

BALKAN DETOX LIFE

Analysis of the use of legal and illegal agricultural chemicals used for wildlife poisoning in the Balkan countries - Technical report -

BALKAN DETOX LIFE: STRENGTHENING NATIONAL
CAPACITIES TO FIGHT WILDLIFE POISONING AND RAISE
AWARENESS ABOUT THE PROBLEM ACROSS SEVEN
BALKAN COUNTRIES
(LIFE19 GIE/NL/001016)

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ALBANIAN ORNITHOLOGICAL
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OUR BIRDS



PPNEA
PROTECTION AND PRESERVATION OF
NATURAL ENVIRONMENT IN ALBANIA



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Subject and purpose of the report

This document is prepared within the framework of the BalkanDetox LIFE project (LIFE19 GIE/NL/001016) and relates to *Action B.3: Study about misuse and origin of legal and illegal toxic substances used for wildlife poisoning*.

This document is designed to provide an overview and analysis of the relevant legislation in the Balkans regarding plant protection and plant protection products (PPPs), as well as analysis of the publicly available information regarding the use of legal and illegal agriculture chemicals in order to assess the scale and the impacts of these chemicals used in the region on wildlife.

The methodology used for the elaboration of this report consists of desk research of the legal acts and publicly available information.

The analysis of legal acts consists of listing all the relevant legal acts and regarding describing of the legal procedures regarding control of parasites, registration of the plant protection products, licensing of PPPs, import, trade, storage, use, disposal, and recycling of the PPPs.

The analysis of the publicly available information consists of listing all the available information for the public regarding the legal / illegal use of the legal / illegal agriculture chemicals and describing how and where to find this information.

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About the project

The BalkanDetox LIFE project is a five-year endeavour with a €1.8 million budget, which aims to raise awareness and strengthen national capacities to fight the problem of wildlife poisoning across Albania, Bosnia & Herzegovina, Bulgaria, Croatia, Greece, the Republic of North Macedonia and Serbia. It received funding from the EU's LIFE Programme with a contribution of 1.004.792€ (54,82%) to the total project budget, and it is co-financed by the Vulture Conservation Foundation, the MAVA Foundation and Euronatur, as well as by the Whitley Fund for Nature and Environmental Protection and Energy Efficiency Fund for specific actions. Project partners are the Vulture Conservation Foundation as the coordinating beneficiary, and the Albanian Ornithological Society, Association BIOM, Bird Protection and Study Society of Serbia, Fund for Wild Flora and Fauna, Hellenic Ornithological Society, Macedonian Ecological Society, Ornitološko društvo NAŠE Ptice and the Protection and Preservation of Natural Environment in Albania as associated beneficiaries. Furthermore, this project is based on Spanish best practice experience and counts with the support from the Junta de Andalucía and the Spanish Ministry for the Ecological Transition and the Demographic Challenge.

Learn more at www.balkandetoxlife.eu



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Introduction

The main goal of this report is to identify and assess the impacts of toxic chemicals used widely in agriculture for protection of crops on vulture populations, and on other wildlife in the Balkan Peninsula. This has been achieved through the analysis of the relevant national legislation regarding plant protection and plant protection products, as well as analysis of the publicly available information regarding the use of legal and illegal agricultural chemicals. Detailed reports on this subject have already been produced for Albania, Bulgaria and North Macedonia, and made publicly available within the auspices of the Egyptian Vulture New LIFE project ([LIFE16 NAT/BG/000874](#)). Relevant information for the abovementioned countries has been represented in this report, together with the results of the research conducted in Bosnia and Herzegovina, Croatia, Greece and Serbia under the scope of the BalkanDetox LIFE project.

The methodology used for the preparation of this report consists of desk research of available documents regarding legislation in place and existing legal procedure relevant to acquirement, application in agriculture, trade and control of the use of Plant Protection Products (PPPs) in each of the Balkan countries, and the availability of this information to the general public.

The analysis of relevant national legislation consists of listing all the relevant legal acts and describing of the legal procedures regarding control of parasites and pests, registration of the plant protection products, licensing of Plant protection products (PPPs), import, trade, storage, use, disposal, and recycling of the PPPs. The analysis of the publicly available information consists of listing all the available information for the public regarding the legal / illegal use of the legal / illegal agriculture chemicals and describing how and where to find this information.

Albania

REVIEW OF RELEVANT LEGISLATION IN ALBANIA REGARDING USE, IMPORT, STORAGE, AND TREATMENT OF PLANT PROTECTION PRODUCTS

I. LEGAL ACTS

1. Law no. 105/2016, date 27.10.2016 “On the protection of plants”

Main legal act regarding the use of plant protection products. One of the main purposes of this Law is to protect the health of humans, animals, and the environment from the use of plant protection products. This law is further reinforced and supplemented by orders and decisions of the Council of Ministers, regarding the registration, licensing, trade, transport, storage, use, disposal, recycling, etc. of the plant protection products. Furthermore, Article 3 of this law lists the responsible authorities for enforcing these regulations in Albania.

The relevant terminology within this legal act is as follows:

Good practices for the protection of plants - set of measures and actions for the control of parasites by chemical methods, respecting the conditions under which PPPs are registered.

Plant Protection Product (PPP) - a product containing one or more active substances and used to protect plants or plant products from parasites, to destroy undesirable plants or plant parts, as well as to control or prevent the growth of undesirable plant parts.

Dangerous PPP - a plant protection product containing one of the following properties: explosive, oxidizing, flammable, harmful, corrosive, irritant, sensitive, carcinogenic, mutagenic, toxic to reproduction and dangerous to the environment.

High risk PPP - a plant protection product which contains one of the following qualities: highly toxic (class 1a or T +), toxic (class 1b or T), extremely flammable.

Phytosanitary Certificate - official document issued by the plant protection service from the country of origin or country of production, indicating that the phytosanitary conditions of plants, plant products and other objects meet the phytosanitary safety standards laid down by the legislation in force in the Republic of Albania.

Registration - process of evaluating a PPP, according to the criteria set forth in the provisions of this law and the bylaws.

Trade of PPPs - any activity related to the storage, distribution, presentation for sale or the sale in the territory of the Republic of Albania of registered PPPs.

Tracing - ability to track a plant, dangerous plant production, other PPP that is related to plant health at all stages of production, processing and distribution.

Inspection - visual examination of plants, plant products and other objects carried out by the inspector to determine whether they are infected or affected by parasites and whether they comply with the provisions of this legal Act and the Law "On Inspection".

2. Decision of the Council of Ministers (DCM) no. 146, date 13.3.2018 "On the establishment, organization and functioning of regional agencies for veterinary services and plant protection"

The main purpose of this document is the establishment of regional agencies in Shkodër, Tiranë, Vlorë, and Elbasan for veterinary services and plant protection which have the mission to implement policies and strategies for the health protection of humans, animals, plants and environment. According to this DCM, the Regional Agencies for Veterinary Services and Plant Protection have to maintain constant connections and coordinate their activity with research institutions and other sources of information.

The main duties and responsibilities of the Plant Protection Service within these regional agencies are as follows:

- Monitoring of the phytosanitary condition of plants, plant products and other objects within the territory in their administration.
- Phytosanitary inspections and provision of "Internal Phytosanitary Certificate" for plants or plant products capable of carrying quarantine or dangerous parasites moving within the territory of the country.
- Phytosanitary controls and provision of "Phytosanitary Certificate of Export" for plants or plant products capable of carrying quarantine or dangerous parasites, which move outside the territory of the country.
- Phytosanitary inspection and provision of "Phytosanitary Certificate for re-export" for plants or plant products upon entry into the territory of the country for the purpose of re-exportation and stay in the country for more than 14 days.
- Phytosanitary controls and provision of "Phytosanitary Certificate" for plant materials for propagation or planting.

- Monitoring of cultivated or spontaneous plant parasites, as well as of plant protection funds, which are planned in the annual budget for the ministry.
- Notifying immediately the Responsible Structure for Plant Protection when a quarantine parasite appears in an area and, by declaring this area as an affected area, pursues measures to limit the spread of the quarantine parasite until its eradication in the area concerned.
- Monitoring of the implementation of good plant protection practices, as well as integrated protection criteria.
- Monitoring of the application of special measures for emergencies of mass propagation and proliferation of parasites, which cannot be restricted by common control methods.
- Provision of the appropriate training and issuance of the proof of ability to use PPPs.
- Provision of the information to the entire farmer community and the public, through the mass media.
- Implementation of short-term, mid-term and long-term strategies of plant protection activities.
- Monitoring and implementation of other duties as defined by law no. 105/2016, "On plant protection", as well as in its bylaws.

3. Law no. 27/2016 "On the management of chemicals"

The objective of this law is to define the obligations of manufacturers, importers and users of chemicals for agriculture, to classify the chemicals they place on the market and to provide the Chemical Safety Data Sheet; to determine the obligations to all suppliers for labeling and packaging of chemicals; to determine the obligations on exporters and importers of chemicals subject to the provisions of prior import approval and export notification; to regulate the production, placing on the market, use and export of dangerous chemicals; to define the obligations and procedures for the establishment and maintenance of a register of chemicals placed on the internal market or produced for export outside the Republic of Albania.

This law is partially aligned with:

- Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 "On the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, which amends Directive 1999/45 / EC, repeals Council Regulation (EEC) 793/93 and Commission Regulation (EC) No 1448/94, as well as Council Directive 76/769 / EEC and

Commission Directives 91/155 / EEC, 93/67 / EEC, 93 / 105 / EEC and 2000/21 / EC, "as amended";

- Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16 December 2008 "On the classification, labeling and packaging of substances and mixtures amending and repealing Directives 67/548 / EEC and 1999/45 / EC and amending Regulation (EC) 1907/2006 ", as amended".

4. DCM no. 317, date 15.5.2019 "On the adoption of rules for the sustainable use of plant protection products and the qualification criteria for users"

The purpose of this DCM is to ensure a sustainable use of PPPs, minimizing the risks and impacts of their use on health of humans, animals and environment, and promoting the use of integrated pest management as well as approaches or alternative techniques, such as non-chemical alternatives to PPPs. In Chapter I (2) of this DCM is specified that the measures provided in these Rules do not affect the measures laid down in national law for: conservation of wild birds; conservation of natural habitats, wild fauna and flora; creating a framework in the field of water policy; maximum levels of pesticide residues on or above food and food of plant and animal origin; protecting the health and safety of workers from the risks associated with chemical agents at work; protecting workers from the risks associated with their exposure to carcinogens or mutagens at work; supporting rural development.

This decision is partially aligned with 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 pesticide use.

5. DCM no. 335, date 6.6.2018 "On the approval of rules on the registration procedure and evaluation criteria of plant protection products"

The purpose of this DCM is to lay down the rules for the registration procedure and the evaluation criteria of plant protection products (PPPs) to be imported, placed on the market and used within the territory of the Republic of Albania.

This DCM is accompanied by the relevant terminology which is complementary to the terminology of the law "On the protection of plants", as follows:

Active substance - substance or microorganism, including viruses, having a specific or general action on plants, their products and pests.

Technical active substance - substance used in the manufacture of a plant protection product and containing a pure active substance, together with impurities, within the permissible limits.

New active substance - an active substance manufactured and patented by a particular manufacturer in accordance with international rules protecting the patent right of invention, which is approved by order of the Minister.

Old active substance - the active substance, the production of which, according to international rules, is free and approved by order of the Minister.

Inorganic plant protection product - plant protection product containing only inorganic active substances.

Repellent - an active substance that, for specific characteristics of odor, color, mechanical effect, etc can remove certain phytoparasites.

PPP originated by plants - plant protection product whose active ingredient contains one or more plant originating materials, combined with one or more herbal preparations.

6. Law no. 10081, date 23.2.2009 “On licenses, authorization and permits in the Republic of Albania”, as amended

Sets the principles for determining the activities, actions and types of public goods, the exercise, performance and use of which are subject to licensing, authorization or licensing; the principles for determining the conditions, procedures and terms of validity of licenses, authorizations and permits, and principles for the reasons and procedures for their revocation; the organization and the content of the National Register of Licenses and Permits; the procedures for dealing with certain licenses, authorizations and permits under the jurisdiction of central institutions; the rules of organization and functioning of the National Licensing Center (Article 2 (1)).

7. Order no. 566, date 15.10.2019 “On updating ministers order no. 72, date 2.3.2017 “On approval of active substances in content of PPPs”, changed”

Within this Order are represented some changes in the list of active substances that are allowed to be used in the composition of PPPs. Two additional compounds have been added to the list of active substances which are allowed to be used in the composition of PPPs: 1) *Florpyrauxifen-benzyl*; 2) *Bacillus subtilis* strain. Meanwhile, the following

compounds have been removed from the list: 1) *Desmedipham*; 2) *Dimethoate*; 3) *Methiocarb*.

8. DCM no. 1188, date 20.8.2008 “On the approval of rules on import, trade, transport, storage, use and disposal of plant protection products”

The purpose of this DCM is to describe the legal procedures on the import, trade, transport, storage, use, and disposal of PPPs. There have been some slight changes in some of the procedures described in this legal act, under DCM no. 462, date 11.7.2012 “On some amendments on the DCM no. 1188, date 20.8.2008 “Approving the rules on import, trade, transport, storage, use, and disposal of plant protection products”. According to DCM no. 462 (Chapter I (3, 4)), there are some changes in the naming of the procedures import and trade i.e. *Import of PPPs* has changed to *Wholesale trade*; *Trade of PPPs* has changed to *Retail trade*.

9. DCM no. 462, date 11.7.2012 “On some amendments on the DCM no. 1188, date 20.8.2008 “Approving the rules on import, trade, transport, storage, use, and disposal of plant protection products”

In addition to the changes described in the DCM no. 1188, within this legal act also introduces some changes in the naming of the authorities responsible for the protection of plants, as follows:

- “*Regional Directorate of Agriculture, Food and Consumer Protection*” (DRBUMK) has changed to “*National Food Agency*” (AKU), except chapters V and VI.
- “*DRBUMK Plant Protection Inspectorate*” has changed to “*Sector of Plant Protection and Agricultural input of AKU*”, except chapters V and VI.
- In chapter V, “*DRBUMK Plant Protection Inspectorate*” has changed to “*Sector of advisory service at the Regional Directorate of Agriculture*”.
- In chapter V and VI, “*Regional Directorate of Agriculture, Food and Consumer Protection*” (DRBUMK) has changed to “*Regional Directorate of Agriculture*” (DRB).

10. DCM no. 532, date 11.9.2018 “On the approval of rules on the trade, transport, and storage of plant protection products”

The purpose of this DCM is to comply with the legal requirements and to lay down rules and procedures for the trade, transport, and storage of registered plant protection products.

Relevant international legislation:

Law no. 10277, date 13.5.2010 “On the accession of the Republic of Albania to the Convention of Rotterdam “On the procedure of notification of preliminary approval of some chemicals and dangerous plant protection products in the international trade”

The objective of this Convention is to promote joint responsibility and mutual efforts between the parties to the international trade in certain dangerous chemicals, with a view on protecting human health and the environment from potential harm, and contributing to their safe use from an environmental point of view, helping to exchange information about their characteristics, anticipating a national decision-making process on their import-export and transmitting these decisions to the Parties of the Convention.

EU legislation

DCM no. 201, date 10.4.2019 “On the approval of the National Plan for European Integration 2019-2021”¹

According to Article 70 of the Agreement on Stabilization and Association, Albania has the obligation to put in line its national legislation with the EU acquis.

The cooperation between the Republic of Albania and the European Union in the field of agriculture and in the agro-industrial sector is provided in the Article 96 of the Agreement. The acquis on food safety, veterinary and phytosanitary policies reflect the EU's integrated approach to food safety with a view to ensuring a high level of food safety, animal health, animal welfare and plant health within the European Union through coherent measures and monitoring, ensuring the effective functioning of the internal market. The main preconditions for a candidate country in this field are the transposition of EU legislation, as well as its implementation by a well-structured and trained administration.

The transposition process of EU legislation regarding the phytosanitary policies includes:

- Approval of the DCM “On the adoption of the phytosanitary quarantine rules” during the third quarter of 2020. The Decision will partially approximate the Council

Directive 2000/29/EC of 8 May 2000 on safeguards against the introduction into the Community of harmful organisms to plants or plant products and their spread within the Community. The Decision aims to ensure the health of plants and plant products from parasites.

- Approval of the Guidance “On Rules for Recognizing Clean areas” during the second quarter of 2020. The guidance will partially approximate the Commission Regulation (EC) no. 690/2008 of 4 July 2008 recognizing protected zones exposed to particular plant health risks in the Community.
- Approval of the “Guidance on Rules for the Movement of Plants, Plant Products and Other objects within and between Clean Areas” during the fourth quarter of 2020. It is a document issued by an authorized manufacturer. The Responsible Structure for Plant Protection verifies the fulfillment of the conditions and criteria for the issuance of the plant passport by the authorized producers.
- The main administrative structures responsible for phytosanitary policies and for the official control are determined by the provisions of Law no. 105/2016 “On Plant Protection”. The Ministry of Agriculture and Rural Development is the institution that implements the phytosanitary policy.
- Regarding chemicals, the transposition process of the EU legislation includes:
 - Approval of the Law no.27, date 17.3.2016 “On the management of chemicals”;
 - Approval of DCM no. 488, date 29.6.2016 “On the classification, labeling, and packaging of chemicals”;
 - Approval of DCM no. 489, date 29.6.2016 “List of High risk substances (SVHC), criteria for the inclusion of substances in the SVHC list, and the issuance of a conditional authorization to continue using the SVHC”;
 - Approval of DCM no. 665, date 21.9.2016 “On import and export of dangerous chemicals”.

One of the responsible institutions for the management of chemicals is the Ministry of Tourism and Environment. The obligation to approximate the Albanian legislation with the EU legislation in the field of Environment derives from Article 108 of the Agreement on Stabilization and Association.

II. PROCEDURES

2.1. Control of parasites:

The rules and practices regarding plant protection, as well as the drafting of good plant protection practices and integrated protection criteria are drafted by the Department for the Protection of Plants (DPP) and approved by the order of the Minister, on the proposal

of the Responsible Structure for the Protection of Plants (RSPP) (Article 7(7), law no. 105/2016, date 27.10.2016 “On the protection of plants”).

2.2. Registration of plant protection products (PPPs):

According to the law no. 105/2016, date 27.10.2016 “On the protection of plants” (Article 19(1)), it is obligatory that all the PPPs that are traded or used within the territory of the Republic of Albania have to be registered but only the PPPs registered in one of the European Union countries are allowed to be registered (Article 19(2)).

The “Responsible Structure for the Protection of Plants” (RSPP) is the responsible authority within the Ministry of Agriculture and Rural Development for the registration of PPPs. The registration of PPPs is carried out based on some specific criteria. The criteria for the registration of PPPs is included in the Chapter III in the DCM no. 355, date 6.6.2018 “On the approval of rules on the registration procedure and evaluation criteria of plant protection products” and it is related to: the active substance in the composition of the PPPs – which should be approved by the Minister; the effectiveness of the PPPs; dangerous effects of the PPP on plants or plant products where it has been used; direct, or in-direct impacts in human, animal and environmental health; and other issues related to packing, labeling, fulfillment of the standards set by the Food and Agriculture Organization (FAO), etc. The list of the registered PPPs is published in the official webpage of the Ministry of Agriculture and Rural Development.

The rules on registration, the procedure and the criteria for the evaluation of PPPs are determined by decision of the Council of Ministers, on the proposal of the Minister (Article 19(4), law no. 105/2016, date 27.10.2016 “On the protection of plants”). The approval of the active substances, other constituents of the plant protection products, the technical data in the register for the registration of PPPs, as well as their updating, in accordance with EU legislation, is ordered by the Minister.

2.3. Licensing:

Production and/or trading license for the PPPs is included in the second category, Appendix I in the law no. 37/2016 “On some amendments and changes in law no. 10081, date 23.2.2009 “On licenses, authorization and permits in the Republic of Albania”, as amended. This information is given also as a reference in Article 20(3) in the law no. 105/2016, date 27.10.2016 “On the protection of plants” but it is unclear and not very precise. Applications for licenses / authorizations / permits or their subcategories are submitted to the National Licensing Center (NLC).

2.4. Import of plant protection products:

According to DCM no. 462, date 11.7.2012 "On some amendments on the DCM no. 1188, date 20.8.2008 "On the approval of the rules on import, trade, transport, storage, use and disposal of the plant protection products" (Point 3(a)), the title "*Import of plant protection products*" is replaced by "*Wholesale trade of plant protection products*", while the title "*Trade of plant protection products*" is replaced by "*Retail trade of plant protection products*".

2.4.1. Wholesale and retail trade of plant protection products:

Wholesale and retail trade of PPPs is done by physical persons, graduated in the field of agronomy, or by legal entities, who must hire one or more persons, responsible technicians, who are graduated in this field (Article 20, law no. 105/2016, date 27.10.2016 "On the protection of plants").

Wholesale and retail trade of "Dangerous PPPs" or "High risk PPPs" is carried out under a license issued under the requirements of the legislation, pursuant to law no. 10081, date 23.2.2009 "On licenses, authorization and permits in the Republic of Albania", as amended. Every person licensed for the wholesale trade of PPPs that are classified as "Dangerous PPPs" or "High risk PPPs" is obliged to compile an annual report and submit it to the National Food Agency (AKU) no later than February of the following year, on the quantity and quality of each imported and marketed PPP during the preceding calendar year; and also is obliged to notify the National Food Agency, by self-declaration, of any harmful effects on the user, environment or ecosystem, humans or animals, observed during the use, exposure, distribution and discharge of any imported and marketed PPPs. Every person licensed for the retail trade of PPPs is obliged to compile an annual report and submit it to AKU no later than January of each year, on the quantity and quality of each PPP that has been placed on the market during the preceding calendar year.

Inspection of PPPs on the market, regarding the fulfillment of legal requirements for trading, is carried out on the basis of the annual risk-based inspection plan approved by the Minister. The quality control of marketed PPPs is carried out on the basis of the annual sampling and analysis plan approved by the Minister (Chapter 2 (7), DCM no. 532, date 11.9.2018 "On the approval of rules on trade, transport, and storage of plant protection products").

2.5. Transport of plant protection products:

It is strictly forbidden to transport PPPs together with food for humans and animals and by means of transport which are used for the transportation of humans and animals (Chapter IV (3), DCM no. 532, date 11.9.2018 "On the approval of rules on trade, transport, and storage of plant protection products").

The transport of the PPPs classified as "Dangerous PPP" and "High risk PPP" is carried out according to the Albanian legislation in force for the transport of goods and dangerous substances.

2.6. Storage of plant protection products:

According to DCM no. 532, date 11.9.2018 "On the approval of rules on trade, transport, and storage of plant protection products" (Chapter V (1)), the PPPs must be stored in warehouses, in case of wholesale trade, and in retail trade premises. The space where PPPs are stored must be adapted in such a way as to guarantee the preservation of the physicochemical properties of the plant protection products within the expiration date and to ensure a level of ambient temperature, as required by the PPP label for their storage. For this purpose, the warehouses must be equipped with ventilation systems.

When, during storage of PPPs in warehouses or retail outlets, damage to packaging and PPP leakage occurs, they are removed immediately from the warehouse and retail outlet and disposed of in accordance with applicable rules (Chapter V (6), DCM no. 532, date 11.9.2018 "On the approval of rules on trade, transport, and storage of plant protection products").

End-users store PPPs in special environments, such as: safes, rooms, warehouses secured by unauthorized openings, in original packaging, away from children, in dry conditions, away from fire, protected from direct sunlight, as well as complying with all special instructions provided on the label.

2.7. Quality control of plant protection products:

According to Chapter X (1), DCM no. 532, date 11.9.2018 "On the approval of rules on trade, transport, and storage of plant protection products", the quality control of the PPPs that are imported is carried out by the quarantine inspectors in every border point. While, the quality control of the PPPs that are already in the market is carried out by the Plant Protection inspectors, at National Food Agency, whenever they see it convenient. The quality analyses of PPPs are carried out by the Food Safety and Veterinary Institute (ISUV) according to the protocols described in Chapter X (4, 5), DCM no. 532, date 11.9.2018 "On the approval of rules on trade, transport, and storage of plant protection products".

