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Legal Instruments to Protect the Environment from the Effects of Excessive Chemistry in Agriculture on the Example of Plant Protection Products Regulation

Prawne instrumenty ochrony środowiska przed skutkami nadmiernej chemizacji w rolnictwie na przykładzie regulacji środków ochrony roślin

SUMMARY

Chemical plant protection products used in agricultural production have an impact on human health and life, but also undeniably on the state of individual elements of the environment, including biodiversity. Pollinating insects are representative of the animal world particularly sensitive to modern environmental threats generated by agriculture. The purpose of the article is to analyze and evaluate the legal regulation relating to plant protection products, made in terms of preventing excessive chemisation in agriculture, and consequently ensuring food safety. The subject of the study are the legal conditions for the admission and use of substances that ensure simultaneous benefits for plant production, in the absence of harmful effects on human and animal health and unacceptable effects on the environment. Particular attention has been paid to the authorization, on special terms, of preparations containing neonicotinoids.

Keywords: food safety; precautionary principle; pollinating insects; pesticides; neonicotinoids

INTRODUCTION

As the world's population increases, the intensification and industrialization of agriculture, in order to meet the growing demand for food, creates both opportunities for increasing production and multiple challenges for food security. In the second decade of the 21st century, progressive climate change (including extreme weather

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phenomena, rising temperatures, falling rainfall and water availability) are another factor affecting both food security and food safety.

The World Health Organization (WHO), based on research conducted in 2007–2015, regarding the global burden of food-borne illness[1] stated that Europe is the continent on which food security is best maintained. We owe this to the system of control over the food production and sales chain created in the European Union. Similarly, in the Special Report published in February 2019, the European Court of Auditors[2] drew attention to the problem of pesticide residues in food, which affects not only food safety, but above all on the level of public health protection and ecological safety.

It should be emphasized that the assessment of this safety, in accordance with Article 3 (14) of Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[3], as well as the provision of Article 3 (3) (5) of the Act of 25 August 2006 on Food and Nutrition Safety[4], is carried out through the criterion of protection of human health and life. From this point of view, when assessing all aspects of the food production chain, from primary production to the sale or delivery of food to the consumer, the potential impact on human safety is examined.

The priority of the food safety model, in accordance with Article 3 (14) of Regulation 178/2002 is to combat all three types of food hazards: physical (e.g. processing impurities), biological (e.g. parasites, viruses, bacteria, fungi) and chemical (additives, fertilizers, some metals and pesticides). In accordance with the definition of the term "food safety" adopted in Polish legislation (Article 3 (3) (5) AFNS) the conditions must be met regarding, i.a., additives and flavors used, levels of pollutants or pesticide residues. It should also be noted that the set of EU legal regulations contains regulations on approximately 8,000 chemical substances, including over 1,300 pesticides[5].

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[1] *WHO Estimates of the Global Burden of Foodborne Diseases, Foodborne Disease Burden Epidemiology Reference Group 2007–2015*, World Health Organization 2015, pp. 34–35.

[2] Europejski Trybunał Obrachunkowy, *Sprawozdanie specjalne nr 02/2019: Zagrożenia chemiczne w żywności – unijna polityka bezpieczeństwa żywności zapewnia ochronę konsumentom, lecz stoją przed nią wyzwania*, www.eca.europa.eu/pl/Pages/DocItem.aspx?did=48864 [access: 10.03.2020], hereinafter: ETO Special Report 2019.

[3] OJ EU L 31, 1.02.2002, pp. 1–24, hereinafter: Regulation 178/2002.

[4] Consolidated text Journal of Laws 2019, item 1252, hereinafter: AFNS. For more on this topic, see K. Leśkiewicz, *Bezpieczeństwo żywnościowe i bezpieczeństwo żywności – aspekty prawne*, „Przegląd Prawa Rolnego" 2012, z. 1, p. 179 ff.

[5] ETO Special Report 2019, p. 12 and Annex I, containing a list of chemicals regulated by EU legislation on food and feed.

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The purpose of the article is to analyze and evaluate the legal regulation relating to plant protection products, made in terms of preventing excessive chemisation in agriculture, and consequently ensuring food safety. The subject of the study are the legal conditions for the admission and use of substances that ensure simultaneous benefits for plant production, in the absence of harmful effects on human and animal health and unacceptable effects on the environment. Particular attention has been paid to the authorization, on special terms, of preparations containing neonicotinoids.

THE PRECAUTIONARY PRINCIPLE AND THE PRINCIPLE OF PREVENTION AND THE AUTHORIZATION OF PLANT PROTECTION PRODUCTS ON THE MARKET

As indicated in the natural sciences[6] plant protection products, commonly known as pesticides, constitute a group of preparations used in agriculture, horticulture, forestry and veterinary medicine. The name "pesticide", according to the Latin origin of the word (*pestis* 'pestilence', *occido* 'kill'), means a substance that aims to kill living organisms considered harmful[7]. It is a type of chemical compounds, both natural (from plants) and synthetic, which are used to destroy plant and animal parasites. Toxicity of pesticides results from the presence of biologically active ingredients that may adversely affect the biocenosis of the environment, hence the use of pesticides is associated with environmental and health risks[8]. Chemicals used in the production of pesticides, as biologically active ingredients, are toxic to specific groups of organisms (insecticides, acaricides, bactericides and others) and, therefore, it is important to ensure their selective impact[9].

