
Plant protection products regulation at the crossroad

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Introduction

Food production systems in Europe rely largely on chemical pesticides to maintain crop yields. However, pesticides can have significant negative effects on the environment, particularly on biodiversity. For instance, the use of pesticides in farming practices can lead to runoff of these substances into rivers, lakes and groundwater. If pesticide levels exceed critical thresholds, individually or as mixtures, they affect ecological processes and make ecosystems less diverse and less resistant to disturbances.¹ Besides, pesticides are intrinsically harmful to living organisms² not only to targeted pests but also to pollinators such as bees and butterflies.³ The decrease in pollinators, partly due to pesticides,⁴ raises concerns regarding the sustainability of agriculture.⁵ Although there is a downward trend in the use and risk of chemical pesticides including the more hazardous ones, this decrease has not yet resulted in reduced pesticide levels in surface waters⁶ and soils.⁷ Furthermore, there are significant declines in insect populations and among insectivorous birds. In addition, the health risks associated with pesticide exposure are multi-faceted. Human exposure to chemical pesticides is linked to chronic illnesses such as cancer, and heart, respiratory and neurological diseases.⁸ Pesticide use also leads to pest resistance.⁹ In particular, pesticides known as endocrine disruptors (EDS) can negatively impact health by mimicking or blocking natural hormones in the body.

Where environmental damage is caused by chemical substances released into the environment, product standards are an appropriate instrument. That being said, the divergences between national regulations have always been a major industry concern, as they increase research and marketing costs. In response to these concerns, the Council banned the marketing and use of certain pesticides in the 1970s.¹⁰ As part of its endeavour to complete the internal market, the Council adopted directive 91/414/EEC on 15 July 1991 concerning the placing of plant protection products on the market. Its implementation

¹ EEA (2023).

² Geiger (2010), pp. 97-105.

³ IPBES (2016).

⁴ Quandahor (2024), p. 182; van der Sluijs (2025), p. 39.

⁵ EEA (2025), p. 72.

⁶ At 10-25% of all surface water monitoring sites reported to the EEA between 2013 and 2021, one or more active substances were detected above their effect threshold. See EEA, 2021, *Water Resources Across Europe – Confronting Water Stress: An Updated Assessment*, EEA Report No 12/2021.

⁷ According to the EEA, 83% of agricultural soils tested in a 2019 study contained pesticide residues. See also EEA, *Europe's Environment 2025*, pp. 103-104.

⁸ EEA (2023).

⁹ Pesticide pollution reduces natural pest control and encourages organisms to become resistant to pesticides.

¹⁰ Pallemmaerts (2023), p. 420.

proved so problematic that the EU institutions replaced this directive in 2009 with (EC) Regulation No 1107/2009 (hereafter “PPP Regulation”). The 2009 regulation brought a radical change in terms of legal bases, goals, level of ambition, risk assessment and risk management. Moreover, to endorse a more holistic approach, it was complemented the same year by Directive 2009/128/EC of 21 October 2009 which requires the Member States to achieve a reduction in pesticides-related risks.

At the intersection of the common agricultural policy, the internal market policy, environmental and consumers’ health protection, as well as farmers’ protection, the EU pesticide regulation raises not only numerous controversies, but also thorny legal issues, several of which have been adjudicated by the Court of Justice. So far, the PPP Regulation has given rise to a considerable body of litigation regarding the placing on the market of both active substances and plant protection products (PPPs). Several cases testify to the difficulties that arise in articulating scientific expertise (risk assessment) and the regulatory outcome (risk management), both of which are underpinned by the precautionary principle enshrined in Article 191(2) of the TFEU.

Over the past ten years, glyphosate and Neonicotinoids (NNIs) have been the subject of numerous legal disputes. On the one hand, glyphosate which is the most used herbicide active substance globally, is also one of the most controversial in terms of toxicological potential. Its approval as an active substance has been renewed until the end of 2033.¹¹ On the other hand, NNIs are active substances used as insecticides in agriculture for the purpose of seed coating. They disperse to all parts of a plant making the entire plant toxic to insects that feed on it.¹² Since the early 1990s, they have been widely used in seed-dressing and soil treatment. Although they are among the most widely used classes of insecticides in crop protection worldwide, they raise numerous concerns regarding their effects on biodiversity. Because they affect the central nervous system of insects, NNIs kill or deleteriously affect a wide variety of both target and non-target insects, particularly bees and pollinators.¹³ Insectivorous birds are indirectly affected by these insecticides through their adverse effects on food resources (primarily insects) and their lethal and sub-lethal toxicity. For instance, in France, Imidacloprid has reduced bird population between 9% and 12.9%.¹⁴ After authorising undertakings to place these active substances on the market,¹⁵ the European Commission first issued restrictions in 2013,¹⁶ and then

11 On the renewal of glyphosate by the European Commission, see de Sadeleer (2024), pp. 291-318.

12 O'Connor et al. (2012), p. 351.

13 Maxim and van der Sluijs (2013), pp. 369-406; Hladik, Main and Gouldson (2018), pp. 3329-3335; M. Laure (2025), pp. 2794-2829.

14 Perrot (2025), p. 127-132.

15 In 2013, five neonicotinoid insecticides were approved as active substances in the EU for the use in plant protection products, namely clothianidin, imidacloprid, thiamethoxam, acetamiprid and thiacloprid.

16 Commission Implementing Regulation (EU) 485/2013 (neonicotinoid).

prohibited the marketing and use of seeds treated with these active substances in 2018.¹⁷ The CJEU has repeatedly addressed the use of NNIs in plant protection products. The Court dismissed actions for annulment brought by industry federations and companies against national bans on the marketing of NNIs,¹⁸ and the restrictions imposed by the European Commission.¹⁹

In light of this case law, this chapter examines the procedures that regulate the approval under EU law of active substances and the authorisation of PPPs containing such active substances. It explores the duty placed on the authorities to assess the risks stemming from active substances and pesticides. Furthermore, it discusses the ability for Member States to regulate the use of PPPs. Related to these issues is the consistency of the EU regulatory framework with the precautionary principle.

