the production, placing on the market and use of plant protection products, active substances, adjuvants, fertilizers, soil ameliorators, biologically-active substances and nutrient substrates;

8. control over the implementation of Regulation (EC) No.2003/2003 and Regulation (EC) No. 1107/2009.

(2) The Bulgarian Food Safety Agency is a competent and coordinating national authority in the sense of Article 75, Paragraphs (1) and (2) of Regulation (EC) No. 1107/2009.

(3) The Bulgarian Food Safety Agency, as an administrator of personal data, shall process the data collected during the implementation of the activities under Paragraph (1) in accordance with the requirements of Article 2 (2) of the Personal Data Protection Act.

Article 4. For the sake of implementation of the activities under Article 3 (1), the Executive Director of the Bulgarian Food Safety Agency shall give mandatory instructions and shall approve templates of applications, permits, certificates, notifications, declarations, logbooks and other similar documents under this act.

Article 5. (1) For implementation of the activities under this act, for issuing of permits and certificates, for exercising of control, for laboratory tests and in other instances envisaged by the law, as well as for rendering of services to natural persons and legal entities, fees shall be collected according to the tariff under Article 3(4) and the price schedule under Article 3 (5) of the Bulgarian Food Safety Agency Act.

(2) When the procedures for issuing of permits and certificates under this act are terminated for reasons that have to do with the applicants, the fees paid shall not be refundable.

Article 6. (1) The Bulgarian Food Safety Agency shall create and keep public registers of:

1. the plant protection products for which a permit has been issued for:
 - a) placing on the market and use;
 - b) use when performing scientific research and/or development activities;
 - c) (effective 1.01.2015 - SG No. 61/2014) placing on the market and use in the form of a ready-made solution;
 - d) parallel trade;
2. the plant protection products that have been re-packaged;
3. the official bases of the Bulgarian Food Safety Agency and the approved bases of natural persons and legal entities for biological testing of plant protection products;
4. the persons who hold a certificate for trade in plant protection products and of the respective sites for trade in plant protection products;
5. the persons who hold a certificate for trade in plant protection products and of the respective sites for trade in plant protection products;
6. the persons who produce plant protection products on the territory of the Republic of Bulgaria;
7. the persons who hold a certificate for importation or introduction of a batch of

unapproved active substances;

8. the issued permits for application of plant protection products through aerial spraying;

9. the persons who perform specialized plant protection services:

a) fumigation of plants, plant products and other articles;

b) treatment by plant protection products of sowing seeds;

c) consulting services for integrated pest management;

10. the persons who perform integrated production of plants and plant products;

11. the persons who introduce, produce, process and cultivate plants and plant products subject to phyto-sanitary control, the collection and distribution centres for plants and plant products subject to phyto-sanitary control, commodity exchanges and producers' markets;

12. the persons who hold a permit for importation, possession, storage and movement of quarantine pests, plants, plant products and other objects of scientific research and selection;

13. the persons who hold a certificate under Article 83;

14. the registered fertilizers, soil ameliorators, biologically-active substances and nutrient substrates for which a certificate for placing on the market and use has been issued;

15. the adjuvants which are placed on the market and used.

(2) The registers under Paragraph (1) shall be published on the web page of the Bulgarian Food Safety Agency and shall be updated upon each change in the circumstances recorded therein.

(3) The Registers under Paragraph (1), Items 1-3, 6, 7, 12, 14 and 15 shall be created and kept by the Central Office of the BFSA and the registers under Paragraph (1) Items 4, 5, 8-11 and 13 - by the regional food safety directorates (RFSD).

(4) The national registers that contain the data from the RFSD registers shall be kept at the Central Office of the BFSA.

(5) The content of the registers under Paragraph (1) and the procedure for keeping them up to date shall be stipulated in an ordinance of the Minister of Agriculture and Foodstuffs.

Article 7. (1) The control over the implementation of this act shall be exercised by the plant protection inspectors of the BFSA.

(2) The inspectors referred to in Paragraph (1):

1. shall perform checks of plants, plant products and other articles, plant protection products, active substances, adjuvants, fertilizers, soil ameliorators, biologically-active substances and nutrient substrates;

2. shall place under quarantine plants and plant products, areas, storage facilities, warehouses and other sites;

3. shall perform inspections at the sites where plant protection products, active substances, adjuvants, fertilizers, soil ameliorators, biologically-active substances and nutrient substrates are produced, tested, analysed, re-packaged, stored, transported, traded and are available in some other manner;

4. shall perform checks at the sites that produce, process, grow, test, select, re-package, store, transport, trade or have in some other manner plants and plant products;

5. shall take control samples from plant protection products and work solutions, fertilizers, soils, waters, plants, plant products and other sites for performing laboratory tests;

6. shall seize, place under distraint, order decontamination of biological agents, plant protection products, active substances, adjuvants, fertilizers, soil ameliorators, biologically-active substances and nutrient substrates which do not conform to the requirements of the law and/or to the instruments for the application of the law;

7. shall seize for the benefit of the state, shall confiscate, shall order the destruction or restriction of the movement of plants, plant products and other articles which do not conform to the requirements of the law and/or to the instruments for application of the law;

8. shall require information and documents, including written explanations, relating to their control activity;

9. shall issue orders and prescripts for conducting measures for the remedying of inconsistencies found by stipulating the deadlines for compliance therewith;

10. shall draw up statements of administrative violations established under this act and/or under the instruments for its application;

11. shall notify the respective competent and supervisory authorities of violations found;

12. shall request assistance from other competent and supervisory authorities.

(3) For the purpose of exercising their powers under Paragraph (2), the plant protection inspectors shall have right of access to the sites under Paragraph (2) Items 3 and 4, including to protected territories in the sense of the Protected Territories Act.

Chapter Two

CONTROL OF ECONOMICALLY IMPORTANT PESTS

Article 8. (1) Each year by the 31st of January, the Executive Director of the BFSA shall endorse a list of the economically important pests of the agricultural crops by administrative territorial units - regions. The pests included in this list shall be subject to systemic and constant monitoring.

(2) The Executive Director of the BFSA shall determine thresholds of economic harmfulness of the pests referred to in Paragraph (1).

Article 9. (1) The protection of the plants and plant products from economically important pests shall be performed under terms and according to a procedure stipulated in an ordinance of the Minister of Agriculture and Foodstuffs.

(2) The good plant protection practice shall be applied in the protection of plants and plant products. The stakeholders shall develop rules for good plant protection practices according to a procedure stipulated in the ordinance under Paragraph (1).

(3) (Effective 26.10.2014 - SG No. 61/2014) The protection of the plants and plant products shall be performed according to general integrated pest management principles stipulated in Appendix No.1.

(4) When it comes to the protection of the plants and plant products, specific pest management principles stipulated in an ordinance of the Minister of Agriculture and Foodstuffs can also be applied.

(5) For the purpose of application of the integrated pest managements principles referred to in Paragraphs (3) and (4), the agricultural producers can use consulting services.

Article 10. (1) The Minister of Agriculture and Foodstuffs and the Minister of Environment and Waters shall endorse a list of the biological agents which can be applied in the country under terms and according to a procedure stipulated in the ordinance under Article 9 (1).

(2) The import, introduction, movement and application on the territory of the country of biological agents outside the list of Paragraph (1) shall be prohibited.

Article 11. (1) When performing integrated production of plants and plant products, the general and specific integrated pest management principles shall be applied.

(2) The integrated production referred to in Paragraph (1) shall be performed for an uninterrupted period of 5 years by agricultural producers who:

1. have procured a person who has completed the course of study for integrated production of plants and plant products at a school of higher education or at an institution within the system of vocational training and education according to a curriculum approved by the Executive Director of the BFSA or who has completed his/her higher education in the field of agrarian science;

2. use consulting services by persons entered into the register referred to in Article 6, Paragraph (1), Item 9.

3. have developed a plan for integrated production according to the requirements stipulated in the ordinance referred to in Article 9 (4).

(3) In the cases referred to in Paragraph (2), Item 2, the consultants must have higher education in the field of agrarian science with a professional concentration of "Plant Protection" or must have procured a person of such education.

(4) The integrated production under Paragraph (1) and the control thereof shall be performed under terms and according to a procedure stipulated in the Ordinance under Article 9 (4).

(5) No other types of agricultural production can be carried out on the area on which the integrated production under Paragraph (1) is carried out.

Article 12. (1) Agricultural producers who carry out integrated production of plants and plant products can be entered into the register referred to in Article 6, Paragraph (1), Item 10 under terms and according to a procedure stipulated in the ordinance under Article 9 (4).

(2) The agricultural producers who have been entered into the register under Paragraph (1) shall have the right to place a sign which contain the words "INTEGRATED PRODUCTION" on the plants and plant products that they produce through integrated production. This sign certifies the method by which the plants and the plant products have been produced without characterizing their quality.

(3) The placing of a sign which contains the words "INTEGRATED PRODUCTION" on plants and plant products which have not been produced through integrated production shall be strictly prohibited.

Article 13. (1) The Bulgarian Food Safety Agency shall create, keep and store a national data base on the appearance, spread, density, development and degree of attack by economically important pests on the agricultural crops under terms and according to a procedure stipulated in the ordinance under Article 9 (1).

(2) The Bulgarian Food Safety Agency shall issue regular bulletins and other materials for notification of the appearance, spread and development of economically important pests on the agricultural crops and the means to combat them.

(3) When performing the activities under Paragraphs (1) and (2), the BFSA shall interact with agricultural producers, agronomists, consultants, sectoral and other non-governmental organizations in the field of plant protection.

Article 14. Everybody shall be obligated to maintain in a good health status the plants and plant products that they possess, grow, produce or store.

Article 15. (1) The Minister of Agriculture and Foodstuffs shall declare by an order a

calamity or epiphytotoy of economically important pests for a specific district, region or the territory of the entire country.

(2) The order under Paragraph (1) shall stipulate:

1. the respective territory of the country;
2. the type of the economically important pest;
3. the type of measures for control over the respective pest and the deadline for the application thereof.

(3) The means for pest control shall be procured according to the procedure of the Calamity Protection Act.

(4) If a calamity or an epiphytotoy is declared, everybody, including the state and municipal authorities in the district, region or on the territory of the entire country shall apply the measures for control against the respective pest.

Chapter Three

PHYTO-SANITARY CONTROL

Section I

General conditions

Article 16. (1) The phyto-sanitary control over plants, plant products and other articles shall be performed for the purpose of prevention of the introduction or restriction of the spread of quarantine pests on the plants and plant products.

(2) The phyto-sanitary control shall be exercised under terms and according to a procedure stipulated in an ordinance of the Minister of Agriculture and Foodstuffs.

(3) The phyto-sanitary measures in the events of separate quarantine pests shall be stipulated by ordinances of the Minister of Agriculture and Foodstuffs and/or by resolutions of the European Commission which shall be published on the web page of the BFSA.

(4) In all cases of detecting quarantine pests and undertaking of phyto-sanitary measures, the BFSA shall immediately notify the European Commission and the competent authorities of the other member-states of the type of the pests and of the measures undertaken.

(5) When exercising the phyto-sanitary control, the BFSA can be assisted by experts of other member-states or by experts designated by the European Commission. When exercising phyto-sanitary control, these experts shall have the powers of the plant protection inspectors.

(6) Upon request of the European Commission or of a competent authority of another

member-state, the Minister of Agriculture and Foodstuffs can designate experts for providing help or for participation in missions in other member-states or in third countries.

Article 17. The import, possession, storage and movement of quarantine pests, plants, plant products and other articles stipulated in the ordinance under Article 16 (2) shall be strictly prohibited.

Article 18. An exception to the prohibition in Article 17 shall be permitted only for the purpose of scientific research and selection after the issuing of a permit by the Executive Director of the BFSa or by the official authorized by him/her under terms and according to a procedure stipulated in an ordinance of the Minister of Agriculture and Foodstuffs.

Article 19. (1) The ordinance referred to in Article 16 (2) shall stipulate:

1. the plants, plant products and other articles, by virtue of which quarantine pests may be transmitted and disseminated;

2. the plants, plant products and other articles which are subject to special requirements of import and movement;

3. the protected zones as regards the quarantine pests and the movement of plants and plant products through them;

4. the plants and plant products for which a plant passport or a phyto-sanitary certificate is required.

(2) the movement on the territory of the country of the plants and plant products, for which a plant passport is required, shall occur only provided that there is such a passport.

(3) The plants and plant products, for which a phyto-sanitary certificate is required, shall be imported, shall pass in transit, shall be exported or shall be re-exported from the territory of the country accompanied by such a phyto-sanitary certificate.

(4) A plant passport or a phyto-sanitary certificate shall not be required when the plants and plant products are in small quantities, intended for use for non-industrial and non-commercial purposes or for consumption during travel, provided there is no threat of dissemination of quarantine pests.

(5) A plant passport shall not be required also for the produced and/or processes plants and plant products intended for personal consumption and for retail sale on the local market to persons for end use, provided there is no threat of dissemination of quarantine pests.

(6) For postal and courier consignments, which contain plants and plant products subject to phyto-sanitary control, the requirements of this act and of the instruments for its application shall be applied.

Article 20. (1) When there is a threat for the plants and plant products of penetration and/or

dissemination of quarantine pests thereon which are not stipulated in the ordinance under Article 16 (2) and/or in the resolutions of the European Commission, the Minister of Agriculture and Foodstuffs shall order by an order the application of temporary urgent phyto-sanitary measures for preventing the threat.

(2) The Bulgarian Food Safety Agency shall immediately notify the European Commission, the competent authorities of the member-states and all the stakeholders of the existing threat and of the measures undertaken under Paragraph (1).

(3) The measures under Paragraph (1) shall be applied pending the expression by the European Commission of an opinion as to their extension, expansion or cancellation.

(4) The financial resources for covering the cost of implementation of the measures under Paragraph (1) shall be provided from the budget of the BFSA. Whenever necessary, the Executive Director of the BFSA shall make a proposal to the Minister of Agriculture and Foodstuffs for providing additional financial resources for funding the urgent measures.

Article 21. The Bulgarian Food Safety Agency shall not be liable or responsible for damages sustained and benefits foregone because of the retention of the plants, plant products and other articles for the purpose of exercising the phyto-sanitary control.

Section II

Phyto-sanitary control on the territory of the country in the case of import and passing in transit and in the case of export and re-export

Article 22. (1) The persons who import, produce, process and/or grow plants and plant products under Article 19, Paragraph (1), Item 1, including the collection and distribution centres, commodity exchanges and producers' markets for such plants and plant products, shall be registered with the RFSD.

(2) For the sake of the registration referred to in Paragraph (1), the persons shall submit before the RFSD, on the territory of which they carry out their activity, an application according to a template and shall attach thereto the documents stipulated in the ordinance under Article 16 (2).

(3) The application and the documents attached under Paragraph (2) shall be checked by a plant protection inspector. If omissions or deficiencies are found, the Director of the RFSD shall notify in writing the applicant and shall stipulate a deadline for the remedying thereof.

(4) If the applicant fails to remedy the omissions or deficiencies under Paragraph (3), the application shall be ignored without being considered.

(5) Within a 3-day time limit from the submission of the application or from the remedying of the omissions or deficiencies under Paragraph (3), the plant protection inspector shall perform

a check of the documents and on-the-spot check of the compliance with the requirements stipulated in the ordinance referred to in Article 16 (2). If inconsistencies are found, the Director of the RFSD shall notify in writing the applicant and shall stipulate a deadline for the remedying thereof.

(6) If the check referred to in Paragraph (5) finds that there is no threat of dissemination of quarantine pests, in the cases when the applicants are persons who are not professionally engaged in the production of plants and plant products and produce and/or process plants and plant products intended for personal consumption and/or for retail sale on the local market to persons for end use, the procedure shall be terminated and the plant protection inspector shall notify in writing the applicant.

(7) Within a 3-day time limit from the performance of the check of compliance or from the remedying of the inconsistencies referred to in Paragraph (5), the plant protection inspector shall prepare a written opinion to the Director of the RFSD with a proposal for the issuing of a certificate of registration or refusal.

(8) No fees shall be due and payable for the registration referred to in Paragraph (1).

Article 23. (1) Within a 3-day time limit from receiving the opinion under Article 22 (7), the Director of the RFSD shall issue a certificate of registration or shall refuse to issue such a certificate of registration by citing the grounds for the refusal, when the requirements of Article 22 (5) are not fulfilled.

(2) The term of effect of the registration and of the certificate of registration respectively is indefinite.

(3) The refusal under Paragraph (1) shall be announced in due fashion and may be appealed against according to the procedure laid down in the Code of Administrative Procedure.

(4) The non-issuance of an opinion within the time limit stipulated in Paragraph (1) shall not be considered to be a tacit consent.

(5) The certificate of registration issued shall be entered into the register referred to in Article 6, Paragraph (1), Item 11.

Article 24. (1) Within a 7-day time limit from the occurrence of a change in the circumstances relating to the certificate issued under Article 23 (1), the holder of the certificate shall submit before the respective RFSD an application according to a template and shall attach thereto documents certifying the change.

(2) The certificate shall be re-issued under the terms and according to the procedure of Article 22, Paragraphs (3) - (8) and Article 23. If the change involves circumstances that do not require an on-the-spot check, the certificate shall be re-issued within a 7-day time limit.

Article 25. (1) The Director of the RFSD shall delete the registration by an order:

1. upon written request by the holder of the certificate;
2. in the case of blatant or systematic violations.

(2) If the registration is deleted as referred to in Paragraph (1), the certificate issued under Article 23 (1) shall become null and void.

(3) The order referred to in Paragraph (2), Item 2 shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure.

Article 26. (1) The phyto-sanitary control shall be exercised through regular and surprise checks, checks upon import and passing in transit, upon export and re-export and checks upon presence of evidence of a violation.

(2) The checks under Paragraph (1) shall encompass the plants, the plant products and the other articles.

(3) The regular checks shall be performed on the spot at least once a year and at least through visual inspection.

(4) The control samples during the performance of the checks under Paragraph (1) shall be taken according to a procedure stipulated in the ordinance under Article 16 (2) and shall be tested and analysed in the Central Plant Quarantine Laboratory (CPQL).