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[6] R. Nowak, M. Włodarczyk-Makuła, E. Mamzer, *Ryzyko środowiskowe i zdrowotne wynikające ze stosowania środków ochrony roślin*, „Zeszyty Naukowe Wyższej Szkoły Zarządzania Ochroną Pracy w Katowicach" 2015, z. 1(11), pp. 51–63.

[7] A. Kłys, *Słownik polsko-łaciński, łacińsko-polski*, Czernica 2013.

[8] Z. Makles, W. Domański, *Ślady pestycydów – niebezpieczne dla człowieka i środowiska*, „Bezpieczeństwo Pracy" 2008, nr 1, pp. 5–9; A. Zyska, M. Konodyba-Szymańska, *Wpływ środków ochrony roślin na środowisko i organizm człowieka. Materiały konferencji „Bezpieczeństwo i ochrona zdrowia przy stosowaniu substancji chemicznych w pracy"*, Częstochowa 2014.

[9] R. Nowak, M. Włodarczyk-Makuła, E. Mamzer, *op. cit.*, p. 52.

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Analysis and assessment of environmental and health risk is a basic factor in the introduction of pesticide preparations for widespread use. In 2018, 1,325 pesticides were on the list of chemicals regulated by EU food and nutrition legislation, of which 492 as authorized and 833 as prohibited active substances[10].

There are four main elements in pesticide risk assessment: risk identification, dose relationship assessment, exposure scale, and overall risk characterization[11]. The results of scientific studies must be considered when assessing the acceptability of the product on the market and use.

The need to consider the risk to human health and life and the environment related to the placing of pesticides on the market and use rests on the European Union's decision-making bodies, and then on the EU Member States transposing and implementing European law into national systems. The EU legislator must take into account the complex environmental protection principles arising from the Treaty on European Union[12] and the Treaty on the Functioning of the European Union[13], among others the principle of sustainable development and ensuring a high level of environmental protection (Article 3 (3) TEU), the principle of integration of environmental protection requirements into EU policies and activities (Article 11 TFEU), the principle of prevention or the precautionary principle (Article 191 TFEU).

With regard to plant protection products, the principle of prevention (preventive action) indicates the need to prevent negative effects on the environment[14]. The principle of prevention is based on an objective assessment of whether an activity has a negative impact on the environment, which should, however, be supported by an analysis of the activity in question using the expertise in the field[15].

A further principle is the precautionary principle, as set out in Article 191 (2) TFEU. As emphasized by P. Korzeniowski, the precautionary principle raises the requirements bar against the precautionary principle much higher, because the term "foresight" includes a greater degree of precaution than provided for in the principle of prevention[16].

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[10] See Annex I to the ECA Special Report 2019, containing a list of chemicals regulated by EU legislation on food and feed.

[11] P. Struciński, K. Góralczyk, K. Czaja, A. Hernik, W. Korcz, J.K. Ludwicki, *Ocena ryzyka związana z narażeniem na pozostałości pestycydów w żywności pochodzenia roślinnego na etapie rejestracji środka ochrony roślin*, „Roczniki Państwowego Zakładu Higieny" 2006, t. 57(4), pp. 303–315.

[12] Consolidated version of the Treaty on European Union of 2016 (OJ EU 2016 C 202, p. 13), hereinafter: TEU.

[13] Consolidated version of the Treaty on the Functioning of the European Union of 2016 (OJ EU 2016 C 202, p. 47), hereinafter: TFEU.

[14] More on the principle of prevention, see M. Górski, *Zasada prewencji w prawie ochrony środowiska*, „Studia Prawno-Ekonomiczne" 1995, nr 52, p. 87.

[15] B. Wierzbowski, B. Rakoczy, *Prawo ochrony środowiska. Zagadnienia podstawowe*, Warszawa 2018, p. 112.

[16] P. Korzeniowski, *Zasady prawne ochrony środowiska*, Łódź 2010, p. 400.

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The precaution applies to all activities whose negative impact on the environment is not yet fully recognized. As indicated by M.M. Kenig-Witkowska, the lack of scientific evidence as to the possibility of a phenomenon or process occurring is not a reason for not taking action to avoid potentially serious and irreversible damage to the environment[17]. Precaution requires that appropriate action be taken in advance when there is a reasonable probability that an ecological problem will need to be solved, and not only when practice or science confirms its existence[18]. This obliges the Union bodies to strive to introduce the most effective actions corresponding to the current level of scientific and technical knowledge. This means that the new legal regulations should lead to an increase in the level of protection in force in the Member States, not to a reduction in it.

Referring to the precautionary principle should always be supported by scientific risk assessment and limited to situations where there is a possibility of irreversible changes, when urgent and provisional action must be taken[19].

The precautionary principle is a principle of the Union's environmental policy[20]. In addition, as A. Jurcewicz points out[21] EU institutions should take it into account in the context of the Common Agricultural Policy when taking measures to protect public health.