1. Objectives, principles and legal bases

1.1. The key principles underpinning the Regulation: high level of protection and precaution

In accordance with Article 1(3), the purpose of the PPP Regulation is “to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production”.²⁰ Recital 8 of the regulation adds to these fundamental objectives “the protection of vulnerable groups of the population, including pregnant women, infants and children”, which is a major source of concern in toxicology.

In seeking an equilibrium between health and the environmental protection and economic integration, the regulation mirrors the structure of Article 3(3) TEU, which seeks to reconcile the internal market with sustainable development. Importantly, the authorities in implementing the regulation are called upon to achieve a high level of health and environmental protection.²¹ “The responsibility for determining the level of risk which is deemed unacceptable for society lies, ..., with the institutions responsible for the political choice of determining an appropriate level of protection for society.”²² Although this level does not necessarily need to be the highest that is technically possible, the EU institutions may be required to take preventive measures despite the

17 Commission Implementing Regulation (EU) 2018/784 (neonicotinoid); Commission Implementing Regulation (EU) 2018/785 (neonicotinoid).

18 ECJ C-514/19 (Union des industries de la protection des plantes).

19 ECJ C-449/18P (Bayer CropScience and Bayer v. Commission).

20 Art. 1(3). Articles cited without legal act refer to the PPP Regulation.

21 Art. 114(3), 168(1), 169(3) and 191(2) of the TFEU as well as Arts. 35 and 37 of the EUCFR.

22 ECJ T-31/07 (Du Pont de Nemours and Others) para. 145.

existing scientific uncertainty.²³ Accordingly, risk management presupposes that the authorities determine from the outset “the level of protection which they deem appropriate for society”.²⁴ Although Article 1(3) is unclear on this issue, it is settled case law that the health concerns take precedence over economic interests.²⁵

The level of protection is underpinned by the precautionary principle enshrined in Article 191(2) TFEU as well as in recital 8 and several provisions of the PPP Regulation. In particular, Article 1(4) of the Regulation refers expressly to the primary law principle, which empowers the EU institutions “to take appropriate measures to prevent specific potential risks to public health and safety”.²⁶ This general principle of EU law requires the authorities, in exercising the powers conferred on them by the relevant internal market and environmental rules, to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic considerations.²⁷ A situation in which the principle is applied by definition coincides with one in which scientific uncertainty persists.²⁸

Since the PPP regulation is binding on the EU institutions and the Member States when their measures fall within the scope of secondary law, the EU courts may be called upon to review whether restrictive measures on active substances or authorisations for the placing on the market of PPPs are compatible with the principle. Accordingly, claimants regularly assert in their actions for annulment that EU institutions have violated the requirements stemming from this principle.²⁹

As we shall see below, judgments of the CJEU and the General Court on pesticides often refer to the precautionary principle. As recalled by the CJEU in *Blaise*, the principle which is the cornerstone of the PPP Regulation can justify a rather strict regulatory approach. By way of illustration, the prohibitory measures laid down by Implementing Regulations 2018/784 and 2018/785 were adopted bearing in mind the need to ensure a level of safety and protection consistent with the high level of animal health protection sought within the EU.³⁰

23 ECJ C-284/95 (Safety Hi-Tech) para. 49.

24 ECJ T-13/99 (Pfizer) para. 151.

25 ECJ T-74, 76, & 83/00 to T-85, 132, & 137/00 and T-141/00 (Artegodan) para. 184.

26 ECJ T-429/13 and T-451/13 (Bayer) para. 109.

27 ECJ T 392/02 (Solvay Pharmaceuticals v. Council), para. 121. However, the precautionary principle does not constrain the authorities to refuse to grant an authorisation on the sole ground that there is a risk. For instance, it does not preclude an authorisation being granted under Art. 60(4) of the REACH Regulation on the sole ground that there is no proof of control of the risk. T-108/17 (ClientEarth) para. 139.

28 ECJ T-429/13 and T-451/13 (Bayer) para. 116.

29 For an overview of this case law, see de Sadeleer (2020), pp. 192-221.

30 ECJ C-616/17 (Blaise and Others) para. 45.

Article 191 TFEU and the PPP Regulation make no distinction between the implementation of the precautionary principle by the Member State Rapporteur³¹ and by the other Member States.³² Accordingly, Member States may apply that principle where there is scientific uncertainty regarding the risks posed to human or animal health or to the environment by PPPs to be authorised in their territory.³³ In this context, the principle justifies the adoption of national restrictive measures.

1.2. Legal bases of the PPPR

In 2009, the EU legislator replaced the 91/414/EEC directive with a regulation, which has the advantage of being directly applicable.³⁴ The same approach was taken at the time for most of the regulations governing the marketing and the use of chemical substances. The preference for a regulation instead of a directive could be explained by the fact that the more flexible nature of a directive entails a genuine risk of market fragmentation.

It is settled case law that each EU piece of legislation must be founded on one or more legal basis set out in the founding EU treaties. The choice of the legal base is not a purely formal question, but rather one of substance, being a matter of “constitutional significance”³⁵ which is regularly ruled on by the CJEU. Exceptionally, it is possible to base an act whose components are intertwined on different legal bases, provided that the procedures are compatible.