Article 27. (1) A plant passport or a phyto-sanitary certificate for the plants and plant products under Article 19, Paragraph (1), Item 4 shall be issued by a plant protection inspector of the BFSA under terms and according to a procedure stipulated in the ordinance under Article 16 (2).

(2) Fees according to the tariff under Article 5(1) shall be paid for the issuing of a plant passport or of a phyto-sanitary certificate.

Article 28. (1) When in the process of a check under Article 26 (1) there is a doubt of or actual contagion by a quarantine pest found, the plant protection inspectors shall:

1. place under quarantine plants, plant products and other items relating to the check;
2. take control samples for laboratory testing.

(2) When the laboratory tests find or confirm contagion by a quarantine pest, measures under Article 30 (1) shall be imposed.

(3) When the laboratory tests do not find contagion by a quarantine pest, the quarantine under Paragraph (1), Item 1 shall be cancelled immediately.

(4) The instrument under Paragraph (1), Item 1 can be appealed against before the Director of the respective RFSD according to the procedure laid down in the Code of Administrative

Procedure. The appeal shall not suspend the enforcement.

(5) The instrument under Paragraph (1), Item 1 can be appealed through the courts only provided that it has already been appealed against through the administrative channels according to the procedure of Paragraph (4). The appeal shall not suspend the enforcement.

(6) The failure of the Director of RFSD to pass judgment within the stipulated time limit under Paragraph (4) shall be considered confirmation of the instrument in the appealed-against part thereof.

Article 29. Every person, who has a doubt or detects contagion by a quarantine pest, shall be obligated to immediately notify the RFSD, which shall perform an inspection according to the procedure laid down in Article 28.

Article 30. (1) If contagion by a quarantine pest is detected, one or several of the following measures shall be applied:

1. placing under quarantine of plants, plant products and other articles;
2. prohibition to sow seeds, to plant plants and to multiply plants;
3. chemical, physical or mechanical processing of plants, plant products and other articles;
4. destruction of plants, plant products and other articles;

(2) When the quarantine pest found is not present and is not spread on the territory of the country, the measures under Paragraph (1) shall be applied by an order of the Executive Director of the BFSa.

(3) When the quarantine pest found is present or is spread to a limited extent on the territory of the country, the measures under Paragraph (1) shall be applied by an order of the Director of the RFSD.

(4) The order referred to in Paragraphs (2) and (3) shall stipulate:

1. the time limit for application of the measures - in the cases under Paragraph (1), Item 1 and 2;
2. the time limit and method of processing - in the cases under Paragraph (1), Item 3;
3. the time limit, place and method of destruction - in the cases under Paragraph (1), Item 4.

(5) The destruction of plants, plant products and other articles shall be performed by the persons affected by the measures in the presence of a plant protection inspector and of the mayor of the populated settlement or of an official authorized by the mayor according to the Waste Management Act, the ordinance and resolutions of the European Commission under Article 16 (3) or according to methodologies approved by the Executive Director of the BFSa.

(6) In case of non-compliance with the orders under Paragraphs (2) and (3), the BFSA shall apply the measures under Paragraph (1), Items 3 and 4 instead of the obligated persons.

(7) The orders referred to in Paragraphs (2) and (3) shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure. The appeal shall not suspend the enforcement.

(8) The financial resources for covering the cost of implementation of the measures under Paragraph (1) shall be provided from the budget of the BFSA.

Article 31. (1) In the case of shortage of the financial resources under Article 20 (4) and Article 30 (8), including of financial resources for compensation of the owners of plants, plant products and other articles destroyed, as envisaged in the budget of the BFSA, the necessary financial resources for the application of the measures under Article 20 (1) and Article 30 (1) shall be provided additionally from the state budget. The financial resources shall be provided subject to strict adherence to the provisions of the law of the European Union in the field of state aid.

(2) The terms and procedure for spending the financial resources under Paragraph (1) shall be stipulated by an ordinance of the Council of Ministers.

(3) No compensation shall be paid to the owners of destroyed plants, plant products and other articles, when the persons under Article 22 (1) have failed to fulfil their obligations under Article 29 and/or under prescripts issued by the plant protection inspectors.

Article 32. (1) The plants, plant products and other articles stipulated in the ordinance under Article 16 (2) and in a resolution of the European Commission shall be subject to phyto-sanitary control upon importation and upon passing in transit.

(2) The import of plants, plant products and other articles under Paragraph (1) shall be performed through border inspection phyto-sanitary points stipulated by an order of the Minister of Agriculture and Foodstuffs. The requirements to the border inspection phyto-sanitary points shall be stipulated in the ordinance under Article 16 (2).

(3) Phyto-sanitary control upon importation shall be exercised at:

1. border inspection phyto-sanitary points;
2. warehouses under customs control;
3. the sites of the persons entered into the register under Article 6, Paragraph (1), Item 11;
4. the exporting country.

(4) The terms and procedure for exercising the phyto-sanitary control upon importation shall be stipulated in:

1. the ordinance under Article 16 (2) - for the control at the places under Paragraph (3), Items 1 and 4;

2. an ordinance of the Minister of Agriculture and Foodstuffs - for the control at the places under Paragraph (3), Items 2 and 3.

(5) When exercising phyto-sanitary control upon importation, the checks can be performed at a reduced frequency.

(6) Phyto-sanitary control upon passing in transit shall be exercised at the places under Paragraph (3), Item 1 under terms and according to a procedure stipulated in the ordinance under Article 16 (2).

(7) A fee according to the tariff under Article 5 (1) shall be paid for the performance of a check upon importation or passing in transit.

Article 33. (1) When the phyto-sanitary control upon importation finds that the plants, plant products and other articles conform with the requirements of this act and/or of the instruments for the application of this act, the plant protection inspector shall admit them for free movement within the European Union by issuing a plant passport in the cases stipulated in the ordinance under Article 16 (2).

(2) When the inspection upon importation finds that the plants, plant products and other articles do not conform with the requirements of this acts and/or with the instruments for application of this act, the plant protection inspector shall immediately apply one or more of the following measures:

1. shall refuse to admit the import of the entire consignment of plants, plant products and other articles or of a part thereof;

2. shall order that the consignment move under official control;

3. shall order the removal of the contaminated parts of the consignment;

4. shall order the destruction of the entire consignment or of the parts removed from the consignment under Item 3;

5. shall impose quarantine on the consignment;

6. shall order appropriate processing or treatment of the consignment or parts thereof for the purpose of eliminating the risk of introduction and dissemination of quarantine pests.

(3) The expenses for implementation of the measures referred to in Paragraph (2) shall be at the expense of the importer.

Article 34. (1) The customs authorities shall immediately inform the plant protection

inspectors, when they find that no phyto-sanitary control has been exercised on imported plants, plant products and other articles under Article 32 (1).

(2) No release by the customs authorities and no transportation by the carriers respectively of plants, plant products and other articles under Paragraph (1) shall be permitted unless the appropriate phyto-sanitary control has been exercised.

Article 35. The persons who import plants, plant products and other articles under Article 32 (1) shall be obligated to:

1. comply with the requirements of this act and of the instruments for application of this act;
2. declare before the plant protection inspectors the plants, plant products and other article that they import;
3. provide for phyto-sanitary control the imported plants, plant products and other articles;
4. present a phyto-sanitary certificate for export from the country in which the plants, plant products and other articles have been produced and - in the cases of re-export - a phyto-sanitary certificate for re-export.

Article 36. (1) The phyto-sanitary control upon export and re-export of plants, plant products and other articles shall be exercised according to the phyto-sanitary requirements of the importing country under terms and according to a procedure stipulated in the ordinance under Article 16 (2).

(2) After completion of a check of compliance with the requirements under Paragraph (1), a phyto-sanitary certificate for export or re-export shall be issued.

(3) A fee according to the tariff under Article 5 (1) shall be paid for the performance of a check upon export or re-export.

Chapter Four

ACTIVE SUBSTANCES, ANTIDOTES, SYNERGISTS AND CO-FORMULANTS

Article 37. (1) Active substances, antidotes and synergists shall be approved, renewed and re-examined according to the procedure of Chapter II, Sections 1 and 2 of Regulation (EC) No. 1107/2009.

(2) Co-formulants are not included among the plant protection products in the cases under Article 27 of Regulation (EC) No. 1107/2009.

Article 38. (1) The procedure according to which the Republic of Bulgaria participates in a procedure for approval, renewal and re-examination of an active substance, an antidote or a

synergist in its capacity of reporting or co-reporting member-state shall be stipulated in an ordinance of the Minister of Agriculture and Foodstuffs.

(2) The respective fees according to the tariff under Article 5 (1) shall be paid for the activities for approval, renewal and re-examination of an active substance, antidote or synergist.

Article 39. (1) The persons who produce on the territory of the country active substances, antidotes or synergists shall submit before the Central Office of the BFSA a notification according to a template of the active substances, antidotes or synergists that they produce.

(2) The persons who import or introduce antidotes, synergists or approved active substances for the purpose of production of plant protection products shall submit before the Central Office of the BFSA a notification according to a template at least one month before each import or introduction.

(3) The persons who supply active substances, antidotes or synergists shall provide an information safety sheet in Bulgarian in accordance with Article 31 of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Regulation (EEC) No. 793/93 of the Council and Regulation (EC) No. 1488/94 of the Commission, as well as Directive 76/769/EEC of the Council and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission, hereinafter referred to as "Regulation (EC) No. 1907/2006 (REACH)".

Article 40. The active substances, antidotes and synergists shall be classified, packaged and labelled according to Regulation (EC) No.1272/2008 of the European Parliament and of the Council of 16 December 2008 concerning the Classification, Labelling and Packaging of Substances and Mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No.1907/2006 (OJ, L 353/1 of 31 December 2008), hereinafter referred to as "Regulation (EC) No. 1272/2008 (CLP)".

Article 41. (1) Unapproved active substances shall be imported or introduced after the issuing of a certificate for import or introduction of the batch of unapproved active substances by the Executive Director of the BFSA or by an official authorized thereby, if they are intended for production on the territory of the country of plant protection products intended for export.

(2) Unapproved active substances shall be produced, if they are intended for production on the territory of the country of plant protection products intended for export. The production of unapproved active substances shall also be permitted for the purpose of export.

(3) Unapproved active substances shall be stored, transported and exported from the territory of the country under terms and according to a procedure stipulated in the ordinance under Article 38 (1).

(4) Paragraphs (1) - (3) shall be applied provided there is a system for control over the import or introduction, production, storage, transport and export of unapproved active substances.

Article 42. (1) For the purpose of obtaining a certificate for import or introduction in the country of a batch of unapproved active substances, the persons shall submit before the Central Office of the BFSa an application according to a template and shall attach thereto the documents stipulated in the ordinance under Article 38 (1).

(2) The application and the documents attached under Paragraph (1) shall be checked by experts from the BFSa. If deficiencies and/or inconsistencies are found, the Executive Director of the BFSa or an official authorized thereby shall notify in writing the applicant and shall stipulate a deadline for remedying thereof.

(3) If the deficiencies and/or inconsistencies under Paragraph (2) are not remedied, the application shall be ignored without consideration and the applicant shall be notified in writing of that fact.

Article 43. (1) Within a 7-day time limit from the performance of the check under Article 42 (2) or from the remedy of the deficiencies and/or inconsistencies, the Executive Director of the BFSa or an officer authorized thereby shall issue a certificate for import or introduction of the batch of unapproved active substances.

(2) The certificate under Paragraph (1) shall be issued with a term of validity of 1 year and shall be entered into the register under Article 6, Paragraph (1), Item 7.

(3) A fee according to the tariff under Article 5 (1) shall be paid for the issuing of the certificate under Paragraph (1).

(4) If no judgment is passed on the application within the time limit referred to in Paragraph (1), it shall be deemed that this is an act of tacit consent and Articles 28 and 29 respectively of the Restriction of the Administrative Regulation and Administrative Control on Economic Activity Act shall be applied. The applicant shall have the right to import or to introduce the unapproved active substances that the application pertains to, after notifying in writing and in advance thereof the Central Office of the BFSa, and the Executive Director of the BFSa or an officer authorized thereby fails to pass judgment as to a refusal within a 7-day time limit of receiving the notification.

(5) In the cases of tacit consent, the entry into the register shall be performed with a 14-day time limit from the notification under Paragraph (4).

Chapter Five

PLANT PROTECTION PRODUCTS

Section I

General conditions

Article 44. (1) Plant protection products shall be placed on the market and used after the

issuing of a permit for placing on the market and use according to Regulation (EC) No. 1107/2009.

(2) The plant protection products shall be placed on the market in original packaging or repackaged with a label in Bulgarian.

(3) The Bulgarian Food Safety Agency shall create and keep a public register of the plant protection products, for which there is an application for authorization, and this register shall contain the date of application, the applicant, the active substances and the commercial name.

(4) When a plant protection product has been authorized or has been applied for authorization to be placed on the market and used under a specific commercial name, the same commercial name cannot be used in an application for authorization for placing on the marketing and using another products by another applicant.

(5) Within a 5-year period after the revocation or expiration of the term of an authorization for placing on the market and for using a specific plant protection product, its commercial name cannot be used for another product.

Article 45. (1) A permit for placing on the market and use of a plant protection product shall be issued by the Executive Director of the BFSA to a person established on the territory of a member-state, under terms and according to a procedure stipulated in an ordinance of the Minister of Agriculture and Foodstuffs.

(2) Fees according to the tariff under Article 5 (1) shall be paid for the activities for authorization of plant protection products.

(3) When a person under Paragraph (1) is not established on the territory of the Republic of Bulgaria, it shall authorize in writing a representative, hereinafter referred to as "authorized representative". The authorized representative shall be a natural person or a legal entity established on the territory of the country, who/which is explicitly authorized by the person under Paragraph (1) to act on his/her behalf and for his/her account before the BFSA for the purpose of fulfilling his/her obligations under this act. The date, content and signature of the authorization or empowerment must be certified by an official competent authority.

(4) The holder of a permit for placing on the market and using a plant protection product shall be responsible and liable for the plant protection products placed on the market. The designation of an authorized representative shall not relieve the holder of the permit of his/her responsibility or liability.

Article 46. (1) A plant protection product shall be permitted for placing on the market and use, when it conforms to the requirements of Chapter III, Section 1 of Regulation (EC) No. 1107/2009.

(2) The conformity of a plant protection product with the requirements under Paragraph (1) shall be ascertained by:

1. performing an evaluation of the plant protection product and of the active substance included therein, or

2. recognition of a report of an evaluation performed under Item 1 by a member-state.

(3) The type and the requirements to the evaluation under Paragraph (2), Item 1 shall be stipulated in the ordinance under Article 45 (1).

(4) The evaluation and/or the recognition of the report under Paragraph (2) shall be performed by:

1. experts of the BFSA;

2. external experts who meet the requirements stipulated in the ordinance under Article 45 (1).

(5) The persons under Paragraph (4) shall sign an affidavit of confidentiality according to a template, by virtue of which they shall undertake not to divulge the information presented to them for performing the evaluations or for recognizing the reports, as well as not to use it to their benefit or to the benefit of third parties.

Article 47. The plant protection products shall be produced, shall be placed on the market, shall be traded, shall be re-packaged, shall be transported and shall be stored under terms and according to a procedure stipulated in an ordinance of the Minister of Agriculture and Foodstuffs.

Article 48. (1) Plant protection products which are not authorized for placing on the market and for use can be produced, stored and transported on the territory of the country only in the cases under Article 28, Paragraph (2), Letters "c" and "d" of Regulation (EC) No. 1107/2009.

(2) The plant protection products produced under Paragraph (1) shall not be used on the territory of the country and shall be exported from the country up to 6 months prior to the expiration of their shelf life at the latest.

(3) The producers of plant protection products under Paragraph (1) shall notify the Central Office of the BFSA of the warehouses in which they store the products produced by them.

Article 49. (1) The producers of plant protection products shall submit before the Central Office of the BFSA a notification, according to a template, of the plant protection products that they produce on the territory of the country.

(2) The holders of permits for placing on the market and use of plant protection products shall submit before the Central Office of the BFSA a declaration, according to a template, according to Article 67 (3) of Regulation (EC) No. 1107/2009.

(3) The persons who produce, re-package, place on the market and trade in plant protection products shall keep and store documentation according to Article 67 (1) of Regulation (EC) No. 1107/2009.

(4) The persons who supply plant protection products shall provide an information safety list in Bulgarian in accordance with Article 31 of Regulation (EC) No. 1907/2006 (REACH).

(5) The persons who place on the market plant protection products shall develop and implement a system for blocking and recalling plant protection products from the market.

(6) (Effective 1.01.2016 - SG No. 61/2014) The persons who place on the market plant protection products and the persons who re-package plant protection products shall develop and implement a system for collecting back the empty packagings from the end user of plant protection products.

(7) The system referred to in Paragraph (6) shall be developed and implemented in accordance with the Waste Management Act.

Article 50. (1) The Bulgarian Food Safety Agency shall create and keep a data base of the plant protection products placed on the market and stored on the territory of the country.

(2) The Bulgarian Food Safety Agency shall provide information on the risks and on the possible acute and chronic consequences for the health of humans, non-target organisms and the environment as a consequence of the use of plant protection products, as well as of the use of non-chemical alternatives. The information shall be published on the web page of the BFSA.

(3) The Bulgarian Food Safety Agency shall, upon request, provide to the Ministry of Environment and Waters and to the Ministry of Health available data on the types of plant protection products used in the country. The data shall be provided by regions.

(4) The Bulgarian Food Safety Agency shall participate in the collection of information in the process of conducting research and checks on the types of plant protection products used on the territories of the sanitary protection zones around the water sources for potable and municipal water supply and the water sources of mineral waters used for therapeutic, prophylactic and potable and hygiene needs. The information shall be provided to the Ministry of Environment and Waters, to the Ministry of Health or to their territorial units.

Article 51. The plant protection products shall be unfit for use, when:

1. their shelf life has expired;
2. their physical, chemical or technical parameters, composition, type of formulation or their other characteristics do not conform to those approved upon their authorization and/or when their packagings or labels are damaged.

