

**Egyptian Vulture New LIFE
LIFE16 NAT/BG/000874**

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

Technical report

Nenad Petrovski



MES, Skopje 2020



Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

Recommended citation: Petrovski, N. 2020. Legal procedures related to use, import, storage and treatment of PPPs in North Macedonia, and Gap Analysis on the publicly available information. Technical report under action A1 of the Egyptian Vulture New LIFE project (LIFE16 NAT/BG/000874). MES, Skopje.

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

Contents

SUMMARY	5
SUBJECT AND PURPOSE OF THE REPORT	5
LIST OF THE LEGAL ACTS	7
Laws	7
Law on Plant Protection Products.....	7
Bylaws	7
Important terms:.....	7
Competent authorities.....	9
Registers.....	10
PROCEDURES.....	10
Authorization of PPP	10
Request for authorization of PPP.....	10
Assessment of the active substances.....	11
Procedures for authorization of products	11
Issuing of authorizations.....	12
Revoking of the authorization.....	12
Mutual recognition of the authorization	12
Providing information on adverse effects	13
Exchange of information.....	13
Handling of PPP.....	14
Packaging and Labeling	14
Production, sale and storage of the product.....	14
Record keeping	15
Usage.....	15
Usage of PPPs.....	15
Control	16
Competences of the Phytosanitary and Agricultural Inspectors	16
SUMMARY ANALYSIS OF THE PROCEDURES FOR USE, STORAGE AND TREATMENT OF AGRICULTURE CHEMICALS.....	17

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

CONCLUSIONS.....	18
RECOMMENDATIONS	19
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	19
OVERVIEW OF THE PUBLICALLY AVAILABLE INFORMATION	19
Gap analysis of publicly available information in respect to the	20
relation between the Plant Protection Products and risks for vultures	20
Update on the List of agricultural products and substances that are authorized for use	20
Record keeping	20
Control	20
Registries for the use of chemical protection legal substances.....	20
Quantities of the chemicals used by types	20
Statistics on the use of the types of chemical protection chemicals.....	20
List of all chemicals banned for import and use	21
Conditions and rules for controlling the import and use of illegal chemicals for chemical protection	21
Sources of information:	22

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

SUMMARY

This report is divided into two main chapters. In the first chapter you will find the legislation analysis regarding the on the use, import, transport, storage, trade, treatment and monitoring of plant protection products (PPPs). Meanwhile, in the second chapter you will find the gap analysis regarding the publicly available information on the use of agricultural chemicals within the territory of the Republic of North Macedonia.

Regarding the Macedonian legislation on the use, storage, and treatment of PPPs, it seems that we have a complete regulation on procedures such as: Control of parasites, Registration, Licensing, Trade, Transport, Storage, Quality control, Use, Disposal, and Recycling of PPPs. Furthermore, the Macedonian legislation is partially influenced by EU legislation and in accordance with International Conventions. On the other hand, we have poor law enforcement. Regarding the alleviation of the PPPs impacts on human and environmental health, there are foreseen some regulatory mechanisms in the legislation, such as disposal. In terms of biodiversity, there is no specific mechanisms that regulate the impacts of PPPs on specific species or groups, except from pollinating insects. Regarding the use of pesticides within the territory of the Republic of North Macedonia, there is very limited information available for the public. The publicly available information includes: List of legal acts regarding plant protection and plant protection products, list of PPPs which are allowed to be imported and traded in North Macedonia, but there is no list of prohibited PPPs, etc. Meanwhile, there is no available information for the public in terms of more specific information, such as quantities and geographical distribution of the legal and illegal use of agricultural chemicals within the territory North Macedonia.

The legislation does not foresee the possibility that the agricultural chemicals might be misused for the purpose of making poison baits for both domestic animals and wildlife.

Information sharing and record keeping on the amounts of PPPs that have been used in the fields is crucial element in terms of investigating the potential harmful effects on the environment and creating a sensitivity map, but the overall conclusion is that this is not adequately regulated nor enforced.