Given that the marketing of pesticides and herbicides intersects with CAP, internal market, environmental and health issues, the EU lawmaker has based the PPP Regulation on three provisions of the TFEU: Article 43(2) concerning the CAP, Article 114 concerning the internal market, and Article 168(4)(b) concerning health protection. These three provisions fall under shared competences pursuant to Article 4(2)(a), (d) and (k). Furthermore, all of them provide for the recourse to the ordinary legislative procedure, so that their simultaneous application does not raise any procedural difficulties.

The choice to base the PPP Regulation on these three legal bases amounted to a significant departure from the previous regulatory approach, as Council directive 91/414/EEC was related to the CAP and adopted pursuant to former Article 43 EEC. In other words, in 2009 the EU lawmaker abandoned the traditional agricultural base in favour of a mixed approach combining agriculture, the internal market, and health protection. Being based on the internal market

31 The Member State Rapporteur performs the initial scientific and technical assessment of the active substance's dossier and drafts an assessment report (DAR), according to the EFSA guidelines. This report, which includes a provisional conclusion on the substance's safety and compliance with criteria, is then submitted to EFSA for peer review.

32 Donati (2023), p. 6.

33 ECJ C-616/17 (Blaise and Others) para. 44.

34 Art. 288 TFEU.

35 ECJ C-370/07 (Commission v. Council) paras. 37, 39, 46, 48.

legal base, the PPP Regulation became more closely aligned with other chemical substances legislations based on Article 114 TFEU.

By fostering the functioning of the internal market, Article 114 TFEU increases the centralisation of the decision-making process. Accordingly, given the completeness of its procedures,³⁶ the PPP Regulation leads to a total harmonisation which limits the Member States' room for manoeuvre.³⁷ Does it mean that the environmental and health concerns are diminished? As will be explained below, pursuant to Article 114(3) TFEU³⁸ and Article 168(1) TFEU,³⁹ the Regulation largely incorporates health and environmental concerns.

2. Active substances and product marketing procedures

2.1. Introductory remarks: a two-pronged approach

The procedure for the approval of active substances must be distinguished from the procedure for the authorisation of PPPs. Before an active substance can be used in a pesticide or in a herbicide, it has to be approved by the Commission.⁴⁰ Once approved, companies may submit applications to the competent authorities for authorisation to place on the market pesticides containing them.⁴¹ It comes as no surprise that the procedures applicable to the assessment of active substances and the authorisation of PPPs are closely linked, particularly because the authorisation of a PPP presupposes that its active substances have previously been approved by the European Commission.⁴² The risk assessment requirements which are at the hearth of the approval procedure of active substances and the subsequent authorisation procedure for PPPs will be discussed thoroughly in a third section.

2.2. Approval of active substances

PPP contains active substances that can be formulated in many ways and used on a variety of plants and plant products, under different agricultural, plant health and environmental (including climatic) conditions.⁴³ Their approval is regulated in Subsections 1 and 2 of Section 1 of Chapter II of the

³⁶ See ECJ T-31/07 (*Du Pont de Nemours and Others*) para. 203.

³⁷ de Sadeleer (2010), pp. 157-161, 291, 304, 353, and 358-382; de Sadeleer (2025), pp. 91-114.

³⁸ According to that paragraph, the internal market European Commission's proposals which have as their object the establishment and functioning of the internal market must pursue a high level of protection, when they concern health, safety, environmental protection and consumer protection.

³⁹ Art. 168(1) TFEU, read in combination with Art. 35 EUCHR, requires that the protection of human health must be integrated into the definition and implementation of the Union policies and activities.

⁴⁰ Art. 7-13.

⁴¹ Art. 33-39.

⁴² Art. 29(1)(a); ECJ C-616/17 (*Blaise and Others*) para. 66.

⁴³ ECJ T-545/11 *RENV* (*Stichting Greenpeace Nederland*) para. 74.

PPP Regulation.⁴⁴ The EU authorities are vested with exclusive competence over the assessment of the active substances found in these products, as well as their inclusion in an EU list adopted in accordance with the comitology procedure.⁴⁵

2.2.1. The identification of the “active substance”

The PPPR does not contain any definition of the expression “active substance”.⁴⁶ In *Blaise*, the French criminal court asked the CJEU whether the concept of active substance is defined with sufficient precision. In its view, the vagueness surrounding this concept in the basic Regulation could mean that, when submitting an application for approval or renewal, the applicant could steer the process by selectively highlighting certain components to avoid a comprehensive review of all the substances involved. The CJEU dismissed that argument on the grounds that the Regulation requires the company applying for approval or renewal to identify all active substances that may be used in a product.⁴⁷ Thus, the basic Regulation specifies that substances with a general or specific action against harmful organisms or on plants, parts of plants or PPPs must be considered as active substances.⁴⁸

The PPP Regulation introduced the concept of low-risk active substances. To qualify as low-risk, a PPP can only contain active substances approved as low-risk⁴⁹ and may not contain any “substances of concern”. The criteria to identify low-risk active substances are hazard-based (point 5 of Annex II) whereas the criteria for authorising the plant protection products containing them risk-based (Article 47). As of September 2019, 16 active substances had been approved as low-risk (3% of all approved active substances).

2.2.2. The approval procedure

The active substance must be expressly “approved” by the European Commission under the so-called “comitology” procedure.⁵⁰ This approval is preceded by various procedural steps, which largely involve national authorities. In summary, the applicant submits a dossier to a national authority or a group of Member States, which then acts as Rapporteur Member State(s).⁵¹ The Member State in charge of the application conducts a comprehensive evaluation of the dossier, that includes a risk assessment for human health and the

⁴⁴ Arts. 4-13.

⁴⁵ See Chapter II.

⁴⁶ ECJ C-616/17 (*Blaise and Others*) para. 52.

⁴⁷ ECJ C-616/17 (*Blaise and Others*) para. 57.

⁴⁸ ECJ C-616/17 (*Blaise and Others*) para. 57.

