

Legal procedures related to use, import, storage and treatment of plant protection products in Bulgaria

TECHNICAL REPORT

Under action A1 of the Egyptian Vulture New LIFE project (LIFE16 NAT/BG/000874)

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SUMMARY

This report represents the results of a desk-based study on the legislation and publically available information about plant protection products (PPPs) from the perspective of vulture conservation in Bulgaria. Targeted desk research was carried out in 2018 in order to obtain publically available information on the regulations of use, trade and transboundary control of PPPs, as well as implementation of the legislation in practice in the country.

The legislation on use, production, import, storage and treatment of plant protection products (PPP) in Bulgaria is rather complicated and to a higher extend influenced by the EU legislation on this issue. Nevertheless that the law seems quite strong in terms of autorisation of PPPs, the highe number of derogations in the procedures set up on EU level weakens the legislation. Low level of ensurance of transparency of the procedures combined with limited range of control mechanisms by law creates risks for implementation of bed practices. It also allows to authorize PPPs which include banned active substances as it could be seen when explore the official register of PPPs in Bulgaria.

In terms of nature protection the law requires safeguarding the environment in broader context, where the water quality as well as bees are the only two components of the environment which explicitly require protection. The way the legislation is designed should be efficient to ensure food safety and human health, but do not have enough mechanisms to ensure protection of the environment in terms of biodiversity in particular, including vultures. It is very important aspect, as many of PPPs can be used to poison animals – both domestic and wild ones.

One positive aspect of the legislation is that it sets out the National Action Plan on Sustainable Use of Pesticides. This plan is expected also to set out specific measures for the protection of the aquatic environment (surface and groundwater) and drinking water from the effects of pesticides. This aspkt of legislations creates, at least on paper, real legal mechanism for practical transition to more nature-friendly and less-ricky agriculture. Unfortunately not much importance is given to this Action plan when all the procedures for authorization, trade, use and control of PPPs are set up in the law.

In terms of further advocacy work, it should be based on the efficiency of the implementation of legislation, as well as cooperation. Advocacy work have to be based on evidence. Where the advocacy is dependent on institutions out of Bulgaria, different strategy have to be applied, involving all the relevant partners.

As part of the advocacy work more efforts should be focused on elaboration and implememntation of the National Action Plan on Sustainable Use of Pesticides, as well as implementation f the Common agriculture policy of EU, whichin reality push for intensification of agriculture.

As long as many PPPs could be used as poisoned agents, advocay work should be focused also to stronger regulation on production, import/export, storage and use of such PPPs. Cooperation between institutions should be encoraged and common strategy against use of poisons should be developed.

Advocay work should include also EU level, as long as many of the regulations are set out at this level and cannot be influenced at local level.

SUBJECT AND PURPOSE OF THE REPORT

This report is developed under the frames of action A1 of the LIFE+ project “Egyptian vulture New LIFE” (LIFE16 NAT/BG/000874, www.LifeNeophron.eu), further referred as “the LIFE project” funded by the European Commission and co-funded by the “A. G. Leventis Foundation”, and implemented by the Bulgarian Society for the Protection of Birds (BirdLife Bulgaria), the Hellenic Ornithological Society (BirdLife Greece), the World Wildlife Fund for nature - WWF Greece, the Royal Society for the Protection of Birds (BirdLife UK) (RSPB), Doğa Derneği / BirdLife Turkey (DD), BirdLife Middle East, BirdLife Africa, A.P. Leventis Ornithological and Research Institute (APLORI), CMS Raptors MoU, Green Balkans.

The main goal of the studies under Action A1 is to identify the scale and significance of impacts of chemicals used in agriculture in the Balkan countries (in particular Bulgaria, FYR of Macedonia and Albania) as poisoning agents to Egyptian Vulture and to propose adequate response to this impact. More specifically the aim is to:

- Create (or update if there is an existing one) and maintain data base about the legal and illegal use of chemicals in agriculture **(A1.1)**;
- Provide direct evidence on the impact of the agricultural chemical use on vultures **(A1.2)**;
- Develop a response strategy to the negative effects from the use of agricultural chemicals **(A1.3)**.

Under the action A1 it is planned to investigate a large variety of agricultural chemicals, including both legally and illegally used pesticides, insecticides, rodenticides, fungicides and herbicides and other agricultural chemicals potentially dangerous for vultures (e.g. acaricides, nematocides, bioinsecticides and repellents, fertilizers). For each chemical identified as potentially dangerous to the Egyptian Vulture, information is to be collected on the legal status; production, import, export and storage; target species, advisable quantities per area, timing of application, site, methodology and stakeholders involved.

This report is elaborated on a base of desk-based study of legislation and publically available information. Targeted desk research was carried out in winter 2018 in order to obtain publically available information about regulations of use, trade and transboundary control of plant protection products, as well as implementation of the legislation in practice. For this purpose extended internet search was carried out of the web sites of the competent authorities. After preliminary analysis of the publically available information a letter for access to public information was send to the Bulgarian Food Safety Agency, in order to obtain further official information about the substances targeted under action A1. In addition series of at least 4 meetings were carried out with laboratories in term of sample analysis from found carcasses. Main findings due to implemented activities are summarized below.

LIST OF THE LEGAL ACTS

Eight laws, 53 Regulations and 2 Statutes regulate the agriculture activities in Bulgaria, where the main law, related to chemical use is the **Plant Protection Act**. Four regulations of EU are directly implemented on the territory of Bulgaria, where 2 of them are particularly related to plant protection products.

Laws

Plant Protection Act

Subject

The Plant Protection Act (PPA) is the main law governing public relations related to the protection of agricultural produce (both plants and products) and introduces international standards at national level. According to Art. 1, this includes phytosanitary measures under the International Plant Protection Convention; the protection of plants and plant products from economically important pests; monitoring, diagnosis, prognosis and signaling in plant protection; phytosanitary control; the implementation measures of EU Regulation No 1107/2009; requirements for plant protection products for the protection of human and animal health and the environment, their biological testing, their use as required by EU Directive 2009/128/EC; the requirements for carrying out specialized plant protection services and the subsequent control over them; implementing measures for EU fertilizer regulation 2003/2003; and the requirements for fertilizers, soil improvers, biologically active substances and food substrates, and control of production, placing on the market and use thereof.

The law introduces the following concepts which are important in terms of law enforcement and environmental protection:

'active substances' - substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products (art.2(2))

'adjuvants' - substances or preparations which consist of co-formulants or preparations containing one or more co-formulants, in the form in which they are supplied to the user and placed on the market to be mixed by the user with a plant protection product and which enhance its effectiveness or other pesticidal properties (art.2(3), item (c))

'ammonium nitrate fertilizers of high nitrogen content' are mono-constituent or complex fertilizers based on ammonium nitrate, which contain more than 28% of the mass of nitrogen in relation to ammonium nitrate.

'authorized plant protection product' means any plant protection product authorized for placing on the market and use.

'authorized use' is the application of a plant protection product to certain plants and plant products and against a specified pest under the conditions of use specified in the marketing authorization and use of the product.

'biodiversity' means variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this variability may include diversity within species, between species and of ecosystems;

'co-formulants' - substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists (art.2(3), item (c)).

'control sample' means a quantity of plants, plant products, plant protection products, fertilizers, soil improvers, biologically active substances or food substrates, which in a laboratory test provides an objective and complete assessment of the conformity of the whole quantity / batch thereof with their statutory requirements.

'good plant protection practice' means a practice whereby the treatments with plant protection products applied to given plants or plant products, in conformity with the conditions of their authorised uses, are selected, dosed and timed to ensure acceptable efficacy with the minimum quantity necessary, taking due account of local conditions and of the possibilities for cultural and biological control;

'environment' means waters (including ground, surface, transitional, coastal and marine), sediment, soil, air, land, wild species of fauna and flora, and any interrelationship between them, and any relationship with other living organisms;

'integrated pest management' is a careful study of all available plant protection methods and the subsequent integration of appropriate measures to limit the development of harmful organisms, to maintain economically and environmentally sound levels of use of plant protection products and other forms intervention and to reduce or minimize the risks to human health and the environment.