This thesis is confirmed by the jurisprudence of the EU Court of Justice and the EU Court (former Court of First Instance). In the jurisprudence of these courts, we often find a reference to the precautionary principle in matters related to food safety. The EU General Court in its judgements of 2003 in case T-392/02 *Solvay Pharmaceuticals BV v. Council of the EU*[22] and of 2007 in case T-229/04 *Kingdom of Sweden v. EU Commission*[23], examining the allegations regarding the introduction in Community provisions of provisions preventing the use in agriculture of

[17] M.M. Kenig-Witkowska, *Prawo środowiska Unii Europejskiej. Zagadnienia systemowe*, Warszawa 2011, p. 86. According to the position of the European Commission of 2000 in the interpretation of the precautionary principle, even the possibility of interpretation that allows shifting the burden of proof of harmlessness to environmental impact is shifted to entities taking up activities (producers, importers) that may threaten the environment. See European Commission, Communication from the Commission on the precautionary principle, Brussels, 2 February 2000, COM 2000/1 final, p. 4. Similarly T. O'Riordan, T.J. Andrew, *The Precautionary Principle in Contemporary Environmental Politics*, "Environmental Values" 1995/4, No. 3, pp. 195–198.

[18] G. Grabowska, *Europejskie prawo ochrony środowiska*, Warszawa 2001, p. 200.

[19] M.M. Kenig-Witkowska, *op. cit.*, p. 92 and the literature cited therein.

[20] *Ibidem*, p. 86.

[21] A. Jurcewicz, *Traktatowe podstawy unijnego prawa rolnego w świetle orzecznictwa. Zagadnienia wybrane*, Warszawa 2012, p. 76.

[22] Judgement of the EU Court of 21 October 2003, T-392/02, *Solvay Pharmaceuticals BV v. EU Council*, ECR 2003, p. II-04555.

[23] Judgement of the EU Court of 11 July 2007, T-229/04, *Kingdom of Sweden v. EU Commission*, ECR 2007, p. II-02437.

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substances that could adversely affect human health, food safety and the environment, he referred to the precautionary principle in order to avoid even a potential threat to health and people or the environment. According to its content, in cases of reasonable suspicion of probable threats, public authorities should take preventive action, even though there is no clear scientific evidence in this respect. However, this does not mean, as the EU Court pointed out in its judgement of 2002 in case T-13/99 *Pfizer Animal Health v. Council of the EU*[24] and in the aforementioned judgement in the case of the *Kingdom of Sweden v. EU Commission*, the obligation of the Community institutions to assume zero tolerance, to take into account purely theoretical threats, based on unsupported hypotheses.

In the above-mentioned judgement in the case of the *Kingdom of Sweden v. EU Commission*, the EU General Court further stressed that the choice of legal solution applied by the Community authorities must be subject to the rule, and the protection of health, safety and the environment is to prevail over economic interests. Such a position of the Court speaks for recognition and interpretation of the extension of the integration principle when it is necessary for the effective implementation of the intended environmental objectives, and the principle set out in Article 11 TFEU and specified in Article 191 TFEU, gives grounds for the obligation to protect the value of the environment, despite obvious economic losses caused by non-approval of the plant protection product.

Otherwise, the Court of Justice in its judgement of 2010 in case C-77/09 *Gowan Comércio Internacional e Serviços Lda v. Ministero della Salute*[25] examined the legality of the provisions of Commission Directive 2006/134/EC[26], in which the use of the active substance in a plant protection product (fenarimol) has been temporarily restricted as a precautionary measure. The manufacturer of the indicated product containing a prohibited substance questioned the lawfulness of applying the precautionary principle as a basis for adopting a Commission Directive. The Court ruled that since there is some scientific uncertainty about the assessment of the endocrine effects of substances such as fenarimol, the Commission's decision to restrict the use of these substances cannot be considered as grossly erroneous application of the precautionary principle. Given the numerous scientific studies that have been invoked to prove the annulment of the Commission's decision, the conclusion maintaining the decision by the Court's judgement seems to suggest a wide application of the precautionary principle[27].

[24] Judgement of the EU Court of 11 September 2002, T-13/99, *Pfizer Animal Health v. EU Council*, ECR 2002, p. II-3305.

[25] Judgement of the Court of Justice of the European Union of 22 December 2010, C-77/09, *Gowan Comércio Internacional e Serviços Lda v. Ministero della Salute*, ECR 2010, p. I-13555.

[26] Commission Directive 2006/134/EC of 11 December 2006 amending Council Directive 91/414/EEC to include fenarimol as active substance (OJ EU L 349, 12.12.2006, p. 32).

[27] D. Langlet, S. Mahmoundi, *EU Environmental Law and Policy*, Oxford 2016, p. 53.

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The precautionary principle applies in the EU approach to food safety, where it is primarily a risk management tool. Where there are reasonable grounds for concern and there is scientific uncertainty, this principle may be invoked in the risk management process[28]. It refers to a situation in which: 1) there are reasonable grounds for fearing that an unacceptably high level of health risk has occurred; 2) available information and supporting data are not sufficiently complete to enable a comprehensive risk assessment to be carried out.

In such special circumstances, as emphasized by the European Court of Auditors in 2019[29], decision-makers or risk managers can apply measures or take other actions based on the precautionary principle while seeking more complete scientific data. Such actions must comply with the principles of non-discrimination and proportionality and should be temporary until more comprehensive information on risk is collected and analyzed.