Foods originated by plants or animals, stored foods, processed foods, and various juices and beverages are not permitted to contain residues of active substances of PPPs used in plant protection, in an amount greater than 0.01 milligrams of active substance per kilogram of the product analyzed. The maximum level of the residues of active

substances of PPPs is based on the EU legislation, the conditions of the country, within the limits set by EU.

2.8. Sustainable use of plant protection products:

According to chapter III (1, 2, 3, 4, 5, 6), DCM no. 317, date 15.5.2009 "On the approval of rules for the sustainable use of plant protection products and the qualification criteria for the users", only the persons more than 18 years old have the right to use the PPPs, excluding pregnant women. These persons must be equipped with a proof of ability which is provided in public and private institutions after completing a 30 hours theory and 10 hours practice course. At the end of this course, an exam is conducted by the commission, which assesses the knowledge of the person seeking the proof of ability. Proof of ability is signed by the representative of the Regional Agency of Veterinary Service and Plant Protection and the representative of the institution where the course is held. Proof of ability has no expiration date and it is accompanied by a health certificate issued every 2 years.

The person seeking to qualify as a professional user must attend a course of instruction in public or private institutions, approved under the legislation on vocational education and training. The course should consist of 40 hours of theory and 20 hours of practice. The PPPs registered for use must be in the course content. At the end of the course, an exam is conducted by the commission, which assesses the knowledge of the person seeking proof of ability. Proof of ability is signed by the representative of the Regional Agency of Veterinary Service and Plant Protection and the representative of the institution where the course is held. Proof of ability is valid for a period of 6 years and is accompanied by a health certificate issued every 2 years.

In the territory where treatment with high-risk PPPs and / or dangerous PPPs is carried out, the passage, grazing and taking of food for humans and livestock is prohibited. Warning signs, 50 x 30 cm in size, are displayed in these areas, accompanied by the note "Caution, risk of poisoning!". These tables and marking shall be resistant to weather conditions, at least for a period of 20 days from the moment of their installation.

According to DCM no. 317, date 15.5.2009 "On the approval of rules for the sustainable use of plant protection products and the qualification criteria for the users", there are some specific practices regarding the use of PPPs which are prohibited within the territory of Albania such as: use of aircraft for treatment with PPPs; use of herbicides on or along national roads, railways, riverbeds and lakes, highly permeable surfaces, near water surfaces or groundwater, in public parks, in forests and, in general, in agricultural areas not designated for the cultivation of the agricultural; use of dangerous PPPs and / or high

risk PPPs in residential centers, in areas used by the general public or vulnerable groups, such as: public parks and gardens, playgrounds and recreational areas, school grounds, and playgrounds for children and in the vicinity of health care facilities as well as in protected areas; preparation of sprinkler solution near springs, water wells, reservoirs, running water, pits, canals, and their spilling and washing of working tools therein; use of poisonous and highly poisonous plant protection products for bees, as well as pollinating insects in greenhouses; plant material disinfected with PPPs, to be used as food for humans, animals and birds, even if it is processed, washed or cleaned, except where the label indicates that such use is permitted. Disinfected planting material is stored in separate places away from children and animals.

To protect beneficial insects and their pollinating activity, the use of plant protection products in flowering plants is prohibited, whether cultivated or spontaneous. Treatments with plant protection products can be carried out up to three days before flowering, as well as after the petals fall, by proceeding with the cutting of spontaneous flowering plants found under or near the crops to be treated. The Ministry of Agriculture and Rural Development publishes the list of toxicities of PPPs to pollinating insects, especially to bees and makes it known on its official website.

During the working process, the plant protection products and their packaging, as well as the spraying solution should not be left out of the user's control for a moment. At the end of the day's work, the residual PPPs and their packaging are returned to storage, and the remaining spraying solution, after diluting over 5 times, is rinsed at the site where the solution is prepared and deeply inverted in 20 cm depth.

2.9. Disposal of plant protection products:

In the group of PPPs, packaging and other materials destined for disposal are included: PPPs that are unusable due to expiration or for other reasons; PPPs that have leaked during storage and transport, and materials used for their absorption and deactivation; empty containers such as tank, bottles, boxes, bags, etc; contaminated items during work such as protective equipment, cleaning agents, different containers, etc, which can no longer be used (Chapter VIII (1), DCM no. 1188, date 20.8.2008 "On the approval of rules on import, trade, transport, storage, use and disposal of plant protection products").

Importers of unusable PPPs, due to their expiration or for other reasons, are obliged to remove them from the territory of the Republic of Albania or to incinerate them in accordance with the legislation in force, or to bury them in landfills. Incineration of PPPs within the territory of the Republic of Albania is done by specialized entities for this purpose, after being verified and authorized by the relevant structures of the Ministry of

Tourism and Environment. The landfill sites of the plant protection products and other materials mentioned above are designated by the Plant Protection Inspector and the Inspector of Environment. The landfill sites are kept surrounded by fences where warning signs are placed. Landfilling is carried out in waterproof, non-flooded lands, away from running water and water basins, away from residential centers, as well as buildings where animals are kept. The pit is filled with debris up to 50 cm below its upper level, and the rest is covered with soil or clay and lime mix and planted with bushes to avoid erosion.

2.10. Recycling of plant protection products:

The users of PPPs return the packages of used PPPs to the retail outlets where they were supplied, being refunded with 10% of the value held in the invoice (Chapter IX (3), DCM no. 1188, date 20.8.2008 "On the approval of rules on import, trade, transport, storage, use and disposal of plant protection products"). PPPs retailers collect empty packages in a separate room, delivering them to the wholesale premises, where they are supplied, at the end of each month, and are also reimbursed 10 % of the values held in the invoice.

Every quarter, the Plant Protection Inspectorate, at National Food Agency, where the PPPs trade units operate, matches the dispersed packages with those collected. the undamaged empty packages collected at the Wholesale units are reused. The damaged empty packages are treated as poisonous and harmful waste and disposed in accordance with the regulation.

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

The Albanian legislation provides a complete regulation on procedures such as: Control of parasites and pests, Registration of plant protection products, Licensing of PPPs, Trade of PPPs, Transport of PPPs, Storage of PPPs, Quality control of PPPs, Sustainable use of PPPs, Disposal of PPPs and Recycling of PPPs. Furthermore, there has been some initiative on aligning the Albanian legislation regarding the phytosanitary services and chemicals management with the EU legislation, although there is still much to be done in this regard.

The responsible authority for the protection of plants in the Republic of Albania is the Ministry of Agriculture and Rural Development, and its subordinate institutions:

- The Responsible Structure for Plant Protection
- National Food Agency

- Regional Agencies for Veterinary Services and Plant Protection
- Food Safety and Veterinary Institute (ISUV)
- Plant Protection Department

Every plant protection product has to be registered in one of the EU countries in order to be registered and used within the territory of the Republic of Albania. There are some specific rules regarding the registration, licensing, trade, storage and transport of PPPs (described above). List of the registered PPPs is published in the official webpage of the Ministry of Agriculture and Rural Development and is available information for the public.

Every plant protection product in the market is subject to quality control which is carried out by the National Food Agency (AKU). The quality control of the plant protection products that are imported is carried out by the quarantine inspector in every border point. The quality control analyzes are carried out by the Food Safety and Veterinary Institute (ISUV).

PPPs which are unusable due to expiration or other reasons, and those which have leaked during storage and transport are destined for disposal. The methods for the disposal of the PPPs include: Incineration and landfill.

The packages of the used PPPs are returned to the retail units and are refunded with 10% of the value in the invoice. The undamaged empty packages are reused in the new PPPs confection. While, the damaged empty packages are treated as poisonous and harmful and are destroyed.

Regarding the use of plant protection products, there are some good regulations which indicate and ensure a sustainable use of PPPs. It is important to emphasize here the criteria for being a user / professional user of PPPs. According to the Albanian legislation, in order to be a user of PPPs you have to be above the age of 18 years old and to be equipped with a proof of ability which is provided by public and / or private institutions after attending a course of 30 hours theory and 10 hours practice. The proof of ability doesn't have an expiration date. The same criteria is also for being a professional user of PPPs, except a few changes regarding the duration of the course (40 hours of theory and 20 hours of practice) and the expiration date of the proof of ability (the proof of ability for being a professional user expires after 6 years). These criteria are important to make people more aware on the sustainable and responsible use of the plant protection products. Nevertheless, most of the users of PPPs in Albania do not meet these criteria, especially those who are not professional users. Starting with the fact that everyone, regardless of age, can buy plant protection products in any of the trading points. Furthermore, the users of PPPs most of the cases are not equipped with a proof of ability and they don't even have the information on the criteria they have to meet in order to use

plant protection products. In cases of personal use of plant protection products, people are instructed on the use of the PPPs by the person, who sells them and who is a graduate in agronomy. This case indicates a good legislation in force but poor law enforcement which might be the case for many other aspects of the Albanian legislation related to the use, storage, control, and treatment of plant protection products within the territory of the Republic of Albania.

IV. CONCLUSIONS

On paper, it seems that the Albanian legislation is complete and addresses all the main issues related to use, storage, control and treatment of plant protection products. It is also partially influenced by EU legislation and in accordance with International Conventions such as International Convention on Plant Protection & Convention of Rotterdam. Meanwhile, in practice, it appears to be poor law enforcement.

It is important to highlight that in order for a plant protection product to be registered in the Republic of Albania, it has to be registered in at least one of the EU countries, setting thus European standards regarding the list of PPPs which are allowed to be used within the territory of the Republic of Albania. Despite this, there have been cases of trading and use of the PPPs that are banned, emphasizing once again the poor law enforcement.

Regarding the human, animal, and environmental health, there are some mechanisms that regulate the impacts of PPPs, mentioning here the mechanisms on disposal and recycling of the plant protection products as well as regulating mechanisms on transport and storage of PPPs.

In terms of biodiversity, there is no specific mechanism that regulates the impacts of PPPs on specific species or groups, besides the impacts of PPPs on pollinating insects. Probably, it is thought as the only directly affected group by the use of pesticides.

V. RECOMMENDATIONS

There are two main issues arising regarding law enforcement on the sustainable use of PPPs within the territory of the Republic of Albania:

1. Lack of information from the public regarding the rules on the use of plant protection products and on the consequences from the misuse of PPPs
2. Lack of control at retail trading points of PPPs

In terms of alleviating these issues it is much needed to inform the public through media and other means of information, about the existing legislation regarding the rules on the use of plant protection products, professionally or not, adding here also the information regarding the consequences from the misuse of PPPs on human, animal, and environmental health.

The rules for being a user of PPPs as well as the information regarding the impacts from the misuse of PPPs should be represented in a billboard which should be placed in a prominent place in the premises of the trading points of PPPs.

The responsible authority for the law enforcement regarding trade of PPPs must carry out periodic inspections at retail trading points of PPPs, in order to control the fulfillment of the criteria on the sale of PPPs, and to whom they are sold (fulfillment of the age criterion).

It is important that all the retail and wholesale trading points of PPPs are obliged by to compile an annual report on the quantity and quality of the PPPs that are classified as “Dangerous” or “High risk” PPPs and submit it to the National Food Agency. It would have been good if the retail trading points would compile an annual report also on the quality and quantity of the PPPs, which are not classified as “Dangerous” or “High risk” PPPs, and submit it to the National Food Agency. These reports should be available to public.

It would help also the imposition of penalties, such as fines, towards all persons who use plant protection products without being equipped with proof of ability. These measures are important in terms of law enforcement and in terms of minimizing the impact of plant protection products on human, animal health and to the environment.

ANALYSIS OF THE PUBLICALLY AVAILABLE INFORMATION ON THE USE OF AGRICULTURE CHEMICALS THAT COULD BE POTENTIALLY DANGEROUS FOR VULTURES AND WILDLIFE

I. OVERVIEW OF THE PUBLICALLY AVAILABLE INFORMATION

The publicly available information regarding agricultural chemicals and their use within Albania is very limited. The only available information for the public are: Legal acts regarding plant protection and plant protection products, List of registered plant fertilizers; List of registered plant protection products, some statistics regarding the agricultural production, and some news regarding the National Food Agency field inspections.

Legal acts regarding plant protection and plant protection products can be found in three main sources, such as: The Official Gazette³, the website www.ligjet.org¹, and the official webpage of the Ministry of Agriculture and Rural Development⁴.

The lists of registered fertilizers and plant protection products can be easily found in the official webpage of the Ministry of Agriculture and Rural Development, under the section "Publications"². This information is available in pdf format, and it is updated.

Regarding the use of the agricultural chemicals (pesticides, fertilizers) there is no publicly available information, or it may not be easily found. In the official webpage of the Ministry of Agriculture and Rural Development, under the section "Statistics"⁵ are represented some short reports on the annual statistics regarding the agricultural production. The latest report is from 2017 and shows an increase in the vegetable, cereal, and potato production, mentioning also the counties with the highest agricultural production, such as: Fier, Tiranë, Korçë, etc. Nevertheless, there is no information on the quantity and the frequency of the agrochemicals used, or if there is used any agricultural chemical.

In the official webpage of the National Food Agency (AKU), under the section "News"⁶ are represented the latest news regarding the National Food Agency activity as well as weekly summaries on their field inspections. The information in these news is very short and doesn't provide much details i.e. on these weekly news are represented the number of the subjects inspected and what were the penalties undertaken during the week. Moreover, the access of information in this section is not an easy task because you need to check the entire news history in order to find something that might interest you.

II. LEGAL USE OF PESTICIDES FOR THE WHOLE COUNTRY

2.1. List of all crop protection chemicals: pesticides, rodenticides, insecticides, herbicides, fungicides

In total there are 332 plant protection products (fungicides, insecticides, rodenticides, herbicides, pesticides, pheromones, growth hormones) which are allowed to be imported and traded; 103 PPPs (fungicides, herbicides, insecticides, pesticides) which are not allowed to be imported but only marketed and used in the territory of Albania, and 291 plant fertilizers.

2.2. Standard procedures for the use of each type of crop protection substance (for each substance)

The information regarding the use of registered plant protection products is limited. In Annex II and Annex III, is given information regarding the name, the active substance, the type, registration (date and register number) of the PPPs as well as the name of the applicant for the registration of the PPP. According to table 1, there are:

- 172 plant protection products used as fungicides
- 79 plant protection products used as insecticides
- 39 plant protection products used as herbicides
- 16 plant protection products used as nematocides, moluscides, etc
- 7 plant protection products used as pheromones
- 6 plant protection products used as growth hormones
- 4 plant protection products used as rodenticides

According to table 2, there are:

- 58 plant protection products are used as fungicides
- 21 plant protection products are used as insecticides
- 15 plant protection products are used as herbicides
- 8 plant protection products are used as acaricides, nematocides, etc
- 2 plant protection products are used as rodenticides
- 2 plant protection products are used as growth hormones

There is no publicly available information (or hard to find) on the requirements for the storage and treatment of PPPs, nor on the geographical distribution regarding the use of registered PPPs. However, following a logical line, most of the PPPs are used throughout the Western lowlands where is concentrated most of the agricultural activity in Albania. Regarding the amount of the PPPs used per hectare, there is still a lack of the publicly available information. There are no annual agricultural reports published, or any register regarding the annual use of the agricultural chemicals.

2.5. Regulation (prohibition) for use / storage / disposal (landfill, safety)

There are two legal methods to destroy PPPs: Incineration and Landfill. Burning of the PPPs is carried out in ventilated places, away from people, animals, housing or crops. Unburnable packaging is washed, broken, crushed and buried.

The landfill sites of the plant protection products and other materials are designated by the Plant Protection Inspector and the Inspector of Environment. The landfill sites are kept surrounded by fences where warning signs are placed.

2.6. Registries for the use of chemical protection legal substances

There is no publicly available information regarding registries for the use of chemical protection legal substances.

2.7. Quantities of the chemicals used by types

There is no publicly available information regarding the quantities of the chemicals used by types.

2.8. Statistics on the use of the types of chemical protection chemicals

There is no publicly available information regarding the statistics on the use of the types of chemical protection chemicals.

2.9. Import procedures, authorization regime and storage of legal chemical protection substances

A. Import

According to the law no. 1188, date 20.8.2008 "On the approval of the rules on the import, trade, transport, storage, use, and disposal of the plant protection products", it is allowed only the import of the PPPs registered in accordance with the requirements of the legislation in force.

B. License conditions

According to the law no. 10081, date 23.2.2009 "On licenses, authorization and permits in the Republic of Albania", as amended, the evaluation process regarding licensing is divided into three different stages according to the three different groups to be evaluated. The division of these groups is based on the criteria that each group must meet in order to be licensed.

III. ILLEGAL DISPOSAL OF PESTICIDES – ILLEGAL LANDFILLS

3.1. List of all chemicals banned for import and use

There is no publicly available information regarding the list of the chemicals banned for import and use in the Republic of Albania.

3.2. Conditions and rules for controlling the import and use of illegal chemicals for chemical protection

There is no publicly available information regarding the conditions and rules for controlling the import and use of illegal chemicals for chemical protection.

3.3. Statistics of cases of detected illegal import of illegal chemicals for the last 5 years - date, substance, quantity, place of perception, action

There is no publicly available information regarding cases of detected illegal import of illegal chemicals. However, there is a case of detected illegal import of PPPs which are not allowed to be imported in the territory of the Republic of Albania. This case was published in the official webpage of the National Food Agency, on November 18, 2019. According to this news, 800 liters of PPP (Tilt 250 EC) was stopped in the border point "Hani i Hotit". The amount of PPP came from Germany and its destination was Albania. The 800 liters of Tilt 250 EC was stopped in the border point with the purpose to return it to the country of origin.

3.4. Statistics of the cases of established illegal dumping of illegal chemical substances for the last 5 years - date, substance, quantity, location of the perpetuation (municipality, land, property no / address if possible or geographic coordinates)

There is no publicly available information regarding the statistics on the cases of established illegal dumping of illegal chemical substances.

IV. CONCLUSIONS

Based on our research we can conclude that there is very limited information available for the public regarding the use of agriculture chemicals and it is not always updated. The list of the publicly available information includes:

- List of legal acts regarding plant protection and plant protection products: This information is available and free to access in three main sources, such as: The Official Gazette, the website: www.ligjet.org, and the Ministry of Agriculture and Rural Development and it is updated.
- List of PPPs which are allowed to be imported and traded in the Republic of Albania: This information is available and free to access in the official webpage of the Ministry of Agriculture and Rural Development and it is updated.
- List of PPPs which are not allowed to be imported but only marketed and used in the territory of the Republic of Albania. This information is available and free to

access in the official webpage of the Ministry of Agriculture and Rural Development and it is updated.

- List of registered plant fertilizers: This information is available and free to access in the official webpage of the Ministry of Agriculture and Rural Development and it is updated.
- Annual reports regarding the statistics on the agriculture production: This information is available in the official webpage of the Ministry of Agriculture and Rural Development and it is not updated. The latest report in this regard is from 2017.

Meanwhile, in terms of quantities, and geographical distribution of the legal use of the agriculture chemicals, there is no available information for the public.

Regarding the list of illegal chemicals and illegal use of the illegal chemicals, there is a complete lack of publicly available information, the same for cases of detected illegal import of illegal chemicals and disposal of the illegal chemicals.

V. RECOMMENDATIONS

It is important that all the responsible institutions on plant protection and plant protection products to provide information to the public regarding legal and illegal agriculture chemicals and their use within the territory of the Republic of Albania. This can be achieved through annual reports and registers on the quantity, geographical distribution, and legal / illegal use of the agriculture chemicals.

These reports, registers should be published in the official webpage of the relevant institutions and be free to access from the public, or at least disclose their existence on the official webpage of the relevant institutions and provide the information on how to access them.

SOURCES OF INFORMATION:

Ministry of Agriculture and Rural Development

National Food Agency

Law no. 105/2016, date 27.10.2016 "On the protection of plants"

Decision of the Council of Ministers (DCM) no. 146, date 13.3.2018 "On the establishment, organization and functioning of regional agencies for veterinary services and plant protection"

Law no. 27/2016 "On the management of chemicals"

DCM no. 317, date 15.5.2019 "On the adoption of rules for the sustainable use of plant protection products and the qualification criteria for users"

DCM no. 335, date 6.6.2018 "On the approval of rules on the registration procedure and evaluation criteria of plant protection products"

Law no. 10081, date 23.2.2009 "On licenses, authorization and permits in the Republic of Albania", as amended

Order no. 566, date 15.10.2019 "On updating ministers order no. 72, date 2.3.2017 "On approval of active substances in content of PPPs", changed"

DCM no. 1188, date 20.8.2008 "On the approval of rules on import, trade, transport, storage, use and disposal of plant protection products"

DCM no. 462, date 11.7.2012 "On some amendments on the DCM no. 1188, date 20.8.2008 "Approving the rules on import, trade, transport, storage, use, and disposal of plant protection products"

DCM no. 532, date 11.9.2018 "On the approval of rules on the trade, transport, and storage of plant protection products"

Law no. 8483, date 10.5.1999 "On the accession of the Republic of Albania in the "International Convention on Plant Protection"

Law no. 10277, date 13.5.2010 "On the accession of the Republic of Albania to the Convention of Rotterdam "On the procedure of notification of preliminary approval of some chemicals and dangerous plant protection products in the international trade"

DCM no. 201, date 10.4.2019 "On the approval of the National Plan for European Integration 2019-2021"

Bosnia and Herzegovina

REVIEW OF RELEVANT LEGISLATION IN BOSNIA AND HERZEGOVINA REGARDING USE, STORAGE, AND TREATMENT OF PLANT PROTECTION PRODUCTS

I. LEGAL ACTS

Bosnia and Herzegovina is a complex country; it is comprised of two entities – the Federation of Bosnia and Herzegovina and Republika Srpska – and the District of Brčko. The Federation of Bosnia and Herzegovina consists of 10 cantons, and the local authorities are comprised of towns and municipalities. Republika Srpska has the same structure for local authorities. The District of Brčko, on the other hand, has a specific legal and constitutional status. A territorial organization this complex carries with it a complex legal frame reflecting multiple levels of authority when it comes to legislating and enforcing the law.

1. Law on Phytopharmaceutical Products of Bosnia and Herzegovina, ('Official Gazette B&H' no. 49/04)

Law on Phytopharmaceutical Products of Bosnia and Herzegovina is influenced by the EU laws, and it regulates:

I GENERAL PROVISIONS

Scope of the Law

1. This Law regulates the traffic of and supervision over active materials which are phytopharmaceutical products, registration of PPPs, issuance of licenses on the basis of this law, traffic, use of and supervision over PPP, PPP residuum, keeping the PPP register and the register of legal entities and individuals involved in PPP traffic, reporting on the data and keeping of register on PPP, technical requirements for PPP application devices (hereinafter the devices) and their components, authorization of institutions responsible for the implementation of this Law and monitoring of its implementation and the implementation of the relevant implementing regulations.

2. The production of PPP, the traffic required for the purpose of PPP production, good laboratory practices, the procedure of approval of the previous report, supervision and sorting, packing and marking of PPP shall be regulated by the law on chemical substances.
3. The PPP residuum and its waste packing, the level of PPP emission into human environment shall be regulated by the environment law.

Relevant terminology:

1. The terms used in this Law shall be understood to mean the following:
 - a) **Phytopharmaceutical products** in their final form are active materials and preparations, intended for:
 - 1) protection of plants and crop farming from pests and prevention of their damaging effects
 - 2) making influence on the vital process of plants, different from feeding
 - 3) maintenance of plant products, unless they are regulated by different legislation
 - 4) prevention of undesired plants, parts of plants, deterrence or prevention of undesired growth of plants.
 - b) **PPP residuum** - one or more materials present in and/or on plants and plant products; in the country or abroad in human environment and are the consequence of use of PPP, including their metabolites or products as a consequence of their decomposition or reaction.
 - c) **Preparations** - mixtures or solutions of two or more substances of which at least one is an active material.
 - d) **Materials** - chemical elements and their compounds found in nature or produced in a production process, including any contaminants which are an unavoidable consequence of production consequences.
 - e) **Active materials** - materials or micro-organisms, including viruses which have general or special effect on pests and plants, their individual parts or plant products.
 - f) **A list of active materials** - consists of active materials licensed to be used in PPP in the European Union member-states (hereinafter the EU) and the conditions under which these materials may be used (hereinafter the list).