'integrated production' is a system for the production of plants and plant products by applying the specific principles of integrated pest management.

'minimum use' means the use of a plant protection product in a Member State on plants or plant products which: (a) are not widespread in that Member State; or (b) are widespread in order to respond to an extraordinary need for plant protection;

'pesticide' is a plant protection product.

'phytosanitary control' means any action and measure taken against the transfer and / or dissemination of quarantine pests of plants, plant products and other objects.

'residues' means one or more substances present in or on plants or plant products, edible animal products, drinking water or elsewhere in the environment and resulting from the use of a plant protection product, including their meta- bolites, breakdown or reaction products; (art.3(1))

'safeners' - substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants (art.2(3), item (a)).

'substance of concern' means any substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a plant protection product in sufficient concentration to present risks of such an effect. Such substances include, but are not limited to, substances meeting the criteria to be classified as hazardous in accordance with EU Regulation No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (¹), and present in the plant protection product at a concentration leading the product to be regarded as dangerous within the meaning of Article 3 of Directive 1999/45/EC; (art.3(4))

'**synergists**' - substances or preparations which, while showing no or only weak activity as referred to in paragraph 1, can give enhanced activity to the active substance(s) in a plant protection product (art.2(3), item (b)).

'**unauthorized use**' means the use of an authorized plant protection product other than that specified in its authorization to place it on the market and use it.

'**use category**' means the determination of a plant protection product to a group in order to limit its use to a particular category of consumer.

Competent authorities

Plant protection falls within the competence of the **Ministry of Agriculture, Food and Forestry (MAFF)** and the Minister implements the state policy in this field (Art. 2).

The **Bulgarian Food Safety Agency (BSFA)** carries out all activities regulated by the PPA, including: authorization of plant protection products and registration of fertilizers, soil improvers, biologically active substances and food substrates for placing on the market and use ; control over the persons who trade and repackage plant protection products; control on the manufacture, placing on the market and use of the above substances and products; control of the implementation of EC Regulations 2003/2003 and No 1107/2009 (Article 3 (1)). In order to carry out these activities, the Executive Director of BSFA provides obligatory instructions and approves models of applications, permits, certificates, notifications, declarations, diaries and others under this Act (Art.4).

The control over the implementation of this law is carried out by the **BSFA plant protection inspectors** (Art. 7 (1)), which: carry out inspections of plants, plant products and other objects, plant protection products, active substances, adjuvants, fertilizers, soil improvers, biologically active substances and food substrates (Art. 7(2-1)); carry out inspections at the sites in which the substances and products listed above are manufactured, tested, researched, repackaged, stored, transported, marketed or otherwise available (Art. 7(2-3)); take control samples from the aforementioned substances and products and from other sites for carrying out laboratory tests (Art. 7(2-5)); require information and documents, including written explanations related to their control activities (Art. 7(2-8)); issue instructions and prescriptions for carrying out measures for correction of established discrepancies, setting deadlines for their implementation (Art. 7(2-9)); draw up acts for established administrative violations under this Act and/or the acts for its implementation (Art. 7(2-10)); refer the relevant competent authorities and control bodies for found violations; request the assistance of other competent authorities and control bodies (Art. 7(2-11)). For implementing their obligations the plant protection inspectors have the right of access to the sites, including protected areas within the meaning of the Protected Areas Act (Art. 7(3)).

Council for plant protection products (CPPP) is established as a permanent consultative body on matters relating to plant protection products (Art. 53 (1)), which consul the Executive Director of BSFA. The MAFF issues regulation on the organization and activity of the CPPP and, on a proposal of the Executive Director of the BSFA, determines its composition, including representatives of the MAFF, Ministry of Health, and Ministry of environment and water and scientific institutes (Art. 53 (2)). Members of the CPRS shall sign a confidentiality statement in a standard form, under which they undertake not to distribute the information submitted to them when authorizing plant protection products and not to use it for their own benefit or for the benefit of third parties (Art. 53 (3)). Pursuant to Article 54, the CPPP takes decisions and makes suggestions to the BSFA Executive

Director to: authorize the placing on the market and use of a plant protection product in accordance with Chapter III, Section 1 of EU Regulation No 1107/2009 or a refusal; authorizing the placing on the market and use of a plant protection product in the form of a ready solution or refusal; renewal or amendment of the marketing authorization and use of a plant protection product, including a ready-to-use solution or a refusal; and withdrawal or termination of a marketing authorization and use of these products.

An Expert Committee on Fertilizers, Soil Improvers, Biologically Active Substances and Food Substrates is established to the BFSA Executive Director, as a standing advisory body on issues related to fertilizers, soil improvers, biologically active substances and food substrates (Art. 132 (1)). The BFSA Executive Director approves rules for the organization and operation of the Expert Committee (Art. 132 (2)). The composition of the Expert Committee is determined by an order of the Minister of Agriculture, Food and Forestry and includes representatives of the MAFF, the Ministry of Health, the MoEW and the BFSA (Art. 132 (3)). The Expert Committee shall make suggestions to the BFSA Executive Director for: the registration or change in registration of fertilizers, soil improvers, biologically active substances and food substrates not placed on the market in a Member State or refusal; deletion of registration of above mentioned products and substrates (Art. 132 (4)).

Registers

Pursuant to Article 6, paragraph 1 of the PPA, BFSA creates and maintains 15 public registers, out of which 12 can be defined as essential in terms of providing public information that is useful for carrying out our work:

- (1) Register of plant protection products for which an authorization has been granted** for: (a) placing on the market and use; (b) use in the conduct of research and/or development activities; (c) placing on the market and use as a ready-to-use solution; (d) parallel trade;
- (2) Register of plant protection products which are repackaged;**
- (4) Register of persons holding a certificate for trade of plant protection products** and of the relevant sites for trade with plant protection products;
- (5) Register of persons holding a certificate of repackaging of plant protection products** and of the relevant repackaging places for plant protection products;
- (6) Register of persons who produce plant protection products** on the territory of the Republic of Bulgaria;
- (7) Register of persons holding a certificate of import or entry of a batch of non-approved active substances;**
- (8) Register of authorizations for application of plant protection products by aerial spraying;**
- (9) Register of persons carrying out specialized plant protection services:** (a) fumigation of plants, plant products and other objects; (b) treatment of plant protection products for seed; (c) integrated pest management advisory services;
- (10) Register of persons engaged in integrated production of plants and plant products;**
- (13) Register of persons holding a certificate under Art. 83 for professional use of PPPs** (distributors, consultants and professional users of plant protection products);

(14) Register of fertilizers, soil improvers, biologically active substances and food substrates for which a certificate has been issued for placing on the market and use;

(15) Register of adjuvants to be placed on the market and used.

The registers are published on the BFSA website and updated upon each change in the circumstances entered therein (Art. 6 (2)). The registers under para. 1, items 1 - 3, 6, 7, 12, 14 and 15 shall be established and maintained by the Headquarter of BFSA. The registers are published on the NVS website and updated upon each change in the circumstances entered therein (Art. 6 (2)). The registers under para. 1, items 1 - 3, 6, 7, 12, 14 and 15 shall be established and maintained by the BFSA Central Administration and the registers under para. 1, items 4, 5, 8 - 11 and 13 - by the Regional Directorates of Food Safety (RDFS) (Art. 6 (3)). The BFSA Central Administration maintains national registers which contain the data from the RDFS registries (Art. 6 (4)). The contents of the registers and the order for keeping them shall be determined by an ordinance of the Minister of Agriculture, Food and Forestry (Art. 6 (5)). The draft of the ordinance made in 2015 describes the contents of each of the registers under Article 6, but this draft is not adopted yet.

National Action Plan for Sustainable Use of Pesticides under Art. (4) of Directive 2009/128 / EC

The Council of Ministers approves a National Action Plan for the Sustainable Use of Pesticides to reduce the risks and impacts of pesticide use on human health and the environment and to promote the development and introduction of Integrated Pest Management and alternative approaches or methods (Art. 124 (1)).

