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THE NEED TO CONDUCT ENVIRONMENTAL AND TOXICOLOGICAL STUDIES IN UKRAINE IN ACCORDANCE WITH THE PRINCIPLES OF GOOD LABORATORY PRACTICE

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INTRODUCTION

The use of pesticides is an integral part of modern technologies for growing crops. First of all, agrophytocenoses are exposed to pesticides, which creates the possibility of their entry into agricultural products. In particular, up to 70 % of toxins of various nature can enter the human body through food[1]. In addition, it is impossible to prevent the circulation of pesticides in the biosphere, so they are able to spread over large areas, which leads to the distribution of ecotoxicants. The systematic use of pesticides in agricultural technologies leads to the fact that they become a permanent factor of negative impact on the environment[2]. Pesticides of various chemical classes have a detrimental effect on biota[3]: they inhibit cellular respiration, disrupt the transport ability of cell membranes, in particular, due to the effect on the lipid component, etc.

State regulation of the circulation of chemical substances is designed to maintain a reasonable balance between the need to use plant protection products and the possible negative consequences of their use[4].

In most countries of the world (in particular, EU countries) the process of the environmental assessment of plant protection products during the registration of plants is formalized by relevant regulatory and methodological documents. For example, for pesticides, EU requirements have been issued since 1993 (93/71/EEC of 27 July 1993), the requirements of the European Committee are valid today:

[1] Prodanchuk M., Velychko M., Shamsutdinov O., Babyak M., Salahor I. Concerning the Food Safety management in Ukraine in accordance With the requirements of Biological Safety in EU. *Problems of Nutrition*. № 1 (46). 2017, P. 5–9.

[2] Walker C. H., Sibly R. M., Hopkin S. P., Peakall D. B. Principles of ecotoxicology. *CRC Press.* 2012. 386 p.

[3] Khyzhnyak S.V; Midyk SV; Polishchuk SV; Velinska AO. Effect of combined fungicide treatments on fatty acid content in *Eisenia fetida* earthworm. *Spanish Journal of Agricultural Research*. 2022. 20 (4). e03SC01. DOI: https://doi.org/10.5424/sjar/2022204-19509

[4] Проданчук М. Г., Лепьошкін І. В., Кравчук О. П., Гринько А. П. Нормативно-правове регулювання досліджень пестицидів в умовах глобалізації світової економіки: міжнародний досвід. *Український журнал сучасних проблем токсикології*. 2018. № 2–3. С. 82–83.

Consolidate text Consleg 1991L0414-01/01/2004[5].

The globalization of the pesticide registration process in the OECD member countries and the European Union, in particular, is manifested in the unification of the regulatory and methodological support of the pesticide registration system and methods for testing plant protection products[6]. Only using standard unified experimental methods for determining the physicochemical properties of pesticides, indicators of their behavior in the environment, human toxicity and ecotoxicity, reproducible and comparative data can be obtained for subsequent pesticide hazard classification and risk assessment. The most widely used in many countries for this purpose are the OECD guidelines for testing chemicals[7].

Dissatisfaction with the quality of non-clinical studies that became the basis for the assessment of the level of danger of chemicals in relation to the health of the population and the environment induced OECD member states to establish criteria for conducting similar tests. International harmonization of test methods and proper laboratory practice has become important to prevent the use of different schemes for performing similar tests. For this purpose, the document "Principles of Good Laboratory Practice (GLP)"[8] was developed for the mutual recognition of data in the evaluation of chemical substances, in particular pesticides.

1. Basic approaches to conducting tests in accordance with the principles of Good Laboratory Practice

Principles of Good Laboratory Practice (GLP) is a quality system that covers organizational measures and regulates the conditions under which experimental studies are planned, performed, corrected, recorded, presented in the form of a report and stored in the archive.

In 1981, the Organization for Economic Cooperation and Development (OECD) formulated the basic principles of good laboratory practice. GLP principles define the responsibilities of test facility managers, testing personnel, quality assurance services, as well as minimum standards for the suitability of research facilities and equipment, the need for Standard

[5] Directive 2004/10/EC of the European Parliament and of the Councilof 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.

[6] OECD Guidelines for the Study of Chemicals Organization for Economic Co-operation and Development. Electronic resource. URL: http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788

[7] OECD Guidelines for the Testing of Chemicals. Electronic resource. URL: http:// www.oecd.org/env/ehs/testing/oecdguidelinesfor-thetestingofchemicals.htm

[8] OECD Guide 1:1998 OECD Principles of Good Laboratory Practice.