⁴⁹ Art. 22; Point 5 of Annex II sets out the EU criteria for low-risk substances.

⁵⁰ Art. 13(2).

⁵¹ Art. 7(2)-(3).

environment.⁵² It prepares a Draft Assessment Report (DAR). The European Food Safety Authority (EFSA) performs a peer review⁵³ in consultation with the other Member States⁵⁴ and the European Chemicals Agency (ECHA). At the end of these consultations, the Agency finalises its opinion.⁵⁵

The European Commission subsequently prepares an implementing act based on the EFSA's opinion.⁵⁶ It can take into consideration "factors legitimate to the matter under consideration" and must pay heed to the precautionary principle.⁵⁷ In order to approve the substance, the Commission must consult the Standing Committee on Plants, Animals, Food and Feed on its draft implementing act.⁵⁸ Following discussions in the comitology committee, the Commission may seek a further opinion from EFSA on risk mitigation measures. If a qualified majority of 55% of Member States representing at least 65% of the EU population votes in favour of the proposal the Commission to list the substance,⁵⁹ the Commission must adopt it. If a qualified majority votes against the proposed act, the Commission may not adopt it. In such a case, it may amend the proposal or send it to an Appeal Committee. Where the Commission deviates from EFSA's scientific determination, it must state the reasons for doing so.⁶⁰

To accelerate the approval and the renewal process of active substances, the Regulation provides strict time limits for each stage of the process. Against this background, an indefinite extension of the time limit for the evaluation of an active substance would be contrary to the objective of ensuring a high level of protection of human and animal health and the environment.⁶¹

A new active substance is usually approved for a maximum of 10 years,⁶² or 15 years if classified as low risk. Indeed, it is in the interest of safety that the approval period for active substances is limited in time and that it should be proportionate to the possible risks inherent in the use of the substances.⁶³

The comitology procedure has been criticised insofar as it strengthens the powers of the Commission. Indeed, the latter adopts the decision when Member

52 Art. 11.

53 Art. 8(5).

54 Art. 12(1).

55 Art. 12.

56 Art. 13(1).

57 Art. 13(2).

58 Where committees involve the participation of Member States, such participation is a matter for the organisation of powers within the Member State. If a Member State decides to be represented by its regional entities in certain matters, such a choice is a matter for their organisation and does not bind the EU court in its assessment of the criterion of direct concern. See ECJ T-178/18 (*Région de Bruxelles-Capitale v. Commission*) paras. 66-67.

59 All approved active substances are listed in Commission Implementing Regulation (EU) 540/2011.

60 Opinion AG Kokott, ECJ C-316/24 P (*PAN Europe v. Commission*) para. 44.

61 ECJ T-719/17 (*FMC Corporation v. Commission*) paras. 187-188.

62 Art. 15.

63 GC T-412/22 (*PAN Europe v. Commission*) para. 59.

States fail to reach agreement within the committee in which they meet.⁶⁴ When the Commission adopts its implementing regulation in the absence of agreement by a majority of Member States, it is perceived by the public as technocratic at best, or as susceptible to be influenced by pressure groups, at worst.⁶⁵

2.2.3. Criteria to fulfil to approve an active substance

The applicant must thus provide proof that the active substance does not have the harmful effects referred to. Accordingly, he must submit a complete dossier alongside its application for authorisation demonstrating that the active substance satisfies the approval criteria.

Both the rapporteur Member State and EFSA are tasked to carry out an independent, objective, and transparent scientific assessment of the risks of an active substance. The rapporteur Member State and then EFSA, with the participation of the other Member States and the public, evaluate the submitted dossier. However, that evaluation is not limited to the information submitted as they must also take into account current scientific and technical knowledge. The EU courts held that the Commission is not obliged to follow in all respects the conclusions of the EFSA or the report of the rapporteur Member State in all respects.⁶⁶

Substances can only be approved by the Commission provided that, on the one hand, they present a clear benefit for plant production and, on the other, that they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment.⁶⁷ Pursuant to Article 4(1) of the PPP Regulation, an active substance can be approved where it meets the criteria set out in Annex II, which will be subject to further development in the fourth section.

Although the procedure for authorising the active substance is distinct from the procedure for authorising the product, there is nonetheless a link between the two procedures. Under Article 4(5), the clear benefit and the absence of harmful effect requirements are deemed satisfied where this has been established “with respect to one or more representative uses of at least one PPP containing that active substance”. Accordingly, the approval or renewal of the approval of an active substance requires the Commission to examine whether at least one representative use of a PPP containing the active substance concerned satisfies the criteria set out in Article 4(1) to (3) of the Regulation.⁶⁸

Article 4(7) provides for a derogation allowing the approval of active substances not meeting the approval criteria in Article 4 and Annex II where it is necessary to do so because of a serious danger to plant health which cannot

⁶⁴ Regulation (EU) 182/2011 (Comitology) Art. 5(4).

⁶⁵ Nihoul (2024), p. 200.

⁶⁶ ECJ C-316/24 P (PAN Europe v. Commission) para. 94.

⁶⁷ Recital 10 and Art. 4(2) PPPR.

⁶⁸ ECJ C-316/24 P (PAN Europe v. Commission) paras. 283-285.

be contained by other available means including chemical and non-chemical methods with comparable costs and efficacy. Member States authorising PPPs containing such active substances must take all measures to reduce exposure to these active substances. They must draw up a phasing-out plan and submit it to the Commission. This derogation does not apply to active substances having particularly hazardous properties.