The Action Plan amongst the other things set quantitative and other objectives, measures and deadlines for reducing the risks and impacts of the use of pesticides on human health and the environment; and encourages the introduction of integrated pest management and alternative approaches or methods to reduce dependence on pesticide use.

The National Action Plan on Sustainable Use of Pesticides sets out specific measures for the protection of the aquatic environment (surface and groundwater) and drinking water from the effects of pesticides.

National regulations

National regulations provide detailed description of the requirements and procedures under certain provisions of the Law

Ordinance No 8 of 27.02.2015 on phytosanitary control

The Ordinance on Phytosanitary Control defines: plants, plant products and other objects with which quarantine pests can be transported and distributed; plants, plant products and other objects subject to special import and movement requirements; protected areas with regard to quarantine pests and

the movement of plants and plant products through them; plants and plant products for which a plant passport or phytosanitary certificate is required (Article 19 (1)).

Ordinance No 1 of 5 January 2017 on the storage, transport and export of unauthorized active substances

Persons who import or import unapproved active substances submit annually by 31 March to the Central Administration of BFSa notification of unauthorized active substances which they have imported or introduced on the territory of the country during the previous year. The notification shall contain the quantities and batch numbers of the substances and the names of the border crossing points through which they have been entered or entered (Art. 3).

Unauthorized active substances are stored in storage facilities of active substance manufacturers and plant protection products that meet the requirements of proper storage of substances, the prevention of the entry of humans and animals, and soil and water contamination substances.

Concerning the transposition of non-approved active substances, the Ordinance makes reference to the requirements of several laws: Road Transport Law, Railway Transport Act, Merchant Shipping Code and Civil Aviation Act. Unauthorized active substances are transported in compliance with the manufacturer's requirements in a way that, among other things, prevents pollution of the environment (Art. 8).

The export of the unauthorized active substances shall be carried out under the conditions and by the order of art. 22a and 22d of the Law for Protection from Harmful Impact of Chemical Substances and Mixtures (Art. 10).

EU regulations

EU regulations are part of the EU legislation, directly implemented in all the EU Member States, including Bulgaria.

REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

This Regulation lays down: rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within the Community (art.1(1)); and both rules for the approval of active substances, safeners and synergists, which plant protection products contain or consist of, and rules for adjuvants and co-formulants (art.1(2)). The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. (art.1(3)). The provisions are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory (art.1(4)).

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation (Art.1(1)). This Regulation lays down provisions on substances and preparations within the meaning of Article 3. These provisions shall apply to the manufacture, placing on the market or use of such substances on their own, in preparations or in articles and to the placing on the market of preparations (Art.1(2)). This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle (Art.1(2)).

Every five years, Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement as described in Article 127 (Art. 117).

The following information held by the Agency on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e): (a) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC, without prejudice to paragraph 2(f) and (g); (b) if applicable, the name of the substance as given in EINECS; (c) the classification and labelling of the substance; (d) physicochemical data concerning the substance and on pathways and environmental fate; (e) the result of each toxicological and ecotoxicological study; (f) any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I; (g) the guidance on safe use provided in accordance with sections 4 and 5 of Annex VI; (h) analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

PROCEDURES

There are 10 main procedures under the Plant Protection Act which could be directly or indirectly connected to production, use, storage, trade, import of Plant Protection Products. These are described below.

1. Control of economically important pests

Each year until 31 January, the Executive Director of BFSA approves a list of economically important pests on agricultural crops by administrative-territorial units (districts) and sets thresholds for economic harm by pests. The pests on the list are subject to systematic and permanent observations (Art. 8). Protection of plants and plant products from economically important pests shall be carried out under conditions and by an order determined by an ordinance of the Minister of Agriculture, Food and Forestry¹, applying good plant protection practice (Art.9 (1 and 2)). Protection of plants and plant products shall be carried out in accordance with the general principles for integrated pest management set out in Appendix 1 to the PPA (Art. 9 (3)).

BFSA establishes, maintains and maintains a national database on the occurrence, spread, density, development and extent of attack by economically important pests on agricultural crops under the terms and conditions set out in the Ordinance under Art. 9 (1) (Art. 13 (1)) and issue periodic bulletins and other materials for the disclosure of the occurrence, distribution and development of economically important pests on agricultural crops and the means of combating them (Art.13 (2)). In carrying out the activities under para. 1 and 2, BFSA interacts with farmers, agronomists, consultants, branch organizations and other non-governmental organizations in the field of plant protection (Art. 13 (2)). The Minister of Agriculture, Food and Forestry declares by order a calamity or epiphytis of economically important pests for a certain region, district or for the territory of the whole country (Art.15 (1)). The order shall determine the respective territory of the country, the type of the economically important pest and the type of control measures against the respective pest and the period for their implementation (Art.15 (2)). In the case of a calamity or epiphitosis, all persons, including the state and municipal authorities in the area, the district or the territory of the whole country, apply the control measures against the respective pest (Art.15 (4)).

2. Phytosanitary control

The phytosanitary control of plants, plant products and other objects shall be carried out in order to prevent the penetration or limitation of the spread of quarantine pests on plants and plant products (Art. 16 (1)) under conditions and by an order determined by an ordinance of the Minister of agriculture, food and forestry² (Art. 16 (2)). The phytosanitary measures for individual quarantine pests are determined by ordinances of the Minister of Agriculture, Food and Forestry and/or by decisions of the European Commission, which shall be published on the BFSA website (Art. 16 (3)). In all cases of establishment of quarantine pests and phytosanitary measures, the BFSA shall

¹ Ordinance No. 14 of 19.09.2016 for the protection of plants and plant products from economically important pests
http://www.babh.government.bg/userfiles/files/fito-plodove-obrazci/NAREDBA_14_ot_19.09.2016_g..pdf

² Ordinance No 8 of 27.02.2015 on phytosanitary control
http://www.babh.government.bg/userfiles/files/Registri/fito-sanitaren/ORIGINAL_NAREDBA_8_ot_27.02.2015_g._za_fitosanitarniq_kontrol.pdf

immediately notify the European Commission and the competent authorities of the other Member States of the type of pest and of the measures taken (Article 16 (4)). The import, possession, storage and movement of quarantine pests, plants, plant products and other objects, as defined in the Ordinance under Art. 16 (2) (Article 17).

3. Active substances, antidotes, synergists and co-formulants - approval, production, packaging and labeling procedures

Active substances, antidotes and synergists shall be approved, renewed and reviewed by the Food Chain Risk Assessment Center as set out in Sections 1 and 2 of Chapter II of EU Regulation No 1107/2009 (Art. 37 (1)). Co-formulants shall not be included in plant protection products in the cases under Art. 27 of EU Regulation No 1107/2009 (Article 37 (2)), which include, among other things, "unacceptable effects on the environment".

Persons who produce active substances, safeners or synergists on the territory of the country shall submit to the Central Administration of BFSa notification for the substances listed above (Art. 39 (1)). A model notification shall also be filed with the persons importing antidotes, synergists or approved active substances for the production of plant protection products (Art. 39 (2)). Persons supplying active substances, antidotes or synergists shall provide a safety data sheet in Bulgarian in accordance with Art. 31 of EU Regulation 1907/2006 (REACH)³ (Article 39 (3)).

Active substances, safes and synergists are classified, packaged and labeled according to EU Regulation No 1272/2008 (CLP)⁴.

Unauthorized active substances

Unauthorized active substances are imported or introduced after the issue of a certificate of import or entry of a batch of unauthorized active substances by the BFSa Executive Director or his officially authorized representative if they are intended for the production on the territory of the country of plant protection products intended for export (Art. 41 (1)). Unauthorized active substances are produced if they are intended for production of plant protection products on the territory of the country, but are intended for export. Production of unauthorized active substances is also allowed for export purposes (Art. 41 (2)).

