Ewa MATYJASZCZYK • Sławomir ZAPŁATA

THE QUALITY SYSTEM OF GOOD EXPERIMENTAL PRACTICE (GEP) AND ITS ROLE IN ENVIRONMENTAL SAFETY

Ewa MATYJASZCZYK (ORCID: 0000-0001-9848-8902) – Bydgoszcz University of Science and Technology
Sławomir ZAPŁATA (ORCID: 0000-0001-6134-9765) – Poznań University of Economics and Business

Correspondence address:
prof. S. Kaliskiego Avenue 7, 85-796 Bydgoszcz, Poland
e-mail: ewa.matyjaszczyk@pbs.edu.pl

ABSTRACT: Good Experimental Practice (GEP) is a quality system that has been used in the European Union since the 1990s to ensure the reliability of field experiments on pesticides used in crop production, also known as plant protection products. The field trials for efficacy evaluation of plant protection products in the European Union must be carried out by GEP-recognised units in order that the results are considered by governmental authorities in the Member States. The evaluation of the trial results and subsequent registration are obligatory in order that plant protection products are placed on the market. The paper presents a brief history of GEP system implementation, as well as an overview of its requirements. The focus of the paper is on the role of GEP system in proper recommendations for the use of plant protection products, which further translates into ensuring environmental safety in the European Union.

KEYWORDS: pesticides, efficacy, plant protection, quality system, environmental safety, GEP, Good Experimental Practice, sustainable agriculture, European Union regulations

Introduction

The use of agrochemicals in plant production has long been a source of legitimate concerns (Carson, 1962; Vieira et al., 2024; Zhang et al., 2024). The area used for agricultural production in the 29 EU Member Countries exceeds 150 million hectares (Eurostat, 2024). Hence, commercial products used in agriculture may be applied on quite significant acreages. Once introduced to the environment, they influence not only the target organisms like crop plants, weeds or harmful insects but also potentially any other organisms, including e.g. soil organisms, pollinators and human beings. The concerns are particularly strong in case of agricultural pesticides or plant protection products (PPP), which by definition are toxic, as they are applied to control agricultural pests (Matyjaszczyk, 2024).

The safety concerns regarding the use of PPP have been addressed by extensive legal regulations in many countries around the world. In the European Union (EU) the common requirements regarding PPP have been in place for over 30 years (Directive, 1991; Matyjaszczyk, 2017). The common EU law on plant protection stresses the priority of environmental safety over improving the level of agricultural production.

The paper focuses on the quality system of Good Experimental Practice (GEP) that has been implemented in the EU as a means of ensuring that field studies focused on plant protection products' efficacy are reliable and may be used in decision-making process by EU registration authorities. Abbreviated history of GEP system implementation, as well as the overview of its requirements, are presented here. The main goal of the paper to explain the role of GEP system in formulating proper recommendations for the use of PPP, which further translates into ensuring environmental safety in the European Union. Another goal of the paper is to highlight and place more emphasis on the efforts of government bodies to ensure the safe use of PPP.

Implementation of GEP system in the EU

PPP, before their registration, undergo many studies to make clear their impact on human health, the ecosystem and efficacy of their application (Feldmann et al., 2023; Marchand, 2023). Some of those studies are performed in laboratory conditions while others are carried out in the field (Jankowska et al., 2024; Piepho et al., 2024). The study results are presented to the governmental authorities for evaluation.

For efficacy and selectivity evaluation, the field experiments are required to make clear that PPP is suitable for the intended use. However, the field studies may need to be carried out across diverse countries, in many crops and under varied climatic, pest and agricultural conditions. Hence, to demonstrate the effectiveness of a PPP, the involvement of numerous testing facilities may be needed. The idea behind setting rules for GEP certification was to ensure high-quality and standardised testing of PPP in development. Consequently, regardless of the testing unit, the trial results have to be of comparable quality and can be used by registration authorities across the EU.

The legal basis for the development of the GEP system in the EU was Directive 91/414 (Directive, 1991), which also presented the basic rules of the system (see next chapter). The Member States were obliged to introduce those requirements into their own legal systems within two years of Directive notification. The Directive 91/414 was published in August 1991. Considering that the Member Countries needed time not only to prepare necessary administrative provisions but also to give time to implement those rules on their territory, it may be considered that among the Member Countries the Directive was implemented in the mid-nineties of 20th century. The new EU Member Countries, which became EU members at the beginning of the 21st century implemented the GEP system at different pace, quite often before EU accession.