In contrast to former Directive 91/414/EEC, the PPP Regulation represents a real step forward for health and environmental protection. The EU regulatory approach has been shifting from risk-based to hazard-based assessment: substances that do not meet the EU's predetermined cut-off hazard-based criteria (PBT, POP, vPvB, or endocrine disruptive⁶⁹) cannot receive approval, or renewal of approval.⁷⁰ In other words, the Commission cannot list an active substance if it displays some hazardous properties, regardless of the likelihood of the hazard causing actual harm (i.e. the risk). Once such property is identified, the substance is deemed to be intrinsically dangerous and it cannot be authorised.⁷¹ The probability of harm associated with the PBT, POP, vPvB characteristics is deemed to be too high to authorise these substances. The procedure relying on cut-off hazard-based criteria is faster and less expensive,⁷² as it avoids the need to perform an entire risk assessment on a case-by-case basis, which can be time- and resource-consuming. In practical terms this means that experts are not required to fully perform the additional steps of the assessment procedure (hazard characterisation, risk identification, and risk characterisation). The Regulatory Fitness and Performance evaluation (REFIT) of the PPP Regulation found that the approval criteria for active substances in Regulation 1107/2009 are among the most stringent in the world.⁷³

69 An active substance is not considered to have EDS properties that may cause adverse effect in humans, unless the exposure of humans is negligible, without further considerations on risk or socio-economic factors (point 3.6.5). With its Regulation (EU) 2018/605, the Commission supplemented the Plant Protection Regulation with scientific criteria for the determination of endocrine disrupting properties in point 3.6.5 of Annex II to the Plant Protection Regulation. The European Commission was found to be in default for failing to adopt delegated acts in virtue of the Biocides Regulation (EU) 528/2012 specifying the scientific criteria for determining EDS properties.

70 PPPR, Annex II, 3.6.2 to 3.6.5. However, in 2017, the Commission took on board "potency" and transformed the hazard-based for the listing of EDCs (PPPR, Annex II, 3.6.5) into a risk-based one. See Regulation (EU) 2017/2100 (endocrine disruptor criteria) and Regulation (EU) 2018/605 (endocrine disruptor criteria amendment). See Kuraj (2018), p. 299.

71 Bozzini (2017), p. 30.

72 Bozzini (2017), pp. 32, 67.

73 See Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues, Executive Summary 10 October 2018.

2.2.4. Conditions and restrictions on the approval

Approval may be subject to conditions and restrictions including conditions of application or the designation of areas where the use of PPPs containing the active substance may not be authorised.⁷⁴

2.2.5. Renewal of the approval of active substances or review of their approval

Since active substances can be approved for a period not exceeding 10 years, their continued use requires the renewal of that approval upon expiry. Besides, the approval of the substance can be reviewed by the Commission “at any time”.⁷⁵ Member States have a right to request a review of approval, extension or renewal, in the light of new scientific, technical knowledge and monitoring data. However, individuals have not been granted a right to make such a request.

The criteria of clear benefit for plant production and the absence of health and environmental harmful effects must be applied at the time of renewal or review of their approval.⁷⁶ In addition, the absence of harm has to be established with respect to one or more representative uses of at least one PPP containing the renewed active substance.⁷⁷ In principle an active substance shall only be approved where a complete dossier is submitted.⁷⁸ Specific implementing measures have been adopted by the Commission regarding the submission of the application for renewal and its contents and format.⁷⁹

When applying for renewal, the producer of the active substance must identify new data intended to be submitted and demonstrate their necessity, either because of data requirements or because criteria have changed since the last approval.⁸⁰ The applicant must therefore demonstrate why such data and risk assessments, which were not part of the approval dossier or subsequent renewal dossiers, are necessary to reflect changes in legal requirements and in scientific and technical knowledge.⁸¹

Strict deadlines have been set for every step of the renewal process, which allows the preparatory process to be ended in two and a half years. However, the difficulties encountered in gathering scientific evidence can lead to significant delays. Where, for reasons beyond the control of the applicant, it appears that

⁷⁴ Art. 6.

⁷⁵ Art. 21(1).

⁷⁶ Recital 10, Art. 14(1).

⁷⁷ Art. 14(1).

⁷⁸ Point 2.2 of Annex II.

⁷⁹ See in particular Commission Implementing Regulation (EU) 844/2012 (renewal procedure for active substances).

⁸⁰ Art. 15(2) Regulation (EU) 844/2012; PPPR Art. 6.

⁸¹ Art. 7(1) d).

the approval of the substance is likely to expire before a decision on renewal has been taken, Article 17 empowers the Commission to adopt “a decision ... postponing the expiry of the approval period”, “for a period sufficient to examine the application”. In particular, Article 17 has the effect of allowing the procedure for the renewal to be extended on account of reasons arising in the course of the procedure itself that were previously unknown.⁸² That being said, Article 17 derogatory mechanism should be applied on an exceptional basis, when the conditions it lays down are met. A systematic application allowing for successive extensions of that mechanism is therefore not compatible with the spirit of the PPP Regulation.⁸³ The Commission discretion to determine what constitutes a “sufficient period” to extend the authorisation is not absolute.⁸⁴

The Commission must attach particular importance to ensuring a high level of protection of human and animal health and the environment when it is managing a procedure for the renewal of the approval of an active substance.⁸⁵ At the end of the renewal procedure, the Commission adopts a regulation in accordance with the comitology procedure.⁸⁶ The approval of the active substance is either renewed or not renewed.⁸⁷ Where the Commission decides not to renew the approval of an active substance due to immediate concerns for human or animal health or the environment, PPPs containing that substance shall be immediately withdrawn from the market.⁸⁸ Renewals may not exceed 15 years.⁸⁹ Where the approval of an active substance is renewed by the Commission, it is incumbent on the holder of a marketing authorisation for a plant protection product containing that substance to apply for the renewal of that authorisation.⁹⁰

When deciding on the renewal of approval, the Commission must undertake a complex scientific and technical assessment. In doing so it has a broad discretion, the exercise of which the EU judiciary may review substantively only to verify whether the relevant procedural rules have been complied with, whether the facts accepted by the Commission have been accurately stated and whether there has been a manifest error of appraisal or a misuse of powers.⁹¹ The following cases illustrate that the Commission is not endowed with an unfettered discretion.