THREATS FROM PLANT PROTECTION PRODUCTS FOR POLLINATING INSECTS

Agriculture is one of the major sources of threat to the environment, directly through soil, groundwater and indirectly through surface water and marine pollution[30]. The literature on the subject lists many factors related to agricultural activity that cause the degradation of natural values and at the same time cause the impoverishment of biological diversity[31]. Among the greatest threats are the intensification of technologies used in agriculture, including excessive chemisation (the use of mineral fertilizers, pesticides), the degradation of so-called buffer zones (copper, mid-field forestation). These factors, inherent in the intensification of agriculture, caused the destruction of many biocoenoses and vegetation refuges

[28] Motive 21 and Article 7 of Regulation 178/2002.

[29] ETO Special Report 2019, pp. 21–23.

[30] For more on this topic, see J. Igras, M. Pastuszak, [in:] *Udział polskiego rolnictwa w emisji związków azotu i fosforu do Bałtyku*, red. J. Igras, M. Pastuszak, Puławy 2009, p. 13; M.A. Król, *Gospodarowanie zasobami wodnymi na obszarach wiejskich a prawna ochrona Morza Bałtyckiego przed eutrofizacją*, [in:] *Współczesne problemy prawa rolnego i cywilnego. Księga jubileuszowa Profesor Teresy Kurowskiej*, red. D. Łobos-Kotowska, P. Gała, M. Stańko, Warszawa 2018, p. 213 ff.

[31] B. Poskrobko, T. Poskrobko, K. Skiba, *Ochrona biosfery*, Warszawa 2007, p. 178. The most frequently mentioned are: fragmentation of rural areas, drainage meliorations, reduction of water retention, monoculture, soil and water pollution due to excessive chemisation of agriculture, introduction of biogeographically alien species and genetically modified plant varieties, as well as the disappearance of breeding traditional animal breeds.

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and contributed to the deepening of problems resulting from the sharp decline in the diversity of pollinating insects[32].

Pollinating insects, which include bees, Hymenoptera, butterflies, flies, beetles and many more, are particularly sensitive to the progressive degradation of the environment[33]. Alarming is, in particular, the example of bees, whose progressive decline in numbers, referred to as so-called Colony Collapse Disorder[34], which in effect led to the listing of these insects on the European Red List of endangered species by the International Union for Conservation of Nature (IUCN)[35]. The result of the massive disappearance of honeybee families are huge economic losses in the production of oilseeds, fruits and vegetables, as well as a threat to beekeeping[36].

Pesticides are one of the main factors affecting the weakening of health and the disappearance of pollinating insects[37]. When examining the impact of "pesticides" on the environment, the interaction of up to several hundred active substances of plant protection products and carriers, stabilizers and auxiliary substances present in these preparations is primarily considered. Plant protection products, depending on what they are supposed to fight, are divided among others for insecticides (insecticides), fungicides (fungicides) and herbicides (herbicides)[38].

Insecticides include neonicotinoids used in agriculture on a large scale for about 20 years[39]. Unfortunately, many studies show their adverse effect not only on the

[32] L.G. Carvalheiro, J.Ch. Biesmeijer, G. Benadi [et al.], *The potential for indirect effects between co-flowering plants via shared pollinators depends on resource abundance, accessibility and relatedness*, "Ecology Letters" 2014, Vol. 17(11), DOI: https://doi.org/10.1111/ele.12342, p. 1397.

[33] M. Zych, *Pszczoła miodna a różnorodność biologiczna dzikich zapylaczy i roślin entomofilnych*, „Wieś i Doradztwo" 2018, z. 1, p. 7.

[34] K. Buczek, *Zespół masowego ginięcia pszczoły miodnej (CCD)*, „Annales UMCS sectio DD" 2009, nr 1, pp. 1–4.

[35] *IUCN Red List of Threatened Species*, www.iucn.org/resources/conservation-tools/iucn-red-list-threatened-species [access: 20.07.2019].

[36] K. Buczek, *op. cit.*, p. 1; K. Różański, *Prawne formy wsparcia działalności pszczelarskiej w świetle rozporządzenia 1308/2013 ustanawiającego wspólną organizację rynków produktów rolnych*, „Studia Iuridica Lublinensia" 2017, nr 1, DOI: http://dx.doi.org/10.17951/sil.2017.26.1.445, p. 445 and 447.

[37] M. Zych, B. Denisow, A. Gajda, T. Kiljanek, P. Kramarz, H. Szentgyörgyi, *Narodowa strategia owadów zapylających*, Warszawa 2018 (maj), p. 39 and the literature cited therein.

[38] *Ibidem*; *EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)*, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2013.3295 [access: 10.03.2020].

[39] In Poland, over 2,000 plant protection products are approved. See Ministerstwo Rolnictwa i Rozwoju Wsi, Wyszukiwarka środków ochrony roślin, www.gov.pl/web/rolnictwo/wyszukiwarka-srodkow-ochrony-roslin [access: 8.12.2019]. Compared to 2005, the number of authorized plant protection products doubled (see GUS, *Rocznik Statystyczny. Rolnictwo i obszary wiejskie*, Warszawa 2007). The total mass of plant protection products sold in Poland in 2015 amounted to over 67,000 tons, of which 24 thousand tons was the mass of active substances (GUS, *Rocznik Statystyczny. Rolnictwo*, Warszawa 2016).