Additionally, it should be foreseen that more collaboration among national authorities is to be done for more efficient monitoring to be applied.

SUBJECT AND PURPOSE OF THE REPORT

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

The main goal of the studies under Action A1 is to identify the scale and significance of impacts of chemicals used in agriculture in the Balkan as poisoning agents to Egyptian Vulture and to propose adequate response to this impact.

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

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

This report is elaborated on a base of desk-based study of legislation and publicly available information. Targeted desk research was carried out in winter 2018 in order to obtain publicly available information about regulations of use, trade and transboundary control of plant protection products, as well as implementation of the legislation in practice. For this purpose, extended internet search was carried out of the web sites of the competent authorities.

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

LIST OF THE LEGAL ACTS

Laws

Law on Plant Protection Products

The Law on Plant Protection Products (PPP) 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:

1. 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.
2. Production of the Plant Protection Products (PPP), good laboratory practice, Rotterdam Convention for harmful substances and pesticides and their international trade, classification, packaging and labeling.
3. Leftovers and leftover packaging of used products and the condition of the products in the environment.
4. Transport of active substances and products.

Bylaws

- 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_pakovanje.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)
-

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 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, item.

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

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

very dangerous substances are 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 are active substances that have been up for sale before 26.06.1993 in the EU states.

new active substances are active substances that have been up for sale after 26.06.1993 in the EU states.

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

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

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

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

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

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

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

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

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

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

'minimum use' means the use of a plant protection product in a Member State (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' is a plant protection product.

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

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

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

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

Competent authorities

Plant protection falls within the competence of the Ministry of Agriculture, 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

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

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 on 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 give 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 ect.

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.

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 ect

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

- 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

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

- 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 authorisation granted may apply for an authorisation for the same plant protection product, the same use and under the comparable agricultural practices in another Member State under the mutual recognition procedure, provided for in this subsection, in the following cases: (a) the authorisation was granted by a Member State which belongs to the same zone; (b) the authorisation was granted by a 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.

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

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

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, authorise 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 authorise the plant protection product where: (a) an authorisation is granted by a Member State which belongs to a different zone; (b) it contains a candidate of substitution; (c) 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.

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

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 ect.)
 - 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 dat

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_pakuvanjeta.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).

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

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, soil etc.
- 6) The plants from the vicinity that are not a subject of control should not be damaged
- 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

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

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

Egyptian Vulture New LIFE LIFE16 NAT/BG/000874

see if the content matches the label, have authorization, expiry date etc.	Law on PPPs
Conduct control over the equipment with which the PPPs are being applied, handled etc.	Suggest the revoking of an authorization for use and trade if indicated that there are irregularities related to the trading of the product
Issue a ban on sale of equipment for applying PPPs if it does not possess the proper certificate	Confiscate products that are expired, are not in the original package or the users' manual is not in line with the authorization
Conduct control over the subjects that provide service relevant to the Law on PPPs	Issue a criminal offence against subjects whose work is not in line with the Law on PPP
Issue deadlines for subjects to adjust their work to be in line with the Law on PPPs	
Issue a criminal offence against subjects whose work is not in line with the Law on PPP	

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 extent 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 extent – 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

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

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 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.

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.

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

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

OVERVIEW OF THE PUBLICALLY AVAILABLE INFORMATION

The publically 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

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

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 much details i.e. on this monthly news are represented the number of the subjects inspected and what were the penalties undertaken during the month.

Gap analysis of publicly available information in respect to the relation between the Plant Protection Products and risks for vultures

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 publically available information regarding registries for the use of chemical protection legal substances.

Quantities of the chemicals used by types

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

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

List of all chemicals banned for import and use

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

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 publically 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.

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

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

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_za_proizvodi_za_zastita_na_rastenijata_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)

Egyptian Vulture New LIFE

LIFE16 NAT/BG/000874

- 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_pakovanjeto.pdf)
- Guidelines on the means of requesting an authorization parallel import (http://arhiva.mzsv.gov.mk/files/Pravilnik_za_pararelen_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)