82 GC T-476/17 (*Arysta LifeScience Netherlands v. Commission*) para 104.

83 GT T-412/22 (*PAN Europe v. Commission*) para 69.

84 GT T-412/22 (*PAN Europe v. Commission*) para 71.

85 GT T-412/22 (*PAN Europe v. Commission*) para 78.

86 Art. 19.

87 Art. 20(1).

88 Art. 20(2) second subparagraph.

89 Art. 15(2).

90 Art. 43(1) and (2).

91 See ECJ C-98/78 (*Racke*) para. 5, and ECJ C-16/90 (*Nölle*) para. 12; ECJ C-326/05 P (*Industrias Químicas del Vallés*) para. 76; Opinion AG Kokott, ECJ C-316/24 P (*PAN Europe v. Commission*) para. 38.

The *Bayer* judgment is a case in point. Bayer brought legal proceedings against more restrictive rules on the use of the active substances that have been adopted by the Commission. All outdoor uses of these substances are banned. Bayer challenged the way in which the Commission used scientific data in the application of the reviewing procedure. The CJEU rejected all grounds of appeal. Bayer argued that the review of an approval is justified only if the state of scientific and technical knowledge changes.⁹² The Court considered that the General Court wrongly held that new scientific knowledge was needed to permit the Commission to review the approval of an active substance.⁹³ The first sentence of the first subparagraph of Article 21(1) permits the Commission to review the approval of an active substance at any time, without specifying further conditions.⁹⁴ In fact, the Court has already held that the existence of new scientific and technical knowledge is only one of the situations in which the Commission may re-examine the approval of an active substance.⁹⁵

According to Bayer, in order to carry out the risk assessment, EFSA was obliged, in the context of the review procedure under Article 21(3), to apply the guidance document in force at the time of the initial approvals. The Court dismissed Bayer's plea regarding the breach of Commission's guidelines in focusing on the existence of new scientific and technical knowledge.⁹⁶ It considered that a decision on whether approval criteria are still met⁹⁷ may be "based on any new knowledge, in so far as it is scientific or technical" regardless of its source.⁹⁸ In paying heed to "new knowledge", the judgment reflects the "true nature of scientific research, which is in an ever-changing state. As soon as guidelines are adopted, it is likely that scientific knowledge will advance and supersede the content of the guidelines".⁹⁹ Indeed, it is unwise to assume that methods used to assess the risks of existing technologies are also appropriate for assessing risks stemming from new technologies.¹⁰⁰

Bayer complained that the General Court failed to examine whether the risk assessment and scientific evaluation were sufficiently exhaustive and well informed to justify the adoption of the contested regulation. It argued that the Commission rushed through a review procedure before hurriedly adopting a decision withdrawing the approval without having carried out or relied on a comprehensive risk assessment. The Court recalled that the provisions or the

92 ECJ C-499/19 P (Lupu) para. 45; ECJ C-499/18 P (Bayer CropScience et Bayer), Opinion of AG Kokott, para. 74.

93 ECJ C-499/19-P (Lupu), ECJ C-499/18 P (Bayer CropScience et Bayer), Opinion of AG Kokott, para. 55.

94 ECJ C-352/19 P (Région de Bruxelles-Capitale) para. 50.

95 ECJ C-616/17 (Blaise and Others) para. 99.

96 Art. 21(1).

97 Art. 4.

98 ECJ C-499/18 P (Bayer CropScience et Bayer) para. 69.

99 Jennings (2022).

100 Maxim and van der Sluijs (2013), p. 389.

PPP Regulation are based on the precautionary principle.¹⁰¹ It follows that the Commission can invoke the principle where there is scientific uncertainty concerning risks posed by active substances.¹⁰² Therefore, an exhaustive risk assessment cannot be required in such a situation.

In *PAN Europe v. Commission*, the General Court dismissed the action lodged by an NGO seeking the nullification of the renewal of the approval of an active substance, cypermethrin.¹⁰³ In its 2018 peer review of the risk assessment of the active substance cypermethrin,¹⁰⁴ EFSA underscored the missing information as being required by the regulatory framework and identified four critical areas of concern (“*domaines critiques de préoccupation*”). Despite this assessment, the Commission renewed the approval of the substance. The applicant argued that if the risk had been established with sufficient certainty or if any uncertainties had not yet been resolved, the European Commission could not disregard the conclusions of the EFSA’s risk assessment by relying on its powers as risk manager.¹⁰⁵ It was therefore not possible for the Commission to renew the authorisation for cypermethrin. Admittedly, the renewal of approval for the substance cypermethrin would have been accompanied by European Commission “risk mitigation measures”. However, the Commission had discharged its responsibilities by deferring the determination of “risk mitigation measures” to the Member States, within the context of the procedure for issuing authorisations for PPPs.¹⁰⁶ In this way, the measures in question were no longer set *ex ante* but *ex post*. In spite of the areas of concern identified by the EFSA, the General Court held that the applicant NGO was nevertheless obliged to present “factual elements or the substantial legal arguments” capable of establishing “plausible doubt” regarding the Commission’s appraisal.¹⁰⁷ In doing so, the General Court rejected the view that the precautionary principle could shift the burden of proof, or at least attenuate the burden of proof. In our view, the General Court applied the precautionary principle too formally.¹⁰⁸

In her opinion of 5 June 2025, AG Kokott proposed that the Court of Justice should set aside the judgment of the General Court.¹⁰⁹ In a 337-paragraph judgment, the CJEU follows largely her opinion.¹¹⁰ It would not be possible to analyse here this judgment in depth.

