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CURRENT STATUS OF THE LEGAL FRAMEWORK IN THE PLANT PROTECTION AND ECOLOGY AND HYGIENE MONITORING DOMAIN IN UKRAINE

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Abstract. Presently chemical plant protection products are an inseparable part of agriculture. They have not only their main purpose of plant assistance, but they also have the potential risk of negative impact on biocenosis species (birds, bees, soil microflora, algae, etc.) and the human body and its health respectively.

The purpose of our study was to aggregate data on the existing legal framework of plant protection products in Ukraine and assess their ecology and hygiene monitoring.

For analysis of the plant chemical protection, we used as the basic documents the regulatory framework of domestic legislation in toxicological and hygiene, ecology assessment, and ecology and hygiene monitoring domains.

Currently, many laws and legal acts regulate the use of pesticides by state and private agricultural farms in Ukraine. This number of documents covers not only pre-registration studies of pesticides but also their post-registration monitoring in the environment. The key entities that control potential negative risks of these products through the regulations are the State Emergency Service, Ministry of Environmental Protection, Ministry of Health, Ministry of Housing and Communal Services, Ministry of Agriculture Policy, State Agency of Water Resources, State Committee of Land Resources, State Agency of the Forest Resources. However, the impact of xenobiotics on non-target species of the ecosystem is currently quite underestimated. The decline in biodiversity directly depends on the condition of the environment and the negative impact on it. Instances of acute oral, inhalation, or dermal poisoning of birds, bees, and aquatic invertebrates with pesticides are quite common and among the factors that affect public health. That is why ecology and hygiene monitoring is essential in line with the assessment of the risks of the inappropriate release of pesticides. These should be treated as a critical component of managing environmental sustainability and safety for public health.

The implementation of global approaches to monitoring and controlling the post-registration impact of pesticides on the ecology and hygiene in Ukraine can also take into account the far-reaching consequences of their negative impact, accumulation, and environmental pollution. As a result, this will help to avoid adverse impacts on animal, insect, and bird populations, as well as human health.

Key words. Government monitoring, agriculture, pesticides, eco-system, negative impact.

Pesticides play a key role in modern agriculture, helping to increase yields and food production. However, the widespread use of plant protection products (PPP) raises concerns about their potential negative impact on the environment, ecosystems, and human health. The use of pesticides on agricultural lands can have far-reaching consequences for the environment and the population as a whole. For example, if the PPP from cultivated areas penetrates the groundwater or surface water basins they can impact aquatic ecosystems;

polluted air from cultivated areas and contaminated soil spread pesticides beyond the treated areas, affecting non-target species (birds, bees, soil microflora) and disrupting the ecological balance (the State service for food safety and consumers protection, 2024; Pathak V.M., 2022).

The purpose of the paper is to aggregate data on the existing legal framework of plant protection products in Ukraine and assess their ecology and hygiene monitoring.

Methods and materials. The analysis was based on the scientific literature and national regulatory documents in the domain of toxicology and hygiene, ecology assessment, and ecology and hygiene monitoring.

Results and discussions. The current legal framework of the plant protection domain consists of (Garmash S., 2023; the State Service for Food Safety and Consumers Protection,

2024):

- The Constitution of Ukraine
- The Law of Ukraine "On plants protection".
- The Law of Ukraine "On pesticides and agricultural chemicals",
- The Law of Ukraine "On the system of permits in the economic domain",
- The Law of Ukraine "On the Number of Permission Documents in the Economic Domain",
- The Law of Ukraine "On seeds and planting material",

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- The Law of Ukraine "On the plant variety protection",
- Law of Ukraine "On sanitary and hygiene wellbeing of the population",
- the number of legal acts on the protection and quarantine of plants,
- international agreements of Ukraine,
- The Cabinet of Ministers decrees "On approval of assessment criteria of the rate of risk from agricultural activity in the plant protection domain and determination of the frequency of planned measures of government supervision (control) by the State service for food safety and consumers protection",
 - Customs code of Ukraine and other legal acts.