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central nervous system of pests, but also bees and other pollinating insects[40], but there is scientific evidence for the impact of these measures on animal and human health[41].

NEONICOTINOIDS IN THE LEGAL REGULATION OF PLANT PROTECTION PRODUCTS IN THE EUROPEAN UNION

In relation to the instruments of the Common Agricultural Policy, a broader interpretation of the precautionary principle is justified by legislation regarding the authorization and placing on the market of plant protection products. Already in the 1990s in the provisions of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[42] it was pointed out that the achievement of the goal of improving plant production should not be at the expense of protecting human health and the environment. For this reason, the procedural provisions authorizing the marketing measures were to provide a high level of protection, and in particular had to prevent the introduction of substances posing a risk to human health and the environment.

As a consequence, the implementation of these regulations into national legal systems has contributed to the unification of regulations, however, the form of the directive, despite the undeniable consolidation function, has also left an active role for the EU Member States. This role became apparent through the transfer of many competences to committees consisting of representatives of individual countries and the possibility of derogations due to regional differences. This thesis can be confirmed by the provision of Article 6 of Directive 91/414/EEC, pursuant to which the Standing Committee on Plant Health[43] decision-making was entrusted in many issues crucial for a given regulation, including on the admission of a specific chemical substance and the removal of a substance from the list of authorized substances if, in the light of the current state of knowledge, it no longer meets the safety requirements for human, animal and environmental health[44].

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[40] S.G. Potts, S.P.M. Roberts, R. Dean [et al.], *Declines of Managed Honey Bees and Beekeepers in Europe*, "Journal of Agricultural Research" 2010, No. 49, pp. 20–22.

[41] Studies show the harmfulness of nicotinoids for birds, aquatic invertebrates and even – through research done on rats – for humans. See M. Grotowska, K. Janda, K. Jakubczyk, *Wpływ pestycydów na zdrowie człowieka*, „Pomeranian Journal Life Sciences" 2018, t. 64(2), pp. 42–50 and the literature cited therein.

[42] OJ EU L 230, 19.08.1991, p. 1, hereinafter: Directive 91/414/EEC.

[43] Permanent Committee on Plant Health established by Council Decision EEC 894/76 (OJ L 340, 9.12.1978, p. 25).

[44] For more on this topic, see M.A. Król, *Przejawy europeizacji w prawie rolnym*, „Studia Iuridica Agraria" 2009, t. 7, pp. 78–79.

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The use of plant protection products is regulated in the Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009[45]. In order to ensure a high level of protection of human and animal health and the environment, while maintaining the competitiveness of Community agriculture, measures have been introduced to apply and trade in chemical substances that are included in plant protection products. The criterion for allowing the substance is to ensure simultaneous benefits for plant production and no harmful effect on human and animal health and unacceptable influence on the environment. The list of permitted substances is included in Annex III to the Regulation 1107/2009.

However, pursuant to Article 21 (1) of Regulation 1107/2009, the Commission may at any time evaluate an approved active substance in the light of new scientific and technical knowledge and monitoring data. If, as a result of obtaining new information, there appears that a substance no longer meets the admissibility criteria, the European Commission basing on Article 21 (4) of Regulation 1107/2009 may issue implementing rules to withdraw or amend the approval of the indicated substance[46].

On this basis, in 2013 the Commission seriously restricted the use of three pesticides from the group of neonicotinoids (clothianidin, imidacloprid and thiamethoxam) approved as active substances in plant protection products. The European Commission, in accordance with one of the basic principles of EU environmental law, which is the principle of prevention and the precautionary principle, decided to act in this matter, making her decisions dependent on the results of the verification of scientific reports. Commission Implementing Regulation (EU) No. 485/2013[47] introduces in Article 2 a ban on placing on the market of seeds grown with the mentioned substances, except for seeds used in greenhouses. At the same time, Member States were required to submit "confirmatory information" regarding the risk assessment of these substances (including for bees) in situations that substances were still permitted. The European Food Safety Authority (EFSA), which has been conducting studies on the effects of substances contained in plant protection products used in field crops for several years, has confirmed the high risk of using several authorized substances for bee welfare, and research has also indicated that neonicotinoids leak out to soil and water, and from

[45] Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ EU L 309, 24.11.2009, p. 1), hereinafter: Regulation 1107/2009.

[46] Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011 implementing Regulation (EC) No. 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ EU L 153, 11.06.2011, p. 1).

[47] Commission Implementing Regulation (EU) No. 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No. 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances (OJ EU L 139/12, 25.05.2013).

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there to other plants[48]. In EFSA report, issued on behalf of the European Commission in February 2018[49], confirmed that the previous activities are insufficient.

On 27 April 2018, at the level of the EU Council a decision to prohibit the use in field crops was taken with the restriction of certain neonicotinoids (imidacloprid, clothianidin and thiamethoxam) in the greenhouse cultures throughout the EU. Poland was in the group of countries that abstained from voting[50]. On this basis, the European Commission issued three implementing regulations on 29 May 2019: Regulation No. 2018/783 regarding the conditions for the approval of the active substance imidacloprid[51], Regulation No. 2018/784 as regards the conditions for the approval of the active substance clothianidin[52], Regulation No. 2018/785 with regard to the conditions of approval of the active substance thiamethoxam[53]. Pursuant to the Regulation 1107/2009, Member States were required to amend or withdraw existing authorizations for plant protection products containing the designated substances as active substance by 19 September 2018 at the latest and the use of stocks of these substances by the end of 2018.