Unauthorized active substances shall be stored, transported and exported from the territory of the country under the terms and conditions laid down in an ordinance of the Minister of Agriculture, Food and Forestry⁵ (Art. 41 (3)). Paragraphs 1 to 3 shall apply in the presence of a system for the control of the import or the introduction, manufacture, storage, transport and export of unauthorized active substances. In order to obtain a certificate of import or introduction into the country of a batch of unauthorized active substances, the persons submit to the Central Administration of BFSa an application to which they attach the documents, defined in the Ordinance under Art. 41 (3) (Art. 42 (1)). The application and the attached documents are verified by experts from the BFSa. In case of incompleteness and/or discrepancies, the applicant shall be notified in

³ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF> (EN)

http://www.chemicals.moew.government.bg/chemical/site/File/reach/REACH_bg_consolidated_2011.pdf (BG)

⁴ <https://eur-lex.europa.eu/legal-content/BG/TXT/PDF/?uri=CELEX:32008R1272&from=BG>

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1272&from=BG>

⁵ ORDINANCE No 1 of 5 January 2017 on the storage, transport and export of non-approved active substances
<http://lex.bg/bg/laws/ldoc/2136995820>

writing and shall set a time limit for their removal. If the incomplete and/or inconsistencies are not remedied, the application is left unannounced. Provided that the documentation is complete and free of omissions or non-conformities, BFSA shall issue a 1-year valid certificate of import or entry of a batch of unauthorized active substances within a period of 7 days (Art. 43). The applicant has the right to import or import the unauthorized active substances after having notified in advance this the Central Administration fo BFSA and the BFSA Executive Director or an official authorized representative does not give a refusal within 7 days of receipt of the notification (Art. 43 (1)).

4. Approval of plant protection products

Plant protection products are placed on the market and used after marketing authorization and use in accordance with EU Regulation No 1107/2009 and are available in original packaging or repackaged with a label in Bulgarian (Art. 44 (1 and 2)).

BFSA creates and maintains a public register of plant protection products that have been submitted for authorization, which contains the date of application, applicant, active substances and trade name (Art.44 (3)). Where a plant protection product is authorized or applied for marketing authorization and use under a given trade name, the same name may not be used in the case of an application for authorization to place on the market and use for another product from another applicant (Art.44 (4)). Within 5 years of withdrawal or expiry of the marketing authorization and use of a plant protection product, its trade name may not be used for another product (Art.44 (5)).

Authorization for placing on the market and use of a plant protection product shall be issued by the BFSA Executive Director to a person established in the territory of a Member State under conditions and by an order specified by an ordinance of the Minister of Agriculture (Art.45 (1)). This ordinance is still in a draft⁶, , which is why the Ordinance from 2006 is currently in force⁷. When a person under par. 1 is not established in the territory of the Republic of Bulgaria, it shall authorize its representative in writing. The holder of a marketing authorization and use of a plant protection product is responsible for the plant protection products placed on the market. The appointment of an authorized representative does not relieve the holder of the authorization (Art.45 (4)).

A plant protection product is authorized for placing on the market and use when it meets the requirements of Chapter III, Section 1, of EU Regulation No 1107/2009 to be established by performing a product evaluation in accordance with the Regulation referred to in Article 45 (1) (Art.46).

4.1 Authorization of the placing on the market and use of plant protection products

The law described in details all types of possible authorization procedures. A plant protection product shall be authorized for:

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https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&cad=rja&uact=8&ved=2ahUKewixwdC3n_DgAhWq6KYKHQ5BBdMQFJAEegQIBhAC&url=http%3A%2F%2Fec.europa.eu%2Fgrowth%2Ftools-databases%2Ftris%2Fde%2Findex.cfm%2Fsearch%2F%3Ftrisation%3Dsearch_detail%26year%3D2018%26num%3D80%26dLang%3DBG&usg=AOvVaw1-t2-FMgRWNSFTML6hoC9V

⁷ http://agropal-bg.com/documents/2015/10/Naredba_Razresh_PRZ.pdf

- **placing on the market and use** under the conditions and by the order of art. 33 - 39 of EU Regulation No 1107/2009 and of the Ordinance under Art. 45 (1) (Art. 55 (1));
- **temporary placing on the market and use** under the conditions and by the order of art. 30 of EU Regulation No 1107/2009 and Art. 55 (Art. 56);
- **placing on the market and use by mutual recognition of authorizations** under the conditions and by the order of Art. 40 - 42 of EU Regulation No 1107/2009, of the ordinance under Art. 45 (1) and by the order of art. 55, para. 2-5 (Art. 57);
- **placing on the market and use of a low-risk product** under the conditions and procedure of Art. 47 of EU Regulation No 1107/2009 and Art. 55 (Art. 58);
- **placing on the market and use for parallel trade** under the conditions and by the order of art. 52 of EU Regulation No 1107/2009 and of the Ordinance under Art. 45 (1) (Article 61 (1));
- **placing on the market for limited and controlled use** under the conditions and by the order of Art. 53⁸ of EU Regulation No 1107/2009 and of the Ordinance under Art. 45, para. (1) in the case of a danger to plants and plant products which can not be contained by plant protection products, means and methods applicable in good plant protection practice (Article 62 (1)).

The BFSA Executive Director shall, within 14 days of receipt of a CPPP proposal, issue an **authorization for the placing on the market and use** of a plant protection product or shall reasonably refuse to authorize it if it does not meet any of the requirements of Art. 46 (1) (Art. 55 (2)). The refusal shall be announced and may be appealed in accordance with the Administrative Procedure Code (Art.55 (3)). The issued permit shall be entered in the register under Art. 6 (1), item 1 (Art. 55 (4)).

An **authorized plant protection product shall be placed on the market and used in the form of a ready-to-use solution** after an authorization has been granted under the conditions and by the order of the ordinance under Art. 45 (1) (Art. 65 (1)). The ready solution is permitted in one of the concentrations of the working solutions for the respective use approved in the authorization (Art. 65 (2)). Within 60 days of submitting an application on a CPPP proposal, the BFSA Executive Director shall, by order, authorize the placing on the market and use of the plant protection product in the form of a ready-to-use solution and issue an authorization or reasonably refuse authorization if its fitness has not been demonstrated (Art. 65 (3)). The period of validity of the authorization granted may not exceed the term of validity of the marketing authorization and use of the plant protection product (Article 65 (4)). The issued permit shall be entered in the register under Art. 6 (1), item 1 (Art. 65 (6)). No authorization shall be granted for a prepared solution of a plant protection product that is: authorized for placing on the market for restricted and controlled use, for parallel trade or for use in research and / or development; categorized in category of use first professional (Art. 65 (8)).

Extending the scope of a marketing authorization and the use of a **plant protection product for minimal use** shall be permitted under the conditions and by the order of Art. 51 of EU Regulation No 1107/2009, of the Ordinance under Art. 45 (1) and by the order of art. 55, para. 2 - 5 (Article 60 (1)). The authorization for the placing on the market and use of a plant protection product shall be renewed under the conditions and by the order of Art. 43 of EU Regulation No 1107/2009 and of the Ordinance under Art. 45 (1) (Art. 66 (1)). The amendment or withdrawal of the authorization for placing on the market and use of a plant protection product shall be carried out after its review within the term of its validity under the conditions and by the order of Art. 44 of EU Regulation No 1107/2009 and by an order specified in the Ordinance under Art. 45 (1). The permit shall also be revoked when it has not been renewed under Art. 66 (Art. 67 (1)). The reissued permit, respectively the order for withdrawal of the permit shall be entered in the register under Art. 6 (1), item 1 (Art. 67 (4)).

⁸ Emergency situations in plant protection

The amendment or termination of the authorization for placing on the market and use of a plant protection product shall be carried out at the request of the holder under the conditions and by the order of Art. 45 of EU Regulation No 1107/2009 and under the terms and conditions set out in the Ordinance under Art. 45 (1) (Art. 68 (1)). Within 14 days of receiving a CPPP proposal, the BFSA Executive Director shall, by order, amend the authorization and reissued or reasonably refuse the amendment if the product does not meet any of the requirements of Art. 46 (1), respectively, by an order terminates the permit (Art. 68 (2)). The reissued permit, respectively the order for termination of the permit, shall be entered in the register under Art. 6 (1), item 1 (Art. 68 (4)). By the order of para. 2-4 shall be amended or terminated and the marketing authorizations and uses for parallel trade of plant protection products for which the plant protection product with a reissued or suspended authorization is a reference within the meaning of Art. 52 of EU Regulation No 1107/2009 (Art. 68 (7)).