The domain of ecology and hygiene monitoring has not yet had such a diverse, full-fledged, and clear regulatory framework. Most of the documents relate to pre-registration studies, risk and hazard assessment of new active substances and dosage forms.

In the ecology and hygiene monitoring domain, it is more complicated currently everything is limited to pre-registration assessment. Ukrainian research institutions, such as the Institute of Plant Protection of the National Academy of Agrarian Sciences (Ministry of Environmental Protection, 2024) and other acknowledged scientific institutions, research the pesticides' impact on the environment, on non-target organisms, obtaining valuable data for regulatory resolutions (Kovalenko Yu.L., 2020). However, they use scientific and methodological approaches that are different from European practices. For example, the Organization for Economic Cooperation and Development has elaborated guidelines and recommendations for risk assessment and mitigation of negative impact of pesticides (OECD Guidelines, 2024) together with the principles of good laboratory practice, in particular in the context of pesticide testing (GLP, 2024), which ensures the quality and integrity of preclinical laboratory tests, providing a basis for regulatory decisions. This includes methods for assessing the ecology and impact of pesticides, as well as their influence on human health, Recommendations for determining the biological effectiveness of pesticides have been developed, focusing on pest control efficiency. The recommendations also cover the calculation of pesticide content in food and the environment.

There is an extensive scientific and regulatory framework for toxicological and hygiene inspection and control of pesticides, and a functional system of sequencing the operation of organizations for research, pre-registration testing, and post-registration monitoring (the Cabinet of Ministers decree, 2024).

The state toxicological and hygiene test of pesticides is carried out by accredited research institutions (the Cabinet of Ministers decree, 2024). The State Service of Ukraine on Food Safety and Consumer Protection plays a key role in the supervision of pesticide monitoring procedures (the State Service of Ukraine on Food Safety and Consumer Protection, 2024). It carries out regular inspections and assesses compliance with safety standards for pesticide content in food.

And most important thing is that the post-registration evaluation, control, and monitoring are not considered and conducted. The tests are run only in cases of emergencies, such as massive bee envenomation, etc. But these rare incidents of course cannot give a full picture of a particular pesticide circulation in the environment or the long-term, cumulative impact on non-target species.

Presently, there is an aggregate environment monitoring system that is supposed to register all pollutants. It has its structure and its operation is regulated by a specific framework (Environment e-monitoring, 2024).

The Law of Ukraine "On Environment Protection" (Articles 20, 22) stipulates for creation of the State Environmental Monitoring System (SEMS) and the conducting of observations of the condition and pollution of the environment (Environment e-monitoring, 2024). National executive authorities are responsible for this task, in particular the Ministry of Environmental Protection and Natural Resources of Ukraine, which are the constituents of the State Environmental Monitoring System, as well as the institutions, companies, and organizations whose main activities may potentially or lead to environmental degradation, pollution and denaturation (Environment e-monitoring, 2024).

Each of the eight entities responsible for monitoring (the State Emergency Service, Ministry of Environmental Protection, Ministry of Health, Ministry of Housing and Communal Services, Ministry of Agriculture Policy, State Agency of Water Resources, State Committee of Land Resources, State Agency of the Forest Resources) monitor environment as defined by the Regulation on the State Environmental Monitoring System and the procedures and regulations on State monitoring of certain environmental components (Environment e-monitoring, 2024; Kovalenko Yu.L., 2020).

The basic regulatory documents of the State monitoring of the environment are (Environment e-monitoring, 2024; Kovalenko Yu.L., 2020):

- The Cabinet of Ministers decree as of 20.07.1996 #815 "On approval of the Procedure of State monitoring of waters":
- The Cabinet of Ministers decree as of 09.03.1999 # 343 "On approval of the Procedure of State monitoring of the air protection";
- The Cabinet of Ministers decree as of 26.02.2004 # 51 "On approval of the Statement of monitoring of the soils in agricultural land";
- The Cabinet of Ministers decree as of 20.08.1993 #661 "On approval of the Statement of monitoring of lands".