More restrictive than the EU ban orders were introduced by Austria and Germany and partly the Netherlands. France is also an example of a country that has banned the use of neonicotinoids. In accordance with Article 125 of the French Act of 2016 on the Reconstruction of Biodiversity, Nature and Landscapes[54], the

[48] *Peer review of the pesticide risk assessment for the active substance imidacloprid in light of confirmatory data submitted*, "EFSA Journal" 2016, Vol. 14(11), DOI: https://doi.org/10.2903/j.efsa.2016.4607, p. 4607; *Peer review of the pesticide risk assessment for the active substance sulfoxaflor in light of confirmatory data submitted*, "EFSA Journal" 2019, Vol. 17(3), DOI: https://doi.org/10.2903/j.efsa.2019.5633, p. 5633.

[49] *Peer review of the pesticide risk assessment for bees for the active substance imidacloprid considering the uses as seed treatments and granules*, "EFSA Journal" 2018, Vol. 16(2), DOI: https://doi.org/10.2903/j.efsa.2018.5178, p. 5178.

[50] The ban was supported by Austria, Cyprus, Estonia, France, Greece, Spain, the Netherlands, Ireland, Luxembourg, Malta, Germany, Portugal, Slovenia, Sweden, the United Kingdom, Italy (countries representing 74% of the EU population). The Czech Republic, Denmark, Romania and Hungary were opposed to the ban. Apart from Poland, Belgium, Bulgaria, Croatia, Finland, Lithuania, Latvia and Slovakia abstained from voting.

[51] Commission Implementing Regulation (EU) 2018/783 of 29 May 2018 amending Implementing Regulation (EU) No. 540/2011 as regards the conditions of approval of the active substance imidacloprid (OJ UE L 132, 30.05.2018, p. 31).

[52] Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No. 540/2011 as regards the conditions of approval of the active substance clothianidin (OJ UE L 132, 30.05.2018, p. 35).

[53] Commission Implementing Regulation (EU) 2018/785 of 29 May 2018 amending Implementing Regulation (EU) No. 540/2011 as regards the conditions of approval of the active substance thiamethoxam (OJ UE L 132, 30.05.2018, p. 40).

[54] Loi n° 2016–1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages, JORF n°0184 du 9 août 2016, texte n° 2, www.legifrance.gouv.fr/eli/loi/2016/8/8/2016-1087/jo/texte [access: 10.04.2020].

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use of seed products and mortars containing one or more active substances of the neonicotinoid family is prohibited from 1 September 2018. Derogations may be granted until 1 July 2020 pursuant to a regulation issued jointly by the ministers responsible for agriculture, environment and health. The above regulation may be issued on the basis of an assessment prepared by the National Agency for Food Safety, Environment and Labour, after assessing the benefits and risks of using plant protection products containing active substances from the family of neonicotinoids authorized in France, with substances related to the use of substitutes or available alternative methods (so-called "comparative assessment"). Impact on the environment, including pollinating insects, public health and agricultural activities was indicated as the primary assessment criteria[55].

NEONICOTINOIDS IN LEGAL INSTRUMENTS OF PLANT PROTECTION PRODUCTS IN POLAND

The rules for the prevention of environmental pollution through the use of plant protection products are governed by two legal acts in Poland: the Act of 18 December 2003 on Plant Protection[56] and the Act of 8 March 2013 on Plant Protection Products[57]. They are:

1) rules related to placing plant protection products on the market,
2) the principle of considering first the agrotechnical, physical, mechanical or biological protection methods or integrated plant protection, that minimize the use of chemicals,
3) the obligation to strictly apply the recommendations of the use of measures to prevent contamination of the environment,
4) establishment of a number of control instruments, which were provided by the State Inspectorate for Plant Protection and Seed Production, i.a. land entry, sampling, plant and protection measures, document control[58]. The Agricultural and Food Quality Inspection bodies supervise the marketing of fertilizers and plant health aids, and under this supervision they have

[55] The Act introduced the discussed changes to Article L-153-8 of the French Agricultural and Sea Fisheries Code, consolidated version of 22 November 2019, www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006071367 [access; 20.03.2020].

[56] Consolidated text Journal of Laws 2019, item 972 as amended.

[57] Consolidated text Journal of Laws 2019, item 1900.

[58] For more on this topic, see M.A. Król, *Ochrona biosfery przed nadmierną chemizacją w rolnictwie*, [in:] *Prawo ochrony środowiska*, red. M. Górski, Warszawa 2014, pp. 632–634; M.A. Król, A. Niewiadomski, *Rodzinne gospodarstwa rolne w systemie prawnym ochrony środowiska i zrównoważonego rozwoju*, [in:] *Ekonomiczne i prawne mechanizmy wspierania i ochrony rolnictwa rodzinnego*, red. M. Podstawka, Warszawa 2015, pp. 243–244.

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the right to enter the land, make an inventory of these resources, carry out compliance inspections, access to facilities where these resources are stored, for free of charge sampling for testing.