- g) **Old active materials** - active materials which are not included in the list and were registered and available in the market before December 31, 1991 in any EU member state.
- h) **New active materials** - active materials which are not on the list and were registered and available on the market after December 31, 1991 in any EU member state.
- i) **PPPs are identical** if the content of active material is equal within internationally described deviations, including contaminants and any other ingredients of active material and if physical and chemical features of the preparation, marks, packing and containers, except for a trade name of the preparation, are the same.
- j) **Traffic** - export, import, sale or giving to third persons. Import is any bringing of PPP to the customs area of Bosnia and Herzegovina regardless of which use or application is allowed under the customs regulations for that PPP. Export is any taking of PPP from the customs area of Bosnia and Herzegovina and also includes re-export and temporary export of PPP.
- k) **Good agricultural practice** - execution of an agricultural activity in a manner which enables good husbandry/management of agricultural land and reproduction material with due respect for natural features of the agricultural area. Good agricultural practice includes optimal combination of agro-technical measures, preservation of natural fertility of the agricultural land and prevention of environmental pollution, excessive use of mineral fertilizers and organic manures and PPP and production of plants or plant products intended for food which contains the lowest level of PPP residuum possible.
- l) **Integrated protection of plants** - optimal combination of biological, biotechnological, chemical, agro-technical measures or measures for growing plants, where the use of plant protection chemical substances is limited to the necessary quantity of permitted PPP needed for preservation of the population of damaging organisms below the economically unacceptable damage or loss threshold.
- m) **The authorities responsible** for registration, execution of administrative tasks within the traffic of PPP and PPP applicators, supervision over the implementation of this Law and reporting to the European Commission are: Bosnia and Herzegovina Plant Health Protection Authority (hereinafter the Authority) and the responsible authorities of the two entities and Brcko District.

II TRAFFIC AND USE OF PPPs

General provisions

1. PPP's may not be transported, sold, exported from or imported to or used within Bosnia and Herzegovina if they are not registered or if no license has been issued in accordance with this Law.
2. Exceptionally from paragraph 1, The Authority may allow sale and transport if PPPs are intended for transport to and use in another country, provided that such PPPs will not be used within the territory of Bosnia and Herzegovina. If the PPP is intended for use in an EU member country, transport and storage will be allowed only if PPP is registered in that member country and that PPP will not be used in the territory of Bosnia and Herzegovina.
3. The license by the responsible authority is not required for research and development purposes, except when unregistered PPP's will be emitted into human environment.
4. Exceptionally from paragraph 3, import or export of PPP for research or development purposes may be done by a legal entity or an individual registered for that activity. Such a legal entity or an individual shall inform the Authority and the entity responsible authority or the responsible authority in Brcko District, depending on the location of the seat of the legal entity or the individual.

Sale of PPPs

1. PPPs may be sold as a preparation if they are registered at the responsible authorities and sorted, packed, marked and equipped with an instruction for use in accordance with the regulations for hazardous materials and preparations, and in accordance with the implementing regulations enacted under this Law.
2. PPPs as an active material may be sold if they are registered at the responsible authority and sorted, packed and marked in accordance with the regulations for hazardous materials and in accordance with the regulation enacted under this Law.
3. The regulation governing the sorting, packing, marking of PPP and the provision of an instruction for its use, pursuant to this Law, shall be approved by the Council of Ministers at the proposal of the Authority, in cooperation with the responsible authorities in the two entities and Brcko District.

Requirements for sale of PPP and sale register

1. PPP may be sold by legal entities and individuals seated in Bosnia and Herzegovina, who, in addition to other requirements, also meet special requirements for space, equipment and staff set by the responsible authorities of the two entities and Brcko District in the form of a decision issued in an administrative procedure, within their respective administrative jurisdiction. The decision shall also contain the registration number for entry in the register of physical and natural persons dealing with the sale of PPP (hereinafter the sale register).
2. The legal and natural persons referred to in paragraph 1 of this Article must have a person responsible for sale of PPP, who will be in charge of issuing PPP, reporting and keeping register.
3. The requirements which have to be met by the legal and natural persons regarding space and equipment required for the sale of PPP and the requirements for the staff and professional development shall be defined by the Council of Ministers at the proposal of the Authority.
4. The register referred to in paragraph 1 of this Article shall be introduced and kept by the responsible authorities of the two entities and Brcko District and it shall contain at the least the following data: the name of company, the name and family name of the person involved in selling PPP, address, the seat of the company/person, the address and seat of the branch office, name and family name of an authorized contact person and the name and seat of a foreign producer whom that person represents in Bosnia and Herzegovina.
5. The Authority shall keep a single register for Bosnia and Herzegovina. The authorities of the two entities and Brcko District shall send to the Authority the data contained in the register referred to in paragraph 4 of this Article within 15 days from the date of its entry in the register they keep.

Registers and submission of data

1. The legal and natural persons involved in the sale of PPP shall keep the register on the quantities of purchased PPP, the quantities of PPP sold, the quantities of PPP stored, the quantities of PPP withdrawn from circulation and shall inform the responsible authorities in the two entities and Brcko District accordingly no later than March 31 of the next year. The authorities of the two entities and Brcko District shall inform the Authority.

2. The legal and physical persons referred to in paragraph 2 of Article 11 of this Law must also keep the register on the use of those PPPs, in addition to the register referred to in paragraph 1 of this Article, and submit the data on their use before March 31 of the next year at the latest.
3. The legal and natural persons dealing with the sale of registered PPPs which are sorted, depending on their hazardous effect, into PPP marked with T, shall keep the register with the following data, in addition to the register referred to in paragraph 1 of this Article:
 - a) data on PPP (trade name, purpose of use, validity),
 - b) date of sale, or issuance of PPP,
 - c) quantity of sold or issued PPP,
 - d) for legal entities to which they were sold, or issued: the name of company, seat and tax number, and for natural persons: personal data (name and family name, address and unique citizen identification number),
 - e) signature of the person who issued PPP and the person who received PPP.
4. The data referred to in paragraph 3 of this Article shall be kept by the legal and natural persons dealing with the sale of PPP for at least five years and make it accessible to an authorized authority at its request.
5. The exact content and manner of keeping register and submission of the data shall be prescribed by the Council of Ministers at the proposal by the Authority.

Sale of PPPs

1. PPP may be sold, depending on the classification in the groups of hazards/toxicity, packaging and the manner of use:
 - a) only in specialized shops selling PPP, or
 - b) in flower shops and non-food shops, or
 - c) in a specialized department of grocery shops.
2. The place of sale of PPP shall be defined by the Authority in the registration decision at the proposal of the PPP Commission (hereinafter: the Commission).

The proper use of PPPs

1. PPPs must be used properly.
2. The proper use means the use of PPP in accordance with the instruction for use and the instructions on the label, including the preparation of a prescribed

concentration of PPP, respect for the principles of good agricultural practice, integrated protection of plants if possible, and the protection of human environment and non-target organisms.

3. It is forbidden to apply PPP from air.
4. The use of PPP in the manner which would cause pollution of housing, business and similar buildings in which people and animals reside and the pollution of neighboring lands and waters shall not be allowed.
5. The use of registered PPPs for the purposes defined in the registration decision and the instruction for use, and in accordance with the instruction on the label may be advised, advertised or recommended.
6. The Council of Ministers shall prescribe the duties of the users in regard to the use of PPP at the proposal of the Authority, in cooperation with the responsible authorities of the entities and Brcko District.

Plant protection agents

1. The legal persons or individuals dealing with agricultural production and who are market producers may use PPP only if they meet the prescribed requirements for education, and skills and if they apply PPP with the appropriate devices designed for PPP application.
2. Detailed requirements for professional training and content and manner of testing the knowledge from PPP shall be prescribed by the Council of Ministers at the proposal of the Authority.

PPP residuum

1. The prescribed PPP residuum thresholds on or in the plants and plant products may not be exceeded.
2. If it is established that the residuum threshold is exceeded on or in the plants, they must be destroyed or their use by people and animals prevented in another way.
3. The PPP residuum threshold in or on the plants and plant products and the measures which are implemented in the cases in which excessive amounts are established through laboratory analyses shall be prescribed by the Council of Ministers at the proposal by the Authority.

PPP classified as T+

1. Registered PPP's which are classified as T+ in regard to toxicity, must not be placed in sale and general use.
2. The sale and application of PPP referred to in paragraph 1 shall be allowed only to legal entities and individuals who have permanently employed staff skilled in working with poisons, who meet the prescribed requirements for space and equipment and are licensed by the entity and Brcko District authorities responsible for health.
3. More detailed requirements for space, equipment and staff shall be prescribed by the Council of Ministers at the proposal by the Authority.

Prohibition, restriction of sale and use

1. If there is a reasonable doubt to believe that registered PPP pose threat to human health and/or environment, based on technical and scientific findings, the Council of Ministers may restrict or prohibit the sale and/use of PPP within the territory of Bosnia and Herzegovina and parts thereof, at the proposal by the Authority and with the consent by the Commission.
2. If PPP contains some active materials and if their sale and/or use is restricted or prohibited in the EU, the Council of Ministers shall restrict or prohibit the sale and/use of PPP within the territory of Bosnia and Herzegovina, at the proposal by the Authority.

III Registration of PPPs**Registration**

1. The registration of PPP requires that an application be filed with the relevant Authority. The prescribed documentation for evaluation of active materials in PPP referred to in Article 15 except for cases referred to in Article 16, paragraph 3 of this Law, the prescribed documentation for evaluation of PPP and other data, documents and samples required for the establishment of registration conditions, if this is required by the responsible authority, shall be attached to the application.
2. Active materials and PPP shall be evaluated by skilled experts or legal persons authorized by the Council of Ministers, at the proposal by the authority.

3. The expert or legal experts referred to in paragraph 2 of this Article shall be nominated by the responsible authorities in the entities and Brcko District and the entity and Brcko District responsible for health and the entity authorities and those of Brcko District in charge of human environment.
4. The Council of Ministers shall at the proposal by the authority, in cooperation with the responsible authorities in the entities and Brcko district for health and environment authorize the authority (institution or a legal entity) to do the evaluation of impact of PPP on the human environment and health and the opinion on sorting, packaging and marking of hazardous materials and preparations on the basis of toxicological and eco-toxicological documentation referred to in articles 15 and 16 of this Law. The authorized authority or an institution shall meet the requirements for skills and education of the staff.
5. If PPPs are classified as hazardous, the integral part of the opinion referred to in the preceding paragraph shall also be medical measures in the case of acute poisoning.
6. More detailed requirements for skills to be possessed by the staff in charge of drafting assessments and opinions referred to in this article shall be prescribed by the Council of Ministers at the proposal by the Authority.
7. In assessing the requirements for registration, unified principles for assessment of PPP prescribed by the Council of Ministers at the proposal by the authority shall apply.

IV TYPES OF REGISTRATION

Articles 23-27 regulate requirements for PPP registration, Validity and extension of registration, Temporary registration, Amendments to the registration decision and Cessation of registration

VI PPP REGISTER

The Law regulates keeping of a single PPP register for B&H, as well as Authority's obligation to annually publish list of registered PPPs in 'Official Gazette B&H' and amendments at least twice a year.

PPP register

1. The Authority shall keep a single PPP register for Bosnia and Herzegovina (hereinafter the PPP register) on the basis of issued decisions on PPP registration. The list of registered PPP shall be published by the Authority once a year in the "Official Gazette of BiH" and amendments thereto at least twice a year. The responsible authorities of the two entities and Brcko District shall keep the register on registered PPP on the basis of the decisions submitted to them by the Authority on the basis of Article 19, paragraph 1 of this Law.
2. PPP register shall contain the following data:
 - a) customs mark,
 - b) PPP trade name,
 - c) name and content of all active materials in PPP,
 - d) name of producer, or representative in Bosnia and Herzegovina,
 - e) mark of the sorting in or outside the group of toxicity,
 - f) full name of the Authority (the responsible authority of the entities of Brcko District) which issues a registration decision,
 - g) number and date of registration decision,
 - h) place of sale from Article 7 of this Law.

VII LIST OF ACTIVE MATERIALS

The list of active materials is to be published by the Authority in the "Official Gazette of BiH" and amendments in accordance with amended list in the EU.

VIII LICENSES

Furthermore, the Law regulates Licenses for research or development, Exceptional license and Licenses authorizing extension of use.

Licenses for research or development

1. Any examination for research or development purposes which includes emission of unregistered PPPs in the environment may be done only on the basis of issued license for research or development.
2. The license referred to in paragraph 1 shall be issued by the Authority in an administrative procedure. The responsible authority shall seek opinion from the Commission for PPP which may be dangerous for health of people and animals or may have an unexpected damaging effect on the environment.

3. The license must reveal the data on PPP, quantity of PPP, area of research and requirements for use, and legal entities or individuals who will conduct the research.
4. The license shall be issued for the period of two years maximum. The lice may be extended at the request of the license holder if the license holder requests the extension at least four months prior to the expiration of validity of the license and demonstrates justified reasons for extension. The license shall be issued on the basis of the opinion by the Commission.
5. If the Authority has assessed that proposed research for which license is requested could have damaging effects on the health of people and animals or an unexpected damaging effect on environment, it may forbid the research at the proposal by the Commission or approve it under the requirements needed for the prevention of consequences.
6. A more detailed content of the application and licenses for research and developed shall be prescribed by the Council of Ministers at the proposal by the Authority.

Exceptional license

1. Due to unforeseen danger posed by damaging organisms that cannot be destroyed or adequately restrict with registered PPP or other measures, the Authority may issue an exceptional license for sale or use of unregistered PPP. The procedure for issuance of an exceptional license may be launched ex officio or at the request by the party. During the procedure, the Authority shall request the opinion from the Commission. An exceptional license shall be issued for the period of 120 days maximum for restricted and controlled use which does not pose an unacceptable danger to the health of people and environment.
2. The license referred to in paragraph 1 must contain the data on PPP, PPP quantity, areas and requirements for use, and users.
3. The Authority may change or annul an exceptional license if PPP did not achieve desired results, if PPP is no longer needed or if damaging consequences exceed the damages caused by damaging organisms referred to in paragraph 1 of this Article.

IX PUBLIC SERVICES IN THE PPP AREA AND PPP APPLICATORS

In Chapter IX commitment, responsibilities of the public service and Forms of execution of public services in PPP services is regulated, as well as funding of relevant public services.

X DEVICES

This chapter refers to use and certification of devices for application of PPPs.

XII – INTERNATIONAL TRAFFIC

Chapter XII the Law regulates import of PPPs and PPP applicators.

Import of PPP

1. PPP may be imported only by legal entities and individuals referred to in Article 5 of this Law.
2. Supervision over import of PPP shall be done by a phyto-sanitary inspector.
3. The border crossings via which PPP shall be imported into the country shall be defined by the Council of Ministers at the proposal by the Authority.

Import of PPP applicators

1. The devices which have been issued a certificate or a license by the Authority may be imported. Unless otherwise stipulated by an international agreement, customs authorities may not issue a license authorizing the use, except for authorizing transit and customs storage, if the device does not have a prescribed certificate or the approval.
2. The Council of Ministers shall prescribe the requirements for import on the basis of the license at the proposal by the Authority.
3. Exceptionally from paragraph 1 of this Article, the Council of Ministers may prescribe that a certificate or a license is not needed for certain types of devices of the devices for special purposes.

XIII BOSNIA AND HERZEGOVINA AUTHORITY FOR THE PROTECTION OF HEALTH OF PLANTS

Chapter XIII regulates authorization and tasks of the Authority and Authorization and tasks of the responsible authorities of the entities and Brčko District, while chapter XIV regulates inspection supervision.

XIV INSPECTION SUPERVISION

Inspectors

1. Supervision over the implementation of this Law and its implementing regulations issued on the basis of this Law shall be done by agricultural, phyto-sanitary and sanitary inspectors, within their respective scope of responsibility.
2. The appeal against the decision issued by the inspector referred to in paragraph 1 of this Article shall not operate to delay its enforcement.

Authorization of agricultural inspectors

1. The agricultural inspector shall, on the basis of this Law and the implementing regulations issued on the basis of this Law, be authorized to:
 - a) forbid sale of PPP which is not properly registered,
 - b) forbid sale of PPP if a proper license has not been issued,
 - c) forbid sale and use of prohibited PPP,
 - d) forbid sale of PPP the validity of which has expired,
 - e) monitor compliance with the requirements for the staff of legal and natural persons referred to in Article 5 of this Law,
 - f) pending removal of weaknesses, to forbid activities related to sale of PPP if the legal and natural persons fail to meet the requirements for the staff about which the inspector shall inform the responsible authority in the entities and Brčko District, which in turn shall inform the Authority,
 - g) forbid the sale of PPP, of PPP is not in accordance with the registration decision (packaging, libel, sorting, marks, instructions for use, physical and chemical content etc.),
 - h) forbid the use of PPP if PPP is used improperly,
 - i) establish the identity of the violator in the case of a doubt that the provisions of this Law are violated, in which case the violations shall be taken photos of or filmed, if necessary,
 - j) define the appropriate measures if the PPP residuum threshold is exceeded on or in the plans and plant products before sale,

- k) take samples of plans, plant products, soil, spraying mixtures, PPP and other necessary samples,
- l) take a PPP applicator and order that its harmony with the certificate be checked,
- m) forbid sale of PPP applicators if they were not issued the appropriate certificate,
- n) forbid sale of PPP applicators if the devices are not in accordance with the certificate,
- o) forbid the use of devices if they do not have a mark attesting to regular checks or if they were not checked on a regular basis,
- p) check whether the public service agents under this Law meet the requirements, or whether they act in accordance with the legislation, a concession contract and order that weaknesses be removed,
- q) carry out any other activities and order any other measures needed for the implementation of this Law and its implementing regulations.

Authorization of phyto-sanitary inspectors

1. A phyto-sanitary inspector shall, on the basis of this Law and the implementing regulations issued on the basis of this Law, be authorized to:
 - a) carry out monitoring referred to in Article 50, paragraph 2 of this Law,
 - b) during the import of PPP's sorted as dangerous, check harmony of the safety certificate with the regulations on chemicals,
 - c) forbid import of PPP if PPP is not registered properly, sorted, packed or marked properly or if they do not have the appropriate instruction for use, the appropriate license or if the sale of that PPP is forbidden, except for the cases referred to in Article 3, paragraph 2 of this Law,
 - d) forbid on a temporary basis import of PPP if some weaknesses are to be removed from the PPP shipment or the supporting documentation,
 - e) carry out any other activities and define any other measures for PPP and PPP traffic under this Law and its implementing regulations.

Authorization of a sanitary inspector

2. 1. A sanitary inspector shall, on the basis of this Law and the implementing regulations issued on the basis of this Law, be authorized to:
 - a) prior to entry of the data in the register referred to in Article 5, paragraph 1 of this Law, establish compliance with the requirements for space and equipment of legal and natural persons involved in the sale of PPP,
 - b) check whether the prescribed requirements have been met for space, and equipment of legal and natural persons involved in selling PPP,

- c) pending removal of weaknesses, forbid activities related to sale of PPP if the legal and natural persons fail to meet the requirements for the staff about which the inspector shall inform the responsible authorities.

XVI PENAL PROVISIONS

Chapter XV regulates collection and use of the data and international data exchange and Chapter XVI regulates penal provisions for legal entities, independent entrepreneurs and individuals.

Violations by legal entities and independent entrepreneurs – individuals

1. The legal entity shall be fined 1000 KM to 10,000 KM if:
 - a) it is selling and allowing the use of unregistered or unlicensed PPP in the territory of Bosnia and Herzegovina (Article 3, paragraph 1 of this law);
 - b) if it does not keep the register in accordance with Article 6, paragraph 4 of this Law;
 - c) if it is applying PPP from air (Article 8, paragraph 3 of this Law);
 - d) if it uses PPP in contravention of Article 8, paragraph 4 of this Law;
 - e) if it advises, advertises, or recommends PPP in contravention of the provisions of Article 8, paragraph 5 of this Law;
 - f) if it does not meet the prescribed requirements for professional skills or the requirements for the equipment Article 9, paragraph 1 of this Law);
 - g) if it, as the applicant, does not enquire with the responsible authority whether identical PPP have already been registered (article 17, paragraph 2 of this Law);
 - h) if it fails to inform the responsible authority on all new data on the possible dangerous effects of PPP or its residuum (Article 22 of this Law);
 - i) if it, as the registration holder, does not take care of the deadline and requirements from Article 27, paragraph 3 of this Law;
 - j) if it examines PPP in contravention of a research or development license (Article 30 of this Law);
 - k) if it uses PPP in contravention of the license permitting expansion of use (Article 32 of this Law);
 - l) if it carries out public service in contravention of the regulations or a concession contract (Articles 34 and 36.3 of this Law);
 - m) if it sells the devices which do not meet the requirements set in the certificate (Article 45, paragraph 1 of this Law);

- n) if it fails to allow an inspector to conduct inspection supervision without hindrance under this Law or if it hinders inspection, insults the inspector or prevents his or her access to required documentation, data, explanations or devices.
- 2. An individual shall be fined from 250 KM to 50,000 KM if he or she carries out actions referred to in the previous paragraph in relation to an independent execution of the activity.
- 3. The responsible person in the legal entity shall also be fined 250 KM to 5,000 KM for an offence from paragraph 1 of this Article.

Mandatory punishments of legal entities and independent entrepreneurs – individuals

- 1. The legal entity shall be punished by a mandatory fine of 3,000 KM collected without delay if:
 - a) it sells PPP which is not sorted, packed or marked in accordance with regulations, including the instruction for use (Article 4 of this Law);
 - b) if it fails to meet the set requirements for sale of PPP (Article 5, paragraph 1 of this Law);
 - c) if it does not have a responsible person for sale of PPP (Article 5, paragraph 2 of this Law);
 - d) if it does not submit the data to the responsible authority within the set deadline (Article 6 of this Law);
 - e) if it does not keep the register in a prescribed manner (Article 6 of this Law);
 - f) if it sells PPP at the selling location in contravention of the regulation of the responsible authority (Article 7, paragraphs 1 of this Law);
 - g) if it does not use PPP in the appropriate way (Article 8, paragraphs 1 and 2 of this Law);
 - h) if it sells and allows the use of PPP classified as T+ (Article 11, paragraph 1 of this Law);
 - i) if it does not have a license of the appropriate trained staff for sale and use of the PPP classified as T+ (article 11, paragraph 2 of this Law);
 - j) if it sells or uses PPP in accordance in contravention of prohibition or the restriction ordered by the responsible authority (Article 12 of this Law);
 - k) if it sells or uses unregistered PPP in contravention of an exceptional license (Article 31, paragraph 1 of this Law);
 - l) if it sells the devices without the prescribed certificate (Article 45, paragraph 2 of this Law);
 - m) if it uses the devices which are not checked on a regular basis (Article 47, paragraph 1 of this Law);

- n) if it does not keep and maintain the records in accordance with Articles 46 and 48 of this Law);
 - o) if it imports PPP although it is not registered for import (Article 50 of this law).
2. An individual who performs an action in relation to an independent execution of activity shall be fined 2,000 KM, which is collected without delay, for the offence from the previous paragraph.
3. The responsible person in the legal entity shall also be fined 1,000 KM, collectable without delay, for an offence from paragraph 1 of this Article.