¹⁰¹ ECJ C-499/18 P (Bayer CropScience et Bayer) para. 79.

¹⁰² ECJ C-499/18 P (Bayer CropScience et Bayer) para. 79.

¹⁰³ Cypermethrin is a broad-spectrum insecticide used in large-scale commercial agricultural applications. In November 2021, following years of discussions among the European Commission, the Member States and the EFSA, cypermethrin was re-approved by the Commission for seven years.

¹⁰⁴ EFSA (2018), p. 5402.

¹⁰⁵ Art. 75.

¹⁰⁶ Art. 75 chapter III.

¹⁰⁷ Art. 146.

¹⁰⁸ ECJ T-536/22 (PAN Europe v. Commission). See de Sadeleer (2024), pp. 304-311.

¹⁰⁹ Opinion AG Kokott, ECJ C-316/24 P.

¹¹⁰ ECJ C-316/24 P (PAN Europe v. Commission).

Regarding the obligation to take into consideration the preliminary assessments, the CJEU follows largely the reasoning of the General Court, which held that the Commission is not obliged to follow the conclusions of the EFSA or the report of the rapporteur Member State in all respects.¹¹¹ However, in this case, the assessments carried out by the rapporteur Member State and EFSA respectively were divergent. The PPP Regulation does not specify how the Commission should rule when these two assessments diverge. In this regard, the CJEU considers that the General Court did not explain why the position of the rapporteur Member State should take precedence over that of EFSA, even though the latter had identified a critical area of concern. The statement of reasons is therefore insufficient.¹¹²

In the Court's view, the General Court should also have verified whether the Commission had fulfilled its obligation to examine the different "critical areas of concerns" raised by EFSA carefully and impartially.¹¹³ The General Court's judgment is thus annulled on the grounds that the risk mitigation measures for non-target arthropods in off-field areas were unrealistic and that there was no assessment of the long-term toxicity of the representative use of the PPP containing cypermethrin.

The refusal of renewal has serious consequences for economic operators and for national authorities. Following the non-renewal of the approval of an active substance, Member States must withdraw all PPP authorisations containing the active substance and farmers must stop using these products. In order to avoid creation of waste and give time to farmers to find alternatives, Article 20(2) foresees the possibility in certain cases to provide for grace periods not exceeding maximum deadlines for placing on the market and use of existing stocks of PPPs for which authorisations must be withdrawn.

Although the European Commission has been proposing to abrogate the renewal procedure, it must be noted that this procedure has contributed to the avoidance of risks stemming from 23 substances that are considered genotoxic, toxic to reproduction, or carcinogenic.¹¹⁴

3. Granting of product authorisations

3.1. Procedure

Once the active substance has been approved, companies using it in the composition of their products must apply for authorisation if they wish to market them. This authorisation must be obtained, not from a European

¹¹¹ ECJ C-316/24 P (PAN Europe v. Commission) para. 94.

¹¹² ECJ C-316/24 P (PAN Europe v. Commission) paras. 104-107.

¹¹³ ECJ C-316/24 P (PAN Europe v. Commission) paras. 109-114.

¹¹⁴ See Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues, Executive Summary 10 October 2018.

authority, but from a Member State authority.¹¹⁵ This competence is vested in the Member States themselves, and not their sub-State entities. Where domestic constitutional law provides for a “low level of intensity participation” of regional sub-entities in the procedure for authorising products, such intensity is insufficient, according to the CJEU, to conclude that the applicant is directly affected.¹¹⁶ The Member States examining the application to place the pesticide on the market grants or refuses authorisations.¹¹⁷

The freedom to choose the Member State that will examine the application for marketing authorisation for the product raises controversy. Indeed, some undertakings may be tempted surreptitiously to seek approval from the most lenient State, with a view to subsequently marketing the product throughout the entire “zone” concerned. In addition, according to the Commission, applicants who have obtained product authorisations in a reference Member State having set lower fees than others in order to apply for mutual recognition of these authorisations in other Member States, are not necessarily placing the PPPs concerned on the market in the reference Member State having granted the first authorisation.¹¹⁸

3.2. Criteria to fulfil to grant the authorisation

Under the terms of Article 29(1), a PPP shall only be authorised where it complies with several environment and health requirements: its active substances, safeners and synergists must have been approved in the light of “current scientific and technical knowledge”; it must comply with the requirements provided for in Article 4(3) regarding the nature and quantity of its active substances, and, where appropriate, any toxicologically, eco-toxicologically or environmentally relevant impurities and co-formulants can be determined using appropriate methods.

In order to obtain the authorisation, the applicant must submit to the national authority, in addition to the “known cumulative and synergistic effects”, “any information on potentially harmful effects of the PPP on human and animal health or on the environment”.¹¹⁹ In other words, an information duty applies whenever the impacts are potential and not yet fully demonstrated. The applicant does not have the option of choosing at his discretion which constituent of that product is to be considered an active substance for the purposes of the examination of that application.¹²⁰ He is not exempted from submitting tests on

¹¹⁵ Arts. 33 and 35.

¹¹⁶ ECJ T-178/18 (*Région de Bruxelles-Capitale v. Commission*) para. 66.

¹¹⁷ Art. 36(2).

¹¹⁸ See the explanatory memorandum of the Commission’s proposal for an amending regulation as regards the simplification and strengthening of food and feed safety requirements, COM(2025) 1030 final.

¹¹⁹ ECJ C-616/17 (*Blaise and Others*) para. 73.