For plant protection products whose marketing and use authorizations have been amended, revoked or discontinued, grace periods are defined for disposal, storage, placing on the market and use under the conditions of Art. 46 of EU Regulation No 1107/2009 and in accordance with the procedure laid down in the Ordinance under Art. 45 (1) (Art. 69 (1)). Where the marketing authorization and use of a plant protection product has been withdrawn for reasons relating to the protection of human or animal health or the environment, the placing on the market and the use of the product shall be discontinued without delay, for withdrawal, storage and disposal not longer than 6 months (Article 69 (2)). The grace periods and the term shall be determined in the order amending, withdrawing or suspending the authorization for the placing on the market and use of a plant protection product (Art. 69 (3)).

4.2 Mutual recognition of authorisations under EU Regulation No 1107/2009

The holder of an authorisation granted in accordance with Article 29 may apply for an authorisation for the same plant protection product, the same use and under the comparable agricultural practices in another Member State under the mutual recognition procedure, provided for in this subsection, in the following cases: (a) the authorisation was granted by a Member State (reference Member State) which belongs to the same zone; (b) the authorisation was granted by a Member State (reference Member State) which belongs to a different zone provided that the authorisation for which the application was made is not used for the purpose of mutual recognition in another Member State within the same zone; (c) the authorisation was granted by a Member State for use in greenhouses, or as post-harvest treatment, or for treatment of empty rooms or containers used for storing plant or plant products, or for seed treatment, regardless of the zone to which the reference Member State belongs (art.40 (1)).

Where a plant protection product is not authorised in a Member State because no application for an authorisation has been submitted in that Member State, official or scientific bodies involved in agricultural activities or professional agricultural organisations may apply, with the consent of the authorisation holder, for an authorisation for the same plant protection product, the same use and under the same agricultural practices in that Member State under the mutual recognition procedure referred to in paragraph 1. In that case the applicant must demonstrate that the use of such a plant protection product is of general interest for the Member State of introduction. Where the authorisation holder refuses its consent, the competent authority of the Member State concerned may accept the application, on grounds of public interest. (art.40 (2)).

The Member State to which an application under Article 40 is submitted shall, having examined the application and the accompanying documents referred to in Article 42(1), as appropriate with regard

to the circumstances in its territory, authorise the plant protection product concerned under the same conditions as the Member State examining the application, except where Article 36(3) applies⁹ (art.41 (1)). By way of derogation from paragraph 1, the Member State may authorise the plant protection product where: (a) an authorisation is granted by a Member State which belongs to a different zone; (b) it contains a candidate of substitution; (c) Article 30 has been applied¹⁰; or (d) it contains a substance approved in accordance with Article 4(7)¹¹ (art.41 (1)).

For the purpose of authorization procedure the applicant submit documents described in Art. 42(1) and the Member State to which an application under Article 40 is submitted shall decide on the application within 120 days (Art. 42(2)).

4.3 Authorisation for placing on the market and use of a low-risk product under Art. 47 of EU Regulation No 1107/2009

Where all the active substances contained in a plant protection product are low-risk active substances as referred to in Article 22, that product shall be authorised as a low- risk plant protection product provided no specific risk mitigation measures are needed following a risk assessment. This plant protection product shall also meet the following requirements:

- (a) the low-risk active substances, safeners and synergists contained in it have been approved under Chapter II;
- (b) it does not contain a substance of concern;
- (c) it is sufficiently effective;
- (d) it does not cause unnecessary pain and suffering to vertebrates to be controlled;
- (e) it complies with points (b), (c) and (f) to (i) of Article 29(1)¹².

These products are referred to as 'low-risk plant protection products' (art.47 (1)). An applicant for authorisation of a low-risk plant protection product shall demonstrate that the requirements set out in paragraph 1 are met and shall submit with the application a complete and a summary dossier for each point of the data requirements of the active substance and the plant protection product. The Member State shall decide within 120 days whether to approve an application for authorisation of a low-risk plant protection product.

4.4. Parallel trade

A plant protection product that is authorised in one Member State (Member State of origin) may, subject to granting a parallel trade permit, be introduced, placed on the market or used in another Member State (Member State of introduction), if this Member State determines that the plant protection product is identical in composition to a plant protection product already authorised in its

⁹ By way of derogation from paragraph 2 and subject to Community law, appropriate conditions may be imposed with respect to the requirements referred to in Article 31(3) and (4) and other risk mitigation measures deriving from specific conditions of use.

¹⁰ By way of derogation from Article 29(1)(a), Member States may authorise for a provisional period not exceeding 3 years, the placing on the market of plant protection products containing an active substance not yet approved

¹¹ By way of derogation from paragraph 1, where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005.

¹² Requirements for the authorisation for placing on the market

territory (reference product). The application shall be submitted to the competent authority of the Member State of introduction (Art.52 (1) of EU Regulation No 1107/2009).

The BFSA Executive Director shall, within 14 days of receipt of a CPPP proposal, issue a **protection permit for parallel trade with the plant protection product**, or shall refuse authorization if the plant protection product is not identical to the reference product (Article 61 (2)). Prior to the placing on the market of a plant protection product under para. (1). The holder of the parallel trade permit shall notify in writing the BFSA Central Administration of the quantity and number of the relevant batch of the plant protection product to be placed on the market as well as the taking of a control sample of the product (Article 61 (5)).

Plant protection products shall be considered as identical to the reference products if: (a) they have been manufactured by the same company or by an associated undertaking or under licence in accordance with the same manufacturing process; (b) they are identical in specification and content to the active substances, safeners and synergists, and in the type of formulation; and (c) they are either the same or equivalent in the co-formulants present and the packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.

4.5 Authorisation for placing on the market of plant protection product for limited and controlled use

By way of derogation from Art. 28 of EU Regulation No 1107/2009, in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means. The Member State concerned shall immediately inform the other Member States and the Commission of the measure taken, providing detailed information about the situation and any measures taken to ensure consumer safety (Art.53(1) of EU Regulation No 1107/2009). The Commission may ask the Authority for an opinion, or for scientific or technical assistance.

Within three days after receipt of a CPP3 proposal under Art. 54 the BFSA Executive Director shall, by an order, authorize the placing of a **plant protection product on the market for limited and controlled use** or shall reasonably refuse to authorize it (Article 62 (2)). Where the product is not authorized for placing on the market and use, the order shall also specify the quantities for placing on the market for restricted and controlled use (Article 62 (3)). A plant protection product authorized for placing on the market and use may be authorized for placing on the market for restricted and controlled use and on the initiative of the BFSA when the use to which it applies is not included in the product authorization (Article 62 (7)).

A plant protection product which is not authorized for other uses but is only authorized for placing on the market for restricted and controlled use is only used in the areas for which it is authorized (Article 63 (1)). For each delivery, a person placing such a product on the market shall notify the Central Administration of the BFSA of the quantities of the plant protection product delivered to the country (Article 63 (2)), within 14 days after the expiry of the product authorization period they notify about the amount of non-realized products, (Article 63 (3)) and whether the product will be disposed of or exported from the country (Article 63 (4)). Within 7 days of the disposal or removal of the product, the person who placed it on the market shall submit to the Central Administration a written proof of this (Article 63 (5)).

Plant protection products which are not authorized for placing on the market and use may be produced, stored and transported on the territory of the country only in the cases under Art. 28 (2) (c) and (d) of EU Regulation No 1107/2009¹³ (Article 48 (1)). They are not used on the territory of the country and are exported from it at the latest 6 months before expiry of their shelf life (Art. 48 (2)), the producers of these products shall notify the Central administration of BFSA about the types of plant protection products they produce, (Art. 49 (1)) and for the warehouses in which they store them (Art.38 (3)).