Offences by individuals

1. An individual shall be fined from 1,000 KM to 1,500 KM for an offence if:
- a) he/she does not use PPP in a prescribed manner (Article 8, paragraphs 1 and 2 of this Law);
 - b) if he/she applies PPP from air (Article 8, paragraph 3 of this Law);
 - c) if he/she uses PPP in contravention of the provisions of Article 8, paragraph 4 of this Article;
 - d) if he/she fails to meet the set requirements for the level of training or for the equipment used for application of PPP (Article 9, paragraph 1 of this Law);
 - e) if he/she uses PPP in contravention of the restriction or prohibition by the responsible authority (Article 12 of this Law);
 - f) if he/she fails to inform the responsible authority about the dangerous effects of PPP (Article 22 of this Law);
 - g) if he/she uses unregistered PPP in contravention of an exceptional license (Article 31, paragraph 1 of this Law);
 - h) if he/she uses PPP in contravention of the license permitting expanded use (Article 32 of this Law);
 - i) if he/she prevents an inspector from executing inspection supervision under this Law or hinders inspection, insults the inspector or does not allow access to requested documents, data, explanations or devices.

Mandatory punishments of individuals

1. An individual shall be punished by a mandatory 1,000 KM fine on the spot if:
- a) he/she sells PPP without the proper registration (Article 5, paragraph 1 of this Law);
 - b) he/she applies PPP referred to in Article 11, paragraph 2 of this Law;

- c) he/she uses devices which have not been checked regularly (Article 47, paragraph 1 of this Law);
- d) he/she imports PPP without a proper registration (Article 50 of this Law).

2. Rulebook on Obligations of Phytopharmaceutical produce Users, ('Official Gazette B&H' no. 101/12)

Bosnia and Herzegovina has made implementing regulation, Rulebook on Obligations of Phytopharmaceutical Users, ('Official Gazette B&H', no. 101/12) which regulates obligations of PPP users regarding proper use of PPP, detailed conditions about professional training, content and testing knowledge about PPPs.

This Rulebook, among other things, regulates obligation of PPP users that PPPs can be used only if it's registered, that is if there is research or development license, exceptional license or licenses authorizing extension of use in accordance to the Law, as well as during use of PPPs one has to follow the rules that regulate protection of water, environment, safety at work, waste disposal and public order.

Furthermore, it regulates the use and special obligation regarding proper use of PPPs like preventing PPP skid, protection of bees, use of PPPs close to waters, integral protection of plants, fundamental principles of integral protection of plants, good agricultural practice whit treatment and use of seeds, waste disposal and storage of PPPs.

One chapter of the Rulebook – Part three regulates obligatory training for users, basic and advanced and purpose of training. It regulates obligation of Authority, in coordination with relevant authorities of two entities and District of Brčko, to establish unique program for basic and advanced training of users that will have theoretical and practical part and to determine unique basic material for training program.

Rulebook regulates that there is knowledge test after training program, and after passing the exam users get certificate on acquired knowledge on the use of PPPs. It is regulated that certificate is valid for five years (from the publishing date) and then candidate has to attend advanced training program that is shorter than basic and it emphasizes latest knowledges and discoveries regarding PPP. Candidate has to take knowledge test again.

It is regulated that training host keep evidence about passed professional exams and certificates. It is also regulated that training host must send annual report to relevant authorities of two entities and Brčko District once a year about organized training programs for users and training plan for following year.

3. International Convention on Plant Protection, ('Official Gazette B&H – International Agreements' no. 80/03)

4. Rotterdam Convention, ('Official Gazette B&H – International Agreements' no. 14/06)

CONCLUSIONS

On paper, it seems that the B&H legislation is complete and addresses all the main issues related to use, storage, control and treatment of plant protection products. Law on Phytopharmaceutical Products of Bosnia and Herzegovina and bylaws regulate all necessary provisions and requirements aimed to define the correct, safe and sustainable use and distribution of plant protection products.

This Law further defines the services of public interest regarding plant protection products, the establishment of the Commission for plant protection products, registration, trade, import and application of pesticides in agriculture and forestry services in the field of plant protection products, records, collection and data exchange, as well as other issues of importance for the application of plant protection products.

Legislation is also fully influenced by EU legislation and in accordance with International Conventions such as International Convention on Plant Protection & Convention of Rotterdam.

Meanwhile, in practice, reality is different. Complicated political scene in Bosnia and Herzegovina caused that the most important parts of the Law are not implemented, even now, 17 years after Law was adopted. Main reason for this is blockage of government institutions because of political reasons. Until this day registration of PPPs is not established, there is no PPP register nor professional training for PPP users (regulated by Article 9 of the Law and Articles 15, 16, 17, 18 of Rulebook) has been established.

Because of that, inspectorates can't perform supervision and impose a sanction, which makes room for PPPs misuse by users, as well as people who place PPPs in traffic. Apart from the intentional breaking the law, some PPP users, because of lack of education and knowledge, unintentionally use PPPs improperly and that way they cause danger to human health and have negative impact on whole environment.

One of the things that works well in practice is that the List of registered PPPs is updated and published regularly by Plant Health Protection Authority in Bosnia and Herzegovina, 2-3 times a year. Also, we got information that preparation of new Law on Phytopharmaceutical Products of B&H is currently being prepared. The new Law should be directed more towards implementation on entity levels and District of Brčko and hopefully it will be easier to implement in practice.

Bulgaria

REVIEW OF RELEVANT LEGISLATION IN BULGARIA REGARDING USE, IMPORT, STORAGE, AND TREATMENT OF PLANT PROTECTION PRODUCTS

I. 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

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)).

Authorized plant protection product - any plant protection product authorized for placing on the market and use.

Authorized use - 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.

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 - 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 - a practice whereby the treatments with plant protection products applied to given plants or plant products, in conformity with the conditions of their authorized 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.

Integrated pest management - 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.

Minimum use - 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 - plant protection product.

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

Residues - 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 metabolites, 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 - 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 - 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 - 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 BFSFA 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 **BFSFA 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 BFSFA. The MAFF issues regulation on the organization and activity of the CPPP and, on a proposal of the Executive Director of the BFSFA, determines its composition, including representatives of the MAFF, Ministry of Health, and Ministry of environment and water and scientific institutes (Art. 53 (2)). Pursuant to Article 54, the CPPP takes decisions and makes suggestions to the BFSFA 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.

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 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 authorization 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 authorized 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, Authorization 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)). 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)).

II. 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.

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 Forestry, 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)).

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)).

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 in Bulgaria 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 Forestry 5 (Art. 41 (3)).

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)).

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:

- **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)).

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)).

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)).

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)).

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

The holder of an authorization granted in accordance with Article 29 may apply for an authorization 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)).

4.3 Authorization 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 authorized 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 authorization 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 authorization of a low-risk plant protection product.

4.4. Parallel trade

A PPP that is authorized 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 PPP is identical in composition to a PPP already authorized in its 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).

PPPs 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 license 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 Authorization for placing on the market of PPP 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 authorize, for a period not exceeding 120 days, the placing on the market of PPPs, 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.

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 PPP 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)).

PPPs 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 1107/2009 (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 PPPs 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 PPPs carry out and keep records according to Art. 67 (1) of EU Regulation No 1107/2009 (Article 49 (3)) and the persons who supply PPPs 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 PPPs 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 PPPs, develop and implement a system for the recall of empty packaging by the end user of the products, where the system being implemented in accordance with the Waste Management Act (Art. 49 para. 6 and 7).

BFSA establishes and maintains a database for PPPs 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 PPPs used in the country, and the data are provided by area (Article 50 (3)).

5. Classification, packaging, labeling and categorization of PPPs

According to Article 79 PPPs 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 PPPs 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 PPP 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 PPP 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 PPP, its physical and chemical properties and its existence and behavior in the environment; the uses claimed and the category of users under Regulation (EU) No 547/2011.

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

PPPs 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 PPPs is carried out by persons who are traders within the meaning of the Commerce Act and hold a certificate for trade with PPPs, issued by the director of the Regional Food Safety Directorate (RFSD) (Art. 91 (1)) and have facilities for trade - warehouses for trade of PPPs, 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 PPPs shall be provided in the warehouses and in the agricultural pharmacies (Article 92 (1)).

In order to obtain a certificate for trade with PPPs, 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 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 PPPs 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 PPP concerned. Repackaged PPPs 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 PPPs, issued by the director of the RFSD.

Holders of a repackaging certificate for PPPs are required to enter into repackaging agreements with holders of marketing and use authorization or holders of permits for parallel trade of PPPs and submit a certified copy of the contract to the Central administration of BFSA, in its part regarding the type of PPPs 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.

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

PPPs 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 PPPs.
- the storage for the purpose of sale and trade of PPPs outside the warehouses for trade of PPPs, and / or agricultural pharmacies.
- the marketing of PPPs in warehouses for trade of PPPs, and / or agricultural pharmacies in the absence of the persons under Art. 92 (1),
- storage and marketing of PPPs from the first professional category of use in agricultural pharmacies.
- storage and marketing of PPPs in packages with a capacity of more than 1 liter/kilogram in agricultural pharmacies; the sale of PPPs from a professional category of use to persons who do not hold a certificate under Art. 83.
- the sale of PPPs with the integrity of the packaging or the label; the repackaging of PPPs outside the sites under Art. 96 (5); the repackaging PPPs 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 PPPs 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 PPPs 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

PPPs 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)). PPPs may also be used in accordance with the specific principles of integrated pest management (Article 104 (2)). In the use of PPPs, 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, PPPs are applied by consumers as follows:

1. PPPs 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. PPPs from second professional category of use - from consumers with a certificate under Art. 83.
3. PPPs from a non-professional category of use - by persons over 18 years of age (Art. 105).

PPPs 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 PPPs; the use of PPPs outside the scope of the authorized use or at a dose exceeding the maximum permissible unit dose; the application of PPPs 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 PPPs for purposes other than for sowing; the use of PPPs 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, PPPs 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 PPPs

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).

In the treatment of seed crops, PPPs, 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 PPPs shall be carried out under conditions and by an order determined in the ordinance under Art. 104 (1), item 3 (Art. 114 (1)).

8. Specialized plant protection services

The treatment of PPPs 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 Art. 6 (1), item 9 (Art. 118 (1)).

9. Subsequent controls on the trade, repackaging, storage and use of PPPs

The control over the PPPs 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: PPPs; 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 PPPs 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 PPP (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 PPP 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 PPP pursuant to the Waste Management Act (Article 122 (1)).

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

The legislation on use, production, import, storage and treatment of PPPs in Bulgaria is rather complicated and to a higher extend 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 ordinary citizen 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 mechanism. 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 extend influenced by the EU legislation on this issue. Nevertheless, that the law seems quite strong in terms of authorization of PPPs, the higher number of derogations in the procedures set up on EU level weakens the legislation. Low level of insurance of transparency of the procedures combined with limited range of control mechanisms by law creates risks for implementation of best 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 transparency 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 aspect of legislations creates, at least on paper, real legal mechanism for practical transition to more nature-friendly and less-risky 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 the EU, which in reality pushes 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 also include 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 a way 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) appears to be very important – to prohibit the production, storage and export of PPPs, which are banned in EU. As Europe has the responsibility to protects 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.

Croatia

REVIEW OF RELEVANT LEGISLATION REGARDING USE OF PLANT PROTECTION PRODUCTS

1. International Conventions

1.1. INTERNATIONAL PLANT PROTECTION CONVENTION (NN 16/98)

This legal act is written with the purpose of securing common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control, the contracting parties undertake to adopt the legislative, technical and administrative measures specified in this Convention and in supplementary agreements pursuant to Article XVI. The provisions of this Convention may be deemed by contracting parties to extend, in addition to plants and plant products, to storage places, packaging, conveyances, containers, soil and any other organism, object or material capable of harbouring or spreading plant pests, particularly where international transportation is involved.

Each contracting party shall make provision, to the best of its ability, for an official national plant protection organization. The responsibilities of an official national plant protection organization shall include: a) the issuance of certificates relating to the phytosanitary regulations of the importing contracting party for consignments of plants, plant products and other regulated articles; b) the surveillance of growing plants, including both areas under cultivation and wild flora, and of plants and plant products in storage or in transportation; c) the inspection of consignments of plants and plant products moving in international traffic; d) the disinfection on disinfection of consignments of plants, plant products and other regulated articles moving in international traffic, to meet phytosanitary requirements; e) the protection of endangered areas and the designation, maintenance and surveillance of pest free areas and areas of low pest prevalence; f) the conduct of pest risk analyses; g) ensure through appropriate procedures that the phytosanitary security of consignments after certification regarding composition, substitution and reinfestation is maintained prior to export; and h) training and development of staff.

1.2. REGULATION ON THE PUBLICATION OF THE AGREEMENT BETWEEN THE GOVERNMENT OF THE REPUBLIC OF CROATIA AND THE GOVERNMENT OF THE

REPUBLIC OF TURKEY ON COOPERATION IN THE FIELD OF PLANT PROTECTION (NN 6/99)

The Government of the Republic of Croatia and the Government of the Republic of Turkey have signed this Agreement in order to encourage mutual cooperation in the field of plant protection; in an effort to improve the protection of their territories from the introduction of quarantine plant pests and to limit losses resulting from their action; and to facilitate the mutual trade and exchange of plants and plant products.

The Contracting Parties shall: a) exchange legal regulations on plant protection, no later than 60 days after their entry into force; b) to support the exchange of experts with the aim of getting to know the organization of plant protection, as well as experiences and scientific achievements in the field of plant protection; c) exchange information on all relevant professional journals, monographs and publications in the field of plant protection published in their countries.

2. National laws on plant health**2.1. ORDINANCE ESTABLISHING AN ACTION FRAMEWORK FOR ACHIEVING SUSTAINABLE PESTICIDE USE (NN 142/12)**

This Ordinance creates a framework for the sustainable use of pesticides by reducing the risks and effects of pesticides on human health and the environment, and for promoting integrated plant protection and the application of alternative methods or procedures such as non-chemical alternatives to pesticides.

This Ordinance prescribes: a) conditions and manner of issuing authorizations for the implementation of training of professional users, distributors and consultants, conditions for authorization of lecturers, types and course of training, issuance of certificates and ID cards and other details related to training; b) conditions that must be met by legal and natural persons who trade in plant protection products (distributors); c) keeping records of plant protection products that are produced, imported, exported, stored, placed on the market and applied; d) conditions to be met by professional users of plant protection products; e) conditions for placing on the market of pesticide application equipment; f) conditions and manner of issuing the authorization for inspection, content of the inspection, sign and other details related to the obligatory regular inspection of devices for the application of pesticides in use; g) special procedures for use and restrictions on the use of plant protection products; h) risk indicators, reporting and information exchange, and i) other conditions, requirements, obligations and details which enable the

creation of a framework for the sustainable use of pesticides referred to in paragraph 1 of this Article.

For the purposes of this Ordinance, the following definitions shall apply:

Professional user - a person who uses pesticides in the course of his professional activities, including users, technicians, employers and the self-employed, both in agriculture and in other activities.

Professional user for professional use - a person who uses pesticides intended for professional use which have been approved by a registration decision only for a certain category of professional users.

Non-professional user - a person who uses pesticides intended for non-professional users (amateur users).

Distributor - a natural or legal person who places pesticides on the market, including wholesalers and retailers, sellers and suppliers.

Advisor - any person who has acquired appropriate expertise and advice on plant protection and the safe use of pesticides in the course of his business or trade, including, where appropriate, the private self-employed and public advisory services, trade travelers, food producers and retailers.

Pesticide application equipment - all equipment specifically designed for the application of pesticides, including all associated parts necessary for the effective operation of such devices, such as nozzles, manometers, filters, sieves, tank cleaning equipment and other parts.

Treatment - any application of a plant protection product.

Aerial application - application of pesticides from an aircraft (aircraft or helicopter).

Integrated plant protection - assessment and application of all available plant protection methods and then integrated into appropriate measures to prevent pest population development, maintain the use of plant protection products and other forms of control at a level economically and environmentally justified, and reduce or minimize risks to human health and the environment. "Integrated plant protection" emphasizes the cultivation of healthy crops and plantations with the least possible disruption to agro-ecological systems and encourages natural mechanisms to control harmful organisms.

Non-chemical methods - alternative to chemical methods for the protection of plants and the control of harmful organisms, which are based on agro-technical measures such as

those listed in point 1 of Annex III. of this Ordinance, or by physical, mechanical, biotechnical or biological methods of pest control.

Pesticide:

(a) a plant protection product as defined in Regulation (EC) No 882/2004 of the European Parliament and of the Council. Regulation (EC) No 1107/2009 of 21 October 2009 concerning the placing of plant protection products on the market.

(b) a biocidal product, as defined in the Biocidal Products Act (Official Gazette 63/07 and 35/08).

All professional users, distributors and consultants must have appropriate training consisting of basic and additional training for the acquisition and renewal of relevant knowledge. The Ministry of Agriculture shall authorize the lecturer if they fill the conditions specified in this Ordinance. Furthermore, the implementation of training, exams, issuance of certificates of passing the exam and ID cards are also defined (he also prescribed what they must look like).

Conditions for the sale (trade) of pesticides are regulated in this Ordinances.

Persons who trade in plant protection products (distributors) must be entered in the Register. They are obliged to act in accordance with the provisions of the regulation governing the manner of waste management and environmental protection with waste packaging, residues of plant protection products in packaging and residues resulting from remediation after accidents, the conditions regarding employees, space and other conditions prescribed by this Ordinance must be done by 26 November 2015 at the latest.

2.1.1. Informing and raising awareness

Measures to inform the general public shall be taken in accordance with the needs and circumstances in order to encourage and enable information and awareness-raising programs, and to make accurate and objective information on pesticides available to the general public, especially regarding risks and possible acute and chronic effects. human health, non-target organisms and the environment resulting from the use of pesticides, as well as the use of non-chemical alternatives. For this purpose, the Institute for Medical Research and Occupational Medicine - Poison Control Center collects information on cases of acute pesticide poisoning. Information shall also be collected and monitored on possible chronic poisonings in groups regularly exposed to pesticides such as users, agricultural workers or persons living in the vicinity of areas where pesticides are applied.

2.1.2. National Action Plan

In order to ensure the implementation of this Ordinance, the National Action Plan (NAP) for Achieving Sustainable Use of Pesticides shall be adopted. The NAP shall establish quantitative assumptions, objectives, measures and time plans for reducing the risks and effects of pesticides on human health and the environment and shall encourage the development and introduction of integrated plant protection and alternative procedures or techniques to reduce dependence on pesticide use. These objectives may cover various areas of interest, e.g. occupational safety, environmental protection, pesticide residues, application of special techniques or use on specific crops. The National Action Plan shall be submitted to the European Commission and other EU Member States, and shall be reviewed at least every five years, and all significant changes in the National Action Plan shall be notified to the European Commission.

By the conclusion of the class: 022-03 / 13-07 / 147, registration number: 50301-05 / 25-13-2 adopted by the Government of the Republic of Croatia at the session held on 13 June 2013, the NAP for the period from 2013 to 2023 was adopted. The NAP ensures the implementation of the Ordinance on the establishment of an action framework for achieving the sustainable use of pesticides (Official Gazette 142/12). The NAP applies only to pesticides considered as PPPs as defined in Regulation (EC) No 1907/2006. 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.

The NAP aims to reduce the risks to human, animal and environmental health associated with the use of pesticides and to promote integrated and alternative pest control measures by: a) develop a better understanding of how pesticides are used; b) ensure the use of scientific and other evidence to identify pesticides and procedures that require attention in order to develop and promote measures and procedures that will reduce the harmful effects of the use of these chemicals and enable the user to control pests, diseases and weeds economically; c) ensure the recognition of the own roles of all stakeholders and stakeholders in achieving the common goal of achieving sustainable pesticide use.

2.2. ORDINANCE ON THE AMOUNT OF FEES AND MANNER OF DISTRIBUTION OF FUNDS IN THE PROCEDURE OF REGISTRATION OF PLANT PROTECTION PRODUCTS, EVALUATION OF ACTIVE SUBSTANCES AND ISSUE OF LICENSES FOR PLANT PROTECTION PRODUCTS ([NN 94/07](#), [36/10](#), [55/10](#), [38/13](#))

This Ordinance determines the amount of fees for: the procedure of registration of plant protection products (hereinafter: funds), issuance of a decision on registration of a product and issuance of a decision on a license for a product; conducting post-registration supervision of registered funds; implementation of annual pesticide residue monitoring

programs; conducting systematic training of participants in the implementation of activities related to funds and balances of funds; analyzes for the presence of residues in plants, plant products and products of animal origin, food and feed; analysis of soil and other objects during the inspection of the use of agents or active substances; analysis of plants, plant products and other objects when the inspection revealed incorrect use of the product, ie when the residues of the product exceed the prescribed maximum permissible concentrations or when residues of the product are determined on plants for which the use of the product is not approved; laboratory analysis of assets and review of assets upon import into the Republic of Croatia. According to the Ordinance on Amendments 38/2013 and the implementation of training (basic and supplementary), taking exams and issuing ID cards for those obliged to train; conducting expert supervision over the operation of test stations for regular inspection of pesticide application devices; data entry into the Phytosanitary Information System at the first inspection of pesticide application equipment; regular inspection of the device as well as re-inspection after elimination of identified faults and deficiencies; issuing a mark for new devices, issuing a new mark in case of loss or damage and issuing a mark for used devices when an inspection carried out in one of the EU Member States is recognized. The administrative fees payable on the application for registration of an asset or the application for the issuance of a license for an asset when submitting an application for a decision on the registration of an asset and the decision on a license for an asset when issuing a decision are defined.

2.3. LAW ON PLANT HEALTH (NN 127/2019)

This Act determines the competent authorities, procedures and tasks of the competent authorities in the implementation of Regulation (EU) no. 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protection measures against organisms harmful for plants and amending Regulation (EU) no. 228/2013, (EU) no. 652/2014 and (EU) no. 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464 / EEC, 74/647 / EEC, 93/85 / EEC, 98/57 / EC, 2000/29 / EC, 2006/91 / EC and 2007 (33 / EC) (OJ L 317, 23.11.2016), and keeping registers of specialized entities, financing, fees, costs and compensation, administrative and inspection supervision, and misdemeanor provisions.

It is defined that plant health includes: protection of plants, plant products and other objects from harmful organisms, determination of the presence and determination of harmful organisms, prevention of introduction and spread of harmful organisms and their control and eradication by applying phytosanitary measures, prevention of exports of

plants, plant products and other objects infected with harmful organisms and protection of the environment from the effects of harmful organisms.

2.4. LAW ON SUSTAINABLE USE OF PESTICIDES ([NN 14/14, 115/18, 32/20](#))

The Ministry of Agriculture has published on the e-Conference portal the **Draft Proposal of the Law on Sustainable Use of Pesticides and all interested parties can give their comments on the same as of March 25, 2021. The new law has not yet been adopted.** The currently valid Act on the Sustainable Use of Pesticides (Official Gazette, Nos. 14/14, 115/18 and 32/20) regulating the area of sustainable use of pesticides was adopted on 24 January 2014 and entered into force on 1 February 2014. year. Directive 2009/128 / EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve a sustainable use of pesticides has been transposed into national law. Despite the establishment of a single legal framework at EU level in the field of plant protection products, unwanted pesticide residues can still be found in soil, water and the environment in general, and in a certain percentage of agricultural products of plant and animal origin pesticide residues above maximum pesticide residue levels

This Law regulates the National Action Plan for Achieving Sustainable Use of Pesticides, the system of training professional pesticide users, distributors and advisors, the system of distribution and sale of pesticides, handling pesticides, storage and handling of pesticides and packaging residues, keeping databases and keeping records. use and regular inspection of pesticide application machines, public information and awareness raising on pesticides, pesticide risk reduction measures and basic principles of integrated pest management, special procedures and pesticide use, public information, special environmental protection measures, pesticide use reduction and risk reduction in certain areas, risk indicators, reporting and exchange of information, authorized professional institutions and tasks of authorized professional institutions, fees and violations and supervision over the implementation of this Law and regulations adopted on the basis of this Law.

The main goal of the Law is to achieve sustainable use of pesticides, reduce risks and negative effects of pesticides in a way that ensures a high level of protection of human and animal health and environmental protection and biodiversity, introduction of mandatory application of basic principles of integrated plant protection. alternative approaches and techniques such as non-chemical plant protection measures to achieve sustainable and competitive agriculture.