Article 52. The import, introduction into the country, placing on the market or use of the following products shall be strictly prohibited:

1. unauthorized or unfit-for-use plant protection products;

2. plant protection products from persons who do not hold a permit for placing on the market and use.

Section II

Council for Plant Protection Products

Article 53. (1) A Council for Plant Protection Products (CPPP) shall be created at the Executive Director of the BFSA and this Council shall be a permanent consultative authority on matters pertaining to the plant protection products.

(2) The Minister of Agriculture and Foodstuffs shall issue regulations on the organization and activity of the CPPP and, upon a proposal of the Executive Director of the BFSA, shall designate its members, where representatives of the Ministry of Agriculture and Foodstuffs, Ministry of Health, Ministry of Environment and Waters and scientific institutes can participate in the said Council.

(3) The members of the CPPP shall sign an affidavit of confidentiality according to a template, by virtue of which they shall undertake not to divulge the information presented to them in the process of authorization of the plant protection products, as well as not to use it to their benefit or to the benefit of third parties.

Article 54. The Council for Plant Protection Products shall make decisions and shall make proposals to the Executive Director of the BFSA for:

1. authorizing the placing on the market and use of a plant protection product according to Chapter III, Section I of Regulation (EC) No. 1107/2009 or refusing such authorization;

2. (effective 1.01.2015 - SG No. 61/2014) authorizing the placing on the market and use of a plant protection product in the form of a ready-made solution or refusing such authorization;

3. renewing the authorization for placing on the market and use of a plant protection products or refusing to renew;

4. amending the authorization for placing on the market and use of a plant protection product, including an authorization for placing on the market and use of a ready-made solution thereof or refusing to do so;

5. revoking or terminating an authorization for placing on the market and use of a plant protection product, including revoking or terminating an authorization for placing on the market or use of a ready-made solution thereof.

Section III

Authorizing the placing on the market and use of plant protection products

Article 55. (1) A plant protection product shall be authorized for placing on the market and use under the terms and according to the procedure of Articles 33-39 of Regulation (EC) No. 1107/2009 and of the ordinance under Article 45 (1).

(2) Within a 14-day time limit from receiving a proposal of the CPPP under Article 54, the Executive Director of the BFSA shall authorize by an order the placing on the market and use of a plant protection product and shall issue a permit or shall issue a well-grounded refusal to authorize the plant protection product when it fails to conform with some of the requirements of Article 46 (1).

(3) The refusal under paragraph (2) shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure.

(4) The permit issued under Paragraph (2) shall be entered into the register under Article 6, Paragraph (1), Item 1.

(5) Within a 14-day time limit from receiving the permit under Paragraph (2), the holder of the permit shall present to the Central Office of the BFSA a sample of a label under which the plant protection product shall be placed on the market and used.

Article 56. A plant protection product shall be authorized for temporary placing on the market and use under the terms and according to the procedure of Article 30 of Regulation (EC) No. 1107/2009 and Article 55.

Article 57. A plant protection product shall be authorized for placing on the market and use through mutual recognition of permits under the terms and according to the procedure of Article 40-42 of Regulation (EC) No. 1107/2009, of the ordinance under Article 45 (1) and according to the procedure of Article 55 Paragraphs 2 - 5.

Article 58. A low-risk plant protection product shall be authorized for placing on the market and use under the terms and according to the procedure of Article 47 of Regulation (EC) No. 1107/2009 and Article 55.

Article 59. A plant protection product that contains a genetically-modified organism shall be authorized for placing on the market and use according to the requirements of the Genetically-Modified Organisms Act and under the terms and procedure of Article 48 of Regulation (EC) No. 1107/2009 and Article 55.

Article 60. (1) The expansion of the scope of an authorization for placing on the market and use of a plant protection product for minimal use shall be permitted under the terms and according to the procedure of Article 51 of Regulation (EC) No. 1107/2009, of the ordinance under Article 45 (1) and according to the procedure of Article 55, Paragraphs (2) - (5).

(2) No fees shall be due and payable for the issuing of a permit for placing on the market and use of a plant protection product for minimal use.

(3) If within the time limit under Article 55 (5) the holder of the permit for placing on the market and use of the plant protection product fails to present a sample of a label, the permit under Article 55 (2) shall be published on the web page of the BFSA.

Article 61. (1) A plant protection product shall be authorized for placing on the market and use for parallel trade under the terms and according to the procedure of Article 52 of Regulation (EC) No. 1107/2009 and of the ordinance under Article 45 (1).

(2) Within a 14-day time limit from receiving a proposal of the CPPP under Article 54, the Executive Director of the BFSA shall authorize by an order the plant protection product for parallel trade and shall issue a permit or shall issue a well-grounded refusal to authorize the plant protection product when the plant protection product is not identical to the reference product.

(3) The refusal under paragraph (2) shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure.

(4) The permit issued under Paragraph (2) shall be entered into the register under Article 6, Paragraph (1), Item 1.

(5) Within a 14-day time limit from receiving the permit under Paragraph (2), the holder of the permit shall present to the Central Office of the BFSA a sample of a label under which the plant protection product shall be placed on the market and used.

(6) Prior to the placing on the market of a plant protection product under Paragraph (1), the holder of the permit for parallel trade shall notify in writing the Central Office of the BFSA of the quantity and the number of the respective batch of the plant protection product that shall be placed on the market, as well as of the taking of a control sample from the product.

Article 62. (1) A plant protection product shall be authorized for placing on the market for limited and controlled use under the terms and according to the procedure of Article 53 of Regulation (EC) No. 1107/2009 and of the ordinance under Article 45 (1) in the case of a threat to the plants and plant products which cannot be contained by means of the plant protection products, means and methods applicable in the Good Plant Protection Practice.

(2) Within a 3-day time limit of receiving a proposal of the CPPP under Article 54, the Executive Director of the BFSA shall authorize by an order the placing on the market for limited and controlled use of a plant protection product or shall issue a well-grounded refusal to authorize the plant protection product for placing on the market for limited and controlled use, when there is no threat to the plants and plant products or the threat can be contained in another manner.

(3) When the plant protection product has not been authorized for placing on the market and use, the quantities to be placed on the market for limited and controlled use shall be stipulated in the order under Paragraph (2).

(4) The refusal referred to in paragraph (2) shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure.

(5) The plant protection products authorized by virtue of the order under Paragraph (2) for placing on the market for limited and controlled use shall be entered into the register under Article 6, Paragraph (1), Item 1.

(6) Within a 1-day time limit from the receiving the order under Paragraph (2), the applicant shall present to the Central Office of the BFSa a sample of a label under which the plant protection product shall be placed on the market for limited and controlled use.

(7) A plant protection product which has been authorized for placing on the market and use can be authorized for placing on the market for limited and controlled use also on the initiative of the BFSa, when the use for which it shall be applied is not included in the permit of the product.

(8) In the case referred to in Paragraph (7), within a 1-day time limit from the issuing of the order under Paragraph (2), the BFSa shall make the order known to the holder of the permit, while stipulating for him/her up to a 3-day time limit for presenting a sample of a label under which the plant protection product shall be placed on the market for limited and controlled use.

(9) When the holder of the permit fails to present a sample of a label within the time limit under Paragraph (8), the order under Paragraph (2) shall be published on the web page of the BFSa.

Article 63. (1) A plant protection product, which is not authorized for other uses but is only authorized for placing on the market for limited and controlled use, shall be used only in the fields for which it is authorized.

(2) Upon every delivery, a person who places on the market a product under Paragraph (1) shall notify the Central Office of the BFSa of the quantities of the plant protection product delivered in the country.

(3) A person, who has placed on the market a product under Paragraph (1), shall, within 14 days after the expiration of the term of the permit of the product, notify the Central Office of the BFSa of the quantities of the plant protection product placed on the market and of the quantities of the plant protection product not sold.

(4) When there have remained unsold quantities of the product under Paragraph (1), the person who placed it on the market shall indicate in the notification under Paragraph (3) whether the product shall be decontaminated or exported from the country.

(5) Within a 7-day time limit of the decontamination or export of the product under Paragraph (1), the person who placed it on the market shall present to the Central Office of the BFSa written proof thereof.

Article 64. (1) A plant protection product shall be authorized for use in the performance of scientific research and/or development under the terms and according to the procedure of Article 54 of Regulation (EC) No. 1107/2009 and of the ordinance under Article 45 (1).

(2) The term of the permit under Paragraph (1) cannot be longer than the term of the

experiment, series of experiments or program of experiments.

Article 65. (Effective 1.01.2015 - SG No. 61/2014) (1) An authorized plant protection product shall be placed on the market and used in the form of a ready-made solution after the issuing of a permit for placing on the market and use in the form of a ready-made solution under the terms and according to the procedure of the ordinance under Article 45 (1).

(2) The ready-made solution shall be authorized in one of the concentrations of the work solutions for the respective use as approved upon the authorization of the plant protection product.

(3) Within a 60-day time limit from submission of an application for the issuing of a permit under Paragraph (1), upon a proposal of the CPPP under Article 54, the Executive Director of the BFSA shall authorize by an order the placing on the market and use of a plant protection product in the form of a ready-made solution and shall issue a permit or shall issue a well-grounded refusal to authorize the ready-made solution, when its fitness-for-use has not been proven.

(4) The term of validity of the permit issued cannot be longer than the term of validity of the permit for placing on the market and use of the plant protection product.

(5) The refusal under paragraph 3 shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure.

(6) The permit issued under Paragraph (3) shall be entered into the register under Article 6, Paragraph (1), Item 1.

(7) Within a 14-day time limit from receiving the permit under Paragraph (3), the holder of the permit shall present to the Central Office of the BFSA a sample of a label under which the plant protection product shall be placed on the market and used in the form of a ready-made solution.

(8) No permit shall be issued for a ready-made solution from a plant protection product which is:

1. authorized for placing on the market for limited and controlled use, for parallel trade or for use in the performance of scientific research and/or development;

2. categorized in the 1st professional category of use.

Article 66. (1) The permit for placing on the market and use of a plant protection product shall be renewed under the terms and according to the procedure of Article 43 of Regulation (EC) No. 1107/2009 and of the ordinance under Article 45 (1).

(2) In the cases of Article 43 (6) of Regulation (EC) No. 1107/2009, the Executive Director of the BFSA shall extend by an order the term, for which the plant protection product is authorized and shall re-issue the permit for placing on the market and use of the plant protection product.

Article 67. (1) Withdrawal or revocation of a permit for placing on the market and use of a plant protection product shall be performed after its review within the term of its validity under the terms and according to the procedure of Article 44 of Regulation (EC) No. 1107/2009 and according to a procedure stipulated in the ordinance under Article 45 (1). A permit for placing on the market and use of a plant protection product shall be revoked also when it has not been renewed according to the procedure of Article 66.

(2) Within a 14-day time limit from receiving the proposal of the CPPP under Article 54, the Executive Director of the BFSA shall amend by an order the permit for placing on the market and use of the plant protection product and shall re-issue it or shall revoke by an order the permit.

(3) The order referred to in paragraph (2) shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure. When the permit is revoked by an order, the appeal shall not suspend the enforcement.

(4) The permit re-issued or the order for revoking the permit respectively shall be entered into the register under Article 6, Paragraph (1), Item 1.

(5) When the permit for placing on the market and use of a plant protection product is amended or revoked by an order under Paragraph (2), the permit for placing on the market and use of that same product in the form of a ready-made solution shall also be amended or revoked accordingly according to the procedure of Paragraph (1) - (4).

(6) The procedure of Paragraphs (1) - (4) respectively shall be used for amending or revoking also the permits for placing on the market and use for parallel trade of plant protection products, for which the plant protection product with the revoked or amended permit for placing on the market and use under Paragraph (2) is a reference product in the sense of Article 52 of Regulation (EC) No. 1107/2009.

Article 68. (1) Amendment or revocation of a permit for placing on the market and use of a plant protection product shall be performed upon the request of its holder under the terms and according to the procedure of Article 45 of Regulation (EC) No. 1107/2009 and according to terms and a procedure stipulated in the ordinance under Article 45 (1).

(2) Within a 14-day time limit from receiving a proposal of the CPPP under Article 54, the Executive Director of the BFSA shall amend by an order the permit for placing on the market and use of a plant protection product and shall re-issue it or shall issue a well-grounded refusal to amend the permit, when the product fails to conform with some of the requirements of Article 46 (1) and shall revoke the permit by an order respectively.

(3) The refusal under paragraph (2) shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure.

(4) The permit re-issued or the order for revoking the permit respectively shall be entered into the register under Article 6, Paragraph (1), Item 1.

(5) When the amendment relates to circumstances and data, for which no conformity with the requirements of Article 46 (1) has to be established, the order under Paragraph (2) shall be issued within a 14-day time limit from receiving a request under Paragraph (1).

(6) When the permit for placing on the market and use of a plant protection product is amended or revoked by an order under Paragraph (2), the permit for placing on the market and use of that same product in the form of a ready-made solution shall also be amended or revoked accordingly according to the procedure of Paragraph (2) - (4).

(7) The procedure of Paragraphs (2) - (4) respectively shall be used for amending or revoking also the permits for placing on the market and use for parallel trade of plant protection products, for which the plant protection product with the re-issued or revoked permit for placing on the market and use under Paragraph (2) is a reference product in the sense of Article 52 of Regulation (EC) No. 1107/2009.

Article 69. (1) For plant protection products, the permits of which for placing on the market and use have been amended, revoked or terminated, grace periods for decontamination, storage, placing on the market and use shall be stipulated under the terms of Article 46 of Regulation (EC) No. 1107/2009 and according to a procedure stipulated in the ordinance under Article 45 (1).

(2) When the permit for placing on the market and use of a plant protection product has been revoked because of reasons related to the protection of the health of humans and animals or of the environment, the placing on the market and use of the products shall be terminated immediately and a time limit for withdrawal from the market, storage and decontamination of not more than 6 months shall be stipulated for the available quantities.

(3) The grace periods under Paragraph (1) and the time limit under Paragraph (2) shall be stipulated in the order by virtue of which the permit for placing on the market and use of the plant protection product is amended, revoked or terminated.

Section IV

Biological testing of plant protection products

Article 70. (1) The biological testing of plant protection products shall be performed at official bases of the BFSA and at approved bases of natural persons and legal entities entered in registered under Article 6, Paragraph (1), Item 3.

(2) The Bulgarian Food Safety Agency can commission biological testing of plant protection products to scientific research institutes.

(3) The Bulgarian Food Safety Agency shall exercise control over the performance of the biological testing at the places referred to in Paragraphs (1) and (2).

(4) The biological testing of the plant protection products shall be performed under terms and according to a procedure stipulated in an ordinance of the Minister of Agriculture and Foodstuffs.

(5) The official bases of the BFSA shall be designated by an order of the Executive Director. Prices according to the price schedule under Article 5 (1) shall be paid for biological testing at the official bases.

Article 71. (1) The biological testing of plant protection products shall be performed in accordance with the rules of Good Experimental Practice.

(2) Plant protection products, which have a commercial name or a number of the producer's code for development of the respective product, shall be subject to biological testing.

(3) The plants and plant products treated by plant protection products, in the composition of which there are included one or more active substances, which are not contained in the composition of an authorized product or which are contained in the composition of a product authorized for use against a different pest, shall be destroyed according to the procedure stipulated in the ordinance under Article 70 (4).

Article 72. (1) For the purpose of performance of biological testing of a plant protection product, the applicant shall conclude a contract with the BFSA or with a holder of a certificate for biological testing of plant protection products respectively.

(2) Whenever necessary, the BFSA shall conclude contracts with owners and/or users of agricultural land, according to which it shall perform biological testing of plant protection products on the agricultural crops grown.

(3) In the case of Paragraph (2), the owners of plant and plants products destroyed under Article 71 (3) shall be compensated with financial resources from the budget of the BFSA according to a procedure stipulated in the ordinance under Article 31 (2). The financial resources shall be provided subject to strict adherence to the provisions of the law of the European Union in the field of state aid.

Article 73. (1) A natural person's or a legal entity's base for biological testing of plant protection products shall be approved, when it meets the requirements stipulated in the ordinance under Article 70 (4) and when:

1. it has at least two testing locations situated in the Northern and in the Southern part of the territory of the country;

2. one person with the following qualification is procured for each one of the locations referred to in Item 1:

a) higher education in the field of agrarian sciences with a professional concentration of "Plant Protection" and a certificate under Article 83, who is to manages the biological testing;

b) higher education in the field of agrarian sciences with a professional concentration of "Plant Protection" or "Plant Growing" or high school vocational education in the field of plant growing and a certificate under Article 83, who is to perform the biological testing;

3. the natural person or legal entity or parties related thereto in the sense of the Small- and Medium- Sized Enterprises Act do not have a vested interest in the results from the biological testing and do not perform an activity which is subject to control under this act.

(2) When the base for biological testing of plant protection products is used by a natural person or by a legal entity on the grounds of an instituted right of use, the terms of Paragraph (1), Item 3 shall also be applied in regard to the owner of the base.

(3) The managers of the biological testing by locations can carry out the function also of the persons under Paragraph (1), Item 2, Letter "b".

(4) The obligations of the managers of the biological testing and of the persons under Paragraph (1), Item 2, Letter "b" shall be stipulated in the ordinance under Article 70 (4).

Article 74. (1) For the approval of a base for biological testing, the persons shall submit before the Central Office of the BFSa an application according to a template and shall attach thereto the documents stipulated in the ordinance under Article 70 (4).

(2) The application and the documents attached under Paragraph (1) shall be checked by a commission appointed by an order of the Executive Director of the BFSa. If deficiencies are found, the Executive Director or an officer authorized thereby shall notify in writing the applicant and shall stipulate a deadline for remedying thereof.

(3) If the deficiencies under Paragraph (2) are not remedied, the application shall be ignored without consideration and the applicant shall be notified in writing of that fact.

(4) Within a 30-day time limit from the submission of the application or from the remedying of the deficiencies under Paragraph (2), the commission shall perform a check of the documents and of the places, in which the biological testing shall be performed to find out if they conform to the requirements of the ordinance under Article 70 (4). If inconsistencies are found, the commission shall give recommendations and shall stipulate a deadline for the remedying thereof. Within a 3-day time limit from the remedying of the inconsistencies, a second check shall be performed.