The persons who produce, repackage, place on the market and trade in plant protection products, carry out and keep records according to Art. 67 (1) of EU Regulation No 1107/2009 (Article 49 (3)) and the persons who supply plant protection products shall provide a safety data sheet in Bulgarian in accordance with Art. 31 of EU Regulation No 1907/2006 (REACH) (Article 49 (4)). Persons placing plant protection products on the market develop and implement a system for blocking and withdrawing these products from the market (Article 49 (5)). They, as well as persons who repackage plant protection products, develop and implement a system for the recall of empty packaging by the end user of the products, were the system being implemented in accordance with the Waste Management Act (Art. 49 para. 6 and 7).

BFSA establishes and maintains a database for plant protection products placed on the market and stored on the territory of the country (Article 50 (1)). On request, the BFSA provides the MoEW and the Ministry of Health with available data on plant protection products used in the country, and the data are provided by area (Article 50 (3)).

Import, introduction, placing on the market or use is prohibited for unauthorized or unfit plant protection products as well as plant protection products from persons not authorized to be placed on the market and used (Art. 52).

5. Classification, packaging, labeling and categorization of plant protection products

According to Article 79 plant protection products are: classified in accordance with Regulation (EC) No 1272/2008 (CLP); shall be labeled in accordance with Regulation (EC) No 1107/2009, Regulation (EU) No 547/2011, Regulation (EC) No 1272/2008 (CLP).

According to Art. 80 plant protection products are categorized into two categories of use - professional and non-professional. The professional category of use is divided into two subcategories - first professional and second professional. The category of use of a plant protection product shall be determined when it is authorized for placing on the market and for use according to criteria set out in the Ordinance under Art. 45, para. 1, according to: the conditions and limits for the approval of active substances, antidotes and synergists; the classification of the plant protection product in one or more categories according to Art. 2 of the Law on protection against the harmful effects of chemical substances and mixtures or in one or more hazard classes according to Regulation (EC) No 1272/2008 (CLP); the assessment of the toxicological and ecotoxicological characteristics of the plant protection product, its physical and chemical properties and its existence and behavior in the

¹³ By way of derogation from paragraph 1, no authorisation shall be required in the following cases: ... (c) production, storage or movement of a plant protection product intended for use in another Member State, provided that the product is authorised in that Member State and that the Member State of production, storage or movement has put in place inspection requirements to ensure that the plant protection product is not used in its territory; (d) production, storage or movement of a plant protection product intended for use in a third country provided that the Member State of production, storage or movement has put in place inspection requirements to ensure that the plant protection product is exported from its territory;.

environment; the uses claimed and the category of users under Regulation (EU) No 547/2011. Plant protection products containing an active substance - candidate for substitution are categorized as professional category. Plant protection products containing low-risk active substances or essential substances are categorized as non-professional. The use category is entered in the marketing authorization and use of the plant protection product.

Distributors, consultants and professional users of plant protection products of a professional use category must hold a certificate issued by the BFSА Executive Director or by an official authorized by him (Art. 83). The BFSА Executive Director or an official empowered by him shall cancel the certificate in the case of gross or systemic breaches (Art. 89(1)).

Plant protection products shall be produced, placed on the market, marketed, repackaged, transported and stored under the conditions and procedure laid down in an ordinance of the Minister of Agriculture, Food and Forestry¹⁴ (Art. 47).

6. Trade, repackaging and storage of plant protection products

The trade with plant protection products is carried out by persons who are traders within the meaning of the Commerce Act and hold a certificate for trade with plant protection products, issued by the director of the Regional Food Safety Directorate (RFSD) (Art. 91 (1)) and have facilities for trade - warehouses for trade of plant protection products, and / or agricultural pharmacies (Art. 91 (2)). Only plant protection products from a second professional and / or non-professional category of use are marketed in agricultural pharmacies in packs of up to 1 liter / kilogram (Art. 91 (4)). Plant protection products of professional use category are sold only to persons holding a certificate under Art. 83 (Art. 91 (5)). A person holding a certificate for professional use of plant protection products shall be provided in the warehouses and in the agricultural pharmacies (Article 92 (1)).

In order to obtain a certificate for trade with plant protection products, the persons submit to the RFSD, on the territory of which the object of trade is located, an application in a standard form to which they attach the documents specified in the Ordinance under Art. 47 (Art. 93 (1)). The application and the attached documents under para (1) shall be inspected by inspectors from the RFSD (Art. 93 (2)). If incompleteness or discrepancies are found, removal is required and, if this is not done within the specified time limit, the request is left unannounced. Within three days of filing the application or removing the incompleteness and / or inconsistencies, the inspector shall prepare a written opinion to the Director of the RFSD with a proposal for the issuance of a certificate for trade in plant protection products (Ar. 93 (4)). Within three days of receipt of the opinion, the Director of the RFSD issues a certificate for trade with plant protection products (Art. 94 (1)). The certificate is issued with a term of validity of 10 years and it is necessary to be entered in the register under Art. 6 (1), item 4 (Art. 94 (2) and (4)).

According to Art. 96 plant protection products are repackaged when they have been granted certificates for use marketing and use or parallel trade authorizations. They shall be repackaged in packaging that meets the storage and transport requirements of the plant protection product concerned. Repackaged plant protection products shall be entered in the register under Art. 6 (1), item 2. The trade is carried out by persons who are traders within the meaning of the Commerce Act and have a certificate of repackaging of plant protection products, issued by the director of the RFSD.

¹⁴ Наредба № 3 от 31 юли 2017 г. за условията и реда за производство, пускане на пазара, търговия, преупаковане, транспортиране и съхранение на продукти за растителна защита
http://www.babh.government.bg/userfiles/files/naredbi/%20%E2%84%96%203_2017.pdf

The repackaging shall be carried out by persons with a certificate under Art. 83 in a repackaging plant for plant protection products which meets the requirements set out in the Ordinance under Art. 47.

The repackaging certificate for plant protection products shall be issued under the conditions and by the order of Art. 93 and Art. 94 para. 1 - 3 and shall be entered in the register under Art. 6 (1), item 5 (Art. 94 (1)).

Holders of a repackaging certificate for plant protection products are required to enter into repackaging agreements with holders of marketing and use authorization or holders of permits for parallel trade of plant protection products and submit a certified copy of the contract to the Central administration of BFSA, in its part regarding the type of plant protection products to be repackaged, the material and the capacity of the packaging and the term of the contract (Art. 98, para 1 and 2). They keep the records within at least 5 years.

Plant protection products shall be stored, in accordance with the requirements laid down on the label, in specially designated places in the storehouses of the manufacturer of plant protection products, commercial or repackaging facilities or storage facilities for plant protection products at the farmer's premises for use on the farm of the farmer (Art. 99).

Plant protection products which are unfit or not authorized for placing on the market and use shall be stored at special locations in the sites and warehouses under Art. 99 (1) and are marked with the inscription "SPOILED" or "NONAUTHORIZED" respectively (Art. 100 (1)). Disposable plant protection products are disposed of in accordance with the Waste Management Act (Art. 100, para. 2).

It is prohibited:

- to storage for sale, trade and repackaging of unauthorized and / or unfit plant protection products;
- the storage for the purpose of sale and trade of plant protection products outside the warehouses for trade of plant protection products, and / or agricultural pharmacies;
- the marketing of plant protection products in warehouses for trade of plant protection products, and / or agricultural pharmacies in the absence of the persons under Art. 92 (1);
- storage and marketing of plant protection products from the first professional category of use in agricultural pharmacies;
- storage and marketing of plant protection products in packages with a capacity of more than 1 liter / kilogram in agricultural pharmacies; the sale of plant protection products from a professional category of use to persons who do not hold a certificate under Art. 83;
- the sale of plant protection products with the integrity of the packaging or the label; the repackaging of plant protection products outside the sites under Art. 96 (5); the repackaging of plant protection products for which there are no contracts under Art. 98, item 1 (Art. 101).