Basic rules for the safe use of plant protection products for bees have also been introduced (e.g. compliance with the bee prevention period), not using not recommended and untested mixtures of plant protection products, because the mixture may have a different effect on bees than a single product[59], non-use of pesticides on flowering weeds and slips attracting bees and pollinators. Pursuant to Article 73 (2) of the Act on Plant Protection Products, the competent authority collects information on poisoning bees with plant protection products.

In accordance with the provisions of the Commission Implementing Regulation (EU) No. 485/2013, in Poland the ban on the use of neonicotinoid seed dressing has been in force since 2013.

However, the provision of Article 53 (1) of Regulation 1107/2009 creates extraordinary situations in plant protection, giving the possibility of temporary derogation from the established rules in special circumstances. A Member State may authorize, for a period not exceeding 120 days, the placing of plant protection products on the market, for the purpose of limited and controlled use, where such action proves necessary because of a risk which cannot be prevented by other reasonable measures. As an exception to the established rule, it should be, in my opinion, used in extraordinary circumstances, after fulfilling the condition of earlier application of funds admitted to trading in the EU, their ineffectiveness and clearly endangered socio-economic interests, the breakdown of crop production. The Member State concerned is required to inform the other Member States and the Commission of the action taken, providing detailed information on the situation and any measures taken to ensure consumer safety.

In Poland twice, both in 2018[60] and 2019[61] using the exception from Article 53 (1) of Regulation 1107/2009 and pursuant to Article 7 (1) of the Act on Plant Protection Products, the Minister of Agriculture and Rural Development has allowed temporarily – for a period of up to 120 days – the placing on the market of plant protection products: Modesto 480 FS and Cruiser OSR 322 FS, used for seed mortars, based on i.a. one active substance from the group of neonicotinoids

[59] The classification of plant protection products and their mixtures in terms of their physical and chemical hazards, toxicity and ecotoxicity are regulated in Poland by the provisions of the Act of 25 February 2011 on Chemical Substances and Their Mixtures (consolidated text Journal of Laws 2019, item 1225).

[60] Ministerstwo Rolnictwa i Rozwoju Wsi, *Czasowe zezwolenie na zastosowanie zapraw nasiennych z grupy neonikotynoidów*, 10.07.2018, www.gov.pl/web/rolnictwo/czasowe-zezwolenie-na-zastosowanie-zapraw-nasiennych-z-grupy-neonikotynoidow [access: 8.12.2019].

[61] Ministry of Agriculture and Rural Development permission of 15 May 2019.

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containing clothianidin and thiamethoxam, which in April 2018 were banned by the European Commission.

In 2019, Modesto 480 FS mortar was granted a permit for the period from 20 May to 17 September 2019, and Cruiser OSR 322 FS mortar obtained a temporary permit for the period from 1 June to 28 September 2019, both in the cultivation of winter colza. It should also be stressed that the 120-day permit covers a sufficient period. This means using the exception of an emergency twice and allowing two prohibited neonicotinoids from 2013 in field crops in the EU.

Consent to the use of mortars by Polish producers of rape is therefore not an isolated case. On 21 June 2010, EFSA published a study commissioned by the European Commission to assess the legitimacy of issuing by seven EU countries (Bulgaria, Estonia, Finland, Lithuania, Latvia, Romania, Hungary) temporary emergency permits for mortars from the neonicotinoid group.

For example, the Bulgarian[62] report identified information that is not in line with the EFSA methodology proposed in the EFSA insecticide protocol developed under Article 4 (7) of Regulation 1107/2009. Therefore, EFSA could not assess whether the granting of emergency permits was scientifically substantiated and whether it was necessary because of a danger which could not be stopped by other reasonable measures.

In Romania[63], control of six extraordinary permits granted, pursuant to Article 53 of Regulation 1107/2009, showed, in the absence of alternative measures, justified use of neonicotinoid containing agents in three cases, while in the other three urgent authorization was not justified. A similar situation was found for two permits granted in Lithuania[64] and nine in Hungary[65].

In Estonia[66] two extraordinary authorizations were granted, none of which were justified because there were alternative insecticides for the uses described, a wide range of non-insecticidal methods was available, mainly methods of cultural

[62] *Evaluation of the emergency authorisations granted by Member State Bulgaria for plant protection products containing clothianidin, imidacloprid or thiamethoxam*, "EFSA Supporting Publication" 2018, Vol. 15(6), DOI: https://doi.org/10.2903/sp.efsa.2018.EN-1417.

[63] *Evaluation of the emergency authorisations granted by Member State Romania for plant protection products containing clothianidin, imidacloprid or thiamethoxam*, "EFSA Supporting Publication" 2018, Vol. 15(6), DOI: https://doi.org/10.2903/sp.efsa.2018.EN-1416.

[64] *Evaluation of the emergency authorisations granted by Member State Lithuania for plant protection products containing clothianidin, imidacloprid or thiamethoxam*, "EFSA Supporting Publication" 2018, Vol. 15(6), DOI: https://doi.org/10.2903/sp.efsa.2018.EN-1421.

[65] *Evaluation of the emergency authorisations granted by Member State Hungary for plant protection products containing clothianidin, imidacloprid or thiamethoxam*, "EFSA Supporting Publication" 2018, Vol. 15(6), DOI: https://doi.org/10.2903/sp.efsa.2018.EN-1422.