(5) Within a 7-day time limit from the performance of the check under Paragraph (4), the commission shall prepare a written opinion to the Executive Director of the BFSa with a proposal for either approving the base for biological testing of plant protection products, or for refusing to approve it.

Article 75. (1) Within a 7-day time limit of receiving the opinion under Article 74 (5), the Executive Director of the BFSa or an officer authorized thereby either shall approve the base for biological testing of plant protection products and issue a certificate for biological testing, or shall issue a well-grounded refusal to issue such a certificate, when inconsistencies with the requirements of the ordinance under Article 70 (4) are found.

(2) The refusal under Paragraph (1) shall be announced and may be appealed against

according to the procedure laid down in the Code of Administrative Procedure.

(3) The non-issuance of an opinion within the time limit stipulated in Paragraph (1) shall not be considered to be a tacit consent.

(4) The certificate shall be issued for a term of 10 years and the rights and obligations thereunder cannot be transferred to another person.

(5) The certificates issued under Paragraph (1) shall be entered into the register under Article 6, Paragraph (1), Item 3.

(6) A fee according to the tariff under Article 5 (1) shall be paid for the approval of a base for biological testing of plant protection products and for the issuing of a certificate for biological testing.

Article 76. (1) Within a 7-day time limit from the occurrence of a change in the circumstances pertaining to a certificate issued under Article 75 (1), the holder of this certificate shall submit before the Central Office of the BFSA an application according to a template and shall attach thereto the documents certifying the change and a document certifying that a fee according to the tariff under Article 5 (1) has been paid.

(2) The certificate shall be re-issued under the terms and according to the procedure of Article 74, Paragraphs (2) - (5) and Article 75, Paragraph (1) - (5). If the change involves circumstances that do not require an on-the-spot check, the certificate shall be re-issued within a 7-day time limit.

Article 77. (1) The Executive Director of the BFSA or an officer authorized thereby shall cancel, by an order, an already issued certificate for biological testing of plant protection products:

1. upon written request by the holder of the certificate;
2. in the case of blatant or systematic violations.

(2) The order under Paragraph (1), Item 2 shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure.

Article 78. (1) The import or introduction of plant protection products intended for biological testing shall be performed only by the persons, who have applied for the biological testing of these products, after the issuing of a certificate by the Executive Director of the BFSA or by an officer authorized thereby.

(2) The procedure and terms for the issuing of a certificate under Paragraph (1) shall be stipulated in the ordinance under Article 70 (4).

Section V

Classification, packaging, labelling and categorization of plant protection products

Article 79. (1) The plant protection products shall:

1. be classified in accordance with Regulation (EC) No.1272/2008 (CLP);
2. be labelled in accordance with Regulation (EC) No. 1107/2009, Regulation (EC) No.547/2011, Regulation (EC) No.1272/2008 (CLP).

(2) The plant protection products shall be packaged in accordance with Regulation (EC) No. 1107/2009 and Regulation (EC) No.1272/2008 (CLP). The contraption for closing the packaging must contain a seal or another sealing device, so that upon opening of the packaging the integrity of the seal or sealing device shall be disrupted.

Article 80. (1) The plant protection products shall be categorized in one of two possible categories - professional category and non-professional category.

(2) The professional category of use shall be sub-divided into two sub-categories - first professional category and second professional category.

(3) The category of use of a plant protection product shall be determined at the time of its authorization for placing on the market and use according to criteria stipulated in the ordinance under Article 45 (1) depending on:

1. the terms and restrictions of the approval of the active substances, antidotes and synergists;

2. the classification of the plant protection product in one or more categories according to Article 2 of the Protection from the Harmful Impact of Chemical Substances and Mixtures Act and in one or more hazard classes according to Regulation (EC) No. 1272/2008 (CLP);

3. the evaluation of the toxicological and eco-toxicological characteristics of the plant protection product, its physical and chemical properties and behaviour in the environment;

4. the announced uses and category of consumers according to Regulation (EC) No. 547/2011.

(4) Plant protection products, which contain an active substance, which is a candidate for replacement, shall be categorized as belonging to the professional category.

(5) Plant protection products, which contain active substances, which are of low risk or which are primary substances, shall be categorized as belonging to the non-professional category.

(6) The category of use shall be recorded into the permit for placing on the market and use of the plant protection product.

Section VI

Advertising of plant protection products

Article 81. (1) The advertising of a plant protection product shall be performed in accordance with the terms of its permit for placing on the market and use in the Republic of Bulgarian and in accordance with the requirements of Article 66 of Regulation (EC) No. 1107/2009.

(2) The advertising of a plant protection product must contain information on the restriction of use and warning phrases and symbols, established in the process of labelling, or must refer the user to the label of the product or to the web page of the producer, where these restriction, symbols and signs are indicated.

Article 82. The following shall be prohibited:

1. the advertising of an unauthorized plant protection product or of a product for use outside its authorized use;

2. the advertising and publishing of false instructions for trade, storage and use of a plant protection product;

3. the provision of false consultations as to the use of a plant protection product;

4. claiming non-existent properties of a plant protection product;

5. the failure to mention the dangerous properties of a plant protection product;

6. the use of words that present a plant protection product as safe or create a possibility for underestimating its hazards;

7. the comparison of the properties of an advertised plant protection product to the properties of analogous products of other producers.

Section VII

Training and certification of the persons who have the right to use plant protection products from the professional category of use

Article 83. The distributors, the consultants and the professional users of plant protection products from the professional category of use must hold a certificate issued by the Executive Director of the BFSA or by an officer authorized thereby.

Article 84. (1) The professional users, the distributors and the consultants with higher

education in the field of agrarian sciences with a professional concentration of "Plant Protection" or "Plant Growing" shall be entitled to receive a certificate under Article 83.

(2) Other than the case under Paragraph (1), each professional user and distributor shall receive a certificate under Article 83 after undergoing training according to a curriculum approved by the Executive Director of the BFSA and after successfully passing an exam. The training can be by personal attendance or by remote means.

Article 85. (1) The training under Article 84 (2) shall be conducted by the BFSA, schools and institutions of higher education in the system of vocation education and training according to curricula that include as minimum the topics set out in Appendix No.2.

(2) The curricula under Paragraph (1) shall be developed by the training institutions by taking into consideration the specific functions and responsibilities of the persons under Article 84 (2).

Article 86. In order to receive a certificate under Article 83, the professional users, the distributors and the consultants shall submit before the RFSD of their permanent address an application according to a template and shall attach thereto the following:

1. a certified copy from the diploma of higher education in the field of agrarian sciences with a professional concentration of "Plant Protection" or "Plant Growing" - for the persons under Article 84 (1);

2. a certified copy of a document of completed training - for the persons under Article 84 (2).

Article 87. (1) Within a 14-day time limit from the submission of the application under Article 86, the Executive Director of the BFSA or an officer authorized thereby shall issue a certificate for use of plant protection products from the professional category of use according to a template.

(2) The certificate shall be issued to the persons:

1. under Article 84 (1) - for an indefinite term;

2. under Article 84 (2) - for a term of validity of 10 years.

(3) The certificate issued shall be entered into the register under Article 6, Paragraph (1), Item 13.

Article 88. (1) The certificate with a term of validity of 10 years shall be renewed according to the procedure of Articles 86 and 87.

(2) The training under Article 84 (2) must have been completed within a time limit of 1 year prior to submission of the application for renewal of the certificate.

Article 89. (1) The Executive Director of the BFSA or an officer authorized thereby shall cancel, by the order, the certificate under Article 83:

1. upon written request by the holder of the certificate;
2. in the case of blatant or systematic violations.

(2) In the cases of Paragraph (1), Item 2, the certificate shall become null and void for a period of up to three years.

(3) The order under Paragraph (1), Item 2 shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure. The appeal shall not suspend the enforcement.

Article 90. (1) Each year the Bulgarian Food Safety Agency shall prepare up-to-date information on the training topics under Appendix No.2.

(2) The information under Paragraph (1) shall be published on the web page of the BFSA and shall be provided through the RFSD to the holders of a certificate under Article 83 for updating of their knowledge.

Section VIII

Trade, re-packaging and storage of plant protection products

Article 91. (1) The trade in plant protection products shall be performed by persons who are traders in the sense of the Commerce Act and who hold a certificate for trade in plant protection products issued by the Director of the RFSD.

(2) In order to perform their activity, the persons under Paragraph (1) must have trading sites which are:

1. warehouses for trade in plant protection products, and/or
2. agricultural pharmacies.

(3) For the sites under Paragraph (2), Item 1, the traders must have recruited persons of higher education in the field of agrarian sciences with a professional concentration of "Plant Protection" or "Plant Growing".

(4) Only plant protection products from the second professional category and/or from the non-professional category of use in packaging containing up to 1 litre/kilogram shall be traded in the sites under Paragraph (2), Item 2.

(5) Plant protection products from the professional category of use shall be sold only to

persons who hold a certificate under Article 83.

Article 92. (1) A person holding a certificate under Article 83 shall be procured in the sites under Article 91 (2).

(2) The person under Paragraph (1) shall be present in the site for trade in plant protection products during the sale and shall provide information on the use of the plant protection products, the risk to the health of humans, animals and the environment, as well as on the safety instructions. When it comes to a sale to non-professional users, information shall also be provided on the threats, exposure, correct storage, use, application of the plant protection products and the safe decontamination of the waste thereof in accordance with the Waste Management Act, as well as on lower risk alternatives.

(3) The obligations of the person under Paragraph (1) shall be stipulated in the ordinance under Article 47.

Article 93. (1) In order to receive a certificate for trade in plant protection products, the persons shall submit before the RFSD, on the territory of which the trading site is located, an application according to a template and shall attach thereto the documents stipulated in the ordinance under Article 47.

(2) The application and the documents attached under Paragraph (1) shall be checked by inspectors from the RFSD. If deficiencies and/or inconsistencies are found, the Director of the RFSD or an officer authorized thereby shall notify in writing the applicant and shall stipulate a deadline for remedying thereof.

(3) If the deficiencies and/or inconsistencies are not remedied, the application shall be ignored without consideration and the applicant shall be notified in writing of that fact.

(4) Within a 3-day time limit from the submission of the application under Paragraph (1) or from the remedying of the inconsistencies under Paragraph (2), the inspector shall prepare a written opinion to the Director of the RFSD with a proposal for the issuing of a certificate for trade in plant protection products.

Article 94. (1) Within a 3-day time limit from receiving the opinion under Article 93 (4), the Director of the RFSD shall issue a certificate under Article 91 (1) for trade in plant protection products.

(2) The certificate shall be issued for a term of validity of 10 years.

(3) A fee according to the tariff under Article 5 (1) shall be paid for the issuing of a certificate for trade in plant protection products.

(4) The certificate issued shall be entered into the register under Article 6, Paragraph (1), Item 4.

Article 95. (1) Within a 7-day time limit from the occurrence of a change in the

circumstances pertaining to a certificate issued under Article 94 (1), the holder of this certificate shall submit before the respective RFSD an application according to a template and shall attach thereto the documents certifying the change and a document certifying that a fee according to the tariff under Article 5 (1) has been paid.

(2) The certificate shall be re-issued under the terms and according to the procedure of Article 93, Paragraphs (2) - (4) and Article 94.

Article 96. (1) The plant protection products shall be re-packaged when permits for placing on the market or for parallel trade have been issued for them.

(2) The plant protection products shall be re-packaged in packagings which conform to the requirements for storage and transportation of the respective plant protection product.

(3) The re-packaged plant protection products shall be entered into the register under Article 6, Paragraph (1), Item 2.

(4) The re-packaging of plant protection products shall be performed by persons who are traders in the sense of the Commerce Act and who hold a certificate for re-packaging of plant protection products issued by the Director of the RFSD.

(5) The re-packaging shall be performed in a site for re-packaging of plant protection products that conforms to the requirements stipulated in the ordinance under Article 47.

(6) The activities at a site for re-packaging of plant protection products shall be performed by persons holding a certificate under Article 83.

(7) The obligations of the persons under Paragraph (6) shall be stipulated in the ordinance under Article 47.

Article 97. (1) The certificate for re-packaging of plant protection products shall be issued under the terms and according to the procedure of Article 93 and Article 94, Paragraphs (1) - (3) and shall be entered into the register under Article 6, Paragraph (1), Item 5.

(2) In the case of a change in the circumstances pertaining to a certificate issued under Paragraph (1), Article 95 shall be applied.

Article 98. The holders of a certificate for re-packaging of plant protection products shall be obligated:

1. to conclude contracts for re-packaging with the holders of permits for placing on the market and use or of permits for parallel trade of plant protection products;

2. within a 7-day time limit from the conclusion of a contract under Item 1, to present to the Central Office of the BFSa a certified copy of the contract in its part concerning the type of plant protection products that will be re-packaged, the material and the capacity of the packaging and the term of the contract;

3. to store the documentation on the plant protection products that have been re-packaged for at least 5 years from the date of the re-packaging.

Article 99. (1) The plant protection products shall be stored according to the requirements indicated on the label in specially designated places in:

1. warehouses of a producer of plant protection products;
2. warehouses for trade in plant protection products;
3. sites for re-packaging of plant protection products;
4. warehouses for storage of plant protection products at an agricultural producer, when they are intended for use in the farm of the agricultural producer.

(2) The requirements to the warehouses under Paragraph (1), Item 1 and 4 shall be stipulated in the ordinance under Article 47.

Article 100. (1) The plant protection products which are unfit for use or which have not been authorized for placing on the market and use shall be stored at specially designated places at the sites and in the warehouses under Article 99 (1) and shall be marked with the words "UNFIT" and "UNAUTHORIZED" respectively.

(2) The plant protection products that are to be decontaminated shall be decontaminated according to the Waste Management Act.

Article 101. The following shall be prohibited:

1. the storage for the purpose of sale, the trade and the re-packaging of unauthorized and/or unfit-for-use plant protection products;
2. the storage for the purpose of sale and the trade in plant protection products outside of the sites under Article 91 (2);
3. the trade in plant protection products within the sites under Article 91 (2) but in the absence of the persons under Article 92 (1);
4. the storage and the trade in plant protection products from the first professional category of use in agricultural pharmacies.
5. the storage and the trade in plant protection products in packaging containing more than 1 litre/kilogram in agricultural pharmacies;
6. (effective 26.11.2015 - SG No. 61/2014) the sale of plant protection products from the professional category of use to persons who do not hold a certificate under Article 83;

7. the sale of plant protection products the integrity of the packaging or labelling of which has been disrupted;

8. the re-packaging of the plant protection products outside of the sites under Article 96 (5);

9. the re-packaging of plant protection products, for which there are no contracts concluded under Article 98 (1).

Article 102. (1) The Director of the RFSD shall suspend by an order the effect of a certificate for:

1. trade in plant protection products for a period of:

a) two years - in the case of blatant or systematic violations;

b) one year - in the case of trade in unauthorized or unfit-for-use plant protection products, with the exception of the cases under Article 100 (1);

c) six months - in the case of non-compliance with at least two recommendations issued within a period of 1 year;

d) three months - in the case of sale of plant protection products in an agricultural pharmacy by a person other than the persons under Article 92 (1);

2. re-packaging of plant protection products for a period of:

a) two years - in the case of blatant or systematic violations;

b) one year - in the case of re-packaging of unauthorized or unfit-for-use plant protection products;

c) eight months - in the case of re-packaging of plant protection products without a contract concluded under Article 98 (1);

d) six months - in the case of non-compliance with at least two recommendations issued within the period of one year;

e) three months - in the case of re-packaging of plant protection products, when the activities at the site are performed by persons without a certificate under Article 83.

(2) The order under Paragraph (1) shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure. The suspension of the effect of the certificate shall be recorded in the register under Article 6, Paragraph (1), Items 4 or 5.

(3) After expiration of the respective time period under Paragraph (1), the validity of a certificate for trade in plant protection products or for re-packaging of plant protection products

shall be renewed ex officio and this fact shall be recorded in the register under Article 6, Paragraph (1), Items 4 or 5.

Article 103. The Director of the RFSD shall cancel by an order a certificate for trade in plant protection products or for re-packaging of plant protection products:

1. upon written request by the holder of the certificate;
2. upon termination of the activity or deletion of the legal entity or of the sole trader.

Section IX

Use of plant protection products

Article 104. (1) The plant protection products shall be used:

1. in accordance with Article 55 of Regulation (EC) No. 1107/2009;
2. according to the specific measures for protection of the aquatic environment (surface and ground waters) and of the potable water under Article 125 (2);
3. under terms and according to a procedure stipulated in an ordinance of the Minister of Agriculture and Foodstuffs.

(2) The plant protection products can be used also according to the specific integrated pest management principles.

(3) When using plant protection products, protection zones and clearances from neighbouring sensitive crops shall be respected. The protection zones and the clearances shall be stipulated in the ordinance under Paragraph (1), Item 3.

Article 105. Depending on their category of use, the plant protection products shall be applied by the users as follows:

1. plant protection products from the 1st professional category of use - by users holding a certificate under Article 83 and under the supervision of a person of higher education in the field of the agrarian sciences with a professional concentration of "Plant Protection" or "Plant Growing";
2. plant protection products from the 2nd professional category of use - by persons who hold a certificate under Article 83.
3. plant protection products from the non-professional category of use - by persons who have turned 18 years of age.

Article 106. The plant protection products shall be applied by means of specialized equipment and machinery for application of plant protection products which meet the

requirements of the Registration and Control of Agriculture and Forestry Equipment Act and/or the Civil Aviation Act.

Article 107. The following shall be prohibited:

1. the storage for the purpose of use and the use of unauthorized or unfit-for-use plant protection products;
2. the use of plant protection products outside the scope of the authorized use and in a dosage which exceed the maximum dosage permitted per unit of area;
3. the application of plant protection products through aerial spraying;
4. the harvesting of the agriculture produce prior to expiration of the quarantine period of the use plant protection products;
5. the use of sowing seeds treated with plant protection products for purposes other than for sowing;
6. the use of plant protection products in violation of the prohibitions and restrictions stipulated in the ordinance under Article 135, Paragraph (1), Item 6 of the Waters Act.