Operating Procedures (SOPs), documenting raw data, writing reports, archiving records, etc.

When conducting research according to GLP rules, the main points are the following:

– development of standard testing methods or standard operating procedures (SOPs) for all its stages;

– appointment of a supervisor and person responsible for each type of testing;

– execution by the staff of the operation within the limits assigned to him;

– entry of test results into special journals, their dating;

– double checks for complex operations to avoid errors;

– reporting by the principal investigator of the test results to the manager;

– storage of actual data, records and researched samples in such a way that it is always possible to repeat the research;

– writing a report based on the results of primary data, which is accompanied by a discussion, confirmation of the content of the report with the signatures of the responsible executor and researchers;

– internal inspection of the tests by the Quality Assurance Unit (QAU) and, if necessary, providing recommendations aimed at improving the testing processes.

The OECD principles of GLP apply to tests of a chemical substance or chemical product investigated in a laboratory, greenhouse or field setting. Examples of studies conducted under GLP include:

– physical and chemical tests;

– toxicity studies;

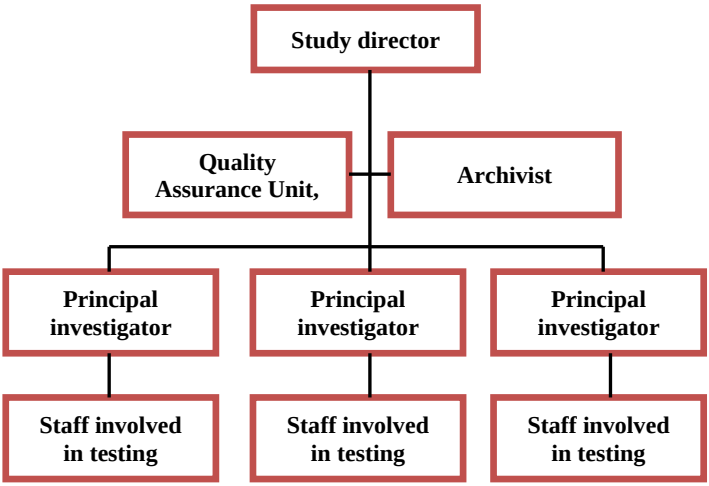
– research on ecological toxicity for aquatic and terrestrial organisms;

– research on behavior in water, soil, air and bioaccumulation;

– determination of pesticide residues in food products or animal feed.

The GLP principles are followed by testing institutions that conduct research, the results of which must be communicated to relevant decision-making bodies for the assessment of the environmental safety of chemicals and chemical products that may be of natural or biological origin.

In order to organize work in accordance with the principles of GLP, an appropriate structure of the test facility (TF), which conducts research, is needed in order to ensure and comply with the established requirements (Scheme 1).



Scheme 1. The structure of test facility that meets therequirements of Good Laboratory Practice

The *study director* bears full responsibility for the organization and conducting tests. Along with this, he is responsible for observing the principles of good laboratory practice.

The *principal investigator* is responsible for the general conduct of tests of a certain direction. In particular, this concerns the preparation of the research protocol, the conduct of the test itself and the preparation of the final report.

The *staff involved in testing* must be familiar with GLP principles and strictly follow Standard Operating Procedures (SOPs). The staff is responsible for the quality and reliability of the data, while special attention should be paid to the registration of the primary test data immediately after obtaining them.

To ensure a certain objectivity, the staff of the Quality Assurance Unit and those responsible for the archive (*archivist*) should not participate in research according to the rules of GLP. Their duties can also be transferred to third-party organizations. In addition, the procedure for replacing positions, which determines the involvement of additional personnel, must be determined. It is necessary to record personal data, such as work experience, job descriptions, and also to conduct regular training, which is confirmed by certificates. Such documentation is subject to regular updating.

The *test facility (TF)* that conducts the tests must have appropriate dimensions and location. The structure of the TF should provide an adequate degree of separation of the various activities for the proper conduct of each test. All test premises must be separated from others, have an appropriate

microclimate (temperature, humidity, lighting) and special equipment to support it.

The room for the preparation of substances should have the necessary equipment to ensure the absence of contamination and possible mixing with foreign substances.