The Director of the RDFS with an order suspends the validity of a certificate for trade with plant protection products for a period of: a) two years - for significant or systematic violations; b) one year - in trade with unauthorized or unfit plant protection products, except for the cases under art. 100 (1); c) six months in the event of failure to comply with at least two prescriptions issued within one 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 Art. 92 (1) (Art. 102 (1), item 1). After the expiration of the relevant period, the validity of a certificate for trade with plant protection products or for repackaging of plant protection products shall be restored ex officio, this fact being reflected in the register under Art. 6 (1), item 4 or 5 (Art. 102 (3)).

The Director of RDFS by an order cancels a certificate for marketing or for repackaging of plant protection products at the written request by the certificate holder or upon termination of the activity or deletion of the legal person or the sole trader (Art. 103).

7. Use of plant protection products

Plant protection products shall be used in accordance with Art. 55 of Regulation (EC) No 1107/2009 and in accordance with specific measures for the protection of the aquatic environment (surface and groundwater) and drinking water under Art. 125 (2) under conditions and by an order determined by an ordinance¹⁵ of the Minister of Agriculture, Food and Forestry (Art. 104 (1)). Plant protection products may also be used in accordance with the specific principles of integrated pest management (Article 104 (2)). In the use of plant protection products, protection zones and distances from adjacent sensitive crops are respected. The protection zones and distances are defined in the ordinance under par. 1, item 3 (Art. 104 (3)).

Depending on their use category, plant protection products are applied by consumers as follows:

1. products of plant protection from the first professional category of use - by users with a certificate under Art. 83 and under the control of a person with higher education in the field of agricultural sciences with a professional field of "Plant Protection" or "Plant Growing";
2. plant protection products from second professional category of use - from consumers with a certificate under Art. 83;
3. plant protection products from a non-professional category of use - by persons over 18 years of age (Art. 105).

Plant protection products are applied with specialized equipment and equipment for the application of plant protection products which meet the requirements of the Registration and Control of Agricultural and Forestry Equipment Act and / or the Civil Aviation Act (Art.106).

It is prohibited: storage for use and the use of unauthorized or unfit plant protection products; the use of plant protection products outside the scope of the authorized use or at a dose exceeding the maximum permissible unit dose; the application of plant protection products by aerial spraying; the harvesting of agricultural crops before the end of the quarantine period of the used plant protection products; the use of crop seeds treated with plant protection products for purposes other than for sowing; the use of plant protection products in violation of the prohibitions and restrictions laid down in the Ordinance under Art. 135 (1), item 6 of the Water Act (Art. 107).

As an exception to the prohibition under Art. 107, item 3, plant protection products may be applied by aerial spraying only after a written authorization issued by the Director of the RFSD in case of danger to plants and plant products where there is: impossibility of application of plant protection products through specialized terrestrial machinery and equipment due to over-wetted terrains and areas or other adverse agro-climatic conditions, heavily intersected and / or inaccessible terrain, including forest areas, risk of erosion or soil compaction; or the need for rapid treatment of compliance with the conditions of use of the plant protection product (Art. 108). For the purpose of obtaining an application for aerial spraying, farmers submit a standard application at least 6 days prior to the date of treatment (Art.110 (1)) in the RFSD on whose territory the area to be treated is located. If urgent measures are needed, the application may be submitted exceptionally at least three days before the date of treatment (Art. 110 (6)).

In the treatment of seed crops, plant protection products, if approved, shall be applied with specialized seed treatment equipment in specialized premises meeting the requirements laid down in the Ordinance under Art. 104 (1), item 3 (Art. 114 (1)). Treatment of seeds for planting with plant protection products shall be carried out under conditions and by an order determined in the ordinance under Art. 104 (1), item 3 (Art. 114 (1)).

¹⁵ Such Ordinance cannot be found at public space

8. Specialized plant protection services

The treatment of plant protection products for seeds as a specialized plant protection service is carried out by persons who are traders within the meaning of the Commerce Act and are entered in the register under Art. 6 (1), item 9 (Art. 117 (1)). Consultancy services for integrated pest management as a specialized plant protection service shall be carried out by natural or legal persons who are entered in the register under under Art. 6 (1), item 9 (Art. 118 (1)).

9. Subsequent controls on the trade, repackaging, storage and use of plant protection products

The control over the plant protection products and the trade, repackaging, storage and use thereof shall be carried out under conditions and by an order determined by an ordinance of the Minister of Agriculture, Food and Forestry (Art.120 (1)). It is carried out through planned and unannounced inspections and checks in the presence of infringement data and covers: plant protection products; persons who carry out activities with plant protection products; the sites in which these activities are carried out; the documentation relating to the performance of the activities; the plants and plant products in their primary production and other objects on which plant protection products are used (Art.120 (2)). The control samples for carrying out the inspections shall be taken in accordance with the procedure laid down in the Ordinance under Art.120 (1) (Art.120 (3)).

The control samples taken during the inspection under para. (2), item 1, shall be examined in the Central Laboratory for Chemical Testing and Control of BFSA and/or accredited laboratories in accordance with EU Regulation No 765/2008 / 9 July 2008 laying down the requirements for on-accreditation and market surveillance relating to the marketing of products and repealing EU Regulation No 339/93 (OJ L 218/30 of 13 August 2008) (Art.120 (4)). The control samples taken during the inspection under para. 2, item 5 shall be examined at the Central Laboratory for Chemical Testing and Control of BFSA and / or by accredited laboratories by a national accreditation body of a Member State (Art.120 (5)).

In the event of non-compliance with the regulatory requirements under Art. 120 (2) plant protection inspectors shall prescribe and may apply one or more of the following measures: 1. stopping the activity on the site; 2. seizing a batch (s) of a plant protection product (s) or seizure of available quantities thereof; 3. foreclosure of plants and plant products; 4. undertaking any other measures necessary for the exercise of their powers (Article 121 (1)).

Where a plant protection product is found to be incompatible with the physical, chemical and technical characteristics, composition, type of formulation or other characteristics approved in the product authorization or in the event of non-conformity on the packaging or on the label of the product, its expiry date, the Executive Director of BFSA may, by order, apply one or more of the following measures: 1. Immediate suspension of trade, repackaging and use of the plant protection product and its withdrawal from the market; 2. re-labeling or processing by the manufacturer where the plant protection product is in the original packaging; 3. export of the plant protection product; 4. disposal of the plant protection product pursuant to the Waste Management Act (Article 122 (1)).

When establishing the use of an unauthorized plant protection product on plants and plant products in their primary production or in the event of an unauthorized use of a plant protection product, the Director of the relevant RFSD with an order may apply one or several of the following measures: export of plants and plant products; destruction of plants and plant products according to the Waste

Management Act, the regulations and decisions of the European Commission under Art. 16 (3) and / or by procedures approved by the BFSA Executive Director (Article 123 (1)).

10. Fertilizers, soil improvers, biological active substances and foodstuffs

According to Art. 130 fertilizers, soil improvers, biologically active substances and food substrates are placed on the market and used after registration and issue of a certificate for placing on the market and use. Fertilizers, soil improvers, biologically active substances and food substrates are registered when they are effective and do not adversely affect humans, animals or the environment under the conditions of use prescribed by the manufacturer.

For the registration of fertilizers, soil improvers, biologically active substances and food substrates and obtaining a certificate for placing on the market and use, the persons submit to the Head Office of the Bulgarian Academy of Sciences a sample application (Art.133 (1)). The registration shall be carried out under conditions and by an order determined by an ordinance of the Minister of Agriculture, Food and Forestry (Art.133 (2)).

When fertilizers, soil improvers, biologically active substances and food substrates are placed on the market in a Member State, certified copies of the documents on the basis of which the product is placed on the market in the Member State or other evidence that the product is placed on the market. Documents shall be recognized in accordance with the provisions of EU Regulation No 764/2008 / 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State , and repealing Decision No 3052/95 / EC (OJ L 218/21 of 13 August 2008) (Art.133 (3)).