2.5. LAW ON OFFICIAL CONTROLS AND OTHER OFFICIAL ACTIVITIES CARRIED OUT IN ACCORDANCE WITH REGULATIONS ON FOOD, ANIMAL FEED, ANIMAL HEALTH AND WELFARE, PLANT HEALTH AND PLANT PROTECTION PRODUCTS (NN 52/2021)

This Act determines the competent bodies and their tasks related to the organization, implementation and coordination of official controls and other official activities, financing of official controls, methods of administrative assistance and cooperation, communication and reporting, border control stations, checkpoints, other border crossings and customs points. for import, further transport of consignments, fees and charges for official controls, regulation of the system of official and reference laboratories, establishment of a computer information system for the management of information and data related to official controls and misdemeanor provisions.

This Act applies to official controls that verify compliance with established rules for the application of legislation in the areas of: a) food and food safety, food integrity and safety at every stage of food production, processing and distribution; b) the deliberate release into the environment of genetically modified organisms (hereinafter: GMOs) for the production of food and feed; c) feed and feed safety at every stage of the production, processing and distribution of feed and the use of feed, including rules aimed at ensuring fair trade practices and protecting the health and interests of consumers and consumer information; d) animal health requirements; e) the prevention of risks to human and animal health arising from animal by-products and derived products and their minimization; f) animal welfare requirements; g) protective measures against organisms harmful to plants; h) requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides, with the exception of pesticide application equipment; i) organic production and labeling of organic products; j) the use and protection of protected designations of origin, protected geographical indications and guaranteed traditional specialties and k) use of labels from the national quality system and optional quality terms.

Pursuant to this Law, the State Inspectorate is responsible for drafting monitoring plans and sampling plans within the scope of sanitary inspection and agricultural inspection, in addition to drafting the National Program for monitoring pesticide residues in food and the Program for monitoring plant protection products formulations. The Ministry in charge of agriculture is responsible for, inter alia, development of monitoring plans, instructions, instructions and programs for surveillance, control, monitoring and eradication of animal diseases, instructions, programs and instructions in the field of pesticide residues. According to this Law official controls of food of plant origin on pesticide residues are carried out by the Agricultural Inspectorate at the level of primary production and related activities, at the level of production, processing and trade and at the border at import,

official controls are performed by sanitary inspection, while official controls of food of animal origin on pesticide residues at all levels performed by veterinary inspection. The Agricultural Inspectorate also supervises the storage, transport, placing on the market of plant protection products and the sustainable use of pesticides.

3. PLACING PLANT PROTECTION PRODUCTS ON THE MARKET

Placing PPPs on the market in Croatia is regulated by the Law on the Implementation of Regulation (EC) no. 1107/2009. This Act has been in force since 1 July 2013 and allows it directly implementation of Regulation (EC) no. 1107/2009 in Croatia. Regulations are legal acts of the European Union whose provisions may not be transposed into the national legislation of the Member States of the European Union by creating a new regulation. Member States are obliged to ensure the direct implementation of the regulations on their own area. For the implementation of some regulations, Member States are not obliged to draft any legal act but are on under the Treaty of Accession to the European Union are obliged to directly implement European Law. In case of failure to implement the regulations, the European Commission may initiate infringement proceedings against the Member State which does not implement the *acquis communautaire*. Some ordinances, such as Regulation (EC) No 1107/2009, require the Member States of the European Union to draft a national regulation which will ensure the direct implementation of regulations and prescribe the competent authorities for the implementation of regulations, tasks competent authorities, misdemeanors for violating the provisions of the decree, etc. In Croatia, the Law on the Implementation of the Decree (EC) no. 1107/2009 ensured the direct implementation of the Regulation and regulated the competent authority, tasks competent authority, authorized professional institutions and their tasks, inspection and administrative supervision and misdemeanor provisions in case of violation of the provisions of the Regulation. Pursuant to Regulation (EC) no. 1107/2009, The European Commission has adopted a number of implementing regulations which are directly applicable in the Member States of the European Union and which regulate the placement in more detail on the market of plant protection products, approval of active substances, safeners, synergists, co-formulants, excipients, low-risk substances, basic substances, zonal system registrations, candidates for replacement, hormonal disruptors, comparative risk assessment, parallel trade, extension of registration for small crops and small purposes, placing on the market treated seed, data protection, etc. In order to facilitate the implementation of Regulation (EC) no. 1107/2009 I implementing regulations adopted on the basis of this Regulation, the European Commission has adopted numerous guidance documents.

3.1. IMPORT OF PLANT PROTECTION PRODUCTS

Imports of plant protection products include only imports from third countries. Procurement of funds for plant protection from a Member State of the European Union is not considered an import. To the Republic of Croatia plant protection products can be placed on the market only by legal and natural persons (distributors) who have seat and address in the Republic of Croatia and which are entered in the central records of the Phytosanitary an electronically controlled information system. They can only be placed on the market registered plant protection products or plant protection products for which an appropriate permit has been issued because plant protection products are not subject to the right of free movement of goods within the market European Union.

3.2. REGISTRATION OF PLANT PROTECTION PRODUCTS

Regulation (EC) No 1107/2009 on the placing of plant protection products on the market was published on 24 November 2009, and its implementation began on 14 June 2011 with many transitional periods. In the Republic of Croatia, the Ministry participates in the registration procedure for plant protection products agriculture and two authorized institutions for documentation assessment and risk assessment. The Ministry of Agriculture is the main coordinator of all activities related to the registration of funds for plant protection and issuing permits for PPPs. The Ministry receives requests for the registration of PPPs or applications for the issuance of certain permits, after which checks the completeness of the submitted documentation (completeness check) and after, if necessary, request additional documentation from the applicant. Once authorized institutions complete the documentation assessment and risk assessment, the institution in charge of coordination of the evaluation procedure submits to the Ministry of Agriculture a proposal for registration. Based on the proposal of the authorized institution, the Ministry of Agriculture issues a decision on registration of plant protection products. Croatian Center for Agriculture, Food and Rural Development - Institute for Plant Protection performs evaluation work documentation and risk assessment in the following areas: assessment of the identity of active substances and plant protection products, analytical methods, effectiveness of plant protection products, pesticide residues in food, behavior in the environment, ecotoxicology, exposure of users, workers and other persons present. At the request of the Ministry of Agriculture, the Institute for Plant Protection prepares proposals for registration of PPPs, proposals for the issuance of certain permits for plant protection products plants, proposals to extend registrations, proposals to extend registrations for small purposes and small crops, expert opinions in the field of plant protection products. The Institute for Medical Research and Occupational Medicine performs documentation evaluation activities and risk assessments in the following areas: mammalian toxicology, exposure of users, workers and other persons present. At the request of the Ministry of Agriculture, the Institute prepares proposals for the registration of funds for plant protection, proposals for the issuance of certain permits for

plant protection products, proposals for extension of registrations, proposals for extension of registrations for small purposes and small crops, expert opinions in the field of mammalian toxicology and exposure of users, workers and others persons present in connection with plant protection products-

There are no significant changes in the process of approving the active substances of PPPs. Active substances continue to be approved at European Union level. The industry is preparing the necessary studies and tests and selects the rapporteur member state Rapporteur Member State (RMS) which represents the company to the European Commission and the European Food Safety Authority (European Food Safety Authority - EFSA) which performs risk assessment in all relevant areas, and the European Commission and the Member States through their representatives on the Standing Committee on food chain and animal health - Plant protection products - Legislation, discussed and enacted decisions on the approval of active substances by a qualified majority. Active substances are most often approved on period of up to ten years and are subject to regular reassessment, and in the case of new scientific ones the findings are subject to reassessment even before the end of the approval period.

4. LABELING, NEW REGULATIONS (CLP)

Changes in the chemical legislation of the European Union also affect changes in criteria and methods classification, labeling and packaging of dangerous chemicals according to Regulation (EC) No. 1907/2006. 1272/2008 or the so-called CLP Regulation (English Classification, Labeling, Packaging - classification, labeling, packaging) which is in the European Union in force since 20 January 2009. The purpose is to put every chemical on the market Of the European Union will be unambiguously classified and labeled and a Safety Data Sheet (STL) will be prepared for it, which will be translated into the languages of the Member States but will not differ in content from country to country. The provisions of Regulation (EC) No 1272/2008 have been transferred to the Ordinance on classification, labeling, labeling and packaging of hazardous chemicals, and from 1 July 2013 this Regulation and its amendments shall be amended in They apply directly to Croatia. The new labeling is being introduced gradually, so it is already mandatory for everyone active substances in plant protection products, while on the label of plant protection products as for other products containing mixtures of chemicals should be introduced by the end of May 2015. The consequence of this is that in the Croatian market and in the European Union market in the transition period to no later than 1 June 2017, plant protection product labels shall contain old or new labeling, i.e. it is possible that the same plant protection product will be found, but labeled in different ways. The classification and labeling of chemicals under the CLP Regulation is primarily the

responsibility of the manufacturer or company which puts the chemical on the market. However, for certain chemicals such as active substances in plant protection products, biocidal products and carcinogens, mutagens and reprotoxic chemicals, the so-called harmonized classification and labeling which is binding at the level Of the European Union and implemented by ECHA.

4.1. LABEL

For a plant protection product, the label is its basic, important and binding document for the user. On labels contain all the information necessary for the use of plant protection products: handling, storage, proper disposal of product residues and its packaging, information on the composition of the product, application, restrictions, protection of health and the environment, and is the responsibility of every person who uses or handles the product study the contents of the label. The information to be provided on the label must be clear and indelible packaging of each plant protection product as prescribed by Regulation (EU) no. 547/2011 on implementation Regulation (EC) No 1107/2009 regarding the labeling requirements for plant protection products.

5. REACH Regulation

In addition to adapting and transposing the *acquis communautaire*, Croatia also needs to implement new regulations in the field of chemical safety. These regulations entered into force on 1 June 2007 into the European Union at the beginning of the application of Regulation (EC) No 1907/2006 better known as the REACH Regulation (Eng. Registration, Evaluation and Authorization of Chemicals - which means registration, evaluation and approval of chemicals). The purpose of adopting this Regulation is to protect human health and the environment in full and rapid identification of harmful properties and possible risks due to exposure to chemicals in all areas of their life cycle: from production and use to disposal and recovery as in industrial processes as well as in everyday life. The goal is optimal production and use chemicals with as few adverse effects on human health and the environment as possible throughout Europe Union by 2020.

6. Official controls

In order to ensure the implementation of laws and other regulations, the competent inspection services shall conduct official inspections in the field regarding PPPs, pesticide residues in food and sustainable uses of pesticides are regulated by a number of legal regulations such as: Law on Implementation of Regulation (EC) no. 1107/2009 on the placing on the market of plant protection products, Law on the implementation of

Regulation (EC) 396/2005 on maximum levels of pesticide residues in and on food and feed of plant and animal origin, Law on Sustainable Use of Pesticides, Food Law, Law on Official Controls Conducted in Accordance with Regulations on Food, Animal Feed, on animal health and welfare, Law on Inspections in Agriculture.

Inspection supervision over the implementation of this Act on the Sustainable Use of Pesticides and regulations adopted on it shall be performed by the Agricultural Inspectorate in accordance with regulations governing the scope and powers of the Agricultural Inspectorate and a special law implementing Regulation (EC) no. 1107/2009 on the placing on the market of plant protection products and the special law on the implementation of Regulation (EC) no. 396/2005 on maximum pesticide residue levels in and on food and feed of plant and animal origin.

The Agricultural Inspection controls the placing on the market of funds for plant protection and control of proper application of plant protection products. This inspection conducts controls sustainable pesticide use systems such as the training system for professional pesticide users, distributors and consultants, pesticide distribution and sales system (wholesale and retail), system mandatory regular inspections of machines for the application of pesticides, the application of the basic principles of integrated plant protection and other controls in the field of sustainable pesticide use. Agricultural inspection conducts controls of pesticide residues in products of plant origin in primary plant production. The Veterinary Inspection controls pesticide residues in products of animal origin in primary animal production, at the level of food production and processing of animal origin and when importing food of animal origin. The Sanitary Inspection controls pesticide residues in plant products origin at the level of processing, retail and import of food of plant origin at the border crossings. The Sanitary Inspection also supervises the production of chemicals, including production of plant protection products. The Environmental Protection Inspector performs control of producers and distributors of plant protection products in order to determine the manner of hazardous waste management in accordance with the regulations governing hazardous waste

7. PPPs

Plant protection products are divided in different ways. According to the origin, PPPs are divided into chemical and biological, while the most common division is according to the type of pest being controlled:

a) ZOOCIDES - means for controlling or repelling animals, are divided into several groups:

insecticides - insect repellents,

acaricides - mite control agents,

nematicides - nematode control agents,

limacides - snail repellents,

rodenticides - rodent control agents,

Corvifuges - for repelling birds from seed.

b) **FUNGICIDES** - agents for the control of fungi and pseudofungi and some bacteria that cause diseases.

c) **HERBICIDES** - weed control agents.

d) Other means - plant growth regulators and auxiliaries.

According to available information from the official website of the Ministry of Agriculture, there are these plant protection products registered in Croatia:

- 291 plant protection products used as fungicides
- 37 plant protection products used as acaricides
- 8 plant protection products used as nematocides
- 1 plant protection products used as repellent
- 2 plant protection products used as disinfection products
- 3 plant protection products used as desiccant
- 127 plant protection products used as insecticides
- 11 plant protection products used as bactericide
- 262 plant protection products used as herbicides
- 8 plant protection products used as molluscicides/ limacid
- 35 plant protection products used as growth hormones
- 3 plant protection products used as rodenticides
- 1 plant protection products used as fumig
- 2 plant protection products used as attractant
- 2 plant protection products used as pheromone
- 1 plant protection products used as talpicide
- 1 plant protection products used as inoculator

CONCLUSIONS

Based on this short research we can conclude that there is very limited information available for the public regarding the use of agriculture chemicals.

Publicly available information includes:

- List of legal acts regarding plant protection and plant protection products. This information is available and free to access in one source, not sure if always updated: Croatian Agency for Agriculture and Food (<https://www.hapih.hr/czb/propisi/>)
- List of plant protection products which are registered in Croatia. This information is available and free to access in the official webpage of the Ministry of Agriculture and it is updated (<https://fis.mps.hr/trazilicaszb>)

Unfortunately, there is no data on reports regarding the statistics on the agriculture production, in terms of quantities, and geographical distribution of the legal use of the agriculture chemicals, there is no available information for the public.

Regarding the list of illegal chemicals and illegal use of the illegal chemicals, there is a complete lack of publicly available information, the same for cases of detected illegal import of illegal chemicals and disposal of the illegal chemicals.

National Action Plan (NAP) for Achieving Sustainable Use of Pesticides should be publicly available, there are links but it is not possible to open it (<http://fisportal.mps.hr/hr/sredstva-za-zastitu-bilja/obavijesti/9-nacionalni-akcijski-plan-za-postizanje-odrzive-uporabe-pesticida-nap>)

RECOMMENDATIONS

It is important that all of the responsible institutions provide information to the public regarding legal and illegal agriculture chemicals and their use within the territory of Croatia. This can be achieved through annual reports and registers on the quantity, geographical distribution, and legal / illegal use of the agriculture chemicals.

These reports, registers should be published in the official webpage of the relevant institutions and be free to access from the public, or at least disclose their existence on the official webpage of the relevant institutions and provide the information on how to access them.

Measures to inform the general public shall be taken in accordance with the needs and circumstances in order to encourage and enable information and awareness-raising programs, and to make accurate and objective information on pesticides available to the

general public, especially regarding risks and possible acute and chronic effects. This is prescribed by law but is clearly not being implemented.

Sources of information:

List of registered plant protection products on 28.02.2022.

(<https://fis.mps.hr/trazilicaszb/#>)

Croatian Agency for Agriculture and Food (<https://www.hapih.hr/czb/dokumenti/>)

Access to European Union law (<https://eur-lex.europa.eu/homepage.html?locale=hr>)

Narodne novine (https://narodne-novine.nn.hr/clanci/sluzbeni/2019_12_127_2552.html)

Croatian Agency for Agriculture and Food – annual report for 2019. For Centre for Plant Protection (<https://www.hapih.hr/wp-content/uploads/2020/11/CZB-Godisnje-izvjesce-za-2019.pdf>)

Report5/2020(<https://op.europa.eu/webpub/eca/special-reports/pesticides-5-2020/hr/#chapter10>)

List of regulations concerning plant protection products

(<https://www.hapih.hr/czb/propisi/>)

INTERNATIONAL PLANT PROTECTION CONVENTION (NN 16/98) (https://narodne-novine.nn.hr/clanci/medunarodni/1998_12_16_153.html)

REGULATION ON THE PUBLICATION OF THE AGREEMENT BETWEEN THE GOVERNMENT OF THE REPUBLIC OF CROATIA AND THE GOVERNMENT OF THE REPUBLIC OF TURKEY ON COOPERATION IN THE FIELD OF PLANT PROTECTION (NN 6/99) (https://narodne-novine.nn.hr/clanci/medunarodni/1999_05_6_141.html)

ORDINANCE ESTABLISHING AN ACTION FRAMEWORK FOR ACHIEVING SUSTAINABLE PESTICIDE USE (NN 142/12) (https://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_142_3012.html)

ORDINANCE ON THE AMOUNT OF FEES AND MANNER OF DISTRIBUTION OF FUNDS IN THE PROCEDURE OF REGISTRATION OF PLANT PROTECTION PRODUCTS, EVALUATION OF ACTIVE SUBSTANCES AND ISSUE OF LICENSES FOR PLANT PROTECTION PRODUCTS (NN 94/07, 36/10, 55/10, 38/13) (https://narodne-novine.nn.hr/clanci/sluzbeni/2013_03_38_703.html)

LAW ON PLANT HEALTH (NN 127/2019) (https://narodne-novine.nn.hr/clanci/sluzbeni/2019_12_127_2552.html)

LAW ON SUSTAINABLE USE OF PESTICIDES (NN 14/14, 115/18, 32/20) (<https://zakon.hr/z/703/Zakon-o-odr%C5%BEivoj-uporabi-pesticida>)

LAW ON OFFICIAL CONTROLS AND OTHER OFFICIAL ACTIVITIES CARRIED OUT IN ACCORDANCE WITH REGULATIONS ON FOOD, ANIMAL FEED, ANIMAL HEALTH AND WELFARE, PLANT HEALTH AND PLANT PROTECTION PRODUCTS (NN 52/2021) (https://narodne-novine.nn.hr/clanci/sluzbeni/2021_05_52_1050.html)

Greece

REVIEW OF RELEVANT LEGISLATION IN GREECE REGARDING USE, STORAGE, AND TREATMENT OF PLANT PROTECTION PRODUCTS

The main law that defines the disposal of phytosanitary products in the market, their rational use and other provisions is the law 4036/2012 that it was amended several times, with last amendment the 4859/2021. Previous amendments were the 4152/2013, the 4235/2014, the 4351/2015, the 4384/2016, the 4472/2017, the 4492/2017, the Joint Ministerial Decree 1840/31408/2019, the law 4625/2019 and the 4691/2020.

The Directive 1107/2009 of European Union is applied also in Greece, as Greece consists a member country. Evaluation file of each drastic substance is sent to European Food Safety Authority (EFSA) and after EFSA conducts an evaluation report of the file, it sends it to the Standing Committee on Plant Animal Food and Feed (SCoPAFF). The evaluation file includes physicochemical, toxicological, ecotoxicological, biological and other examinations.

In Greece there is special legislation targeted to the use of phytosanitary products.

More specifically, according to the law 2538/1997 "2. *It is forbidden the retail sale of phytosanitary products without the written prescription of agronomist who has the right to give these prescriptions after the obtaining of a prescription license*".

Moreover, according to the law 4036/2012, which was amended to the law 4235/2012 "5.a) Precondition for the retail sale of pesticide to professional user is the prescription for its use by scientist who accomplishes the conditions of case b, paragraph 1".

Finally, according to the Ministerial Decree 9497/104760/20-8-2014 as it was amended by the Joint Ministerial Decree 8670/83089/1-8-2017 "1. The prescription of use of agricultural medicine consists of the written opinion about the necessity of use of this medicine, which is issued according the provisions of Annex D of the law 4036/2021 and the Joint Ministerial Decree number 8197/90920/22-7-2013 of the Ministers of Health, Agricultural Development and Food and Environment Energy and Climate Change «Adoption of National Action Plan with goal the application of the Directive 2009/128/EC for the protection of human and environment»".

CHRONOLOGY OF TOXIC SUBSTANCES USED AS POISONED BAITS IN GREECE

Since the beginning of 20th century the use of poisoned baits became common practice in Greek countryside. This practice peaked after World War 2 in order for people to protect their properties from wild animals. In 1969 the use of strychnine became widespread for the eradication of "harmful" species like foxes and wolves.

From 1981 to 1993 the use of poisoned baits was not allowed anymore to the wide public. Responsible for population control of some species (mainly foxes) was the Forest Agency, which instead of strychnine started to use cyanides.

In 1993 any kind of poisoned bait became finally illegal, and their use was banned for everyone.

TOXIC SUBSTANCES USED FOR POISON BAITS TODAY

Unfortunately, regardless the prohibition of their use, poisoned baits are still popular in Greece. For their production are used both legal and illegal toxic substances. According to the toxicological analysis conducted in the country, the most common substance used for poisoned baits is Methomyl, in a percentage of 31%. Methomyl is a broad-spectrum carbamate insecticide, whose use was forbidden in Greece for a while, but after that it became legal again. It is registered for both commercial and professional use under certain conditions. It is used on field, vegetables and orchard crops and generally products with 1% concentration of Methomyl are available to the general public. In Greece it is legal

in the form of Methomyl 20 which is liquid, but what is used for poisoned baits is Methomyl 90 in the form of powder.

Second most popular substances used as poisoned baits are Cyanides and Carbofuran, in a percentage of 24% each, as you can see in the chart below. Although Cyanides are legal in the Greek market, they are highly dangerous even for human health due to their immediate action and to the absence of antidote. As it comes to Carbofuran, it is another carbamate insecticide, same as Methomyl, but this one is banned in the European Union, because of its toxicity. More specifically, only one grain of Carbofuran is enough to kill a bird, while just 1ml can be fatal to humans. Nevertheless, it is worldwide used in agriculture on a big variety of crops, such as potatoes, corn and soybeans. It is one of the most toxic insecticides still in use. In Greece it is not detected anymore to foods, so its illegal trade is not common as it is not used as pesticide and its use as poisoned bait must be possible because it still exists in stocks.