Storage requirements for *test systems* are determined by the type of systems being used. When using animals, places for their maintenance (*vivarium*) are necessary. When using microorganisms, it is necessary to have sterile boxes for working with microorganisms.

Removal /destruction of waste. Processing and disposal of waste must be carried out in such a way as not to endanger the conduct of the tests and not to distort their results. To do this, it is necessary to provide appropriate conditions for the collection, storage and removal of waste, as well as procedures for their decontamination and further transportation.

Instruments and equipment used in testing must be regularly checked, calibrated and repaired. The room in which the equipment is installed must have a constant microclimate and lighting throughout the year. The equipment used in the test must be periodically inspected, maintained and calibrated according to standard operating procedures. Calibration, if necessary, should be performed according to national or international measurement standards. The equipment and materials used in the tests should not have a negative impact on the test systems.

Equipment used to control environmental factors must be properly located and of appropriate design and capability.

The computerized systems used must be designed and validated in accordance with the principles of good laboratory practice. The same requirements apply to their operation and maintenance. At the same time, protection against third-party access must be provided. During validation, it is necessary to adhere to the international standard, the GAM P 5 guide (Good Automated Manufacturing Practice). The head of the institution is responsible for compliance of equipment and software with GLP principles.

If additional equipment is used as part of good laboratory practice, logbooks are required to track the use of the equipment and verify its functionality. In addition, there must be an appropriate operating manual, as well as documentation on maintenance and repair.

Reagents. When performing work it is important that all reagents are properly labeled, including the expiration date and the date the package was opened. Along with this, standard safety instructions and danger symbols must be applied. In the case of the expiration date, the reagent must be disposed of. An extension of the shelf life is possible after the analysis, which is also subject to accurate documentation.

Biological test objects, in order to ensure the quality of the data, must be stored, placed and properly cared for under appropriate conditions. Freshly obtained animal or plant test objects should be isolated before their condition is assessed. In the event of any illness or death, this lot should not be used in testing and should be destroyed. At the time of the start of the tests, the test objects must be in a state that cannot affect the results.

Representatives of aquatic, soil and terrestrial biota are used as test objects in toxicological studies[9]. For example, microalgae, which include representatives of cyanobacteria (*Anabaena flos-aquae* Brébisson ex Bornet & Flauhault, *Synechococcus leopoliensis* (Raciborski) Komárek), diatom algae (*Skeletonema costatum* (Greville) Cleve, *Navicula pelliculosa* (Kützing) Hilse). However, the most common test objects are representatives of green algae belonging to the families Scenedesmaceae (*Scenedesmus quadricauda* (Turpin) Brébisson, *Scenedesmus (Desmodesmus) subspicatus* Chodat), Selenastraceae (*Selenastrum capricornutum* Printz *Pseudokirchneriella subcapitata* (Korshikov) F.Hindák) and Chlorellaceae (*Chlorella vulgaris* Beyerinck).

In toxicological studies, it is recommended to use the following fish species as test objects: *Brachydanio rerio* (Teleostei, Cyprinidae) (Hamilton-Buchanan) Danio rerio; *Pimephales promelas* (Teleostei, Cyprinidae) (Rafinesque) Bullhead minnow; *Cyprinus carpio* (Teleostei, Cyprinidac) (Linnaeus) Carp; *Oryzias latipes* (Teleostei, Cyprinodontidae) (Temminck and Schlegel) Japanese honeydew; *Poecilia reticulata* (Teleostei, Pocciliidae) (Peters) Guppy; *Oncorhynchus mykiss* (Teleostei, Salmonidae) (Walbaum) Rainbow trout.

As test objects are used monocot (for example, rye *Secale cereal* L., wheat *Triticum aestivum* L., barley *Hordeum vulgare* L., oats *Avena sativa* L.) or dicots (for example, white mustard *Sinapis alba*, radish *Raphanus sativus* L.), lettuce *Lactuca sativa* L.) plant species.

Biological test objects used in tests must be certified. Records must be kept of the source of their supply, the date of receipt and the condition at the time of receipt. Before starting the tests, the biological test systems must be acclimatized to the conditions of the research environment for an appropriate period of time. All information necessary for the correct identification of the test system must be located at the place of its maintenance.