The presented system of State environment monitoring is based on the fulfillment of distributed functions by individual entities of the system that includes subordinate subsystems. Each subsystem is at the level of separate entities of the State Monitoring System that has its own scientific, methodological, structural, organizational, and technical basis (Environment e-monitoring, 2024; Kovalenko Yu.L., 2020).

It is worth mentioning that one of the deficiencies of the regulatory framework for organizing and implementing State Environmental Monitoring is the vague statement of the powers of its State System of Environment Monitoring components in the provisions on the relevant environmental objects (Environment Monitoring, 2024).

Apart from the main monitoring spheres (air, water, and soil), there are several special monitoring cases: forests, genetically modified organisms, and waste management (Environment e-monitoring, 2024; Environment Monitoring, 2024). Unfortunately, such an

important subdivision as ecology and hygiene monitoring of pesticides in the environment is lacking. It cannot be included in any of the existing groups, as the use, distribution, migration, metabolism, and impact on the ecosystem (target and non-target species) of plant protection products have several specific features.

We also should bear in mind the unique situation with pesticides: on the one hand, today it is impossible to do without them to ensure high sustainable yields sufficient to overcome famine in the world (Tkachenko, I.V., 2021; K. Chatzimichael, 2022) on the other hand, they are toxicants that can cause not only acute poisoning but also significant long-term effects (embryo and reproductive toxicity, carcinogenicity, endocrine disrupting effect, etc.) on the human body (Ibrahimova I.V., 2022; Antonenko A.M., 2019) and also a negative impact on so-called non-target organisms (birds, insects, soil worms, algae, etc.) (N.-F. Wan, 2023; A. Mitra, 2021; F.Sanchez-Bayo, 2021).

Presently to study the impact on non-target species, the so-called ecotoxicological studies are conducted, but only at the pre-registration stage. The effect on birds (quail, duck), bees, aquatic invertebrates (e.g., Daphnia magna), algae, earthworms soil microorganisms, etc. is studied for the formulation and its active ingredients. The median lethal concentrations and doses (LC50 and LD50) and half maximal effective concentrations (EC50) are measured in acute exposure studies, subthreshold, and threshold doses (NOEL and NOAEL) in subacute exposure experiments.

The accredited institutions also conduct these studies, and their results affect the possibility and status of pesticide registration. However further studies and monitoring have not been conducted. The accumulation and dynamic impact on these ecosystems are not monitored or studied, and that can have significant negative consequences, as changes in the life of these non-target species are directly related to the well-being of the human population and public health.

Many species of wild birds live in agricultural and forest areas where pesticides are often used. Birds can either inhale air contaminated with pesticides or have skin contact during and after pesticide spraying (T. Katagi, 2021). Contact with pesticide content on crops and weeds through feathers can lead to oral absorption of pesticides. Since crops, weeds, and insects are the main food for birds, the most likely route of pesticide content is oral (B. Mohanty, 2024). When pesticides are used to treat seeds, birds can be exposed to higher concentrations through ingestion of the treated seeds. In the case of the granular formulation, birds mistake the granules for seeds or swallow them instead of sand (T. Katagi, 2021; B. Mohanty, 2024). Considering these possible routes of exposure and the feeding habits of birds, the toxicological effects of pesticides should be assessed based on the impact when ingested with direct administration.

That is why ecology and hygiene monitoring of off-target pesticide exposure is a critical aspect of environment and public health management.