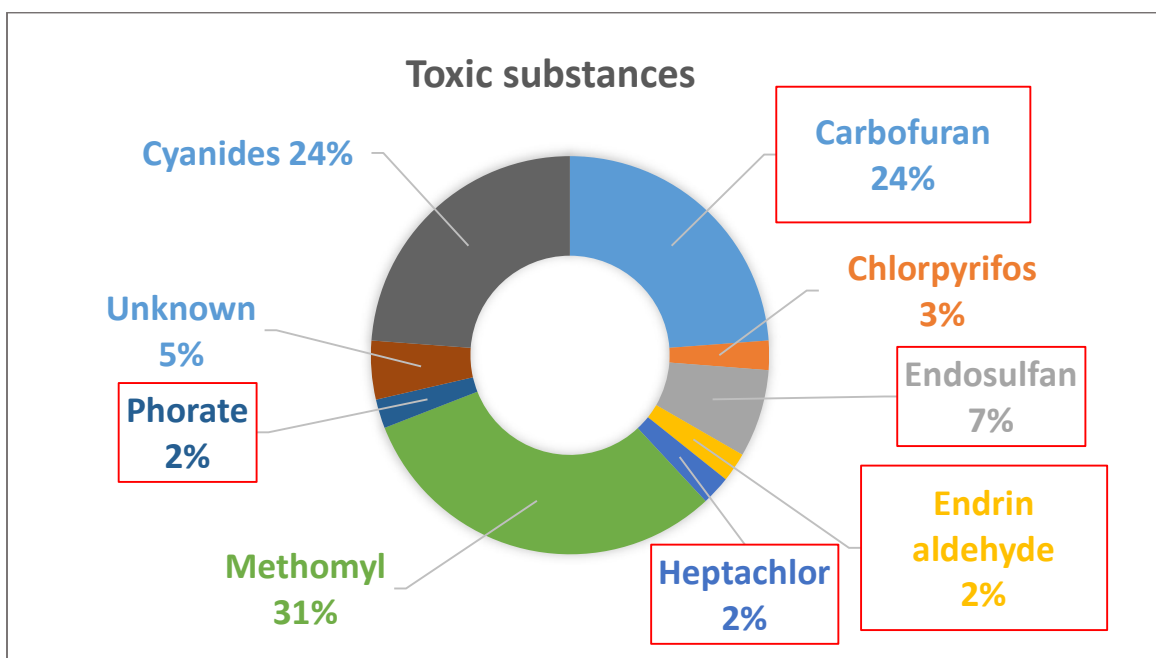


Chart 1: Toxic substances used for poisoned baits in Greece. In red framework, the illegal ones

Next in popularity for the production of poisoned baits is Endosulfan, which is also forbidden in European Union. This one is an organochloride insecticide and acaricide that is used worldwide to control insect pests like aphids, leafhoppers, white flies, Colorado potato beetles and cabbage worms. It is banned in 80 countries because of its toxicity and its potential for bioaccumulation. Endosulfan is neurotoxic and listed as an endocrine disruptor. It is not detected anymore in food products, so its illegal trade is not widespread and when it is used it should be from older stock.

Other toxic substances used in poisoned baits are Chorpyrifos (which is the only legal one), Endrin aldehyde, Heptachlor (which belongs to the group of organochloride pesticides along with Endosulfan) and Phorate which belongs to the group of organophosphate insecticides. It is worth noted that Endrin aldehyde, Heptachlor and Phorate are not legal in Greece, which means that either they are bought from the black market, or there was stock since the time that their use was allowed.

Impressive were the results of a survey conducted in 2016 to 3,190 users of phytosanitary products. Regarding the use of illegal pesticides, 5% of them have told that they have used them, while 25% has replied that they have seen illegal substances used as pesticides, although they have not used them by themselves. Only 70% has never seen or used illegal phytosanitary products. That means that almost 1/3 of the farmers has been in contact with illegal substances, so their use is quite widespread, and it is not very difficult to find and possess them.

ILLEGAL OR FAKE PHYTOSANITARY PRODUCTS

Generally, as illegal phytosanitary products we define those that are not approved by the Ministry of Rural Development and Food (MRDF). There are the following categories of phytosanitary products:

- Products that contain illegal drastic substances and they keep being on the market
- Products that have been retracted
- Fake products, which means that they may contain different drastic substances than the original ones, or cheap solvents and various impurities. That can be:
 - A) Sophisticated copies that copied the label that much efficiently that it is difficult to be distinguished from the original, or
 - B) Low quality products that may not have drastic substance at all
- Products with different characteristics or elements than the ones described in the label
- Illegal imports and illegal trade. Products that are imported from EU countries without following the procedures of parallel trade or imports from third countries.

ORIGIN OF ILLEGAL PHYTOSANITARY PRODUCTS

The majority of illegal phytosanitary products are of Chinese origin. They obtain “European ID” with several ways, in order for their transportation to be free inside EU, without further controls. At the same time, there are illegal imports of phytosanitary products from Turkey and Bulgaria, as well as from other Balkan countries. The illegal trade and sale of dangerous phytosanitary products take place from both land and sea. The phenomenon is nationwide. However, the greatest portion of illegal pesticides enters the country from networks that are taking advantage of the loopholes in the legislation and they are based on the absence of controls of products that they are trading inside EU.

The precise composition of the phytosanitary products can be known only after control of a sample and analysis in a certificated laboratory. In most of the cases the drastic substances that these phytosanitary products contain are revoked according to the European Directives. Regarding products with approved drastic substances, we can ascertain that indeed this product contains them or it contains other impurities only after the control. Sometimes the drastic substance may be totally different than what is written on the label.

CAUSES OF THE PHENOMENON

Although the phenomenon of illegal trade of phytosanitary products is not recent, during the last years it was intensified. This happens due to several reasons:

- The bad economic condition
- The increasing pressure that the farmers face to provide products of low cost
- The Ministry of Rural Development and Food and the competent authorities are focused more on the increasing regulations of use of phytosanitary products and the typical infringements rather than in the monitoring and control of the products in the market
- Low prices on fines of illegal trade of phytosanitary products
- Revokes of phytosanitary products
- Incomplete information to the customs authorities of the country
- Possibility of abuse of the parallel trade process, where the products are replaced by counterfeit ones, thus undermining the operation of the whole system. Lack of harmonized implementation of European parallel trade regulations can be a loophole for trade in illegal products.

CONTROLS

There are two certificated laboratories in Greece that they control the phytosanitary products. The central one is located in Athens and it is called “Laboratory of Chemical Control of Phytosanitary Products in Benakeio Phytopathological Institute”. The second one is the laboratory of Qualitative Control of Regional Plant Protection Center in Thessaloniki.

The controls of use of phytosanitary products consist in controls in situ, controls of residues and controls of rational use. On the other hand, the controls of trade of phytosanitary products consist in controls of electronic registration, prescription and in situ controls of trade as well.

Regarding the controls of industries of phytosanitary products, there are:

- Control of registration in the industry record
- Control of compliance with the provisions of marketing authorizations
- Control of selling in legal shops of trade
- Control of size and material of packaging in accordance with the license of selling in the market
- Control of publicity of phytosanitary products
- Control of content by sampling and laboratory analysis
- Control of packaging and labelling
- Control of parallel trade

There are also controls of imports and exports of phytosanitary products, as well as controls of non-approved phytosanitary products.

CONCLUSIONS

There is a legislative framework in Greece trying to regulate the use of phytosanitary products. Unfortunately, the problem is that there are not enough controls in old storage places in order to confiscate illegal substances that were used in the past and they still remain in warehouses and that the controls in the custom points are difficult. However, there have been confiscations in Kakavia custom point, where illegal Methomyl 90 in powder was found to pass the borders from Albania to Greece with direction to Kyparissia in Peloponnese.

RECOMMENDATIONS

In order for the use of the illegal substances found in phytosanitary products to be restricted there are several actions that the competent authorities should follow:

- The imports of these products must be connected with registrations, approvals and notifications about the quantity and the origin of phytosanitary products
- There must be constant monitoring and strict application of control in the chain custody of these products
- Stricter administrative and criminal sanctions
- Raising of awareness of the farmers and other stakeholders for the impacts of misuse of illegal trade of phytosanitary products
- Construction of new labelling from the industry that would make difficult or even impossible to copy them

SOURCES OF INFORMATION

Greek Association of Phytosanitary Products

<https://esyf.gr/what-are-illegal-pesticides/>

<https://esyf.gr/asfali-fytoprostateytika-proionta/>

<https://esyf.gr/paranoma-fytofarmaka/>

Ministry of Rural Development and Food

<http://minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostatiamenu/elenxoifitoprostateytikonmenu/523-nomo-elegxon>

<http://minagric.gr/index.php/el/for-farmer-2/crop-production/fytoprostatiamenu/elenxoifitoprostateytikonmenu>

http://minagric.gr/images/stories/docs/agrotis/Georgika_Farmaka/elenxoi/N.4036_2012_ConsolidatedVersion_011221.pdf

North Macedonia

REVIEW OF RELEVANT LEGISLATION IN NORTH MACEDONIA REGARDING USE, STORAGE, AND TREATMENT OF PLANT PROTECTION PRODUCTS

I. LEGAL ACTS

LAWS

Law on Plant Protection Products

The Law on Plant Protection Products (PPPs) 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. This law regulates:

- Licensing, sale, usage and control over the active substances and products. Also, it regulates the maximum permitted levels of residues, usage equipment, sharing of information regarding the products and their trade, the circumstances for the authorization of the competent authorities, as well as monitoring and control of the rules provided by this Law.
- Production of PPPs, good laboratory practice, Rotterdam Convention for harmful substances and pesticides and their international trade, classification, packaging and labeling.
- Leftovers and leftover packaging of used products and the condition of the products in the environment.
- Transport of active substances and products.

BYLAWS

- a) Guidelines for record keeping of every application of PPPs on crop cultures (http://arhiva.mzsv.gov.mk/files/Pravilnik_evidencija_korisnici_PZR.pdf)
- b) Guidelines on record keeping from the companies that produce, sell and store PPPs, produces amounts and bought and shipped amounts (http://arhiva.mzsv.gov.mk/files/Pravilnik_evidencija_pravni_lica.pdf)
- c) Guidelines on packaging, declaration and standardizing the terms (http://arhiva.mzsv.gov.mk/files/Pravilnik_zapakovanje.pdf)

- d) Guidelines on the means of requesting an authorization parallel import (http://arhiva.mzsv.gov.mk/files/Pravilnik_za_pararelen_uvoz.pdf)
- e) Guidelines on production, storage and trade (http://arhiva.mzsv.gov.mk/files/Pravilnik_za_Registri.pdf)

Important terms:

Active substances - substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products.

Adjuvants - substances or compounds 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, item.

Very dangerous substances - substances or products which in small concentrations cause death or acute or chronic damages to the human health when swallowed, inhaled or absorbed through the skin (T+).

Old active substances - active substances that have been up for sale before 26.06.1993 in the EU member states.

New active substances - active substances that have been up for sale after 26.06.1993 in the EU member states.

Authorized plant protection product - any PPP authorized for placing on the market and use.

Authorized use - 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.

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, item (c)).

Control sample - 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 - a practice whereby the treatments with plant protection products applied to given plants or plant products, in conformity with the conditions of

their authorized 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.

Integrated pest management - 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 – a system for the production of plants and plant products by applying the specific principles of integrated pest management.

Minimum use - the use of a plant protection product in a Member State (EU) 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 - a plant protection product.

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

Residues - 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 metabolites, breakdown or reaction products.

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, item.

Synergists - substances or preparations which, while showing no or only weak activity, can give enhanced activity to the active substance(s) in a plant protection product.

Unauthorized use - 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 - 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, Forestry and Water Economy (MAFWE), Phytosanitary Agency.

The Ministry of Agriculture, Phytosanitary Agency carries out all activities regulated by the PPP, 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. In order to carry out these activities, the Executive Director provides obligatory instructions and approves models of applications, permits, certificates, notifications, declarations, diaries and others under this Act (Art.62).

The control over the implementation of this law is carried out by the Phytosanitary inspectors and Agricultural inspectors from the State Agricultural Inspectorate (Art. 63), 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; 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; take control samples from the aforementioned substances and products and from other sites for carrying out laboratory tests; require information and documents, including written explanations related to their control activities; setting deadlines for their implementation; draw up acts for established administrative violations under this Act and/or the acts for its implementation; refer the relevant competent authorities and control bodies for found violations; request the assistance of other competent authorities and control bodies. 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.

Council for plant protection products (CPPP) is established as a permanent consultative body on matters relating to plant protection products (Art. 56 (1)). The MAFWE issues regulation about the organization and activity of the CPPP and, on a proposal of the Executive Director of the PSA, determines its composition, including representatives of the MAFWE, Ministry of Health, and Ministry of environment and physical planning (Art. 56 (2)). The council gives advice and draft measures that relate to the protection from import of adverse agents and products. Also, prescribe the necessary equipment for working with plant protection products, gives priorities for research etc.

REGISTERS

Pursuant to Article 18, paragraph 2 of the PPP, PSA creates and maintains a national register for plant protection products which have an authorization for use in agriculture. The list contains consists of PPP and active substances that have been authorized in a EU member state. If a product of a substance is banned in all EU states, it is being taken out of the List.

II. PROCEDURES

Authorization of PPP

No product can be produced, put up for trade or be used on the territory of North Macedonia if it is not authorized under this Law (Art 3 (1)). The product can be sold, only by the authorization holder under Article 8, however a product is allowed to be produced and transported in the country without an authorization only if it is meant for use in a different country and it has the necessary license for that country.

Request for authorization of PPP

A request for authorization has to be sent to the PSA by a company that intends to sell the product (Art 4). The request can be sent either from the producer itself or by a retail company. If the company that is requesting the authorization does not have a registered address in the country, they are obliged to have a designated company that represents them in North Macedonia. Together with the request, under Article 4, the company has to provide:

- 1) Information about the producer and basic information about the product
- 2) Physical and chemical characteristics
- 3) Information on the usage, guidelines on usage, storage, prevention measures etc.
- 4) Analytical methods
- 5) Toxicological studies
- 6) Residues of the active component on or inside the plants, food or livestock food
- 7) Effects of the chemical on the environment
- 8) Ecotoxicological studies
- 9) Identity of the product
- 10) Identity of the producer

The validity of the documents is being checked by experts from the Agency. The company asking for a request does not need to provide all these documents if the product or active component is already in the National register for plant protection products which have an

authorization for use in agriculture, instead they need to provide only the identity of the product. The company has to provide samples from the product in their original package together with the methodology for determining the levels of that product. The criteria for these procedures is being determined by the Minister of Agriculture, Forestry and Water Economy with compliance from the Minister of Health and The Minister of Environment and Physical Planning.

Assessment of the active substances

The assessment of the active substances is being done based on the information provided in the request for authorization from the Article 4 of the Law on PPP. The assessment of the active substances is being done by:

- 1) The Phytosanitary Agency
- 2) Ministry of Health
- 3) Ministry of Environment and Physical Planning

The assessment is being conducted by appropriate experts and lawyers that are designated by the Minister of Agriculture, Forestry and Water Economy with compliance from the Minister of Health and The Minister of Environment and Physical Planning. (Art 6 (4)).

Procedures for authorization of products

The Agency will approve the request if:

- 1) The substance is listed in the **National register for plant protection products which have an authorization for use in agriculture.**
- 2) It is efficient
- 3) Does not possess unacceptable effect on the plants and plant products
- 4) Does not inflict suffering and pain to the vertebrates that are being controlled
- 5) Does not inflict adverse effect to the human health or the animals directly or indirectly (through drinking water or livestock food) or underground water
- 6) Does not possess unacceptable effect on the environment, especially pollution of the groundwater
- 7) Appropriate methodologies for determining residues can be prescribed
- 8) Its physical and chemical characteristics are known and are considered acceptable and are being used
- 9) There is a determined maximal level of residues (MLR)

Issuing of authorizations

If the agency agrees that all the requirements are fulfilled for issuing an authorization it is required to do so the latest after two months from receiving the request. If the agency does not respond in the foreseen period, it is considered that the authorization has been given.

The PSA is responsible for providing guidelines for the means of packaging and labeling of the product and trading and usage. It is also responsible for providing any restrictions if needed regarding prevention of adverse effects on the environment or human health. The agency can also order that the product can only be used by a specific group of workers with a special license.

Revoking of the authorization

The authorization can be instantly revoked if:

- 1) The information provided with the request for authorization are not valid anymore
- 2) False documentations have been provided in the request
- 3) The authorization is expired and will not be reissued
- 4) The producer asks for the authorization to be revoked
- 5) There is a decision in the EU for exclusion of the active substance
- 6) If during inspection it is found that the procedure for production is different than the description in the request for authorization which resulted in different characteristics of the product
- 7) There is a reason to believe that there are adverse effect on the environment

The agency is obliged to inform the authorization holder for the revoking, and provide a tolerance period for disposal, storing and sale of the stock of the revoked product.

Mutual recognition of the authorization

The holder of an authorization granted may apply for an authorization 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 authorization was granted by a Member State which belongs to the same zone; (b) the authorization was granted by a Member State which belongs to a different zone provided that the authorization 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 authorization 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.

Where a plant protection product is not authorized in a Member State because no application for an authorization has been submitted in that Member State, official or scientific bodies involved in agricultural activities or professional agricultural organizations may apply, with the consent of the authorization holder, for an authorization 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 authorization holder refuses its consent, the competent authority of the Member State concerned may accept the application, on grounds of public interest.

The Member State to which an application is submitted shall, having examined the application and the accompanying documents, as appropriate with regard to the circumstances in its territory, authorize the plant protection product concerned under the same conditions as the Member State examining the application. By way of derogation from paragraph 1, the Member State may authorize the plant protection product where: (a) an authorization is granted by a Member State which belongs to a different zone; (b) it contains a candidate of substitution; (c) has been applied; or (d) it contains a substance approved.

For the purpose of authorization procedure the applicant submit the necessary documents and the Member State to which an application is submitted shall decide on the application within 120 days.

Providing information on adverse effects

The holder of the authorization is obliged to immediately inform the Agency for any newly acquired information on the potentially adverse effect of any product, or the residues of the active component on the human health, any animals or groundwater, or the environment. The agency has to immediately inform all the stakeholders, all of the EU members and the European Commission.

Exchange of information

The agency informs the European Commission at the end of every quartal for all the issued authorizations as well as all the revoked ones. During these reports there is a list of information that have to be provided:

- 1) The identity of the authorization holder
- 2) The trade name of the product
- 3) Type of product
- 4) Name and concentration of all the active substances in the product
- 5) Purpose of the product
- 6) New active substances in the product and their MPL
- 7) The study for the MPL
- 8) If relevant the reasons for the revoking of the authorization

The Agency creates a annual National register of authorized products and active substances and the register is being published in the Official Gazette.

HANDLING OF PPP

Packaging and Labeling

- 1) The packaging and labeling of the products have to be in line with this law which in term means that it is in line with EU regulations.
- 2) Every PPP ha to have a label with a stamp, serial number issued by the MAFWE – PSA.
- 3) The packaging has to have the following information listed:

- Trade name or trademark of the product
- Name and address of the manufacturer and number of the authorization
- Name and concentration of every active substance in the product
- If the ISO name is not available, the active substance should be provided with the chemical formula according to the International Union for Applied Chemistry (IUPAC)
- Gross amount of the product
- Information on the first aid and other information defined in the authorization
- The nature of all the specific risks to the human health, animals or the environment
- Information on the category of toxicity (T+ being most toxic)
- Safety measures for precaution for the human health, animals and the environment provided in standard phrases
- The purpose of the product and the means of functioning (e.i. Insecticide, growth regulator, herbicide etc.)
- All the specific terms of use in the agriculture, forestry, environment for which the product should be used, as well as in which circumstances the product must not be used

- How the product should be used and dosed
- Details on the possible phytotoxicity, the sensitivity of the species to the product, secondary effects on the plants
- Guidelines on the means of safe disposal
- Best before date

The guidelines for the packaging and labeling of the PPPs are described in a separate bylaw and are publicly available on the Website of the Ministry (http://arhiva.mzsv.gov.mk/files/Pravilnik_za_pakuvanje.pdf).

Production, sale and storage of the product

Production and marketing of the products and active substances can only be conducted by registered companies that are authorized for such activities. The companies that sell and store PPPs are obliged to maintain the necessary requirements that are designated by this Law.

The guidelines for production, sale and storage of the products are described in a separate bylaw and are available on the website of the Ministry (http://arhiva.mzsv.gov.mk/files/Pravilnik_za_Registri.pdf).

Record keeping

The companies that produce, sell and store PPPs are obliged to keep records for the produced amounts, for the received and shipped products including the expired products (Art. 27).

The data on these matters should be sent to the PSA until 31 of March the next year. The companies that produce and sell products that are listed as T+, besides the above mentioned record keeping, are obliged to keep record additionally on:

- 1) Tradename and date of expiry of the product
- 2) Date of the purchase of the product
- 3) For the companies, name of the firm, address of the firm and tax number
- 4) Signature of the buyer and seller

The record can be kept both in digital format or hard copy. The records should be available for inspection at any time to the PSA.

The guidelines on the record keeping are described in a separate bylaw and are publicly available on the website of the Ministry (http://arhiva.mzsv.gov.mk/files/Pravilnik_evidencija_pravni_lica.pdf).

However the records on sold products are not being sent regularly to the Agency, and the Agency does not possess information on the annual amount of sold PPPs.

USAGE

Usage of PPPs

The PPPs should be used in accordance with the authorization described in Article 3 (4) and Article 8 of the Law on PPPs, as well as the guidelines prescribed in the user's manual that is on or inside the packaging of the PPP.

During usage, it is important to consider:

- 1) Not to overstep the maximal permitted dose
- 2) Intervals of application, prescribed in the users' manual
- 3) To respect the rules for good agricultural practice
- 4) The application of products to be done with appropriate machinery which are safe
- 5) Not to deviate from the guidelines for protection of the human health, animals, groundwater, bees, aquatic ecosystems, soul etc.
- 6) The plants from the vicinity that are not a subject of control should not be damage
- 7) Highly toxic substances should be used at a safe distance from water bodies in order not to contaminate the water
- 8) Safely dispose of the packaging and unused PPPs

Control

The control over all the procedures described under the Law on PPPs is conducted under the MAFWE. The control over the licensing is also conducted under the MAWWE, and the control over the compliance of companies and firms, as well as the individuals that are a subject to the procedures described by the Law on PPPs is conducted by the State Agricultural Inspectorate and Phytosanitary Inspectors.

The control of the Phytosanitary Agency is conducted by designated personal in the MAFWE.

Competences of the Phytosanitary and Agricultural Inspectors

Phytosanitary Inspector	Agricultural Inspector
Ban the use of products if they are not declared or used in the prescribed manners	Ban the sale of PPPs as well as usage of the building where the product is being sold if the

	subject does not possess the appropriate licenses
Ban the use of products that are harmful to bees	Ban the sale of PPPs as well as usage of the building where the product is being sold if they identify irregularities regarding the building, equipment and personal, if it may lead to adverse effects on the human and animal health
Order the implementation of strict measures if the analyses suggest that the MPL are surpassed in the plants (before the launch of the product)	Issue a ban on the trade with the product if they are not authorized or expired
Ban official research and analyses because the other conditions have not been fulfilled	Issue a ban on trade or usage of a product if it is not in line with the prescribed labels, packaging, users' manual, physical and chemical content, purity etc.
Take samples from plants, plant products, PPPs and other necessary samples in order to see if the product is being used in the prescribed manners	Order a revoking of a product that is not in line with the guidelines for selling of the product
Suggest the revoking of the authorization for use of a product or any other process of usage of the product	Order additional measures and deadlines that will regulate the trading of the PPPs with the Law
Temporarily ban the usage of a product because of suspected inappropriate use until the situation is analyzed	Temporarily ban the usage of a product because of suspected inappropriate use until the situation is analyzed
Temporarily ban the usage of a product that does not possess the appropriate label	Temporarily ban the usage of a product that does not possess the appropriate label
Order a revoking of a rogue product during application until they are analyzed in detail	Order a revoking of a rogue product during application until they are analyzed in detail
Take samples of a PPP in order to analyze them if they match the labels	Confiscate certain products that do not possess the necessary labels
Conduct control at the border during import to	Confiscate products that are not in line with the

III. 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 North Macedonia is rather complicated and to a higher extend influenced by the EU legislation on this issue. 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 individuals 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 control mechanism. The procedures for authorization of PPPs 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 (agricultural and phytosanitary) and laboratory analyses.

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. In some cases there is overlap in the competences of the both inspectors (agricultural and phytosanitary), but there is no clear schedule for which inspections are being carried out.

It also should be noted that production, storage and transport of banned PPPs and active substances is allowed in North Macedonia, as long as they must not be used in the country but exported. Nevertheless, this creates the opportunity that some banned PPPs and substances can be used illegally in the country and hence poses a risk to the human health and the environment.

It is clear that there is a lack of publicly available information since only the list of authorized PPPs and substances is available while all the other registers are not. According to the law, the list of authorized substances should be reviewed and published every year while only the one from 2015 is available on the website of the MAFWE.