[66] *Evaluation of the emergency authorisations granted by Member State Estonia for plant protection products containing clothianidin, imidacloprid or thiamethoxam*, "EFSA Supporting Publication" 2018, Vol. 15(6), DOI: https://doi.org/10.2903/sp.efsa.2018.EN-1418.

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control, which are often less effective than insecticidal methods or have certain technical restrictions.

Finland has granted two permits in the absence of alternative insecticides. In the EFSA assessment[67], three insecticidal culture control methods were available, but Finland considered them ineffective or moderately effective (depending on the weather when the plant or crop was changed) and no information was available on their specific use. Finland stated that there was no practical, acceptable, established program effective in combating the identified threat. Similarly in the case of two permits granted in Latvia[68] the lack of sufficient alternative modes of action permitted in this country was found, although some non-insecticidal methods are available here, but not as effective as chemical methods.

The analysis of the discussed cases shows that provided for in Article 53 (1) of Regulation 1107/2009, the exception, giving the possibility of a temporary derogation from the established rules in plant protection in emergencies, has become a common form for evading the ban on the use of neonicotinoids in the Member States, and most in cases where there were other alternative methods of combating threats.

CONCLUSIONS

The use of chemical compounds in pest management has already taken place in antiquity, and the first chemicals to protect plants began to be produced in the 19th century. Modern, effective agriculture is not possible today without the use of soil enriching substances with nutrients and agents protecting plants from harmful organisms. High efficiency in regulating growth and other biological processes in arable crops must be achieved while maintaining safety for human health and life and environmental protection.

Modern agricultural activity, especially the multiplication of agricultural chemisation, causes numerous threats to biodiversity. Particular attention has been paid in recent years to pesticides due to the presence of residues of these substances in food, as well as disclosed scientific results confirming their negative impact on human and animal health, including pollinating insects.

The legislator's role is to create the conditions for the marketing and use of substances that ensure simultaneous benefits for plant production, in the absence

[67] *Evaluation of the emergency authorisations granted by Member State Finland for plant protection products containing clothianidin or thiamethoxam*, "EFSA Supporting Publication" 2018, Vol. 15(6), DOI: https://doi.org/10.2903/sp.efsa.2018.EN-1419.

[68] *Evaluation of the emergency authorisations granted by Member State Latvia for plant protection products containing clothianidin or thiamethoxam*, "EFSA Supporting Publication" 2018, Vol. 15(6), DOI: https://doi.org/10.2903/sp.efsa.2018.EN-1420.

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of harmful effects on human and animal health and unacceptable effects on the environment. In this respect, in the European Union, the basic criterion for admitting a product to trading and use is based on the results of scientific research, and the limitation on the precautionary principle, when the negative impact on the environment has not yet been recognized. An analysis of the jurisprudence of the EU Court of Justice and the EU Court has shown that the courts repeatedly, referring to the principle of prevention and the precautionary principle, in matters related to food safety or environmental protection, examining allegations against non-use of agricultural chemicals, including pesticides, have recognized compliance with the law on restrictive measures to avoid even a potential threat.

Particular attention was paid to insecticides containing chemicals from the neonicotinoid group, which were to be withdrawn from the market in 2018 based on the provisions of the Commission implementing regulations. Several old EU countries have completely banned the use of neonicotinoids in national regulation.

As research has shown, established in Article 53 (1) of Regulation 1107/2009, the extraordinary procedure allowing a temporary derogation for marketing, on the basis of specific measures containing neonicotinoids, is becoming more and more common, especially in the new EU Member States, including Poland. This also creates the danger of opening a legal path for future concessions to the chemical industry and allowing further harmful chemisation of agriculture, to the detriment of food safety and the environment. For this reason, it should be postulated at the level of the provisions of Regulation 1107/2009 or the EU implementing rules for permissible exceptions to the application of this mode allowing for a temporary derogation.

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STRESZCZENIE

Chemiczne środki ochrony roślin stosowane przy produkcji rolnej mają wpływ nie tylko na zdrowie i życie ludzi, lecz także niezaprzeczalnie na stan poszczególnych elementów środowiska, w tym różnorodności biologicznej. Przedstawicielem świata zwierząt, szczególnie wrażliwym na współczesne zagrożenia środowiskowe generowane przez rolnictwo, są owady zapylające. Celem opracowania jest analiza i ocena regulacji prawnej odnoszącej się do środków ochrony roślin, dokonana pod kątem przeciwdziałania nadmiernej chemizacji w rolnictwie, a w konsekwencji zapewnienia bezpieczeństwa żywności. Przedmiotem badań są prawne warunki dopuszczenia do obrotu i stosowania substancji zapewniających jednoczesne korzyści dla produkcji roślinnej przy braku szkodliwego wpływu na zdrowie ludzi i zwierząt oraz niedopuszczalnego wpływu na środowisko. Uwaga została poświęcona zwłaszcza dopuszczeniu do obrotu, na zasadach szczególnych, środków zawierających neonikotynoidy.

Słowa kluczowe: bezpieczeństwo żywności; zasada przezorności; owady zapylające; pestycydy; neonikotynoidy

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