Discussion. Post-registration ecology and hygiene monitoring and control over the use, and accumulation of pesticides, and assessment of negative impact on environment and the human body are too scarce and poor in Ukraine in comparison with international European and United States practices. (Tkachenko, I.V., 2021; K. Chatzimichael, 2022). Besides the preregistration studies, the focus should be made on conducting experiments on the long-term effects of chemical plant protection and its impact on water basins, soils, non-target species of biocenosis, and public health. ((Postanova Kabinetu Ministriv, 2024; N.-F. Wan, 2023; A. Mitra, 2021; F. Sanchez-Bayo, 2021; T. Katagi, 2021; B. Mohanty, 2024). After all, the assessment of the negative impact of drugs only at the time of registration is imperfect, as the acute impact may be renewed in the future and unacceptable, even if there aren't long-term consequences. (K. Chatzimichael, 2022; Ibrahimova I.V., 2022).

State testing and registration of pesticides and agrochemicals are carried out to minimize the negative impact of pesticides and agrochemicals and to meet the requirements for high

biological effectiveness in terms of direct use, and safety for human health and the environment. But, when a pesticide is registered, its monitoring and assessment should not be over. It is of paramount importance to elaborate a comprehensive system of ecology classification of pesticides and agrochemicals based on global best practices and to introduce the possibility and methodology of extrapolating data from the active substance to the formulation of the pesticide.

It is also important to introduce global approaches to post-registration of ecology and hygiene monitoring and control in Ukraine to prevent the accumulation of pesticides, the long-term effects of their impact on the ecosystem, and on human health, and the possibility of timely response to changes in the conditions of animal, bird, insect populations, and the state of the water, soil and air environment.

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СУЧАСНИЙ СТАН ЗАКОНОДАВСТВА У СФЕРІ ЗАХИСТУ РОСЛИН ТА ЕКОЛОГО-ГІГІЄНІЧНОГО МОНІТОРИНГУ В УКРАЇНІ

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Резюме. Хімічні засоби захисту рослин, без яких наразі важко уявити сучасне сільське господарство, крім своєї цільової допомоги для рослинництва мають потенційний ризик негативної дії на представників біоценозу (птахів, бджіл, ґрунтової мікрофлори, водоростей тощо) і відповідно, на організм людини та її здоров'я.

Проведення узагальнення даних щодо наявного державного регулювання засобів

захисту рослин в Україні та оцінка їх еколого-гігієнічного моніторингу.

Основними документами, які були взяті для аналізу сфери хімічного захисту рослин стали нормативна база вітчизняного законодавства в галузі токсикологогігієнічної, екологічної оцінки та еколого-гігієнічного моніторингу.

SECTION 3

В Україні, на сьогоднішній день, існує безліч законів, положень, які займаються регулюванням використання пестицидних препаратів державними сільськогосподарськими і фермерськими приватними господарствами. Ця низка документальної бази охоплює не тільки передреєстраційні дослідження пестицидів, а й постресстраційний моніторинг їх в навколишньому середовищі. МНС, Міндовкілля, Мінжитлокомунгосп. Мінагрополітики, Держводгосп. Держкомзем. Держкомлісгосп – основні суб'єкти, які контролюють відповідними своїми положеннями потенційні негативні ризики препаратів. Проте, дія ксенобіотиків на нецільові види екосистеми, наразі, є досить неоціненою. Так, як зменшення біорізноманіття напряму залежить від стану довкілля та засобів впливу на нього. Випадки гострого перорального, інгаляційного чи нашкірного отруєння птахів, бджіл, безхребетних пестицидами є не поодинокими та одними із чинників від яких залежить громадське здоров'я. Тому, важливо виконувати еколого-гігієнічний моніторинг та проводити оцінку ризиків нецільового впливу пестицидів, що потрапляють у навколишнє середовище з точки зору критичного компоненту управління екологічною стійкістю та безпечністю для організму населення.

Запровадження в Україні світових підходів до моніторингу та контролю післяреєстраційного впливу пестицидів на еколого-гігієнічний стан довкілля може враховувати далекосяжні наслідки їх негативної дії, накопичення, забруднення об'єктів навколишнього середовища. В кінцевому результаті це сприятиме уникненню несприятливих наслідків для популяції тварин, комах, птахів, а також для здоров'я людини.

Ключові слова. Державний моніторинг, сільське господарство, пестициди, екосистема, негативний вплив.

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