The *archive* for saving all primary data, documentation, test reports, and the final report is located in a specially equipped room. Special requirements are imposed on the archive, which is manifested, for example, in strict protection of data from third-party access. Only personnel authorized by the

[9] Хижняк С. В., Баранов Ю. С., Демченко В. Ф., Войціцький В. М. Пестициди та їх еколого-токсикологічна оцінка : монографія. Київ : ЦК «Компринт». 2019. 226 с.

head of the institution should have access to the archive. If necessary, any person can enter the archive, but only accompanied by the appropriate employee. This strict rule is designed to exclude any manipulation of documentation. Data stored in electronic form should not be destroyed without the permission of the laboratory management and appropriate documentation. Other data, such as source code and validation, operation, maintenance and monitoring records, should be kept for at least the same period as the research records.

Standard Operating Procedures (SOPs). The testing laboratory must have written SOPs approved by the laboratory's management, which are designed to ensure the quality and reliability of the data obtained by the testing laboratory in the course of conducting research. All GLP work is performed in accordance with SOPs, which must be available at each workplace. Changes to standard operating procedures must be approved by management TL.

The list of types of SOPs, which must be displayed:

1) test substances and comparison samples/control samples: obtaining, identification, labeling, processing, sampling and storage;

2) equipment, materials and reagents (equipment: use, maintenance, cleaning and calibration; computerized systems: validation, operation, maintenance, safety, change control; materials, reagents and solutions: preparation and labeling);

3) registration, preparation of reports, preservation: coding of studies, data collection, preparation of reports, indexing systems, data processing, including the use of computerized systems;

4) test systems (if necessary):

a) preparation of premises and conditions for storage of test systems;

b) procedures for receiving, transferring, properly placing, storing, describing, identifying and processing the test system;

c) preparation of the test system, observation and analysis before, during and at the end of the study;

d) placement of test systems at test sites;

5) quality assurance procedures: personnel must plan, schedule, conduct, document, and report on the inspection.

Therefore, Good Laboratory Practice (GLP) has been implemented to ensure the reliability of experimental results, as well as their recognition worldwide. The main task is to ensure the possibility of tracing and reproducing the course of tests, as well as the distribution of areas of responsibility and storage of documentation. The principles of GLP determine the structure of the general rules that ensure the conduct of research, but do not dictate how and by what methods it should be conducted.

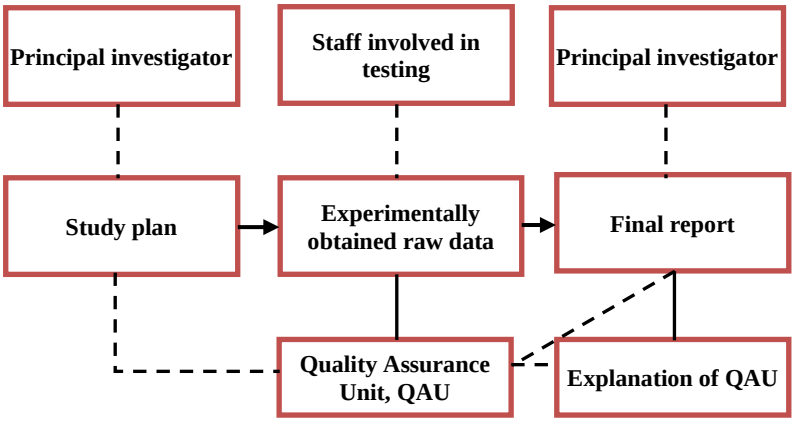
2. Organization of work according of principles of Good Laboratory Practice

When preparing for tests, according to the rules of good laboratory practice, the *study director* (*principal investigator*) must be appointed, who then draws up a test plan. The plan for conducting experimental tests must be submitted before the start of work and approved by the signature of the head of the institution, the quality control service and the customer. Only after that it is allowed to start work.

The course of testing according to the principles of Good Laboratory Practice (Scheme 2).

The *study plan* contains a chronological description of the procedure for conducting tests, as well as the methods and frequency of their conduct. After approval of the test plan, this information is mandatory and subject to change only in extreme cases. Any change is made in the form of an addition to the test plan. At the same time, they distinguish:

– amendments to the plan, which are required in the presence of additions, changes, updates or corrections of information;



Scheme 2. The course of tests according to the principles of Good Laboratory Practice

– deviations from the plan, which are required in unforeseen cases, in the presence of malfunctions or the human factor.