Within three months from the filing of the application under Art. 133 (1) the BFSA Executive Director shall, by order, register a fertilizer, a soil improver, a biologically active substance or a food substrate and issue a certificate for placing on the market and use in a model or reasonably refuses registration when the product does not meet any of the requirements of Art. 130 (2) (Art.134 (1)).

SUMMARY ANALYSIS OF THE PROCEDURES FOR USE, STORAGE AND TREATMENT OF AGRICULTURE CHEMICALS

The legislation on use, production, import, storage and treatment of plant protection products (PPP) in Bulgaria is rather complicated and to a higher extent influenced by the EU legislation on this issue. One of the most complicated aspects is that the texts of the legal acts always refers to other acts, which refer further to other acts, etc., so at certain point it is really difficult to follow the logic and the content of the law. It is necessary to know all the related legal documents in order to apply this legislation correctly, which in practice is not very possible, especially for farmers who directly treat their land with agriculture chemicals. It is also almost impossible for the civil persons easily to recognize if the law is strictly followed or violated in certain case.

On paper there are developed strong procedures for issuing licenses for use, production, trade and import/export of PPPs. All these procedures are developed in order to guarantee the food safety for human consumption, as well as human health and the protection of environment in broader context. Protection of the environment is an objective as a broader term, where it is mostly related to human health, prevention of pollution, especially pollution of water. The need of protection of bees is also respected in this legislation. Under the need of protection of environment it could be interpreted that biodiversity, and the vultures in particular, should also be taken into consideration, as long as they do not pose direct risk for the human health. In practice the prevention of the risk for human health under the procedures, described above could expose the vultures to a higher risk to forage on carcasses of animals poisoned by PPPs. By following the legal procedures strictly the risk for vultures in theory should be avoided.

The legislation related to PPPs is based mainly on license mechanisms and to a less extend – on a control mechanisms. The licensing procedures are non-transparent, even the decision-making bodies are obligated to keep confidentiality. The procedures for authorization of PPP are implemented on a national level, but the ban of a given product should be done on a EU level, which make the last procedure more difficult. The control mechanisms are very limited to inspections and laboratory analyses.

Nevertheless of the strong procedures and influence of the EU legislation, it should be noticed that both the national law and the EU regulation allow numerous derogations at all the stages of licensing, production, trade and use of PPPs. This approach with combination of the complicated legislation and all the references between the different legal acts somehow weaken all this legislation and creates as pace for non-implementation or bad practices. The established mechanisms of control on implementation of the legislation related to PPPs are very limited, which creates further uncertainty and possibilities for non-implementation.

It also should be noted that production of banned PPPs and active substances is allowed in Bulgaria, as long as they must not be used in the country, but exported. Nevertheless mechanisms for control of banned PPPs and substances, it is possible some of them to be used illegally in the country and to pose risks both for humans and also animals.

On a national level there are 15 registers ensured by law to make the information public, where 12 of them are directly related to all the aspects of licensing, production, trade, use, import/export of PPPs. No registers are required to be maintained at local level in terms of use of PPPs.

The structure of the coordination, organization and control of use, trade, import and production of PPPs is very centralized and most of the decision-making power is concentrated in just one person – the Executive Director of the Bulgarian Food Safety Agency. On one hand this very centralized and closed structure could be very useful for the proper implementation of the law, but on the other hand this concentration of power together with very complicated legislation and insufficient transparency of the decision-making process and of the real implementation of the law by the

different actors pose risk for corruption and non-implementation. Lack of sufficient transparency of the in-situ implementation of the law (real practices that are implemented) seem to be a weakness of this very complicated and strong legislation.

CONCLUSIONS

The legislation on use, production, import, storage and treatment of plant protection products (PPP) in Bulgaria is rather complicated and to a higher extent influenced by the EU legislation on this issue. Nevertheless that the law seems quite strong in terms of autorisation of PPPs, the high number of derogations in the procedures set up on EU level weakens the legislation. Low level of ensurance of transparency of the procedures combined with limited range of control mechanisms by law creates risks for implementation of bed practices. It also allows to authorize PPPs which include banned active substances as it could be seen when explore the official register of PPPs in Bulgaria.

In terms of nature protection the law requires safeguarding the environment in broader context, where the water quality as well as bees are the only two components of the environment which explicitly require protection. The way the legislation is designed should be efficient to ensure food safety and human health, but do not have enough mechanisms to ensure protection of the environment in terms of biodiversity in particular, including vultures. It is very important aspect, as many of PPPs can be used to poison animals – both domestic and wild ones.

Apart of numerous derogations in authorization procedures it is important to notice that banned PPPs still can be produced and stored on the territory of the country when the PPPs are targeted for export. This creates further uncertainty in terms of illegal use of banned PPPs and implementation of control mechanism.

Although there are numerous national registers, which ensure transiency of the implementation of this legislation, the detailed information about practical use of PPPs, especially at local level, is not public and it is not available.

One positive aspect of the legislation is that it sets out the National Action Plan on Sustainable Use of Pesticides. This plan is expected also to set out specific measures for the protection of the aquatic environment (surface and groundwater) and drinking water from the effects of pesticides. This aspkt of legislations creates, at least on paper, real legal mechanism for practical transition to more nature-friendly and less-ricky agriculture. Unfortunately not much importance is given to this Action plan when all the procedures for authorization, trade, use and control of PPPs are set up in the law.

RECOMMENDATIONS

On the base of the conclusions made above following recommendations should be made:

In terms of the further study of the use of PPPs in Bulgaria efforts should be targeted to on-spot studies of contamination of PPPs in soil and, seeds and animals which could be potential prey for vultures. It needs collaboration with control bodies of BFSA and laboratories, as well as scientific institutes.

In terms of further advocacy work, it should be based on the efficiency of the implementation of legislation, as well as cooperation. Advocacy work have to be based on evidence. Where the advocacy is dependent on institutions out of Bulgaria, different strategy have to be applied, involving all the relevant partners.

As part of the advocacy work more efforts should be focused on elaboration and implementation of the National Action Plan on Sustainable Use of Pesticides, as well as implementation of the Common agriculture policy of EU, which in reality push for intensification of agriculture.

As long as many PPPs could be used as poisoned agents, advocacy work should be focused also to stronger regulation on production, import/export, storage and use of such PPPs. Cooperation between institutions should be encouraged and common strategy against use of poisons should be developed.

Advocacy work should include also EU level, as long as many of the regulations are set out at this level and cannot be influenced at local level. EU regulations should be improved in away to ensure minimizing of derogation, stricter control of the licensing procedure for PPPs that could be used as non-selective poisoning agents, as well as further ban for use or trade with such products.

One very important improvement of EU legislation (respectively Bulgarian legislation) appear to be very important – to prohibit the production, storage and export of PPPs, which are banned in EU. As Europe have responsibility to protect its wildlife, including migratory species, such as Egyptian vulture, it must not create risks for European wildlife while species are outside Europe. Once certain PPPs are confirmed to be dangerous for human health (and in most cases for wildlife as well) and thus they are prohibited for the EU territory it is not reasonable to produce and export these PPPs to non EU countries.

SOURCES OF INFORMATION

Plant Protection Act

Ordinance No 8 of 27.02.2015 on phytosanitary control

Ordinance No 1 of 5 January 2017 on the storage, transport and export of unauthorized active substances

REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Register of plant protection products for which an authorization has been granted

Register of plant protection products which are repackaged

Register of persons holding a certificate for trade of plant protection products and of the relevant sites for trade with plant protection products

Register of persons holding a certificate of repackaging of plant protection products and of the relevant repackaging places for plant protection products

Register of persons who produce plant protection products on the territory of the Republic of Bulgaria

Register of persons holding a certificate of import or entry of a batch of non-approved active substances

Register of authorizations for application of plant protection products by aerial spraying

Register of persons carrying out specialized plant protection services

Register of persons engaged in integrated production of plants and plant products

Register of persons holding a certificate under Art. 83 for professional use of PPPs (distributors, consultants and professional users of plant protection products);

Register of fertilizers, soil improvers, biologically active substances and food substrates for which a certificate has been issued for placing on the market and use;

Register of adjuvants to be placed on the market and used.