Article 108. (1) It shall be prohibited to use plant protection products from the professional category of use on:

1. areas used by the general public or by vulnerable groups, such as public parks and gardens, sports and recreation grounds, school and children playgrounds, as well as in the immediate vicinity of health care and therapeutic establishments;
2. zones for protection designated in the Waters Act or other area designated by an order of the Minister of Environment and Waters;
3. areas, in which agricultural workers are working at the time of the treatment.

(2) When it is needed to treat areas and zones under Paragraph (1), Items 1 or 2, plant protection products from the non-professional category of use or plant protection products of low risk or biological agents shall be applied.

Article 109. (1) As an exception to the prohibition under Article 107, Item 3, plant protection products can be applied through aerial spraying only after written permission issued by the Director of the RFSD, when there is a threat to the plants and plant products, when there is:

1. an impossibility to apply plant protection products by means of specialized land-based equipment and machinery because of:
 - a) excessively humid terrains and areas or other unfavourable agro-climatic conditions;

b) rugged and/or inaccessible terrains, including forest territories;

c) threat of erosion or compacting of the soils;

2. a necessity to treat the areas in a very short time in order to comply with the terms of use of the plant protection product.

(2) A permission under Paragraph (1) shall be issued when:

1. the plant protection products have been approved for application through aerial spraying;

2. the aviation operator who will perform the aerial spraying holds a certificate for performing specialized aviation works under Article 64 (2) of the Civil Aviation Act;

3. the aircraft, by means of which the aerial spraying is to be performed, is equipped with best available equipment for reduction of the deviation of the stream and complies with the requirements of the Civil Aviation Act and of the instruments for application thereof;

4. a person from the staff of the aviation operator holds a certificate under Article 83;

5. the areas to be treated do not fall within:

a) belts I, II and III of sanitary protection zones around water sources and facilities for potable municipal water supply from surface waters and in belts I and II around water sources for potable municipal water supply from ground waters and for mineral waters used for therapeutic, prophylactic, potable and hygiene needs specified in the ordinance under Article 135, Paragraph (1), Item 6 of the Waters Act;

b) the vicinity of residential territories, territories for parks and gardens or territories for sports and entertainment.

Article 110. (1) In order to obtain a permit for application of plant protection products through aerial spraying, the agricultural producers shall submit before the RFSD, on the territory of which the area to be treated is located, an application according to a template at least 6 days before the date of the treatment.

(2) The following shall be attached to the application under Paragraph (1):

1. a prescription for application of plant protection products because of a threat to the plants and plant products issued by a person of higher education in the field of the agrarian sciences with a professional concentration of "Plant Protection" or "Plant Growing";

2. individualized data on the properties to be treated;

3. a copy of a contract with the aviation operator which will perform the aerial spraying;

4. a declaration according to a template for compliance with the requirement under Article

109, Paragraph (2), Item 5.

(3) The permission under Paragraph (1) shall be issued according to a procedure stipulated in the ordinance under Article 104, Paragraph (1), Item 3.

(4) Within a 3-day time limit from the submission of the application under Paragraph (1), the Director of the RFSD or an officer authorized thereby either shall issue a permission for application of plant protection products through aerial spraying, or shall issue a well-grounded refusal to issue such permission, when the requirement of Article 109 are not met.

(5) The permission under Paragraph (4) shall be issued for a term not longer than 5 days and shall be entered into the register under Article 6, Paragraph (1), Item 8. The permit shall contain also measures and deadlines necessary for timely warning of the population and for protection of the environment in the vicinity of the area to be treated.

(6) If urgent measures have to be applied, the application under Paragraph (1) can be submitted, as an exception, at least 3 days before the date of the treatment.

Article 111. The Regional Food Safety Directorates shall, through the mayors and through the local mass media or through other appropriate means, disseminate information about the forthcoming application of plant protection products through aerial spraying. The information shall be published on the web page of the respective RFSD and shall include the location of the areas to be treated, the date and time when the aerial spraying will be performed and the type of plant protection product that will be used.

Article 112. The persons who use plant protection products either by land-based equipment or by aerial spraying shall personally inform the owners of bee hives situated in the land area of the populated settlement where the areas to be treated are situated, as well as the owner of bee hives situated in the neighbouring land areas, of the date and time of each application of plant protection products.

Article 113. (1) The plant protection products shall be applied in the case of fumigation of plants, plant products and other articles:

1. if they are approved for application during fumigation;
2. by persons who have undergone training for fumigation in a school or institution of higher education in the system of vocational education and training according to the curriculum approved by the Executive Director of the BFS.

(2) Fumigation of plants, plant products and other articles shall be performed under terms and according to a procedure stipulated in the ordinance under Article 104, Paragraph (1), Item 3.

Article 114. (1) When treating sowing seeds, the plant protection products shall be applied:

1. if they are approved for treatment of sowing seeds;

2. by specialized equipment and machinery for treatment of sowing seeds;

3. in specialized premises that meet the requirements stipulated in the ordinance under Article 104, Paragraph (1), Item 3.

(2) Treatment of sowing seeds by plant protection products shall be performed under terms and according to a procedure stipulated in the ordinance under Article 104, Paragraph (1), Item 3.

Article 115. All cases of acute and/or chronic poisoning by plant protection products of persons regularly exposed to impact of plant protection products, such as professional users, agricultural workers or persons who live close to zones in which plant protection products are used, shall be reported under the terms and according to the procedure of Article 7e (9) of the Protection from the Harmful Impact of Chemical Substances and Mixtures Act.

Section X

Specialized plant protection services

Article 116. (1) Fumigation of plants, plant products and other articles, as a specialized plant protection service, shall be performed by persons who are traders in the sense of the Commerce Act and who are entered into the register under Article 6, Paragraph (1), Item 9.

(2) In order to be entered into the register under Article 6, Paragraph (1), Item 9, the persons under Paragraph (1) shall submit before the RFSD, on the territory of which they are established, a notification according to a template and shall attach thereto certified copies of:

1. a diploma of higher education in the field of agrarian sciences with a professional concentration of "Plant Protection" of the person who will supervise the fumigation process and a contract concluded therewith;

2. a document for completed fumigation training - for the person under Article 113, Paragraph (1), Item 2 and a contract concluded therewith;

3. a list of the equipment and/or machinery for application of plant protection products in the process of fumigation.

(3) Within a 7-day time limit from the submission of the notification under Paragraph (2), the Director of the RFSD shall issue an order for entry into the register under Article 6, Paragraph (1), Item 9 which shall be announced according to the procedure laid down in the Code of Administrative Procedure.

(4) The entry under Paragraph (3) shall be for an indefinite term and no fees shall be due and payable for it.

(5) In case no judgment is passed within the time limit under Paragraph (3), this shall be interpreted as tacit consent and the persons under Paragraph (1) shall be able to perform fumigation of plants, plant products and other articles as a specialized plant protection service.

Article 117. (1) The treatment by plant protection products of sowing seeds, as a specialized plant protection service, shall be performed by persons who are traders in the sense of the Commerce Act and who are entered into the register under Article 6, Paragraph (1), Item 9.

(2) In order to be entered into the register under Article 6, Paragraph (1), Item 9, the persons under Paragraph (1) shall submit before the RFSD, on the territory of which they are established, a notification according to a template and shall attach thereto certified copies of:

1. a diploma of higher education in the field of agrarian sciences with a professional concentration of "Plant Protection" or "Plant Growing" of the person who will supervise the treatment of the seeds and a contract concluded therewith;

2. a document of ownership or of right to use a specialized premise under Article 114, Paragraph (1), Item 3;

3. a list of the specialized equipment and machinery for treatment of sowing seeds;

(3) Within a 7-day time limit from the submission of the notification under Paragraph (2), the Director of the RFSD shall issue an order for entry into the register under Article 6, Paragraph (1), Item 9 which shall be announced according to the procedure laid down on the Code of Administrative Procedure.

(4) The entry under Paragraph (3) shall be for an indefinite term and no fees shall be due and payable for it.

(5) In case no judgment is passed within the time limit under Paragraph (3), this shall be interpreted as tacit consent and the persons under Paragraph (1) shall be able to perform treatment of sowing seeds by plant protection products as a specialized plant protection service.

Article 118. (1) Consulting services for integrated pest management, as a specialized plant protection service, shall be performed by natural persons or legal entities who/which are entered into the register under Article 6, Paragraph (1), Item 9.

(2) In order to be entered into the register under Article 6, Paragraph (1), Item 9, the persons under Paragraph (1) shall submit before the RFSD of their permanent address, a notification according to a template and shall attach thereto certified copies of:

1. a diploma/s of higher education in the field of agrarian sciences with a professional concentration of "Plant Protection" or "Plant Growing" of the consultant/s and a contract concluded therewith;

2. a certificate/s under Article 83 of the consultant/s.

(3) Within a 7-day time limit from the submission of the notification under Paragraph (2), the Director of the RFSD shall issue an order for entry into the register under Article 6, Paragraph (1), Item 9 which shall be announced according to the procedure laid down on the Code of

Administrative Procedure.

(4) The entry under Paragraph (3) shall be for an indefinite term and no fees shall be due and payable for it.

(5) In case no judgment is passed within the time limit under Paragraph (3), this shall be interpreted as tacit consent and the persons under Paragraph (1) shall be able to perform consulting services for integrated pest management as a specialized plant protection service.

(6) Consulting services for integrated pest management shall be provided under terms and according to a procedure stipulated in the ordinance under Article 9 (4).

Article 119. (1) Within a 7-day time limit from the occurrence of a change in the circumstances entered into the register under Article 6, Paragraph (1), Item 9, the persons under Article 116 (1), Article 117 (1) and Article 118 (1) shall submit before the respective RFSD a notification according to a template and shall attach thereto documents certifying the change.

(2) Within a 7-day time limit from the submission of the notification under Paragraph (1), the Director of the RFSD shall issue an order for entry of the change into the register under Article 6, Paragraph (1), Item 9.

Section XI

Follow-up control over the trade, re-packaging, storage and use of plant protection products

Article 120. (1) The control over the plant protection products and over the trade, re-packaging, storage and use thereof shall be performed under terms and according to a procedure stipulated in an ordinance of the Minister of Agriculture and Foodstuffs.

(2) The control under Paragraph (1) shall be performed through planned and surprise checks and checks in the presence of evidence of a violation and shall encompass:

1. the plant protection products;
2. the persons who perform the activities under Paragraph (1);
3. the sites at which the activities under Paragraph (1) are performed;
4. the documentation pertaining to performance of the activities under Paragraph (1);
5. the plants and plant products at the time of their initial production and other articles, on which plant protection products have been used.

(3) The control samples in the process of performing the checks under Paragraph (2) shall be taken according to a procedure stipulated in the ordinance under Paragraph (1).

(4) The control samples taken in the process of performing a check under Paragraph (2), Item 1 shall be tested at the Central Chemical Testing and Control Laboratory of the BFSA and/or by accredited laboratories according to Regulation (EC) No.765/2008 of the European Parliament and of the Council of 9 July 2008 on Determining the Requirements for Accreditation and Supervision of the Market in Connection with the Placing on the Market of Products and Repealing Regulation (EEC) No. 339/93 (OJ, L 218/30 of 13 August 2008), hereinafter referred to as "Regulation (EC) No. 765/2008".

(5) The control samples taken in the process of performing a check under Paragraph (2), Item 5 shall be tested at the Central Chemical Testing and Control Laboratory of the BFSA and/or by laboratories accredited by the national accreditation authority of a member-state.

(6) When a batch of a plant protection product does not have a laboratory analysis certificate or when an inconsistency under Article 122 (1) has been found, the expenses for the laboratory tests of the control samples taken in the process of performing the check under Paragraph (2), Item 1 shall be at the expense of the holder of the permit for placing on the market and use of the plant protection product.

Article 121. (1) When an inconsistency with the statutory requirements is found in the process of a check under Article 120 (2), the plant protection inspectors can give recommendations and can apply one or several of the following measures:

1. suspension of the activity at the site;
2. placing under distraint the batch/es of the plant protection product/s and confiscation of available quantities thereof;
3. placing plants and plant products under distraint;
4. undertaking any other measures needed for exercising their powers.

(2) The measures under Paragraph (1) shall be applied by an order, which can be appealed against before the Director of the respective RFSD according to the procedure laid down in the Code of Administrative Procedure.

(3) The order under Paragraph (2) can be appealed through the courts only provided that it has already been appealed against through the administrative channels.

Article 122. (1) When an inconsistency of a plant protection product with its physical, chemical and technical parameters, its composition, type of formula or any other of its characteristics approved upon the authorization of the product is found or when an inconsistency in the packaging or in the label of the product is found or when its shelf life has expired, the Executive Director of the BFSA can apply by an order one or several of the following measures:

1. immediate cessation of the trade, re-packaging and use of the plant protection product and its withdrawal from the market;

2. re-labelling or re-processing by the producer, when the plant protection product is in its original packaging.

3. export of the plant protection product;

4. decontamination of the plant protection product according to the Waste Management Act.

(2) The measures under Paragraph (1) can be applied also only in regard to specific batches of the plant protection product.

(3) The order under paragraph (1) shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure. The appeal shall not suspend the enforcement.

(4) The expenses for implementation of the measures under Paragraph (1) shall be at the expense of the holder of the permit for placing on the market and use of the plant protection product.

(5) Within a 7-day time limit from the implementation of the measures under Paragraph (1), the obligated person shall submit before the Central Office of the BFSa written evidence of their implementation.

(6) In case of non-compliance with a measure under Paragraph (1), Items 2 or 3, the plant protection product shall be subjected to decontamination according to the Waste Management Act.

Article 123. (1) When use of unauthorized plant protection product on plants and plant products is found at the time of their initial production or when unauthorized use of a plant protection product is found, the Director of the respective RFSD can apply by an order one or several of the following measures:

1. export of the plants and plant products;

2. destruction of the plants and plant products according to the Waste Management Act, the ordinance and the resolution of the European Commission under Article 16 (3) and/or according to methodologies approved by the Executive Director of the BFSa.

(2) The order under Paragraph (1) shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure. The appeal shall not suspend the enforcement.

(3) The expenses for implementation of the measures referred to in Paragraph (1) shall be at the expense of the agricultural producer.

(4) Within a 7-day time limit from the implementation of the measures under Paragraph (1), the agricultural producer shall submit before the respective RFSD written evidence of their

implementation.

Section XII

National action plan for sustainable use of pesticides according to Article 4 of Directive 2009/128/EC

Article 124. (1) The Council of Ministers shall approve a National Action Plan for Sustainable Use of Pesticides for the purpose of reducing the risks and the impact of the use of pesticides on human health and the environment and for the purpose of promoting the development and introduction of integrated pest management and of alternative approaches or methods.

(2) Representatives of the competent state authorities and of the stakeholders shall participate in the preparation of the plan.

(3) The National Action Plan for Sustainable Use of Pesticides shall be developed in accordance with other adopted plans and measures regarding the use of pesticides, including the river basin management plans under the Waters Act.

(4) After approval by the Council of Ministers, the National Action Plan for Sustainable Use of Pesticides shall be presented to the European Commission and to the competent authorities of the other member-states.

(5) The National Action Plan for Sustainable Use of Pesticides shall be reviewed at 5-year intervals as a minimum according to the procedure of Paragraphs (1) - (4).

Article 125. (1) The National Action Plan for Sustainable Use of Pesticides:

1. shall set quantitative and other targets, measures and deadlines for reducing the risks and the impact of the use of pesticides on human health and on the environment;

2. shall encourage the introduction of integrated pest management and of alternative approaches or methods in order to reduce the dependency on the use of pesticides;

3. shall include indicators for monitoring the use of plant protection products containing active substances, which have been approved in accordance with Directive No.91/414/EEC of the Council of 15 July 1991 concerning the Placing on the Market of Plant Protection Products but which do not meet the criteria for approval under Sub-Items 3.6 - 3.8 of Appendix II of Regulation (EC) No. 1107/2009, when the active substances are subject to renewal or approval according to the procedure of that same regulation;

4. shall establish time schedules and targets for reducing the use of the active substances under Item 3 and, in particular, if the reduction of the use is an appropriate method for accomplishing a reduction of the risk as regards priority sites;

5. shall include requirements for informing of persons who could be exposed to deviation of the stream in the cases of application of plant protection products;

6. shall establish harmonized and nationwide risk indicators.

(2) Specific measures for protection of the aquatic environment (surface and ground waters) and of the potable water from the impact of pesticides shall be stipulated in the National Action Plan for Sustainable Use of Pesticides.

(3) The measures under Paragraph (2) shall include:

1. giving priority to plant protection products which:

a) have not been classified as hazardous for the aquatic environment in accordance with Regulation (EC) No. 1272/2008 (CLP) and the ordinance under Article 5 (2) of the Protection Against the Harmful Impact of Chemical Substances and Mixtures Act;

b) do not contain priority hazardous substances designated according to the procedure of the Waters Act;

2. giving priority to the most efficient techniques for application, such as the use of equipment for application of plant protection products which features limited deviation of the stream, especially for crops such as hops crops, fruit orchards and vineyards;

3. reducing the risk of pollution by plant protection products of areas outside the region of their application, because of deviation of the stream in the process of spraying, drainage or outflow, including establishing of:

a) non-treated buffer zones near the surface waters for the purpose of protection of the non-target aquatic organisms - the buffer zones shall be designated individually for each plant protection product in the process of its evaluation and authorization for placing on the market and use and shall be specified on the label of the product;

b) prohibitions and restriction of the use and storage of plant protection products in the sanitary protection zones for surface and ground waters, which are used for potable municipal water supply and/or mineral waters used for therapeutic, prophylactic, potable and hygiene needs;

4. reducing or terminating the application of plant protection products on or alongside roads, railway lines, highly-permeable surfaces or other infrastructure situated in the vicinity of surface or ground waters or on impermeable surfaces, in the cases of which there is a great risk of an outflow into the surface waters or into the sewerage networks.