IV. CONCLUSIONS

The legislation on use, production, import, storage and treatment of plant protection products (PPP) in North Macedonia is rather complicated and to a higher extend influenced by the EU legislation on this issue. Low level of insurance of transparency of the procedures combined with limited range of control mechanisms and overlap in competences by inspectorates creates risks for implementation of bad practices. Given the fact that there is no list of banned PPPs and substances, but rather authorized ones complicate the matters even more. For a product or a substance to be authorized it should be authorized at least in one EU member state, and no further testing and studies are needed.

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 does not have enough mechanisms to ensure protection of the environment in terms of biodiversity, including vultures. It is very important aspect, as many of PPPs can be used to poison animals – both domestic and wild ones. Additionally, all control is based on trade, storage and/or use, but other missuses such as installing poison baits outside of the agricultural facilities and fields are not monitored.

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.

There is not much transparency in the whole system since registers are publicly available apart from the List of PPPs and substances that are authorized for use. This in term makes studying the use of PPPs even harder. There is no statistical evidence for the amounts of PPPs that are used in agriculture annually nor in which regions it is used most.

V. 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 North Macedonia 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 Phytosanitary Agency 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 must be based on evidence. Where the advocacy is dependent on institutions out of North Macedonia, different strategy must be applied, involving all the relevant partners.

As long as many PPPs could be used as poisoning 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.

More work should be done on information sharing and record keeping on the amounts of PPPs that have been used in the fields. This can contribute to a sensitivity map to be created and will give insight to other organizations and institutions where to focus on their work towards reducing the harmful effects to the human health and the environment.

GAP ANALYSIS OF THE PUBLICALLY AVAILABLE INFORMATION ON THE USE OF AGRICULTURE CHEMICALS THAT COULD BE POTENTIALLY DANGEROUS FOR VULTURES AND OTHER BIRDS OF PREY

I. OVERVIEW OF THE PUBLICALLY AVAILABLE INFORMATION

The publicly available information regarding agricultural chemicals and their use within the territory of North Macedonia is very limited. The only available information for the public is: Legal acts regarding plant protection and plant protection products, List of registered, List of registered plant protection products, some statistics regarding the agricultural production, and some news regarding the Phytosanitary and Agricultural inspections.

Legal acts regarding plant protection and plant protection products can be found in three main sources, such as: The Official Gazette, and the official webpage of the Ministry of Agriculture, Forestry and Water Economy. The lists of registered plant protection products can be easily found in the official webpage of the MAFWE, under the section “Documents”. This information is available in pdf format, and it is updated. Regarding the use of PPPs there is no publicly available information, nor a legal basis for systematically gathering data nationwide. There is no information on the quantity and the frequency of the agrochemicals used, or if there is used any agricultural chemical. In the official webpage of the MAFWE, are represented the latest news regarding the Phytosanitary activities as well as monthly summaries on their field inspections. The information on this news is very short and doesn't provide many details i.e. on this monthly news are represented the number of the subjects inspected and what were the penalties undertaken during the month.

Update on the List of agricultural products and substances that are authorized for use

According to Article 18 from the Law on PPPs, the Ministry of Agriculture, Forestry and Water Economy should update the List of authorized PPPs once a year and it should be published and set publicly available. However, on the website of the Ministry the only register that is publicly available is the one from 2015. This creates confusion between the sellers and users of PPPs and opens the possibilities for illegal use of plant protection products.

Record keeping

According to Article 27 from the Law on PPPs, every subject that produces, trades, stores or/and uses plant protection products have to keep record on the amounts received, used or sold/shipped products or substances. There is a list of information that they have to keep which is regulated inside the law. The gap here is that the subject are not obliged to send these data to the Agency, but instead they are only obliged to provide them in case of inspection. This in term makes impossible for the Government to keep statistics on the amount of PPPs that are being used or traded with.

Control

There are two bodies responsible for conducting the control over the production, storage, trade and usage of the plant protection products and those are the Phytosanitary

inspectors and the State Agricultural Inspectorate. Although they have designated responsibilities, their competences and responsibilities overlap in some cases which can lead to responsibility avoidance. Additionally, it seems as all the control is focused on the authorizations, licensing, storage, trade and usage. However, if the PPPs are to be used as poisoning agents in poison baits outside of the agricultural fields, there is no body that will be able to inspect that other than the police and Hunting inspectorate.

Registries for the use of chemical protection legal substances

There is no publicly available information regarding registries for the use of chemical protection legal substances.

Quantities of the chemicals used by types

There is no publicly available information regarding the quantities of the chemicals used by types.

Statistics on the use of the types of chemical protection chemicals

There is no publicly available information regarding the statistics on the use of the types of chemical protection chemicals.

List of all chemicals banned for import and use

There is no publicly available information regarding the list of the chemicals banned for import and use in North Macedonia. Instead, all the PPPs that are not on the List of authorized products and substances are considered banned.

Conditions and rules for controlling the import and use of illegal chemicals for chemical protection

There is no publicly available information regarding the conditions and rules for controlling the import and use of illegal chemicals for chemical protection.

Statistics of cases of detected illegal import of illegal chemicals

There is no publicly available information regarding cases of detected illegal import of illegal chemicals.

II. CONCLUSIONS

In conclusion, there is very limited information available for the public regarding the use of agriculture chemicals and it is not always updated.

Meanwhile, in terms of quantities, and geographical distribution of the legal use of the agriculture chemicals, there is no available information for the public. Regarding the illegal chemicals and illegal use, there is a complete lack of publicly available information, the same for cases of detected illegal import of illegal chemicals and disposal of the illegal chemicals. All this leads to insufficient amount of information to properly study the impact that PPPs have on vultures and biodiversity in general. Additionally, the possibility for pesticides to be used for preparing poison baits have not been addressed at all, besides the guidelines for proper use of the products. Until these issues have been properly addressed the legislation will remain poor in terms of the protection of biodiversity in the country.

III. RECOMMENDATIONS

It is important that all the responsible institutions on plant protection and plant protection products to provide information to the public regarding legal and illegal agriculture chemicals and their use within the territory of North Macedonia. This can be achieved through annual reports and registers on the quantity, geographical distribution, and legal / illegal use of the agriculture chemicals. These reports, registers should be published in the official webpage of the relevant institutions and be free to access from the public, or at least disclose their existence on the official webpage of the relevant institutions and provide the information on how to access them.

Also, it is important that the relevant institutions acknowledge that some PPPs can be used for the preparation of poison baits which is the most crucial threat that vulture face. The control over the sale of the most toxic substances (T+) must be better monitored and records should be kept and delivered to the institutions on the traded amounts.

SOURCES OF INFORMATION:

The Law on Plant Protection Products Official Gazette No. 110/2007; 20/2009; 17/2011 и 53/2011.

(http://arhiva.mzsv.gov.mk/files/Zakon_zaproizvodi_zazastita_narastenijata_0.pdf)

Guidelines for record keeping of every application of PPPs on crop cultures.

(http://arhiva.mzsv.gov.mk/files/Pravilnik_evidencija_korisnici_PZR.pdf)

Guidelines on record keeping from the companies that produce, sell and store PPPs, Produces amounts and bought and shipped amounts.

(http://arhiva.mzsv.gov.mk/files/Pravilnik_evidencija_pravni_lica.pdf)

Guidelines on packaging, declaration and standardizing the terms.

(http://arhiva.mzsv.gov.mk/files/Pravilnik_za_pakuvanje.pdf)

Guidelines on the means of requesting an authorization parallel import.

(http://arhiva.mzsv.gov.mk/files/Pravilnik_za_paralelni_uvoz.pdf)

Guidelines on production, storage and trade.

(http://arhiva.mzsv.gov.mk/files/Pravilnik_za_Registri.pdf)

www. <http://mzsv.gov.mk>

National register for plant protection products which have an authorization for use in agriculture (http://arhiva.mzsv.gov.mk/files/Nacionalna_lista_2015.pdf)

Serbia

REVIEW OF RELEVANT LEGISLATION IN SERBIA REGARDING USE, STORAGE, AND TREATMENT OF PLANT PROTECTION PRODUCTS

I. LEGAL ACTS

1. Law on Plant Protection Products:

Main legal act regarding the use of plant protection products. This law regulates the registration, control, trade, import and application of plant protection products in agriculture and forestry, activities of public interest in the field of plant protection products, as well as other issues of importance for plant protection products.

Important terminology:

Active substance - a substance or micro-organism, including viruses, that has a general or specific effect on harmful organisms, plants, plant parts or plant organisms.

Low-risk active substance - a substance which, in accordance with the regulations governing chemicals, is not classified in at least one of the following hazard classes: carcinogenic, mutagenic, toxic to reproduction, sensitization, very toxic, toxic, explosive, corrosive, and not persistent (half-life in soil less than 60 days); a substance with a bioconcentration factor of less than 100; a substance that does not lead to endocrine disorders; a substance that does not cause neurotoxic or immunotoxic effects.

Adjuvant - an auxiliary means of plant protection, ie a substance or preparation, ie. a product consisting of a co-formulant, or a preparation, i.e. a product containing one or more co-formulants, which the user mixes with a plant protection product or a general use plant protection product and thus improves their effectiveness or other pesticidal properties.

Distributor - a legal entity, ie an entrepreneur who trades in plant protection products, without changing their characteristics.

Good agricultural practice - recommended, approved or registered safe use of plant protection products in accordance with existing conditions at any stage of production, storage, transport, distribution and processing of food and feed and involves the application of the principles of integrated pest management in certain climatic areas , as well as the application of minimum amounts of plant protection products and determining the maximum concentrations of residues of plant protection products at the lowest level, in order to achieve the desired effect.

Control of plant protection products - the control carried out by the competent authority to confirm compliance with this Law and the application of regulations in the field of plant protection products, namely monitoring, supervision, inspection, audit, inspection, sampling and laboratory testing (hereinafter: official control).

User - a legal entity, entrepreneur, or natural person who uses plant protection products in the course of their professional activities (including operators, technicians, employers and self-employed persons in agriculture and other sectors), as well as who uses plant protection products in small areas (backyards, gardens, gardens, etc.) on plants or plant products that he produces or uses for his own needs.

Co-formulant - substance or preparation, i.e. a product which is used or intended to be used in a plant protection product or an adjuvant but which is not an active substance, a protecting agent or a synergist.

The list of approved active substances (hereinafter: the list of approved substances) - list of evaluated and approved active substances and basic substances and low-risk substances, which is harmonized with the corresponding list in the territory of the European Union.

Basic substance - substance that is not primarily produced as a plant protection product, but which exhibits a certain biological activity, as well as an active substance that meets the criteria for food in accordance with the law governing food safety.

Residues of plant protection products - one or more active substances or basic substances or other substances, including their metabolites and products resulting from their decomposition or reaction, which are present on plants and in plants, ie on products of plant origin and in products of plant origin or in edible products of animal origin or anywhere in the environment (air, water, soil), resulting from the use of plant protection products.

Auxiliary plant protection product - a product that contains one or more substances of natural or synthetic origin in final form and which is used together with a plant protection product.

Preparation - a mixture or solution of substances intended for use as a plant protection product, of which at least one substance is an active substance.

Plant protection product - a product that consists of or contains an active substance or a basic substance and co-formulants, and may also contain a protector or synergist and is applied:

- (1) to protect plants or plant products from harmful organisms or to prevent the action of harmful organisms, unless these products are used for hygienic purposes,
- (2) as a plant growth regulator that affects plant life processes differently from the mode of action of plant nutrition products,
- (3) for the preservation of plant products, in the case of substances or products that are not regulated by special regulations governing preservatives,
- (4) for the destruction of unwanted plants or parts of plants, other than algae, unless those products are applied to soil or water for plant protection purposes,
- (5) to control or prevent the undesired growth of plants, other than algae, unless those products are applied to soil or water for plant protection purposes

Product of general use for plant protection - a preparation containing a low-risk active substance or another product that can be prepared for direct use or for use on small areas, and whose use does not pose a danger to users and does not require personal protective equipment.

Producer - a legal entity, ie an entrepreneur engaged in the production of a PPP.

Turnover - any supply of plant protection products with or without compensation other than storage for export, ie for re-export from the customs territory of the Republic of Serbia or storage for their safe disposal.

Protector - an auxiliary means for plant protection, ie a substance or preparation, ie. product added to a plant protection product to eliminate or reduce the phytotoxic effects of a plant protection product.

Registration of PPPs - a procedure on the basis of which the production, trade and application of plant protection products is allowed.

Synergist - a substance or preparation, ie. a product which, although it does not exhibit or exhibits a weak action as a plant protection product, may enhance the action of the active substance or substances in the plant protection product.

Substance - a chemical element and its compounds, which occur in nature or as a result of the production process, including all impurities caused by the production process.

Technical product - a material that contains the active substance and impurities that occur during its production, and may also contain the necessary amount of additives.

Tests and studies - researches or experiments whose purpose is to determine the properties and behavior of an active substance, synergist, protector, co-formulant or plant protection product, predict exposure to the active substance, synergist, protector, co-formulant or their relevant metabolites and determine safe levels of exposure and determine the conditions for safe use of plant protection products.

PPPs may be produced, placed on the market and applied on the territory of the Republic of Serbia if they are registered and supplied with a declaration and instructions for use in accordance with this Law and regulations adopted on the basis thereof. plants containing may be produced and placed on the market in the territory of the Republic of Serbia, if it is entered in the List of Approved Substances in accordance with this Law and regulations adopted on the basis thereof.

PPPs not registered in Serbia, as well as active substance, ie basic substance contained in plant protection products, which is not entered in the List of approved substances, may be produced and stored in Serbia, ie their import and transport via territories of the Republic of Serbia can be performed only if they are intended for placing on the market in the country to which they are exported.

PPPs, packaged and labeled in accordance with this Law and regulations adopted on the basis thereof and in accordance with the regulations governing chemicals that apply to the content and delivery of the safety data sheet.

PPPs, active substance, ie basic substance that have been placed on the market contrary to the provisions of this Law and regulations adopted on the basis thereof, as well as packaging of plant protection products shall be considered waste.

Examination of the properties and impact of plant protection products, active substances, ie basic substances on human, animal and environmental health must be conducted in laboratories whose treatment is in accordance with the guidelines of good laboratory practice in accordance with the law governing drugs and medical devices.

RELEVANT ENTITIES IN THE FIELD OF PPPs

Activities in the field of PPPs, within its powers, are defined by the Republic of Serbia through the Ministry responsible for agriculture (hereinafter: the Ministry), as well as entities that perform activities of public interest. Activities of public interest in the field of plant protection products include laboratory and related professional activities.

Laboratory and related professional activities referred to in Article 6 of this Law shall be performed by a laboratory established by the law governing food safety. These activities may also be performed by a laboratory accredited in accordance with the standard SRPS EN ISO / IEC 17025 - "General requirements for the competence of testing laboratories and calibration laboratories", selected through a competition and authorized by the Ministry to perform these tasks (hereinafter: the official laboratory), and a laboratory founded by the Republic of Serbia, ie the Autonomous Province, which is accredited in accordance with the standard SRPS EN ISO / IEC 17025 - "General requirements for the competence of testing laboratories and calibration laboratories" , selected through a competition and authorized by the Ministry to perform these tasks (hereinafter: reference laboratory).

Accreditation may refer to individual types of tests or groups of tests (tests). One reference laboratory can be a reference for one or more types (groups) of tests.

If there is no reference laboratory in the Republic of Serbia that meets the prescribed conditions, the Minister responsible for agriculture (hereinafter: the Minister) may, for certain types of testing, designate a laboratory from the territory of another country for the required tests. The selection of the reference laboratory and the official laboratory

referred to in Article 7 of this Law shall be made through a competition announced by the Ministry and published in the "Official Gazette of the Republic of Serbia".

REGISTRATION OF PPPs

A plant protection product shall be registered if, in the assessment procedure referred to in Article 14 of this Law, it is determined that:

1) the active or basic substance contained in the plant protection product is entered in the List of Approved Substances and the source of the active or basic substance is identical or equivalent to the source on the basis of which the active or basic substance was entered in that list.

2) plant protection product, taking into account real conditions of application and good agricultural practice:

- (1) is effective for the proposed application,
- (2) has no direct or indirect harmful effect on human health (especially the most vulnerable groups) or on animal health, either directly or through drinking water (including substances resulting from water treatment), food, feed or air, or as a consequence of contact at the workplace or through other indirect impacts, and taking into account known cumulative and synergistic effects if scientific methods for assessing those impacts are available and adopted,
- (3) has no direct or indirect harmful effect on groundwater,
- (4) has no adverse effects on plants or plant products,
- (5) does not cause unnecessary suffering and pain to vertebrates for the control of which it is used,
- (6) there is no unacceptable impact on the environment (when scientific methods for assessing these impacts are available and adopted), in particular having regard to:

- its fate and distribution in the environment, in particular the contamination of surface waters (including watersheds and coastal waters), groundwater, air and land, taking into account places far from the place of application of plant protection products and monitoring its long-distance transmission in the environment,
- impact on non-target species, including the behavior of those species,
- biodiversity and ecosystem;

3) the plant protection product does not contain a co-formulant entered in the List of Unacceptable Co-Formulants.

4) the technical formulation of the plant protection product is such that user exposure and other risks are limited to a minimum.

5) the physical and chemical properties of the plant protection product have been tested and are considered acceptable from the aspect of appropriate application and storage of that plant protection product.

6) the nature and quantity of active substances, protecting agents, synergists and, where relevant, impurities of toxicological or ecotoxicological significance or environmental impurities, as well as co-formulants, may be determined by appropriate methods.

7) residues of toxicological and ecotoxicological significance, resulting from approved applications, may be determined by appropriate methods generally accepted, with appropriate limits of determination in the relevant samples.

8) is a synergist, ie a protector when the plant protection product contains is entered in the List of approved protectors and synergists and that the source of the synergist or protector is identical or equivalent to the source on the basis of which the synergist or protector was entered in that list.

For the active substance contained in the PPP to be registered, the maximum permitted levels of residues in or on plants or plant products used as food or feed must be determined in accordance with this Law and regulations adopted on the basis thereof.

SALE OF PPPs

Registered PPPs may be placed on the market if they are packed in packaging safe for human health and the environment. The packaging must have a declaration and instructions for use with the data contained in the registration decision, in Serbian, clear, unambiguous and legible, so that they cannot be deleted or removed. The declaration and instructions for the use of plant protection products must also specify specific risk and warning signs for humans and the environment.

PPPs may be traded by a distributor registered in the Register of Business Entities in accordance with the law governing the registration of business entities and if entered in the Register of Distributors and Importers of Plant Protection Products led by the Ministry.

The Minister prescribes in detail the content of the declaration and instructions for the application of PPPs, as well as specific requirements and risk and warning labels for humans and the environment and the manner of handling emptied packaging of plant protection products.

Entry in the Register of Distributors and Importers is made on the basis of a request submitted by the distributor or importer to the Ministry. The distributor or importer is entered in the Register of Distributors and Importers, if he meets the requirements in terms of facilities, equipment and professional qualifications of staff.

Transport and storage of PPPs must be performed in a way that does not endanger the life and health of humans and animals and the environment and in conditions that ensure the maintenance of unchanged physical and chemical properties and conveniences for the use of PPPs. The sale, storage or transport of plant protection products in the same area as food or feed is prohibited.

Import and transit of plant protection products and PPPs active substances, ie basic substances may be carried out through border crossings where there is an organized phytosanitary inspection and which meet the hygienic-technical and working conditions. The import of consignments may also be carried out through border crossings where phytosanitary inspection has not been organized, and which are temporarily opened for that purpose by a decision of the Minister.

USE OF PPPs

PPPs must be applied:

- 1) in accordance with the decision on registration, ie in accordance with the decision referred to in Article 21 of this Law or the decision referred to in Article 26 of this Law or the decision referred to in Article 27 of this Law
- 2) in accordance with the declaration and instructions for application
- 3) in accordance with the principles of good agricultural practice or integrated pest management
- 4) in accordance with the purpose of plant protection products and with the aim of control
- 5) in a manner that does not endanger the health of humans and animals and unnecessarily increases their exposure to plant protection products
- 6) in a way that does not endanger the environment

It is prohibited to use PPPs:

- 1) in a manner that would cause pollution of facilities and premises used by humans or used for breeding and keeping animals
- 2) in a manner that would cause water pollution, ie contrary to the provisions of the law governing water, except for plant protection products that are registered for use in the aquatic environment

- 3) in a way that would cause pollution of the areas bordering the treated areas
- 4) for the control of non-target organisms, damage to their habitat, ie prevention of their spread in terms of plant protection measures
- 5) in water protection zones for water sources and water supply of the population
- 6) from aircraft that are toxic to bees
- 7) at the time of flowering plants that are toxic to bees
- 8) in protected areas
- 9) which contain an active substance, ie a basic substance that is not entered in the List of Approved Substances, as well as protectors, ie synergists that are not entered in the List of Approved Protectants and Synergists, as well as co-formulants entered in the List of Unacceptable Co-Formulants, unless application approved in accordance with Art. 26 and 27 of this law.

Exceptionally from paragraph 1 item. 4) and 7) of this Article PPPs may be applied only in case of control of quarantine or regulated non-quarantine harmful organisms or other harmful organisms and based on the consent of the Ministry in the case referred to in paragraph 1 item 4) of this Article. environment in the case referred to in paragraph 1, item 7) of this Article.

In case of application of PPPs in protected areas, after obtaining the consent of the ministry responsible for the environment referred to in paragraph 2 of this Article, persons applying plant protection products must inform the managers of protected natural areas about the upcoming application of plant protection products no later than 48 hours before applications.

Notwithstanding paragraph 1, item 6) of this Article, PPPs may be applied only in case of control of harmful organisms from prescribed lists or treatment of plants, plant products and prescribed facilities from prescribed lists, under the conditions referred to in Article 49 of this Law.

The user is obliged to implement plant protection products and all activities related to the use of plant protection products, such as handling, storage, transport and disposal, under conditions and in a way that does not endanger the life and health of humans and animals and animals. environment.

The user is obliged to:

- 1) inform the owners of the parcels bordering the parcel which he intends to treat with PPPs at least 24 hours before the beginning of application
- 2) apply PPPs in accordance with Art. 44 and 45 of this Law

A legal entity, entrepreneur, ie a natural person who uses PPPs within his professional activities, as well as in the case of placing his agricultural products on the market, is considered a professional user. A user who uses PPPs on small areas (backyards, gardens, orchards, etc.) on plants or plant products he produces for his own needs is not considered a professional user.

The professional user, in addition to the obligations referred to in paragraph 2 of this Article, is obliged to:

- 1) regularly performs adjustment and technical inspection of application devices
- 2) use application devices that have been periodically inspected in accordance with this Law

If the harvest must be done before the expiration of the withdrawal period, the professional user is obliged to store plants or plant products, whose harvest or harvest before the expiration of the withdrawal period, separately from other plants or plant products and can not put them on the market as food or animal feed until the examination determines that the level of residues of PPPs is in accordance with the regulation governing the maximum permitted amounts of residues of PPPs in food and animal feed.

A PPP intended for a professional user may be purchased and applied by a natural person who has a professional user certificate issued in accordance with this Law, as well as a legal entity or entrepreneur who has an employee who has a professional user certificate. The professional user certificate is issued by the Ministry. The professional user certificate is issued to a person trained in the safe use, handling, storage, transport and disposal of PPPs. The professional user certificate is issued for a period of five years and can be extended to a professional user who, after issuing the certificate, attended training according to the prescribed program. The relevant Minister prescribes in detail the program, the manner of conducting the training and the manner of testing the knowledge for the purpose of issuing a professional user certificate, as well as the form of that certificate. The Minister also prescribes in detail the conditions and manner of application of plant protection products, which do not endanger the life and health of humans and animals and the environment, as well as the conditions and manner of handling, storage, transport and disposal of plant protection products. The certificate of professional user is made and printed by the National Bank of Serbia - Institute for the Production of Banknotes and Coins.