For example, Estonia, Latvia, Lithuania, as well as Poland introduced the GEP system on their territory bottom-up, before joining the EU on 1 May 2004 (Matyjaszczyk, 2011; Ordinance, 2002). According to Matyjaszczyk (2004), in 2002, in Poland 15 units received GEP recognition, which translated into the fact that the results of trials for registration purposes carried out by them were accepted in all EU Member Countries.

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The requirements of the GEP system

The GEP system is focused on the management of field trials regarding PPP efficacy and the conditions under which such trials must be planned, recorded, conducted, evaluated and interpreted in order that their results are reliable and comparable. Initially, the basic rules of GEP system were listed as an Annexe to the Directive 91/414. In parallel, an international standard was developed by the European and Mediterranean Plant Protection Organisation. EPPO Standard PP 1/181. Conduct and reporting of efficacy evaluation trials, including good experimental practice, was published in 1992, setting technical rules for the GEP system. Currently, this standard is still basis for GEP system, although in the meantime it has been revised several times. The Directive 91/414 was replaced by Regulation 1107/2009 (Regulation, 2009).

After the GEP system implementation, the EU Member Countries were obliged to appoint the body responsible for supervising the system and all GEP units on their territory. The basic rules of GEP system as regards the units carrying out the efficacy trials are presented in Table 1. For more details, please see EPPO Standard PP 1/181.

Table 1. Requirements of Good Experimental Practice (GEP)

NNo	Scope	GEP Requirements as regards the units carrying out efficacy trials
11	Staff	The unit should have sufficient scientific and technical staff with the necessary education, technical knowledge and experience to perform the assigned function.
22	Equipment	The unit should have the appropriate equipment required to properly perform those tests and measurements for which it claims competence. Equipment should be maintained in proper condition and calibrated (if it requires regular calibration) before and after use, according to a standard operating procedure.
33	Experimental areas	The unit should have suitable experimental fields and, if necessary, greenhouses, growth chambers or storage facilities. The environment in which the experiments are conducted should not bias the results or adversely affect the accuracy of the measurements.
44	Standard operating procedures	Should clearly describe the areas relevant to the quality of results and be made available to all responsible personnel.
55	Study protocols	Should exist and be made available to all responsible personnel.
66	Quality of the work	The unit should ensure that the quality of the work carried out corresponds to its type, scope and intended use.
77	Storage of records	The unit shall keep the original records and test reports as long as the product is authorised for marketing and use in the European Union, providing data protection.
88	Provision of information on experiments	On request of the inspection body, the unit shall, before the start of the experiments, make available detailed information about the experiments including at least a description of the location of the experiments and the plant protection products tested at that location.
99	Methodological requirements of the trials	The level of testing must at least comply with EPPO standards.
110	Supervision	The unit should report to the surveillance body all details necessary to demonstrate compliance with the GEP requirements. The unit should accept at any time inspections by the controlling body to check compliance with the requirements. Inspections should be organised on a regular basis

Source: authors' work based on Directive (1991), Directive (1993), Regulation (2009) and European and Medditerranean Plant Protection Organization (2021).

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How GEP system contributes to the environmental safety?

Environmental safety and quality management methods have long been linked together (Matuszak-Flejszman et al., 2013; Kafel et al., 2024). The GEP system contributes to environmental safety in several ways:

1) GEP is focused on efficacy and selectivity assessment, and as such, by a suitable study design it prevents products that are ineffective from positive evaluation and from entering the market. This translates into the fact that only useful PPP can be used in agriculture. In consequence, GEP contributes to the elimination of the use of redundant agrochemicals.
2) GEP is focused on demonstrating a suitable dosage of PPP for each use. When needed, a range of doses may be given to be used, e.g. in different growth stages of the plant or depending on climatic conditions. Adequate dose rate means the dosage is sufficiently effective but not too high or too low. Too high a dose would mean using an excessive amount of agrochemicals, which would put unnecessary pressure on the environment. Too low a dose may mean insufficient efficacy and hence failure of a treatment. Treatment failure also has a negative effect on the environment, as it means the use of agrochemicals as well as other means to carry out the treatment (equipment, fuel, labour) without obtaining the intended effect. One of the most important tools for avoiding pest resistance is to use an adequate dosage of PPP.
   Following the requirements of the GEP system, the studies on doses are, by default, introduced in the study design.
3) Focus on unwanted side effects. Following the rules of GEP if efficacy trials show unwanted side effects, a special trial may need to be performed. The side effects in question that may need more detailed studies are: phytotoxicity, effects on succeeding crops and cases of resistance against PPP.
4) One of the requirements of GEP system is careful observation of organisms that are not the target of PPP application, including pollinators. Any influence on non-target organisms should by default, be recorded and subsequently presented in the trial reports. GEP system ensures that any results and observations relevant to environmental safety are recorded.
   Apart from the main environmental benefits of the GEP system, further advantages may be mentioned as well.
5) GEP recognises the development of computer technology. It also recognises the need for an electronic version of notes and documents. In this way, it helps to reduce the consumption of resources and the cost of storage of trial records, which is beneficial for the environment.
6) GEP helps to eliminate national practices in the area of performing and reporting PPP trials if those practices are not in line with the EPPO standards. Hence, it prevents redundant effort, contributes to improved communication, saving time and resources.
7) GEP system improves communication between GEP units and regulatory authorities (in both directions) that is essential for saving time and authority workload.

Conclusions

European agriculture plays an important role in global food security, but at the same time makes an impact on the environment (Łącka et al., 2024; Gallardo, 2024). It is important to limit this impact as far as possible.

The GEP quality system is focused on units carrying out PPP efficacy trials. The GEP addresses various aspects presented in Table 1, such as: staff qualification, equipment and facilities, standard operating procedures, study protocols and recording of results. The system is not focused on environmental safety, but on the efficacy of plant protection products efficacy. In spite of it, GEP influences agricultural productivity and plays a positive role in ensuring environmental safety in several ways described above.

The most important challenge for the GEP system at the moment is including digital technologies in efficacy studies, as there have been significant recent advances in this area (Zamani-Noor & Feistkorn, 2022). It is important to clarify how digital technologies can further improve compliance and

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record-keeping within GEP, as well as how they can be validated and accepted by regulators in the future.

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The contribution of the authors

Conceptualization, E.M..; literature review, E.M and S.Z.; formal analysis, E.M. and S.Z; writing, E.M and S.Z.; conclusions and discussion, E.M., and S.Z.

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Ewa MATYJASZCZYK • Sławomir ZAPŁATA

SYSTEM ZARZĄDZANIA JAKOŚCIĄ DOBREJ PRAKTYKI EKSPERYMENTALNEJ (GEP) I JEGO ROLA W ZAPEWNIANIU BEZPIECZENSTWA SRODOWISKA

STRESZCZENIE: Dobra Praktyka Eksperymentalna (GEP) to system zarządzania jakością stosowany w Unii Europejskiej od lat 90-tych XX wieku w celu zapewnienia wiarygodności badań skuteczności pestycydów stosowanych w produkcji roślinnej, znanych również jako środki ochrony roślin. Badania oceny skuteczności środków ochrony roślin w Unii Europejskiej muszą zgodnie z prawem być przeprowadzane na polach doświadczalnych przez jednostki posiadające certyfikat GEP aby ich wyniki mogły być uznane przez organy rządowe w państwach członkowskich. Ocena środków ochrony roślin przez państwa członkowskie i rejestracja są obowiązkowe, przed wprowadzeniem do obrotu handlowego. W artykule przedstawiono skróconą historię wdrażania systemu GEP, a także przegląd jego wymagań. Skupiono się na roli systemu GEP dla formułowania zaleceń stosowania środków ochrony roślin, które mają znaczenie dla bezpieczeństwa środowiska w Unii Europejskiej.

SŁOWA KLUCZOWE: pestycydy, skuteczność, ochrona roślin, system jakości, bezpieczeństwo środowiska, Dobra Praktyka Eksperymentalna, GEP, zrównoważone rolnictwo, rozporządzenia Unii Europejskiej