Article 126. (1) For the purpose of achieving sustainable use of pesticides:

1. The Ministry of Agriculture and Food shall:

a) shall designate priority sites, such as active substances, agricultural crops, regions or

practices requiring special attention or good practices;

b) shall encourage the development and introduction of integrated pest managements and of alternative approaches and techniques;

2. The Bulgarian Food Safety Agency:

a) shall calculate risk indicators by using statistical data on the plant protection products and other appropriate data;

b) shall establish the trends in the use of specific active substances.

(2) The Bulgarian Food Safety Agency shall notify the European Commission and the other competent authorities of the other member-states of the results of the activities performed under Paragraph (1) and shall publish information about them on its web page.

(3) For the appropriate procurement for the activities under Paragraph (1), Item 2, the Ministry of Health, the Ministry of Agriculture and Foodstuffs and the Executive Environment Agency shall, within their competencies, provide to the BFSA the available data, upon request. This data can be requested also by other state authorities, if necessary.

Chapter Six

ADJUVANTS

Article 127. (1) Adjuvants shall be placed on the market and used under the terms of Article 58 of Regulation (EC) No. 1107/2009 after entry into the register under Article 6, Paragraph (1), Item 15.

(2) The adjuvants shall:

1. be classified in accordance with Regulation (EC) No. 1272/2008 (CLP);

2. be packaged in accordance with Regulation (EC) No. 1107/2009, Regulation (EC) No.1272/2008 (CLP);

3. be labelled in accordance with Regulation (EC) No. 1107/2009, Regulation (EC) No. 1272/2008 (CLP).

(3) The adjuvants shall be placed in the market in the producer's packaging with a label in Bulgarian. The contraption for closing the packaging must contain a seal or another sealing device, so that upon opening of the packaging the integrity of the seal or sealing device shall be disrupted.

Article 128. (1) For entry into the register under Article 6, Paragraph (1), Item 15, the persons shall submit before the Central Office of the BFSA a notification according to a template and shall attach thereto:

1. a sample of a label, under which the adjuvant shall be placed on the market which is prepared according to the requirements of Regulation (EC) No. 1272/2008 (CLP);

2. an information safety list on the adjuvant prepared in accordance with Article 31 of Regulation (EC) No.1907/2006 (REACH).

(2) Within a 7-day time limit from the submission of the notification under Paragraph (1), the Executive Director of the BFSA shall issue an order for entry into the register under Article 6, Paragraph (1), Item 15, which shall be announced according to the procedure laid down in the Code of Administrative Procedure.

(3) The entry under Paragraph (2) shall be for an indefinite term and no fees shall be due and payable for it.

(4) If no judgment is passed within the time limit referred to in Paragraph (2), it shall be deemed that this is an act of tacit consent and Articles 28 and 29 respectively of the Restriction of the Administrative Regulation and Administrative Control on Economic Activity Act shall be applied. The person under Paragraph (1) shall have the right to place on the market the adjuvant after notifying in advance and in writing thereof the Central Office of the BFSA, and the Executive Director of the BFSA fails to issue a refusal within a 7-day time limit of receiving the notification.

(5) In the cases of tacit consent, the entry into the register shall be performed with a 14-day time limit from the notification under Paragraph (4).

(6) When a plant protection products is authorized for placing on the market and use with an adjuvant, the Executive Director of the BFSA shall enter ex officio the adjuvant into the register under Article 6, Paragraph (1), Item 15.

Article 129. The Executive Director of the BFSA shall, by an order, delete an entry into the register under Article 6, Paragraph (1), Item 15 within a 14-day time limit from the submission of a written request by the person who places the adjuvant on the market.

Chapter Seven

FERTILISERS, SOIL AMELIORATORS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES

Article 130. (1) Fertilizers, soil ameliorators, biologically-active substances and nutrient substrates shall be placed on the market and used after registration and issuing of a certificate for placing on the market and use.

(2) The fertilizers, soil ameliorators, biologically-active substances and nutrient substrates shall be registered, when they are effective and have no adverse impact on people, animals or the

environment given the terms of use prescribed by the producer.

Article 131. No registration under Article 130 (1) shall be required for products which are:

1. manure in the sense of Article 3 (20) of Regulation (EC) No.1069/2009 of the European Parliament and of the Council of 21 October 2009 Establishing Health Rules Regarding Animal By-Products and Derivative Products Intended for Human Consumption and Repealing Regulation (EC) No.1774/2002 (Regulation on Animal By-Products) (OJ, L 300/1 of 14 November 2009);

2. fertilizers, soil ameliorators, biologically-active substance and nutrient substrates intended for use for potted plants;

3. inorganic fertilizers which meet the requirements of Regulation (EC) No.2003/2003 and are marked with the words "EC FERTILIZER".

Article 132. (1) An Expert Commission on Fertilizers, Soil Ameliorators, Biologically-Active Substances and Nutrient Substrates, hereinafter referred to as the "Expert Commission", shall be created under the Executive Director of the BFSA and this commission shall be a permanently acting consultative body on the matters pertaining for fertilizers, soil ameliorators, biologically-active substance and nutrient substrates.

(2) The Executive Director of the BFSA shall endorse the rules of organization and activity of the Expert Commission.

(3) The members of the Expert Commission shall be appointed by an order of the Minister of Agriculture and Foodstuffs and shall include representatives of the Ministry of Agriculture and Foodstuffs, the Ministry of Health, the Ministry of Environment and Waters and the Bulgarian Food Safety Agency.

(4) The Expert Commission shall make proposals to the Executive Director of the BFSA for:

1. registration of fertilizers, soil ameliorators, biologically-active substances and nutrient substrates, which have not been placed on the market in a member-state or refusal of registration;

2. a change in the registration of fertilizers, soil ameliorators, biologically-active substance and nutrient substrates or refusal;

3. deletion of the registration of fertilizers, soil ameliorators, biologically - active substances and nutrient substrates.

Article 133. (1) For registration of fertilizers, soil ameliorators, biologically-active substances and nutrient substrates and for obtaining a certificate for placing on the market and use, the persons shall submit before the Central Office of the BFSA an application according to a template and shall attach thereto:

1. an administrative and technical dossier of the product;

2. a document certifying payment of the fee according to the tariff under Article 5 (1).

(2) The registration under Paragraph (1) shall be performed under terms and according to a procedure stipulated in an ordinance of the Minister of Agriculture and Foodstuffs.

(3) When fertilizers, soil ameliorators, biologically-active substances and nutrient substrates have been placed on the market in a member-state, the application shall be accompanied by the documents, on the basis of which the product has been placed on the market in the member-state or other evidence that the product has been placed on the market. The documents shall be recognized according to the provisions of Regulation (EC) No.764/2008 of the European Parliament and of the Council of 9 July 2008 concerning Establishment of the Procedures Relating to the Application of Some National Technical Rules for Products Legally Offered on the Market of Other Member-States and Repealing Resolution No.3052/95/EC (OJ, L 218/21 of 13 August 2008).

Article 134. (1) Within a 3-month time limit from the submission of the application under Article 133 (1), the Executive Director of the BFSA shall register by an order a fertilizer, a soil ameliorator, a biologically-active substance or a nutrient substrate and shall issue a certificate for placing on the market and use according to a template or shall issue a well-grounded refusal of registration, when the product does not meet any of the requirements under Article 130 (2).

(2) The term of validity of the registration and of the certificate under Paragraph (1) shall be indefinite.

(3) The refusal under Paragraph (1) shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure.

(4) The non-issuance of an opinion within the time limit stipulated in Paragraph (1) shall not be considered to be a tacit consent.

(5) The certificate issued under Paragraph (1) shall be entered into the register under Article 6, Paragraph (1), Item 14.

(6) When the fertilizer, soil ameliorator, biologically-active substance or nutrient substrate, for the registration of which an application has been submitted, has been placed on the market in a member-state, the order and the certificate under Paragraph (1) shall be issued within a 30-day time limit from receiving the application under Article 133 (1).

Article 135. (1) Within a 7-day time limit from the occurrence of a change in the circumstances pertaining to the registration and the certificate issued under Article 133 (1), the holder of this certificate shall submit before the Central Office of the BFSA an application according to a template and shall attach thereto documents certifying the change and a document certifying that a fee according to the tariff under Article 5 (1) has been paid.

(2) The change shall be made under terms and according to a procedure stipulated in the ordinance under Article 133 (2).

(3) Within a 1-month time limit from the submission of the application under Paragraph (1), the Executive Director of the BFSA shall change, by an order, the registration and shall re-issue, by an order, the certificate for placing on the market and use or shall issue a well-grounded refusal of the change, when after the change the product no longer meets any of the requirements under Article 130 (2).

(4) The refusal under paragraph (3) shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure.

(5) The certificate re-issued under Paragraph (3) shall be entered into the register under Article 6, Paragraph (1), Item 14.

(6) When the change does not have to do with the composition, effect or method of use of the fertilizer, soil ameliorator, biologically-active substance or nutrient substrate, the order and the certificate under Paragraph (3) shall be issued with a 7-day time limit from receiving the application under Paragraph (1).

Article 136. (1) The registration of a fertilizer, soil ameliorator, biologically-active substance or nutrient substrate shall be deleted and the certificate for placing on the market and use under Article 133 (1) shall be cancelled:

1. upon written request by the holder of the certificate;
2. upon a proposal of the Expert Commission, when the fertilizer, soil ameliorator, biologically-active substance or nutrient substrate:
 - a) no longer conforms to the terms under which it has been registered;
 - b) has been registered on the basis of false data;
 - c) is not effective or has an adverse impact on humans, animals or the environment.

(2) Within a 14-day time limit from receiving the written request or the proposal of the Expert Commission, the Executive Director of the BFSA shall delete, by an order, the registration and shall cancel, by an order, the certificate. The order shall stipulate the time limit for exhausting the available quantities of the respective fertilizer, soil ameliorator, biologically-active substance or nutrient substrate.

(3) The order under paragraph (2) shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure.

(4) The deletion of the registration and the cancellation of the certificate respectively shall be entered into the register under Article 6, Paragraph (1), Item 14.

Article 137. (1) The control over the fertilizers, soil ameliorators, biologically-active substance and nutrient substrates shall be performed under terms and according to a procedure

stipulated in the ordinance under Article 133 (2).

(2) The control over the EC fertilizers shall be performed according to the procedure of Regulation (EC) No.2003/2003 in strict compliance with the requirements of Chapter III of Regulation (EC) No.765/2008.

(3) When performing the control under Paragraphs (1) and (2), control samples shall be taken according to a procedure stipulated in the ordinance under Article 133 (2) and according to the procedure of Regulation (EC) No. 2003/2003 respectively.

(4) The control samples taken in the process of performing a check under Paragraph (1) shall be tested at the Central Chemical Testing and Control Laboratory of the BFSA and/or at laboratories accredited according to Regulation (EC) No. 765/2008.

(5) The control samples taken in the process of performing a check under Paragraph (2) shall be tested at laboratories under Paragraph (4) which have been notified according to the procedure of Article 30 of Regulation (EC) No. 2003/2003.

(6) When a batch of fertilizers, soil ameliorators, biologically-active substances, nutrient substrates or EC fertilizers lacks a certificate of laboratory analysis or when an inconsistency under Article 139 (1) has been found, the expenses on the laboratory tests of the control samples taken in the process of performing a check under Paragraph (1) and (2) shall be at the expense of the holder of the certificate for placing on the market and use of the fertilizer, soil ameliorator, biologically-active substance or nutrient substrate or at the expense of the person who places the EC fertilizer on the market respectively.

(7) The laboratories that wish to be approved and notified according to the procedure of Article 30 of Regulation (EC) No. 2003/2003 shall submit before the Central Office of the BFSA an application accompanied by a copy of a certificate of accreditation, within the scope of which testing for compliance of the EC fertilizers according to the requirements and methods stipulated in Regulation (EC) No. 2003/2003 is included. The Bulgarian Food Safety Agency shall notify to the European Commission the list of the approved laboratories on the territory of the Republic of Bulgaria.

Article 138. (1) When an inconsistency with the statutory requirements is found in the process of the check under Article 13, Paragraph (1) or (2), the plant protection inspectors can give recommendations and can:

1. place under distraint a specific quantity or a specific batch/es of fertilizers, soil ameliorators, biologically-active substances or nutrient substrates or confiscate available quantities thereof;

2. undertaking any other measures needed for exercising their powers.

(2) The measures under Paragraph (1) shall be applied by an order, which can be appealed against before the Director of the respective RFSD according to the procedure laid down in the Code of Administrative Procedure.

(3) The order under Paragraph (2) can be appealed through the courts only provided that it has already been appealed against through the administrative channels.

Article 139. (1) When an inconsistency of a fertilizer, soil ameliorator, biologically-active substance, nutrient substrate or EC fertilizer with their announced parameters or with their other characteristics is found or when an inconsistency in the packaging or in the label of the product is found or when its shelf life has expired, the Executive Director of the BFSA can apply, by an order, one or several of the following measures:

1. immediate cessation of the trade and use of the fertilizer, soil ameliorator, biologically-active substance, nutrient substrate or EC fertilizer and its withdrawal from the market;

2. re-labelling or re-processing by the producer until the announced parameters are achieved;

3. export of the fertilizer, soil ameliorator, biologically-active substance or nutrient substrate;

4. decontamination according to the Waste Management Act, when the fertilizer, soil ameliorator, biologically-active substance or nutrient substrate poses a threat to the health of humans, animals or the environment.

(2) The measures under Paragraph (1) can be applied also only in regard to specific quantities or specific batches of the product.

(3) The order under paragraph (1) shall be announced and may be appealed against according to the procedure laid down in the Code of Administrative Procedure.

(4) The expenses for implementation of the measures under Paragraph (1) shall be at the expense of the holder of the certificate for placing on the market and use of the fertilizer, soil ameliorator, biologically-active substance or nutrient substrate or of the person who placed the EC fertilizer on the market.

(5) Within a 7-day time limit from the implementation of the measures under Paragraph (1), the obligated person shall submit before the Central Office of the BFSA written evidence of their implementation.

(6) In case of non-compliance with a measure under Paragraph (1), Items 2 or 3, the fertilizer, soil ameliorator, biologically-active substance, nutrient substrate or EC fertilizer shall be subjected to decontamination according to the Waste Management Act.

Article 140. (1) The ammonium-nitrate fertilizers with a high nitrogen content shall be placed on the market in strict compliance with the restrictions of Item 58 from Appendix XVII of Regulation (EC) No. 1907/2006 (REACH).

(2) The ammonium nitrate fertilizers of high nitrogen content shall be offered to end users

only in packaged form.

(3) Each batch of ammonium nitrate fertilizers of high nitrogen content shall be accompanied by a certificate of detonation-resistance issued not earlier than 3 months prior to their placing on the market. The person who places them on the market shall submit before the Central Office of the BFSA the results from the testing at least 5 days prior to their placing on the market or at least 5 days prior to the arrival of the batch at the frontier of the Republic of Bulgaria - in the case of importation.

(4) In order to ensure a high degree of traceability when placing on the market ammonium nitrate fertilizers with a high nitrogen content, the producer shall be obligated to keep and store documentation with the names and addresses of the sites, in which the fertilizers and their main ingredients have been produced. The documentation shall be presented upon request to the plant protection inspectors throughout the entire period of offering on the market of ammonium nitrate fertilizers with a high nitrogen content and for a period of two years after the cessation of their offering on the market.

Article 141. (1) The fertilizers, soil ameliorators, biologically-active substance and nutrient substrates shall be labelled in Bulgarian under terms and according to a procedure stipulated in the ordinance under Article 133 (2).

(2) The fertilizers, soil ameliorators, biologically-active substances and nutrient substrates, including the EC fertilizers, shall be stored and transported in strict compliance with the requirements of fire and explosion safety in a manner that precludes any damages to the health of humans, animals and the environment.

(3) The inorganic fertilizers shall be stored in warehouses which meet the requirements of Article 655 from the ordinance under Article 169 (4) of the Spatial Development Act.

Article 142. (1) The holders of certificates for placing on the market and use of fertilizers, soil ameliorators, biologically-active substances or nutrient substrates shall be obligated to inform the BFSA of the surfacing of new data on their effect relating to their effectiveness and safety for humans, animals or the environment.

(2) The producers, the importers and the persons who place on the market fertilizers, soil ameliorators, biologically-active substances and nutrient substrates, including EC fertilizers, shall keep and store documentation on their origin throughout the entire period of their offering and two years thereafter.

(3) The agricultural producers shall be obligated to keep records of the used quantities and types of fertilizers, soil ameliorators, biologically-active substances and nutrient substrates.

Article 143. The following shall be prohibited:

1. the import, introduction, placing on the market, use and storage for the purpose of placing on the market or use of unregistered fertilizers, soil ameliorators, biologically-active substances or nutrient substrates;

2. the placing of the "EC fertilizer" mark on a product which does not comply with the requirements of Regulation (EC) No. 2003/2003;

3. the advertising of fertilizers, soil ameliorators, biologically-active substances and nutrient substrates, which do not comply with the requirements of this acts and of the instruments for application of this act.

Chapter Eight

ADMINISTRATIVE AND PENAL PROVISIONS

Article 144. (1) Whoever violates a prohibition under Article 10 (2) or fails to fulfil an obligation for notification under Article 112 shall be punished by a fine of BGN 1,500 to BGN 2,400.

(2) When the violation under Paragraph (1) is perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 2,400 to BGN 3,600 shall be imposed.

Article 145. (1) Whoever violates the prohibition under Article 12 (3) or provides consulting services for integrated pest management without being entered in the register under Article 6, Paragraph (1), Item 9 shall be punished by a fine from BGN 400 to BGN 800.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 800 to BGN 1,600 shall be imposed.

Article 146. (1) Whoever fails to apply the measures for control against the respective pest in the case of a calamity or epiphytoty declared shall be punished by a fine from BGN 500 to BGN 1,000.

(2) When the violation under Paragraph (1) is perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 800 to BGN 1,800 shall be imposed.

Article 147. (1) Whoever fails to provide assistance to a plant protection inspector in the process of exercising of his/her powers under Article 7 (2) or fails to provide access under Article 7 (3) shall be punished by a fine from BGN 500 to BGN 1,000.

(2) When the violation under Paragraph (1) is perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 800 to BGN 1,500 shall be imposed.