Research within the framework of GLP is conducted on the basis of a test plan and documented in the established manner. The documentation must be done in such a way that the documentation can always be accurately and completely correlated with the relevant test. In addition, all data must have a

date and cannot be changed later. In this way, data tracking is ensured during the entire study and after its completion. Along with this, inspections by the quality control department, which monitors compliance with the principles of GLP, are possible.

The *study plan* should contain the following information:

1) identification of tests, test substance and comparative / control sample;

2) a description of the research design (including a chronological description of test procedures, all methods, materials and conditions, the type and frequency of analyses, measurements, and observations to be conducted);

3) information about the purpose and tasks of the tests;

4) identification of the investigated substance according to IUPAC (International Union of Theoretical and Applied Chemistry)[10], etc.;

5) the investigated substance (description, nature of origin and characteristics);

6) information about the developer and the test facility;

7) the date of approval of the test program with the signature of the Head of institution, the study director and the developer. Proposed study initiation date and study completion date;

8) a detailed description of the test methods is provided (references to the used methodological recommendations of the OECD[11] or other guidelines and methods), the names of the test systems used, with the justification of their choice (characteristics of the test system, with an indication of the species, strain, substrain, source of receipt, quantity, weight fluctuation limits, gender, age and other necessary information), methods of statistical processing, other documents related to conducting research. Ecological and toxicological tests of pesticides are based on biotesting methods using appropriate reactions of test systems of organisms. Moreover, a set of test organisms and biotesting methods are used, which are recognized by the international society (OECD) and standardized in ISO[12,] which allows to evaluate the effect of pesticides on terrestrial, aquatic and soil biota organisms;

9) detailed information on the structure of the tests, including a description of the chronology, all methods, materials and conditions, the type and frequency of performed analyses, measurements, observations and studies;

10) data registration and storage. Quality control of test results.

A particularly important stage of GLP is the reliable processing of primary research data, as any data manipulation affects the process of issuing a permit. Therefore, GLP regulates not only the requirements for personnel, premises

[10] Globally Harmonized System of Classification and Labelling of Chemicals (GHS):eighth revised edition. UNITED NATIONS, N-Y and Geneva, 2019. 564 p.

[11] Standards-OECD. URL: https://www.oecd-ilibrary.org

[12] Standards-ISO. URL: https://www.iso.org/ standards.html

and special equipment, but also the sphere of responsibility during and after the tests. Several signatures must be placed under the permit documentation, and to obtain a permit it is extremely important to submit the entire set of documentation.

Conducting tests according to the principles of good laboratory practice should be carried out as follows

1. Each test must be assigned a unique number. All used samples, equipment and materials must be documented in the research materials for the purpose of their traceability. The test must be carried out according to the program. Samples of test substances and comparison samples/control samples should be marked in an appropriate manner that ensures their identification.

2. All data obtained during the research must be registered, signed or certified and dated.

3. All amendments and changes made to the protocol /program must be recorded with the reasons and justification, dated and signed.

4. Data collected by computer input must be identified at the time of data input by the person. The computerized system must ensure the preservation of all control logs with all data changes, without hiding the original data. Keeping records only in electronic form is allowed in the presence of validated computerized systems.

Issuance of test results

For each test, a final report is prepared, which must be signed and dated by the manager (responsible executor), this indicates acceptance of responsibility for the reliability of the data. The report is then approved by the quality control department, which completes it with an explanation and the results of its inspection. The degree of compliance of the data with GLP principles should be indicated. The final report must be sealed with the seal of the organization.

General requirements for drawing up a report

1. Identification of the test, test substance and comparative /control sample.
2. Detailed description of the trial design.
3. Identification of the investigated substance according to IUPAC etc.
4. Identification of the comparative sample /control sample.
5. Characterization of properties of the substance under investigation, including purity, stability and homogeneity.
6. Information about the developer and test facility (surnames, addresses, etc.).
7. Experimental dates of the beginning and end of the test and its stages.
8. Purpose and tasks
9. Description of materials and methods

10. Brief review of test results.

11. Providing results, including calculations and quantitative determination of statistical significance, summarizing tables (graphs) with appropriate statistical processing and comments to them.

12. Evaluation and discussion of results and conclusions.

13. The place of storage of the protocol /program, samples of the investigated substance and comparative samples / control samples, initial data of the final report.