INSPECTION CONTROL

Inspection supervision over the application of the provisions of this Law and regulations adopted on the basis thereof is performed by the Ministry through phytosanitary inspectors. The activities of a phytosanitary inspector in the field of plant protection products may be performed by a person who has acquired higher education in the scientific field of biotechnical science - plant protection department or crop or fruit and vineyard department or general or agroeconomic department in basic academic studies in the amount of at least 240 ECTS credits, master's academic studies, master's vocational studies, specialist academic studies, ie undergraduate studies lasting at least four years, as well as having work experience in the profession of at least three years and passed the state professional exam.

In performing inspection activities, the phytosanitary inspector has the right and duty to:

- 1) verify whether PPPs placed on the market in the territory of the Republic of Serbia are registered in accordance with this Law, ie whether the active substance or basic substance is entered in the List of Approved Substances in accordance with this Law.
- 2) check whether PPPs are not registered in the Republic of Serbia, ie whether the active substance or basic substance is not entered in the List of Approved Substances, and are stored in the Republic of Serbia, ie whose import and transport performs through the territory of the Republic of Serbia, intended for placing on the market in the country to which they are exported.
- 3) verify the fulfillment of contractual obligations referred to in Article 8 of this Law.
- 4) checks whether the legal entity or entrepreneur meets the requirements in terms of facilities, equipment, operational procedures, guidelines of good experimental practice and number, education and training of staff, to issue a certificate of compliance with the guidelines of good experimental practices (Article 9, paragraph 2).
- 5) check whether PPPs have been placed on the market and whether they are applied in accordance with the decision referred to in Article 21, paragraph 5 of this Law.
- 6) check whether the users have been informed about the application of PPPs for small crops and minor purposes in the prescribed manner.
- 7) check whether PPPs are in circulation after the prescribed deadline referred to in Article 23, paragraph 2 of this Law.
- 8) check whether the preparation and auxiliaries for plant protection containing new active substance are on the market after the prescribed deadline referred to in Article 25, paragraph 6 of this Law.
- 9) check whether the producer, importer and distributor takes all necessary measures to withdraw PPPs from the market within the period determined by the decision referred to in Article 23, paragraph 1 and Article 25, para. 4 and 5 of this law.

- 10) check whether the producer has changed the declaration and instructions for the application of PPPs in accordance with Article 23a paragraph 7 and Article 24 paragraph 5 of this Law.
- 11) check whether experiments or tests involving the release into the environment of unregistered PPPs, ie registered PPPs for applications not listed in the registration decision, are performed on the basis of the decision, ie in accordance with the decision on permit for Research & Development.
- 12) verify whether unregistered PPPs or registered PPPs for applications not listed in the registration decision are applied in accordance with the decision referred to in Article 27, paragraph 1 of this Law.
- 13) take samples of PPPs, plants, plant products and prescribed facilities, free of charge, as well as water, land, bees, aquatic organisms and other non-target organisms, for testing.
- 14) check whether the producer has immediately informed the Ministry and users about the possible harmful effects of PPPs, ie residues of PPPs, on human and animal health, surface and groundwater or the environment, as well as new information on possible fertility restrictions.
- 15) check whether the conditions regarding packaging, declaration and instructions for the application of PPPs referred to in Article 31 of this Law have been met.
- 16) check whether the distributor or importer meets the conditions for entry in the Register of Distributors and Importers referred to in Article 32, paragraph 2 of this Law, as well as whether in case of changes in data entered in the Register of Distributors and Importers notified the Ministry.
- 17) check whether the person who trades in PPPs is registered in the Register of Distributors and Importers.
- 18) check whether the sale of PPPs is carried out in facilities and points of sale registered in the Register of Distributors and Importers in accordance with Article 33, paragraph 5 of this Law.
- 19) check whether the distributor or importer entered in the Register of Distributors and Importers meets the conditions for obtaining marketing authorization for particularly dangerous PPPs.
- 20) check whether the sale, storage or transport of PPPs is carried out in accordance with the provisions of Article 36 of this Law.
- 21) check whether the person performing the storage of PPPs meets the conditions referred to in Article 36, paragraph 3 of this Law.
- 22) check whether expired PPPs are on the market.
- 23) check whether the PPPs that have expired are applied in accordance with the provisions of Article 37, paragraph 2 of this Law.

- 24) check whether the advertising and display of PPPs is carried out in accordance with the provisions of Article 38 of this Law.
- 25) check whether the import is carried out in accordance with the provisions of Article 39 of this Law.
- 26) check whether the import and transit are performed at the border crossings referred to in Article 40 of this Law.
- 27) inspect and simple shipments in accordance with the provisions of Art. 41 and 42 of this Law.
- 28) check whether the importer, ie customs agent fulfills the obligations referred to in Article 41, paragraph 2 of this Law.
- 29) check whether PPPs are applied in accordance with the provisions of Art. 44 and 45 of this Law, as well as whether the user performs the obligations referred to in Article 46 of this Law.
- 30) check whether the legal entity or entrepreneur meets the conditions for obtaining approval for the use of particularly hazardous PPPs.
- 31) check whether PPPs are applied in accordance with the provisions of Article 47, paragraph 3 and Art. 48 and 49 of this Law.
- 32) check whether the devices for use are subjected to periodic inspection in accordance with the provisions of Article 51, paragraph 1 of this Law.
- 33) check whether the Ministry has been notified within the prescribed time limit in the event of a change in the conditions for performing periodic inspection activities.
- 34) check whether food and feed contain residues of PPPs.
- 35) verify whether the service provider is registered in the Register of Service Providers in accordance with the provisions of Article 54 of this Law.
- 36) check whether the records and submission of data from the records are performed in accordance with the provisions of Article 64 of this Law.
- 37) check whether the records are kept in accordance with this Law.
- 38) check whether the fees for performed phytosanitary inspections have been paid.
- 39) control the execution of measures under this Law.

In performing the tasks referred to in Article 74 of this Law, the phytosanitary inspector may:

- 1) order the persons performing efficiency testing activities to harmonize the performance of activities within a certain period of time, ie eliminate deficiencies with regard to the prescribed conditions in accordance with Article 9 of this Law.
- 2) prohibit the use of PPPs for small crops and minor purposes that is carried out without the approval of the Minister referred to in Article 21, paragraph 5 of this Law.
- 3) order the person who has been approved by the decision of the Minister to use PPPs for small crops and minor purposes to inform users on the additional instructions for

application on the use of PPPs for small crops and minor purposes, in accordance with Article 21, paragraph 7. of this Law.

4) order the undertaking of the necessary measures for the withdrawal from circulation of stocks of PPPs, preparations, ie auxiliary PPPs.

5) order the producer to change the declaration and instructions for application, if he finds that after the change or amendment of the decision on registration he did not change the declaration and instructions for application of PPPs in accordance with Article 23a paragraph 7 and Article 24 paragraph 5 of this Law.

6) prohibit the use of unregistered PPPs, if it determines that they are not applied in accordance with the decision referred to in Article 27, paragraph 1 of this Law.

7) order the producer to eliminate the deficiencies, if he finds that the packaging, declaration and instructions for the use of PPPs do not meet the requirements of Article 31 of this Law.

8) order the distributor and importer to report any change in the data entered in the Register of Distributors and Importers to the Ministry, ie to report the change of data within the period prescribed by Article 33, paragraph 4 of this Law.

9) prohibit the sale of PPPs in facilities and points of sale that are not entered in the Register of Distributors and Importers.

10) prohibit the trade in especially dangerous PPPs, if it determines that the trade is carried out without the approval referred to in Article 35 of this Law.

11) order the withdrawal from the market of PPPs, if their use has expired.

12) prohibit the use of expired PPPs, if it determines that they are not applied in accordance with the provisions of this Law.

13) prohibit advertising and display of PPPs, if it determines that advertising and display is not carried out in accordance with this Law.

14) prohibit the use of PPPs, if they are not applied in accordance with the provisions of Art. 44–49. of this Law.

15) prohibit the placing on the market and application of PPPs that do not meet the conditions specified in the decision on registration.

16) order that plants, ie plant products whose harvest or harvest is done before the expiration of the withdrawal period, be stored separately from other plants, ie plant products, ie that such plants, ie plant products placed on the market as food or food for animals before the examination has determined that the level of residues of PPPs is in accordance with the regulation governing the maximum permitted quantities of residues of PPPs in food and feed, withdrawn from circulation.

17) order the keeping of records on the harvest, ie harvest which is performed before the expiration of the withdrawal period.

18) prohibit the use of PPPs intended for professional use by a person who does not meet the conditions referred to in Article 46, paragraph 5 of this Law.

- 19) temporarily prohibit the use of application devices and order their periodic inspection.
- 20) order the persons performing periodic inspections and service providers to harmonize the performance of activities within a certain period of time, ie eliminate deficiencies in terms of prescribed conditions, in accordance with Article 51, paragraph 3 and Article 53, paragraph 2 of this Law.
- 21) order appropriate measures if official examinations determine that residues of PPPs in plants or on plants, plant products and prescribed facilities are above the prescribed maximum permitted amounts of residues.
- 22) temporarily prohibit the placing on the market and application of PPPs, ie their series for which it is suspected that they do not meet the conditions specified in the registration decision, until the tests are completed.
- 23) order safe disposal, ie destruction of PPPs that do not meet the conditions for registration or whose expiration date has expired.
- 24) prohibit the work of entities in the field of PPPs until the conditions provided by this Law are met.
- 25) prohibit the work of persons who prevent the performance of inspection control or do not submit the necessary data, documentation at their disposal or otherwise prevent inspection control, for a period of three months.
- 26) prohibit the import and order the return of the consignment, if the conditions prescribed by this Law and regulations adopted on the basis thereof are not met.
- 27) submit a request for initiating misdemeanor proceedings, a report for an economic crime and a criminal report for violation of the provisions of this Law and regulations adopted on the basis thereof.
- 28) order other measures and take other actions in accordance with this Law.

PENAL PROVISIONS

Criminal act

A person who manufactures, places on the market or uses an unregistered PPP or active substance, or basic substance that is not entered in the List of Approved Substances, or manufactures, places on the market or uses a PPP for which there is a ban on production, marketing or application and thus causing harmful consequences for human health or the environment, shall be punished by imprisonment for a term not exceeding one year.

If, as a result significant damage occurred, the perpetrator shall be punished by imprisonment for a term not exceeding three years.

If the act referred to in paragraph 1 of this Article was committed through negligence, the perpetrator shall be punished by a fine or imprisonment for a term not exceeding one year.

Economic crime

A fine of 700,000 to 3,000,000 RSD shall be imposed on a legal entity for an economic offense if:

- 1) performs the activities of a reference or official laboratory contrary to the contract referred to in Article 8, paragraph 6 of this Law.
- 2) performs activities of assessment of PPPs, contrary to the contract referred to in Article 14a, paragraph 7 of this Law.
- 3) use the data contrary to the prescribed conditions from Art. 18 and 19 of this Law.
- 4) places on the market and applies a PPP that is not registered in accordance with this Law.
- 5) places on the market and applies a preparation, ie auxiliary means for plant protection on the territory of the Republic of Serbia, which is not registered in accordance with Article 25 of this Law.
- 6) performs testing of an unregistered PPP without a decision on a permit for research and development.
- 7) in the cases provided for in Article 27 of this Law, apply a PPP that has not been registered without a decision approving the use of unregistered PPPs.
- 8) places on the market a PPP that has expired.
- 9) applies a PPP that has expired.
- 10) applies a PPP contrary to Article 44 of this Law, ie contrary to the prohibition of the use of PPPs referred to in Article 45 of this Law.
- 11) applies PPPs and does not meet the conditions for the application of funds referred to in Article 46, paragraph 1 of this Law, ie during the application of PPPs does not take all necessary activities and measures referred to in Article 46, paragraph 2 and 5 of this Law.
- 12) plants, ie plant products, the harvest or harvest of which is performed before the expiry of the withdrawal period, are not stored separately from other plants, ie plant products, ie placed on the market as food or feed before the examination determines that the level of residues plants in accordance with the regulation governing the maximum permitted quantities of residues of PPPs in food and animal feed.
- 13) buys and applies a PPP and does not meet the conditions for application referred to in Article 46, paragraph 8 of this Law.
- 14) applies a PPP, but does not have a decision approving the use of particularly dangerous PPPs.
- 15) applies a PPP contrary to the provisions of Article 48, para. 1 and 2 of this Law.
- 16) applies a PPP toxic to bees contrary to the provisions of Article 49, paragraph 1 of this Law.

17) apply PPPs that are classified in the class of danger "danger to the aquatic environment" and marked in accordance with the regulations governing the classification, packaging and labeling of chemicals.

18) food and animal feed placed on the market contains residues of PPPs above the maximum permitted quantities.

19) provides services and is not registered in the Register of Service Providers (Article 53).

20) does not act upon the decision of the phytosanitary inspector, in accordance with this Law.

The responsible person in the legal entity shall also be fined from 70,000 to 200,000 RSD for the economic crime referred to in paragraph 1 of this Article. For actions referred to in paragraph 1 of this Article, in addition to a fine, a protective measure prohibiting a legal entity from engaging in certain economic activities, or a protective measure prohibiting a responsible person from performing certain duties for a period of six months to seven years.

Misdemeanor of a legal entity

A fine of 500,000 to 1,000,000 RSD shall be imposed on a legal entity for a misdemeanor if:

1) submits incorrect data in the procedure of registration of PPPs (Articles 12, 13, 21, 23a, Article 24, paragraph 2 and Article 25).

2) performs an examination on vertebrates contrary to Article 17 para. 1 and 2 of this Law.

3) uses PPPs for purposes not specified in the decision on registration, without a decision approving the use of PPPs for small crops and minor purposes.

4) fails to inform the users of PPPs through additional instructions on the approval of the use of PPPs for small crops and minor purposes.

5) does not withdraw from the market the PPP within the period referred to in the decision referred to in Article 23, paragraph 3 and Article 23a, paragraph 5 of this Law.

6) does not handle stocks of PPPs in accordance with Article 23, paragraph 3 and Article 23a, paragraph 5 of this Law.

7) has not amended the declaration and instructions for application in accordance with Article 23a paragraph 7 and Article 24 paragraph 5 of this Law;

8) applies an unregistered PPP for which a decision referred to in Article 27, paragraph 1 of this Law has not been issued.

9) submits incorrect data in the procedure of issuing a permit for research and development, ie in the procedure of issuing a decision approving the use of unregistered PPPs in emergencies.

- 10) fails to inform the Ministry and users about possible harmful consequences of PPPs.
- 11) packs, declares, gives instructions for the application, advertises or exhibits PPPs contrary to Article 31, paragraph 3 and Article 38 of this Law.
- 12) trades in PPPs and is not entered in the Register of Distributors and Importers in accordance with Article 32 of this Law.
- 13) fails to report changes in the data entered in the Register of Distributors and Importers, ie fails to report changes in such data within the prescribed time limit.
- 14) sells PPPs in facilities and points of sale that are not entered in the Register of Distributors and Importers.
- 15) trades in PPPs without a decision approving the marketing of particularly dangerous PPPs referred to in Article 35, paragraph 1 of this Law.
- 16) sells, stores or transports PPPs contrary to Article 36, paragraph 2 of this Law.
- 17) fails to ensure that the storage of PPPs is performed by a person who is professionally qualified to perform those activities.
- 18) import a plant protection product through a border crossing that is not designated for phytosanitary inspection.
- 19) imports the consignment without inspection and sampling.
- 20) relocate, open or share a consignment for which the decision on transport has determined customs supervision until the completion of inspection.
- 21) uses devices for application that have not been subjected to periodic inspection.
- 22) fails to report to the Ministry a change in the conditions for performing periodic inspection activities.
- 23) does not keep records and does not submit data from the records in accordance with Article 64 of this Law.

For the misdemeanor referred to in paragraph 1 of this Article, the responsible person in the legal entity shall also be fined from 20,000 to 50,000 RSD.

Violations by the entrepreneur

An entrepreneur are fined from 300,000 to 500,000 RSD for a misdemeanor if he commits actions referred to in Article 79, paragraph 1, item 4), 5), 7), 8), 9), 10), 11), 12), 13), 14), 15), 16), 17), 18), 19), 20) of this Law.

An entrepreneur will be fined from 100,000 to 400,000 RSD for a misdemeanor if he commits actions referred to in Article 80, paragraph 1, item 1), 2), 3), 4), 5), 6), 7), 8), 9), 10), 11), 12), 13), 14), 15), 16), 17) , 18), 19), 20), 21), 22) and 23) of this Law.

Violations by individuals

Fines of 35,000 to 50,000 RSD are imposed on an individual for a misdemeanor if he commits acts referred to in Article 79, paragraph 1, item 9), 10), 11), 12), 13), 14), 15), 16), 17), 18) and 20) of this Law, as well as if:

- 1) applies a plant protection product contrary to the prohibitions or restrictions referred to in Article 23, para. 1, 2 and 3 and Article 23a paragraph 4 of this Law.
- 2) provides services in the field of plant protection products without a license to provide services referred to in Article 57, paragraph 1 of this Law.

Fines of 5,000 to 30,000 dinars are imposed on a natural person for a misdemeanor if he commits acts referred to in Article 80, paragraph 1, item 3), 8), 21) and 23) of this Law, as well as if it does not inform the Ministry that the plant protection product adversely affects human or animal health or surface and groundwater or the environment in accordance with Article 30, paragraph 2 of this of the law.

2. Rulebook on the conditions and manner of application of plant protection products, which do not endanger the life and health of humans and animals and the environment, as well as the conditions and manner of handling, storage, transport and disposal of plant protection products.

This Rulebook prescribes in more detail the conditions and manner of application of PPPs, which do not endanger the life and health of humans and animals and the environment, as well as the conditions and manner of handling, storage, transport and disposal of plant protection products.

The application of PPPs is carried out:

- 1) in accordance with the decision on registration.
- 2) in accordance with the declaration and instructions for application.
- 3) in accordance with the principles of good agricultural practice or integrated pest management.
- 4) in accordance with the purpose of plant protection products and with the aim of control.
- 5) in a manner that does not endanger the health of humans and animals and unnecessarily increases their exposure to plant protection products.
- 6) in a way that does not endanger the environment.

PPPs must be applied in a way that prevents adverse effects on:

- 1) humans, animals and other non-target organisms.

- 2) water sources, watercourses, wells, canals, lakes, ponds and other surface and groundwater.
- 3) facilities for water supply of people and animals.
- 4) premises and facilities used by people or used for breeding and keeping animals.
- 5) areas bordering the treated areas. taking into account:

a) time intervals from application to:

- sowing and planting of protected crops,
- sowing or planting of subsequent crops in the crop rotation,
- entry of humans and animals on the treated area,
- harvesting, harvesting, mowing, extraction from land and processing of stored agricultural products,
- use or consumption of products.

b) precautionary measures to prevent the spread of plant protection products to nearby facilities and areas, and accordingly the use of devices that reduce the spread, especially in perennial plantations (orchards, vineyards, hop gardens, etc.).

c) proximity to water sources, watercourses, wells, lakes, rivers and other groundwater and surface water, as well as human and animal water supply facilities in accordance with the law.

d) compliance with water protection zones in accordance with the regulations governing water protection, instructions, warnings, notices and markings on the declaration and instructions for use.

e) giving priority to the use of plant protection products that are not classified as dangerous for the environment in accordance with the decision on registration.

f) cleaning and washing of devices for the application of plant protection products and spillage and spillage of unspent quantities of plant protection products, near water sources, watercourses, wells, lakes, rivers and other groundwater and surface water, as well as human water supply facilities and animal.

g) unspent quantities of plant protection product solutions that can be sprayed on the treated area or disposed of as waste in accordance with the regulations governing waste.

h) flowering time of plants, in the case of plant protection products toxic to bees.

i) time and manner of application in order to protect non-target organisms and damage their habitats.

j) protected areas in accordance with the regulations governing nature protection.

Other relevant legal acts, derived from the Law on Plant Protection, include:

- Rulebook on the form and content of the request for registration of plant protection products: 86/2019-159. Available at: <http://www.pravno-informacioni-sistem.rs/SlGlasnikPortal/eli/rep/sgrs/ministarstva/pravilnik/2019/86/7/reg>
- Rulebook on documentation submitted in the procedure of recognition of registration of plant protection products on the basis of registration made in another country: 3/2020-9. Available at: <http://www.pravno-informacioni-sistem.rs/SlGlasnikPortal/eli/rep/sgrs/ministarstva/pravilnik/2020/3/6/reg>
- Rulebook on the conditions and manner of application of plant protection products, which do not endanger the life and health of humans and animals and the environment, as well as the conditions and manner of handling, storage, transport and disposal of plant protection products: 109/2021-46. Available at: <http://www.pravno-informacioni-sistem.rs/SlGlasnikPortal/eli/rep/sgrs/ministarstva/pravilnik/2021/109/1/reg>
- Rulebook on the manner of performing periodic inspection of devices for application of plant protection products and the time period in which it is performed, as well as the manner of recording the periodic inspection of devices for application of plant protection products, certificate form on functionality of application devices, marking of application devices, as well as application devices in use, for which periodic inspection is not performed: 51/2021-50. <http://www.pravno-informacioni-sistem.rs/SlGlasnikPortal/eli/rep/sgrs/ministarstva/pravilnik/2021/51/3/reg>
- Rulebook on the maximum permitted quantities of residues of plant protection products in food and feed: 132/2020-2. Available at: <http://www.pravno-informacioni-sistem.rs/SlGlasnikPortal/eli/rep/sgrs/ministarstva/pravilnik/2020/132/1/reg>

The Minister of Agriculture, Forestry and Water Management annually publishes the **List of approved substances for use in agriculture**. The List is publicly available at:

<http://www.pravno-informacioni-sistem.rs/SlGlasnikPortal/eli/rep/sgrs/ministarstva/drugiakt/2021/13/1/reg>

3. The Law on the approval of the Rotterdam Convention on the procedure for granting consent on the basis of prior notification for certain hazardous

chemicals and pesticides in international trade, as amended. ("Official Gazette of RS - International Agreements", No. 38/2009).

The aim of this Convention is to promote shared responsibility and cooperation between the Parties in the field of international trade in certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to the use of those chemicals in an environmentally sound manner. easier flow of information on their characteristics, taking care of the decision-making process at the national level on imports and exports and the transfer of these decisions to other contracting parties.

Source of information

- <https://www.pravno-informacioni-sistem.rs/>

CONCLUSIONS

The legislation regarding the use, storage, import, control and treatment of PPPs in Serbia appears to be complete and addresses all the main issues regarding the use of these substances in agriculture. The Law on Plant Protection regulates all necessary provisions and requirements which aim to define the proper, sustainable, and safe use of PPPs and is to a certain extent influenced by the relevant EU legislation.

Regarding nature protection, the relevant legislation in force prohibits any damage to the environment and animals caused by the use of PPPs. However, water and soil quality, and bees are the only components of the environment which are explicitly mentioned that require protection. The legislation is designed in a way which ensures primarily food safety and human health and does not have enough mechanisms to ensure protection of the environment in terms of biodiversity, which is an important aspect to be considered, as numerous PPPs are used to poison animals. On the other hand, the penal measures for misuse of pesticides are quite clear, detailed and focused mainly on the use, production and distribution of unauthorized and banned PPPs and active substances. This is beneficial for the struggle to prevent wildlife poisoning, as mostly banned PPPs, such as Carbofuran, are used for preparation of poison baits. However, the very frequent documentation of the use of Carbofuran in poisoning incidents that occur in Serbia every

year, frequent advertising of this and other toxic substances on the internet, on public fairs in rural areas et.al. clearly indicates that the enforcement of this legislation is very poor.

Regarding the list of illegal PPPs and other chemicals, and the use of these illegal substances, there is a complete lack of publicly available information. Similar situation is for cases of detected illegal import and disposal of illegal PPPs. Although it is clear that expired, unauthorized and banned PPPs must be destroyed, the legislation provides no clear guidelines on how and where these substances should be destroyed. This unclear aspect of the national legislation is most likely one of the causes behind stockpiling of banned and unauthorized substances which eventually appear and are sold in the black market. This component of the legislation should be more precisely defined, and complementary rulebooks and guidelines need to be developed where the responsibilities for destruction of these chemicals would be clearly stated.