Article 148. (1) Whoever fails to comply with a requirements under Article 19, Paragraphs (2) or (3) shall be punished by a fine from BGN 500 to BGN 800.

(2) When the violation under Paragraph (1) is perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 2,000 to BGN 2,500 shall be imposed.

Article 149. (1) Whoever imports, produces, processes and/or grows plants and plant

products, by the route of which quarantine pests can be transmitted and disseminated, without being registered under Article 22 (1), or whoever fails to comply with a measure under Article 30 (1) shall be punished by a fine from BGN 800 to BGN 1,500.

(2) When the violation under Paragraph (1) is perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 1,500 to BGN 2,000 shall be imposed.

Article 150. (1) Whoever violates a prohibition under Article 17 or fails to comply with measures under Article 20 (1) shall be punished by a fine from BGN 1,000 to BGN 3,000, if the act does not constitute a crime.

(2) Whoever fails to comply with a measure under Article 28, Paragraph (1), Item 1 or with measures applied according to the procedure of Article 30, Paragraphs (2) and (3) shall be punished by a fine from BGN 1,000 to BGN 3,000, if the act does not constitute a crime.

(3) When the violations under Paragraphs (1) and (2) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 2,000 to BGN 5,000 shall be imposed.

Article 151. (1) Whoever performs scientific research and selection of quarantine pests, plants, plant products and other articles without a permission under Article 18 shall be punished by a fine from BGN 1,000 to BGN 2,000.

(2) When the violation under Paragraph (1) is perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 2,000 to BGN 3,000 shall be imposed.

Article 152. (1) Whoever, in the presence of a doubt or in the case of establishing a contagion by a quarantine pest, fails to notify the respective RFSD shall be punished by a fine from BGN 200 to BGN 500.

(2) When the violation under Paragraph (1) is perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 800 to BGN 1,800 shall be imposed.

Article 153. (1) Whoever fails to fulfil an obligation under Article 35, fails to fulfil an obligation for notification under Article 61 (6) or a measure under Article 33 (2) shall be punished by a fine of BGN 1,500 to BGN 2,500.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 2,000 to BGN 4,000 shall be imposed.

Article 154. (1) Whoever fails to fulfil an obligation under Article 49, Paragraphs (1) - (5) shall be punished by a fine from BGN 1,000 to BGN 2,000.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 1,500 to BGN 3,000 shall be imposed.

Article 155. (1) Whoever violates a prohibition under Article 52, Article 101, Items 1 or 2, Article 107, Item 1 or fails to comply with a condition or obligation under Article 48 shall be

punished by a fine from BGN 1,000 to BGN 3,000, if the act does not constitute a crime.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 2,000 to BGN 5,000 shall be imposed.

Article 156. (1) Whoever, in the process of performing scientific research and/or development, uses a plant protection product without a permission under Article 64 (1) shall be punished by a fine from BGN 400 to BGN 800.

(2) When the violation under Paragraph (1) is perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 800 to BGN 1,800 shall be imposed.

Article 157. (1) Whoever performs biological testing of plant protection products from a professional category of use, without holding a certificate under Article 83, or whoever performs biological testing of unauthorized plant protection products, for which there is no issued certificate for import or introduction under Article 78 (1) or in violation of the ordinance under Article 70 (4) shall be punished by a fine from BGN 1,000 to BGN 2,000.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 2,000 to BGN 5,000 shall be imposed.

Article 158. (1) Whoever, in the process of performance of activities under this act, pollutes the environment shall be punished by a fine from BGN 2,000 to BGN 5,000.

(2) When the violation under Paragraph (1) lead to a risk to the health of humans or animals, a fine from BGN 3,000 to BGN 6,000 shall be imposed, if the act does not constitute a crime.

(3) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 3,000 to BGN 10,000 shall be imposed.

(4) When the violations under Paragraph (2) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 5,000 to BGN 15,000 shall be imposed.

Article 159. (1) Whoever fails to comply with the requirement under Article 44 (2), fails to fulfil the obligation under Article 55 (5), packages or labels plant protection products or adjuvants in violation of the requirements of Article 79, Paragraph (1), Items 2 or Paragraph (2), of Article 127, Paragraph (2), Item 2 or 3 or Paragraph (3) respectively shall be punished by a fine from BGN 1,000 to BGN 2,400.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 1,900 to BGN 3,600 shall be imposed.

Article 160. (1) Whoever trades or re-packages plant protection products without a certificate under Article 91 (1) or under Article 96 (4) respectively or whoever performs specialized plant protection services, without having notified the respective RFSD, shall be punished by a fine from BGN 1,000 to BGN 3,000.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 2,000 to BGN 5,000 shall be imposed.

Article 161. (1) Whoever violates the requirements of the ordinance under Article 47, fails to fulfil an obligation under Article 63 or 98, fails to fulfil an obligation for notification under Article 95 (1) or fails to provide information under Article 92 (2) shall be punished by a fine from BGN 500 to BGN 2,500.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 1,000 to BGN 4,000 shall be imposed.

Article 162. (1) Whoever sells plant protection products from a professional category of use to persons who do not hold a certificate under Article 83, places on the market or trades in a plant protection product in the form of a ready-made solution without a permission under Article 65 (1) or places on the market, offers or sells sowing seeds treated with unauthorized plant protection products, in violation of Article 49 (1) of Regulation (EC) No. 1107/2009, shall be punished by a fine from BGN 500 to BGN 2,500.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 1,000 to BGN 4,000 shall be imposed.

Article 163. (1) Whoever violates the requirements of the ordinance under Article 104, Paragraph (1), Item 3, uses plant protection products from a professional category of use, without holding a certificate under Article 83, fails to fulfil an obligation under Article 49 (6) or fails to present information envisaged in Article 56 of Regulation (EC) No. 1107/2009 shall be punished by a fine from BGN 400 to BGN 1,400.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 800 to BGN 2,600 shall be imposed.

Article 164. (1) Whoever advertises a plant protection product in violation of Article 81 or whoever violates a prohibition under Article 82 shall be punished by a fine from BGN 500 to BGN 1,000.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 1,000 to BGN 2,500 shall be imposed.

Article 165. (1) Whoever violates a prohibition under Article 101, Item (3) - (9), Article 107, Items 2 - 6 or Article 108 (1) shall be punished by a fine from BGN 1,500 to BGN 3,800.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 3,600 to BGN 6,000 shall be imposed.

Article 166. (1) Whoever places on the market unfit-for-use fertilizers, soil ameliorators, biologically-active substances and nutrient substrates or any of the above which do not conform to the parameters announced in their accompanying documentation and/or on their labels or whoever violates the requirements of the ordinance under Article 133 (2) shall be punished by a

fine from BGN 1,000 to BGN 2,400.

(2) Whoever fails to fulfil obligations under Article 141 or under Article 142 (2), violates a prohibition under Article 143, Items 1 or 2 or violates a provision of Article 7 - 13 of Regulation (EC) No. 2003/2003 shall be punished by a fine from BGN 1,000 to BGN 2,400.

(3) When the violations under Paragraphs (1) and (2) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 1,900 to BGN 3,600 shall be imposed.

Article 167. (1) Whoever fails to fulfil an obligation under Article 140, Paragraphs (2), (3) or (4) or an obligation under Article 26 (3), Article 27 or Article 28 of Regulation (EC) No.2003/2003 shall be punished by a fine from BGN 1,500 to BGN 4,000.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 3,000 to BGN 8,000 shall be imposed.

Article 168. (1) Whoever fails to fulfil an obligation under Article 140, Paragraphs (1) or under Article 142, Paragraphs (1) or (3) shall be punished by a fine from BGN 300 to BGN 900.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 600 to BGN 1,800 shall be imposed.

Article 169. (1) Whoever violates a prohibition under Article 143, Item 3 shall be punished by a fine from BGN 300 to BGN 600.

(2) When the violation under Paragraph (1) is perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 1,200 to BGN 2,800 shall be imposed.

Article 170. An official, who guiltily fails to fulfil an obligation under Article 34, Article 36 (2) or Article 121 (1) shall be punished by a fine from BGN 150 to BGN 300.

Article 171. (1) Whoever violates and/or fails for fulfil a recommendation of the supervisory authorities under this act, which was issued in connection with the performance of their official obligations and duties in their capacity of officials, shall be punished by a fine from BGN 150 to BGN 300, if the act does not constitute a crime.

(2) When the violation under Paragraph (1) is perpetrated by a legal entity or by a sole trader, a financial penalty from BGN 200 to BGN 400 shall be imposed.

Article 172. Whoever hampers the performance of the official obligations of the officials under this act shall be punished by a fine from BGN 600 to BGN 1,200, if the act does not constitute a crime.

Article 173. (1) Whoever violates the provisions of this act, other than in the case under Article 144 - 172, shall be punished by a fine from BGN 50 to BGN 500.

(2) When the violations under Paragraph (1) are perpetrated by a legal entity or by a sole

trader, a financial penalty from BGN 200 to BGN 1,000 shall be imposed.

Article 174. (1) When violations are found, the inspectors of the BFSA shall seize material evidence related to establishing the violations according to the procedure of Article 41 of the Administrative Violations and Sanctions Act.

(2) The seized material evidence shall be subject to confiscation for the benefit of the state by virtue of a penal decree according to the procedure of Articles 20 and 21 of the Administrative Violations and Sanctions Act.

(3) The articles seized for the benefit of the state, which are unfit for use and/or are prohibited, shall be destroyed or decontaminated by the RFSD at the expense of the offenders according to the Waste Management Act and the ordinance under Article 16 (3).

(4) The articles or a part of the articles seized for the benefit of the state can be provided free-of-charge by the Executive Director of the BFSA to state authorities or to the local self-government authorities, to educational institutions for educational purposes or to special purpose organizations.

(5) The items seized and withheld by virtue of statements of establishing administrative violations or by virtue of statements of findings shall be stored until the completion of the administrative proceedings with a ruling of a competent authority that has entered into force.

(6) The control samples shall be stored until the completion of the administrative proceedings according to the appropriate procedure, after which they shall be returned or destroyed respectively.

Article 175. (1) The statements of establishing violations under this act shall be drawn up by the plant protection inspectors and the penal decrees or the well-grounded resolutions for termination of the administrative penal proceedings shall be issued by the directors of the respective RFSD.

(2) The establishment of violations, the issuing, the appeal against and the enforcement of the penal decrees shall be performed according to the procedure of the Administrative Violations and Sanctions Act.

SUPPLEMENTARY PROVISIONS

§ 1. Within the meaning of this Act:

1. "Adjuvants" shall be the substances or preparations under Article 2, Paragraph (3), Letter "d" of Regulation (EC) 1107/2009.

2. "Active substances" shall be substances or microorganisms under Article 2, Paragraph (2) of Regulation (EC) 1107/2009.

3. "Ammonium nitrate fertilizers of high nitrogen content" shall mean simple or complex ammonium nitrate-based fertilizers containing more than 28 percent of nitrogen by weight of fertilizer in relation to the ammonium nitrate.

4. "Antidotes" shall be the substances or preparations under Article 2, Paragraph (3), Letter "a" of Regulation (EC) 1107/2009.

5. "Biological agent" shall be a biological unit able to reproduce itself, which is used for control of harmful organisms.

6. "Biologically-active substances" shall be substances or mixtures, other than the nutrient substances and the plant protection products, which, when applied to plants, seeds, soils or nutrient substrates, change the physiological processes in the plants in a manner, which creates conditions for improving the growth, development, yield, quality or resilience to abiotic stress factors.

7. "Type of formulation" shall be the aggregate state and nature of a plant protection products or an adjuvant, marked in accordance with Technical Monograph No.2 of GIFAP - International Group of the National Associations of the Producers of Pesticides.

8. "Pest" shall be each plant or animal species, gender, bio-type or pathogenic agent, harmful to the plants and/or the plant products.

9. "Introduction" shall be an intra-Community delivery of a plant protection product from another member-state onto the territory of the Republic of Bulgaria.

10. "Distrain" shall be a set of temporary restrictive measures, including cessation of sale and use, imposed on products or goods, which do not comply with the requirements of this act and/or with the instruments for the application of this act.

11. "Aerial spraying" shall be the application of plant protection products from an aircraft - an airplane or a helicopter.

12. "Border inspection phytosanitary points" shall be special self-contained areas in the area of the border checkpoint intended for the performance of phytosanitary control.

13. "Blatant violations" shall be violations of the requirements of this act or of the instruments for application of this act, which have resulted in immediate threat to the health of humans, animals, plants, pollution of the environment or considerable economic losses.

14. "Distributor" shall be a person who offers plant protection products within the bounds of his/her professional activity.

15. "Good health status of the plants and plant products" shall be a status, in which it has been established that the pests are below the threshold of economic harmfulness.

16. "Other sites" shall be areas, premises, buildings, transportation vehicles, containers or

packagings, in which there were or there are plants and plant products; machines and facilities, soil and nutrient environments, as well as other articles or materials capable of containing or disseminating pests, for which it is considered that the imposing of phyto-sanitary measures is justified.

17. "Member-state" shall be a country which is a member of the European Union.

18. "EC fertilizer" shall be a fertilizer that complies with the requirements of Regulation (EC) No.2003/2003 and is included in Appendix I of that same regulation.

19. "Epiphytoty" shall be the massive onslaught of a disease that involves a sharp increase of the incidence of an ailment and infliction of considerable damages on the plants.

20. "Agricultural producer" shall be a natural person or a legal entity entered into the register of the agricultural producers under Article 7 (1) from the Assistance to the Agricultural Producers Act, who/which produces on the territory of the country plants and plant products intended for sale.

21. "Economically important pests" shall be diseases, pests and weeds, which attack the crops each year, inflict considerable losses of agricultural produce and exert an impact on the safety and quality of the plants and plant products.

22. "Integrated production" shall be a system for production of plants and plant products through application of the specific principles of integrated pest management.

23. "Integrated pest management" shall be the careful research of all available plant protection methods and subsequent integration of appropriate measures for limiting the development of the populations of harmful organisms, for maintaining economically and environmentally justified levels of the use of plant protection products and of other form of intervention and for reducing or minimizing the risks to the health of humans and the environment. The integrated pest management shall be aimed at the production of healthy crops with the least possible disruptions of the agro-ecological systems and at promoting the natural mechanisms for pest control.

24. "Calamity" shall be the mass onslaught of hostile organisms involving the infliction of considerable damages on the plants.

25. "Quarantine" shall be a set of temporary restrictive measures imposed on plants, plant products and other articles or activities.

26. "Quarantine pest" shall be a pest who has potential importance for the economy of the threatened zone and has not yet been established in this zone or is already in it, but is not widely disseminated and is a subject of official control.

27. "Category of use" shall be the assigning of a plant protection product to a specific group for the purpose of limiting its use to a specific category of users.

28. "Consultant" shall be a person who has acquired the respective knowledge and who provides advice on the pest management and on the safe use of plant protection products within the bounds of its professional activity or as a commercial service.

29. "Control sample" shall be a certain quantity of plants, plant products, plant protection products, fertilizers, soil ameliorators, biologically-active substances or nutrient substrates, which, when subjected to laboratory testing, provides an objective and comprehensive evaluation of the conformity of the entire quantity/batch thereof with the requirements stipulated therefor.

30. "Co-formulants" shall be the substances or preparations under Article 2, Paragraph (3), Letter "c" of Regulation (EC) 1107/2009.

31. "Local market" shall be an area in the sense of the Administrative and Territorial Development of the Republic of Bulgaria Act, in which plants and plant products have been produced and are offered for sale.

32. "Unauthorized use" shall be the use of an authorized plant protection product other than the uses specified in the permit for placing on the market and use thereof.

33. "Equipment for application of plant protection products" shall be a device especially intended for application of plant protection products, including accessories which are of significant importance for the effective functioning of this equipment, such as nozzles, manometers, filters, sieves and accessories for the cleaning of tanks.

34. "Threat to the plants and plant products" shall be a calamity or epiphytotoy, or penetration, dissemination and/or mass multiplication of pests on the plants and plant products or a threat of penetration, dissemination and/or mass multiplication of pests resulting in considerable economic losses.

35. "Original packaging" shall be the packaging of a producer of plant protection product with a label and a batch number, which has been approved in the process of authorization for placing on the market and use of the plant protection product in terms of type and capacity of the packaging, as well as type and characteristics of the material it is made of.

36. "Batch of plants, plant products and other articles" shall be a certain number of units of a particular species identified by the homogeneity of its composition and origin constituting a part of a consignment.

37. "Pesticide" is a plant protection product.

38. "Repeated violation" shall be any violation which is perpetrated within one year after the entry into effect of a penal decree whereby a penalty for the same kind of violation has been imposed.

39. "Risk indicator" shall be result from a method of calculation, which is used for assessment of the risks from pesticides for the health of humans and/or the environment.

40. "Soil ameliorators" shall be materials, which are added to the soils and the main function of which is to improve the physical and/or chemical properties and/or the biological activity of the soil.

41. "Threshold of economic harmfulness" shall be such a density of the pest population, in the case of which the yield losses exceed twice the expenses needed for chemically combating the pest.

42. "Consignment" shall be a quantity of goods covered by the same document needed according to the customs requirements, such as a unique phyto-sanitary certificate or measure. The consignment can consist of one or more batches.

43. "Plant protection products" shall be products under Article 2, Paragraph (1) of Regulation (EC) 1107/2009.

44. "Professional user" shall be a person who uses plant protection products within the bounds of his/her professional activity.

45. "Authorized plant protection product" shall be any plant protection product, for which there is a permit for placing on the market and use.

46. "Authorized use" shall be the application of a plant protection product on certain plants and plant products or against a certain pest under terms of use as stipulated in the permit for placing on the market and use of the product.

47. "Plant passport" shall be an official label, which certifies that the provisions pertaining to the phyto-sanitary norms and specific requirements have been complied with.

48. "Plant products" shall be products of plant origin, including grain, unprocessed or processed in an ordinary manner, as long as they are no longer plants.

49. "Synergists" shall be the substances or preparations under Article 2, Paragraph (3), Letter "b" of Regulation (EC) 1107/2009.