Data registration and storage

Documents related to the test must be kept in the archive for a period of time established by the relevant authorities: Protocol/program of the test, initial data, samples of the test substance and comparative/control samples, final report; documents on all conducted inspections and audits; documents regarding qualifications, training, experience and job descriptions of personnel; documents and reports regarding the use and calibration of equipment; regarding the validation of computerized systems; regarding environmental control.

Data stored in archives must be identified. This makes it easier to organize, store and retrieve information. Access to the archives must be given to personnel authorized by management. The movement of data from and to the archive should be carefully recorded.

Quality control of tests

One of the requirements of the GLP standard is the effectiveness of measures that guarantee the quality of tests in institutions in accordance with GLP criteria. The implementation of the quality assurance program enables the management of the performing institution, customers, and representatives of government bodies to make sure that the research is carried out in accordance with the principles of GLP. The purpose of the work of the quality assurance and control service is to ensure the successful conduct of tests, which involves the supervision of compliance with SOPs and basic GLP standards.

Quality Assurance Unit, QAU (the head of the institution is responsible for the recruitment and management of the service) is created as a monitoring body for the test stages, the task of which is to reduce the number of potential errors to a minimum, to ensure the rapid detection of inadequate indicators and incorrect experimental conditions in the research process.

Employees who are not involved in the test, but who are familiar with the specifics of the work and all test procedures, standards and systems used in the test laboratory or in its interests, are involved in the work of the department.

The personnel of the quality department must undergo appropriate training and have the experience necessary to perform their duties. Training of quality department personnel should be documented and their competence assessed. These documents must be constantly updated and saved.

The staff of the quality department is responsible for checking the test protocols for compliance with the GLP principles, checking the stages of the study, their compliance with the test protocol and SOPs, reviewing the final reports to confirm the compliance of the submitted results with the original data and the accurate description of the test methods.

The conclusion of the quality department must be signed and included in the final report, which indicates the types of inspections and their time. Management's responsibilities include carrying out procedures that ensure that the conclusion issued by the quality department is consistent with the manager's statement of compliance with these rules and corresponds to the issued final test report. It is necessary that the conclusion contains the full name of the test, dates and stages of the relevant types of control.

Criteria for accreditation of a test facility according to GLP principles

1. The organization, which includes a test facility, must have state registration and the right to conduct experimental research.
2. The test facility must be accredited to carry out the declared research methods.
3. The test facility must be staffed with the necessary number of employees who have the necessary education, training and experience to perform their functional duties.
4. Employees of the testing laboratory should not be influenced by persons interested in the results of research. Employees should not be influenced by persons who have an interest in the results of the study.
5. The test facility must be provided with appropriate equipment in sufficient quantity, healthy laboratory animals, which are necessary in research.
6. It is necessary to maintain an appropriate microclimate, which makes it impossible to influence the reliability and quality of the obtained results.
7. It is necessary to organize regular monitoring of tests and fulfillment of all accreditation conditions.

3. Implementation of Good Laboratory Practice in Ukraine

Ukraine's progress towards integration into the EU to a certain extent depends on the introduction of a system of technical regulation of product access to the market in accordance with International and European Standards.

Pesticide expertise is regulated by a number of legislative and regulatory documents: Laws of Ukraine "On Ensuring Sanitary and Epidemic Welfare of

the Population" and "On Pesticides and Agrochemicals"; Resolutions of the Cabinet of Ministers of Ukraine "On approval of the procedure for conducting state tests, state registration and re-registration, publishing a list of pesticides and agrochemicals permitted for use in Ukraine", "Permissible levels of pesticides in agricultural raw materials, food products, working area air, atmospheric air, water, soil"; State Sanitary Standards "Transportation, storage and use of pesticides in the national economy"; "List of pesticides and agrochemicals allowed for use in Ukraine".

The system of principles of Good Laboratory Practice (GLP) is aimed at ensuring the quality and reliability of the results obtained during research. The principles of GLP are an administrative concept that covers the organizational process and conditions under which laboratory tests are planned, performed, recorded and stored, and provide a report on test results.

Ukraine is gradually harmonizing national legislation with international and European rules and requirements, which, in particular, is facilitated by the signed Association Agreement between Ukraine and the EU[13].

In accordance with the Association Agreement of Ukraine with the EU to ensure the implementation of paragraphs 67–68 "Plan of measures regarding the registration of plant protection products and fertilizers" within the framework of the Comprehensive implementation strategy of Chapter IV ("Sanitary and phytosanitary measures"), approved by the Order of the Cabinet of Ministers of Ukraine dated 24.02.2016 No. 228-r.[14], the need arose for experimental and normative-methodical regulation of ecological and toxicological assessment of pesticides in Ukraine. In particular, when assessing the ecotoxicity of pesticides, it required the introduction of methods recognized by the international community (OECD)[15] and standardized by ISO/IEC[16], improvement of existing and development of new modern methods, in particular, for the the ecological and toxicological assessment of pesticide mixtures according to their impact on biota[17, 18], for the

[13] МЗС України. Угода про асоціацію між Україною та ЄС. Електронний ресурс. URL: http://mfa.gov.ua/ua/about-ukraine/european-integration/ua-eu-association

[14] Про схвалення Всеохоплюючої стратегії імплементації Глава IV (Санітарні та фітосанітарні заходи) Розділу IV «Торгівля і питання, пов'язані з торгівлею» Угоди про асоціацію між Україною та Європейським Союзом. Затверджено розпорядженням Кабінету Міністрів України від 24.02.2016 р. № 228-р. URL: https://zakon.rada.gov.ua/laws/show/228-2016-%D1%80#Text

[15] Standards-ISO. URL: https://www.iso.org/ standards.html

[16] Standards-OECD. URL: https://www.oecd-ilibrary.org

[17] Хижняк С. В. Методичні рекомендації щодо еколого-токсикологічної оцінки пестицидів та агрохімікатів: методичні рекомендації. Київ :ТОВ «ПРІНТЕКО», 2018. 32 с.

[18] Хижняк С. В., Незбрицька І. М., Самкова О. П., Ушкалов В. О. Методичні рекомендації щодо еколого-токсикологічної оцінки сумішей пестицидів за їх впливом на біоту: методичні рекомендації. Київ :ТОВ «ПРІНТЕКО», 2020. 32 с.

determination of residual trace amounts of pesticides in animal and plant products, environmental objects.

A research institution authorized to test plant protection products in Ukraine must be guided by Directive 2004/10/EC of the Parliament and the Council of Europe on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and verification of their implementation in the testing of chemical substances.

At the National university of life and environmental sciences of Ukraine, the Ukrainian Laboratory of Quality and Safety of Agricultural Products was established, which is accredited by the National Accreditation Agency of Ukraine in accordance with the requirements of DSTU EN ISO/IE C 17025:2019. The laboratory conducts tests to determine the residual amount of pesticides in environmental objects, food products and feed, as well as studies of products of the agro-industrial complex according to quality and safety indicators, carries out ecological and toxicological tests and laboratory support for the production of plant and animal products (more than 800 types of tests in accordance with national and international standards).

The implementation of GLP principles into the work of the Ukrainian Laboratory of Quality and Safety of Agricultural Products promotes environmental and toxicological testing in Ukraine, the results of which will be recognized by the world community. It also contributes to the elimination of risks to human health and the environment from pollutants, in particular pesticides.

CONCLUSIONS

Good Laboratory Practice (GLP) is a quality system that covers organizational measures and regulates the conditions under which experimental studies are planned, performed, corrected, recorded, presented in the form of a report and kept in the archive. The principles of GLP determine the structure of the general rules that ensure the conduct of researches, but do not dictate how and by what methods it should be conducted. The implementation of international standards and rules, in particular GLP, when conducting ecological and toxicological tests in Ukraine contributes to obtaining reproducible and comparative data, which are necessary for the classification of the dangers of pesticides and their risk assessment.

SUMMARY

Long-term use of pesticides on large areas has led to large-scale environmental pollution. The migration of toxic substances in ecological

systems and food chains leads to the accumulation of residual amounts of pesticides in natural objects and their entry into food products. Obtaining reproducible and comparable data to establish the danger of pesticides is possible only under the conditions of implementation of the principles of Good Laboratory Practice (GLP) – a quality system that covers organizational measures and regulates the conditions under which experimental studies are planned, performed, corrected, registered, presented in the form of a report and stored in the archive. Ukraine is moving towards the harmonization of national legislation with international and European rules and requirements, which is particularly facilitated by the signed Association Agreement between Ukraine and the EU. Therefore, there is a general need to introduce a system of principles of Good Laboratory Practice (GLP) into the work of research centers that are authorized to test plant protection products in Ukraine, which is aimed at ensuring the quality and reliability of the obtained results, which are necessary for the classification of pesticide hazards and their risk assessment.

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