50. "Systematic violations" shall be two or more violations of the requirements of this act or of the instruments for application of this act, for which administrative penalties have been imposed on the respective person, the penal decrees for which have entered into force within one year.

51. "Composition of a plant protection product" shall be the qualitative and quantitative content of active substances, antidotes, synergists and co-formulants in the product.

52. "Third country" shall be each country which is not a member-state of the European Union.

53. "Trade in plant protection products" shall be all activities for purchase and sale, acquisition, supply, storage and offering for the purpose of sale of plant protection products. The

import, the introduction onto the territory of the country and the export shall be considered "trade".

54. "Phyto-sanitary control" shall be each action and measure undertaken against transmission and/or dissemination of quarantine pests on the plants, plant products and other articles.

55. "Phyto-sanitary certificate" shall be an official international document complying with the template attached to the International Plant Protection Convention (Rome, 1951) certifying the absence of quarantine pests in the consignment.

56. "Fumigation" shall be a method for destruction of pests in closed spaces, in the case of which plant protection products in gaseous form are used.

57. "Nutrient substrates" shall be products, which provide a favourable environment and nutrient substances for growth and development of the plants.

§ 2. This act introduces the requirements of Directive 2000/29/EC of the Council of 8 May 2000 on Protective Measures against the Introduction into the Community of Organisms Harmful to Plants or Plant Products and against Their Spread within the Community and Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 Establishing a Framework for Community Action to Achieve the Sustainable Use of Pesticides (OJ, L 309/71 of 24 November 2009).

§ 3. All registers, lists and bulletins under this act shall be public and shall be published on the web page of the BFSa in strict compliance with the Personal Data Protection Act.

TRANSITIONAL AND FINAL PROVISIONS

§ 4. This act repeals the Plant Protection Act (promulgated, SG No 91 of 1997; amended, SG No 90 of 1999, No 96 of 2001, No 18 of 2004, Nos 26, 30, 31 and 96 of 2006, Nos 13, 36 and 43 of 2008 and No 82 of 2009 and Nos 8 and 28 of 2011).

§ 5. The statutory instruments of secondary legislation issued on the basis of the repealed Plant Protection Act shall be applied, provided that they don't contradict this act and pending their explicit repealing.

§ 6. (1) The certificates, permits and other documents issues prior to the entry into force of this act shall preserve their validity and effect for the term for which they have been issued.

(2) The proceedings for the issuing of the documents under Paragraph (1) that were initiated prior to the entry into force of this act shall be completed according to the former procedure, with the exception of the proceedings for the issuing of permits for placing on the market and use of plant protection products, initiated by an application after 14 June 2011, which shall be completed according to the procedure of this present act.

(3) The proceedings for the issuing of renewed permits for placing on the market and use of plant protection products, which were initiated prior to 14 June 2011, shall be completed according to the procedure of this present act, upon a written request by the applicant.

§ 7. The Ministry of Environment and Waters shall perform an expert evaluation of the eco-toxicological characteristics of the active substances and plant protection products and of the existence and behaviour in the environment of the products, whereas the Ministry of Health - of the toxicological characteristics of the active substances and of the products for the proceedings for authorization and change of the authorization of plant protection products that were initiated prior to 14 June 2011 under Article 15d and 15p of the repealed Plant Protection Act.

§ 8. The notification under Article 49 (1) shall be submitted within a 6-month time limit from the entry into force of this act.

§ 9. The categorization of plant protection products, that exists prior to the entry into force of this act, shall be converted into the categorization under Article 80, Paragraph (1) and (2) as follows:

1. "first (professional)" into "first professional";
2. "second (limited)" into "second professional";
3. "third (liberal)" into "non-professional".

§ 10. The following amendments and supplementations shall be made in the Bulgarian Food Safety Agency Act (Promulgated, SG No 8 of 2011; amended Nos 38 and 102 of 2012 and No 15 of 2013):

1. Article 11a shall be created in Chapter Three:

"Article 11a. When performing their official obligations, the supervisory authorities of the BFSA shall identify themselves by an official card and the employees working at the border inspection points shall also wear uniforms."

2. In Article 13:

- a) in Item 2, the words "Article 6, Item 3" shall be replaced by "Article 20 (1) and Article 30 (1)";

- b) in item 3, after the word "plants", a comma shall be placed and the words "and plant products according to Article 6, Item 3" shall be replaced by "plant products and other articles in the cases under Article 30, Paragraph (1), Item 4 and Article 71 (3)".

§ 11. The following amendments and supplementations shall be made in the Registration and Control of Agricultural and Forestry Equipment Act (Promulgated, SG No 79 of 1998; amended and supplemented No 22 of 2003, Nos 74 and 88 of 2005, Nos 30, 34, 80, 82 and 102 of 2006, No 53 of 2007, Nos 36,43, 69 and 100 of 2008, No 93 of 2009, No 88 of 2010, No 28 of

2011, No 38 of 2012 and No 15 of 2013):

1. In Article 10:

a) in Paragraph (1), the word "and the international" and the words "for safety of the equipment from accredited laboratories" shall be deleted;

b) in Paragraph (3), after the words "under Paragraph (1)" a comma shall be placed and the text till the end shall be deleted.

2. Article 10b and 10c shall be created in Chapter Three:

"Article 10b. (1) The equipment for application of plant protection products in the sense of the Plant Protection Act, which is in use, shall be subject to a mandatory check as regards the safety and protection of the health of humans and the environment.

(2) The checks under Paragraph (1) shall be regular and shall be performed by the Technical Control Inspectorate.

(3) The new equipment for application of plant protection products shall be subject to checks for up to 5 years after being purchased.

Article 10c. (1) The procedure for performing the regular checks of the equipment for application of plant protection products, the system for certification and control of the checks of the equipment and the recognition of certificates issued by other member-states of the European Union shall be stipulated in an ordinance of the Minister of Agriculture and Foodstuffs.

(2) A fee according to a tariff stipulated by the Council of Ministers shall be paid for the performed checks of the equipment under Article 10b (1).

3. Article 22b:

a) In paragraph (1), Item 6 shall be created:

"6. which has not undergone a check under Article 10b.";

b) in Paragraph (2), after the words "Article 16", the words "and to a check under Article 10b" shall be added.

4. In the Transitional and Final Provisions, § 3a shall be created:

"§ 3a. (1) The frequency of the checks of the equipment under Article 10b (1) shall be as follows:

1. one check until 26 November 2016;

2. a check every 5 years until 2020;

2. a check every 3 years after 2020;

(2) After 26 November 2016, only equipment for application of plant protection products, which has successfully passed the check under Article 10b (1), shall be used."

§ 12. The Apiary Act (promulgated, SG No 57 of 2003; amended, SG No 87 of 2005, No 30 of 2006, No 51 of 2007, Nos 36 and 43 of 2008, No 26 of 2010 and Nos 8 and 19 of 2011) shall be amended and supplemented as follows:

1. In Article 8:

a) in Paragraph (5), in the second sentence, the words "his/her name (name of the company), address (seat), PIN (BULSTAT), number of the bee hives and" shall be deleted and the words "according to an ordinance of the Minister of Agriculture and Foodstuffs" shall be added at the end;

b) Paragraph (7) shall be created:

"(7) The Bulgarian Food Safety Agency shall publish on its web page a list which shall contain information on the location of the bee hives by mayoralties and data on their owners."

2. In Article 19:

a) in Paragraph (2), the words "Paragraph (3) - (6)" shall be replaced by the words "Paragraphs (3) - (7)";

b) in Paragraph (3):

aa) in the text preceding Item 1, the words "the respective regional agriculture directorate" shall be replaced by the words "the regional agriculture directorate by location of the apiary";

bb) Item 2 shall be amended as follows:

"2. positive opinion for registration of the respective type of activity, issued by the breeding organization, in which the persons who have submitted the application participate;"

b) a new Paragraph (4) shall be created:

"(4) The positive opinion under Paragraph (3), Item 2 shall be issued, when the following conditions are simultaneously met:

1. availability of equipment and application of instrumental insemination of the elite queen bees or secured 10-kilometer isolation in the case of their natural mating in the tribal apiaries;

2. availability of 5-kilometer isolation for reproductive apiaries;

3. availability of an equipped laboratory in the process of production of elite and/or tribal queen bees;

4. the reproduction material meets

the accepted value of belonging to a race according to the adopted Breeding Program;

5. the technology announced by the producer and approved by the Breeding Organization for the respective type of activity has been complied with;

6. the requirements for keeping the zoo-technical documentation have been complied with.";

d) what was formerly Paragraph (4) becomes Paragraph (5);

e) what was formerly Paragraph (5) becomes Paragraph (6) and in it the words "Paragraph (4)" shall be replaced by the words "Paragraph (5)";

f) what was formerly Paragraph (6) becomes Paragraph (7) and in it the words "Paragraphs (4) and (5)" shall be replaced by the words "Paragraphs (5) and (6)";

g) what was formerly Paragraph (7) becomes Paragraph (8) and in it, in the first sentence, the words "time limit of one year" shall be replaced with the words "the term of validity of the opinion under Paragraph (3), Item 2" and in the second sentence the words "on the basis of a positive opinion under Paragraph (3), Item 2 and Paragraph (4)" shall be replaced with the words "under the terms and according to the procedure of Paragraphs (3) - (7)";

(h) what was formerly Paragraph (8) becomes Paragraph (9) and in it the words "Paragraphs (3) and (4)" shall be replaced with the words "Paragraphs (3) and (5);

i) what was formerly Paragraph (9) becomes Paragraph (10) and in it:

aa) in Item 1 at the end, the words "with a copy to the breeding organization" shall be added;

bb) Item 4 shall be amended as follows:

"4. in the case of a received proposal by the chairman of the breeding organization, because of a change in the conditions on the basis of which the opinion under Paragraph (3), Item 2 was issued";

cc) Item 5 shall be repealed;

j) what was formerly Paragraph (10) becomes Paragraph (11) and in it the words "Paragraph (9)" shall be replaced with the words "Paragraph (10)";

3. Article 19a shall be created:

"Article 19a. (1) A public list of the persons registered under Article 19 (7) shall be kept at

the Ministry of Agriculture and Foodstuffs.

(2) The following shall be entered into the list under Paragraph (1):

1. name of the natural person/name of the legal entity-trader and contact details;
2. date of last registration with the Regional Agriculture Directorate;
3. type of activity - production.

(3) The Regional Agriculture Directorates shall be obligated to announce before the Ministry of Agriculture and Foodstuffs every change in the circumstances under Paragraph (2), Item 2 within a 1-month time limit of its occurrence."

4. In Article 20, Paragraph (1), Item 3, the words "health status" shall be replaced with the words "movement/transportation of animals".

5. In Article 24, at the end, the words "with the exception of the apiaries registered under Article 19 (7)" shall be added.

6. In Article 48:

a) Paragraphs (1) and (2) shall be amended as follows:

"(1) The statements of establishing the violations under Article 32, 33, 42 - 46 shall be drawn up by the supervisory authorities of the Bulgarian Food Safety Agency. The penal decrees shall be issued by the Executive Director of the Bulgarian Food Safety Agency or by officials authorized thereby.

(2) The statements of establishing the violations under Articles 37 and 38 shall be drawn up by officials authorized by the directors of the Regional Agriculture Directorates and the penal decrees shall be issued by the directors of the Regional Agriculture Directorates".";

b) a new Paragraph (3) shall be created:

"(3) The statements of establishing the violations under Articles 40 and 41 shall be drawn up by officials authorized by the Executive Director of the Executive Agency of Selection and Reproduction in Animal Breeding and the penal decrees shall be issued by the Director of the Executive Agency of Selection and Reproduction in Animal Breeding.";

c) what was formerly Paragraph (3) shall become Paragraph (4).

7. In § 1 of the supplementary provision, in Item 10, the word "professional" shall be deleted.

§ 13. In the Forestry Act (Promulgated, SG No 19 of 2011; amended No 43 of 2011, Nos 38, 60, 82 and 102 of 2012, Nos 15, 27, 66 and 109 of 2013 and Nos 28 and 53 of 2014), everywhere

in Article 135 the word "preparations" shall be replaced with the words "plant protection products".

§ 14. The certificates issued under Article 26 (5) of Ordinance No.104 of 2006 on Control over the Offering on the Market and Use of Plant Protection Products (SG No 81 of 2006) shall be considered to be certificates under Article 83 with a term of validity of 10 years from the date of being issued.

§ 15. (1) The plant protection products authorized for placing on the market and use shall be approved for application through aerial spraying under the terms and according to the procedure of the ordinance under Article 45 (1) within a period of three years from its entry into force.

(2) Pending the approval under Paragraph (1), the plant protection products authorized for placing on the market can be applied through aerial spraying, if their terms of use do not include an explicit prohibition of application through aerial spraying.

§ 16. Until 1 June 2015, the ordinance under Article 5 (2) from the Protection Against the Harmful Impact of Chemical Substances and Mixtures Act shall also be applied in regard to the classification, labelling and packaging of the plant protection products and adjuvants.

§ 17. The implementation of this Act is assigned to the Minister of Agriculture and Foodstuffs.

§ 18. (1) Article 9 (3) shall enter into force within a 3-month period from the promulgation of the act in the State Gazette.

(2) Article 6, Paragraph (1), Item 1, Letter "c", Article 54, Item 2 and Article 65 shall enter into force from 1 January 2015.

(3) Article 101, Item 6 shall enter into force from 26 November 2015.

(4) Article 49 (6) shall enter into force from 1 January 2016.

Appendix No. 1

to Article 9 (3)

General integrated pest management principles

1. The protection from pests and/or the limiting thereof must be achieved or assisted mainly through:

- a) crop rotation;
- b) conducting appropriate agro-technical activities (for example: preliminary preparation of the seed beds, timing and density of sowing, sub-sowing, optimal distance between the crops, anti-erosion processing, sanitary measures and trimming);
- c) use of appropriate resilient/tolerant sorts of plants and of standard/certified seed and sowing material;
- d) application of balanced fertilization, liming, practices for irrigation and drainage;
- e) prevention of the dissemination of harmful organisms through implementation of sanitary

measures (for example: through regular cleaning of the machines and equipment);

f) protection and sustenance of the beneficial organisms (for example: through application of appropriate plant protection measures or through the use of ecological infrastructures in or out of the cultivated areas).

2. The pests must be monitored by appropriate methods and means. Such methods must include scientifically-justified systems for warning, forecasting and early diagnostics, as well as the use of professional consultations.

3. On the basis of the results from the monitoring, the professional user must decide whether and when to apply plant protection measures. A pivotal factor, when taking the decisions, shall be the approved thresholds of economic harmfulness. The thresholds of economic harmfulness, the specific areas, crops and climate conditions must be taken into consideration prior to treatment, if possible.

4. The sustainable biological, physical and other non-chemical methods are to be preferred relative to the chemical methods, provided they ensure a satisfactory level of pest control.

5. The applied plant protection products must be selective in terms of their target and must have minimum side effects on the health of humans, beneficial organisms and the environment.

6. The professional user must limit the use of plant protection products and other forms of intervention to the necessary degree, such as for example to use low doses, a reduced number of treatment or partial treatment (for example: hot spot-focused or strip-oriented) when he/she is of the opinion that the degree of risk to the crop is acceptable and that the threat of building resistivity to the pests is not increased.

7. When there is a threat of creation of resistivity but the protection of the crop requires multiple applications of the plant protection product, in order to preserve the effectiveness of the products, the available strategies against development of resistivity must be applied. This may include the use of several plant protection products with different mechanisms of effect.

8. On the basis of the data on the plant protection products used and of the data from the monitoring of the pests, the professional user shall check the extent to which the applied plant protection measures are successful.

Appendix No. 2

to Article 85 (1)

Training topics

1. The applicable legislation regarding the plant protection products and their use.

2. Existence and risks of illegal (counterfeited) plant protection products and methods for the detection thereof.

3. The threats and risks related to the plant protection products, as well as the methods for the identification and control thereof and in particular:

a) risks to the human beings and factors which increase these risks;

b) symptoms in the event of poisoning by plant protection products and rules for rendering first aid;

c) risks for the non-target plants, the beneficial insects, the wild nature, the biological diversity and the environment as a whole.

4. Knowledge of the main principles of integrated management of the pests, the plant species, the principles of biological agriculture, biological methods for pest control, information about the

general and specific principles for certain crops.

5. Development and introduction of a comparative assessment for assisting the professional users in choosing the most appropriate plant protection product of all those authorized for a specific pest, where the chosen product must have minimum side effects to the health of humans, non-target organisms and the environment.

6. Familiarity with the measures needed for limiting the risks to people, non-target organisms and the environment: safe work practices for storage, use and mixing of plant protection products, as well as decontamination of empty packagings, other polluted materials and residual quantities of plant protection products (including mixtures from tanks); recommendations to the operators for using personal protection devices.

7. The risk-based approaches which take into consideration the local variable characteristics of the water yield, such as climate, soils, types of crops and lay of the land.

8. Precise adherence to the procedures for preparation for work of the equipment for application of plant protection products, including its calibration, as well as for its operation in order to ensure minimization of the risks to the user thereof, to other people, to non-target organisms, to the biological diversity and to the environment.

9. Best practices for protection of the waters from pollution caused by point sources when using plant protection products.

10. Use of the equipment for application of plant protection products and maintenance thereof according to the requirements, application of the specific techniques for spraying (for example: small-volume spraying and nozzles for limitation of the deviation-of-the-stream effect), as well as the objectives of the technical check of the used spraying machines and the methods for improving the quality of spraying. Familiarity with the specific risks that have to do with the use of equipment for manual application of plant protection products or of back-mounted spraying machines and the respective risk management measures.

11. Performance of the necessary urgent actions for protection of human health and of the environment, including the water resources, in the case of accidental leakage and pollution by plant protection products and under extreme weather conditions.

12. The special requirements in regard to the use of plant protection products on the territory of the National Ecological Network and other territories of special status, established according to the applicable legislation.

13. Submission of information on all actual and suspected incidents related to plant protection products by all the types of health care establishments.

14. Collection and storage of data on every use of plant protection products in accordance with this act.

This act, together with the appendices hereto, was passed by the 42nd National Assembly on 10 July 2014 and has been sealed with the official seal.