¹²⁰ ECJ C-616/17 (*Blaise and Others*) para. 57.

long-term carcinogenicity and toxicity relating to the PPP that is the subject of an application for authorisation.¹²¹ In effect, such a product cannot be considered to satisfy the safety requirements laid down by the EU lawmaker “where it exhibits any long-term carcinogenicity and toxicity”.¹²² As a result, applicants would be required to submit tests of long-term carcinogenicity and toxicity.

The Member State examines the application with a view to making an “independent, objective and transparent assessment in the light of current scientific and technical knowledge” using guidance documents available at the time of application. It gives all Member States in the same zone the opportunity to be considered in the assessment.¹²³ Ultimately, the Member State concerned shall grant or refuse authorisations accordingly on the basis of the conclusions of the risk assessment.¹²⁴

The question arises as to whether the national authorities comply with the obligation to take into account the most rigorous data. In its landmark judgment of September 3, 2025, the Paris Administrative Court of Appeal held that the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) did not systematically base its risk assessments regarding biodiversity on the most recent scientific data available. The Court ordered the French State to assess the risks posed by pesticides “in light of the latest scientific knowledge, particularly with regard to non-target species”, in accordance with the precautionary principle enshrined in PPP Regulations. The Court then ordered the State to review, by September 3, 2027, all marketing authorisations previously granted to pesticides whose toxicity to biodiversity has not been sufficiently assessed.¹²⁵

3.3. Comparative assessment of pesticides containing particularly hazardous substance

The PPP Regulation represents a watershed in the development of the substitution principle,¹²⁶ according to which the mere existence of an alternative substance that appears to be less dangerous than the substance in question constitutes a sufficient basis for a restriction or a prohibition. This principle is often coupled with precaution.

Before authorising pesticides containing particularly hazardous substance that are considered “candidates for substitution”, Member States have to conduct a “comparative assessment” to determine if those pesticides can be replaced by others containing less hazardous active substances or by non-chemical

¹²¹ ECJ C-616/17 (Blaise and Others) para. 113.

¹²² ECJ C-616/17 (Blaise and Others) para. 115.

¹²³ Art. 36(1).

¹²⁴ Art. 36(1).

¹²⁵ CAA Paris, 3rd ch., September 3, 2025, No. 23PA03881.

¹²⁶ Winter (2007), pp. 313-329.

alternatives.¹²⁷ In other words, national authorities must check if a less hazardous active substance or a non-chemical alternative exists that can replace the candidate substance. The European Commission is required to establish a list of active substances in pesticides considered to be “Candidates for Substitution” which must undergo a comparative assessment.¹²⁸

4. Principle of mutual recognition

The principle of mutual recognition is one of the means of ensuring the free movement of goods within the EU.¹²⁹ In accordance with this principle, authorisations granted by one Member State must be accepted by the other Member States. However, this principle is not absolute as plant health and environmental including climatic conditions differ across the continent. Against this background, Annex I of the Regulation divides the Union into three zones (north, centre and south) with comparable environmental and climatic characteristics.¹³⁰ Mutual recognition is the basic rule in each of these zones, whereby a PPP authorised by a Member State will automatically be declared eligible for use in the other Member States of the respective zone.

Article 36 sets forth the conditions under which Member States belonging to the same zone shall grant or refuse the authorisation of PPPs. In this regard, Article 36(2) provides that Member States belonging to the same zone shall grant or refuse the authorisation of PPPs based on the conclusions of the assessment of the Member State Rapporteur. In accordance with Article 36(3), where a Member State’s concerns relating to human or animal health or the environment cannot be controlled by the establishment of the national risk mitigation

¹²⁷ Art. 50. The PPP Regulation sets out four criteria to be taken into consideration in the comparative assessment, notably whether: (a) a safer authorised pesticide or non-chemical control or prevention method exists for the same uses; (b) substitution would not present significant economic or practical disadvantages; (c) the chemical diversity of the active substances or methods and practices of crop management and pest prevention are sufficient to minimise the risk that the target organism (or pest) could develop resistance; and (d) the consequences on ‘minor use’ authorisations have been taken into account. These criteria were fleshed out in a Commission’s guidance document (SANCO/11507/2013) concerning the comparative assessment of pesticides by Member State authorities, which, in 2014, was endorsed by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF). A complainant criticised the Commission for referring to a standard developed by the European and Mediterranean Plant Protection Organization (EPPO) on how to perform comparative assessment. The Ombudsman opened an inquiry into the consistency of the Commission guidance document with the regulation. The Ombudsman found the document to be in line with EU law. See EU Ombudsman Decision on how the European Commission adopted a guidance document on comparative assessment in the context of the substitution of hazardous substances in pesticides (case 177/2023/VB).

¹²⁸ The candidates for substitution are listed in Part E of the Commission Implementing Regulation (EU) 540/2011.

¹²⁹ Recital 29.

¹³⁰ See PPPR, recital 23, art. 40 and Annex IV.

measures (buffer zones to protect water bodies or nature sanctuaries, wearing special protections), it may refuse authorisation of the product in its territory, provided that “it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment”. The General Court held that the PPP Regulation allows a Member State receiving a request for mutual recognition to assess the appropriate response to that request by refusing, where necessary, the entry of products containing glyphosate into its territory.¹³¹

Finally, Article 44(3) of the PPP Regulation defines the conditions under which a Member State may withdraw the authorisation of a product that it has previously granted.

5. Assessing the health and environmental risks of the active substance

5.1. The scientific paradigm

In EU chemical law, a standardised risk assessment (RA) has been singled out as the predominant tool for verifying safety criteria. Under the PPP Regulation, when deciding on the approval or the renewal of approval of an active substance, the Commission must undertake a complex scientific and technical assessment of the health and environmental effects of the proposed active substance. It shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are met, the assessment shall continue to determine whether the other approval criteria set out in points 2 and 3 of Annex II are also fulfilled.¹³² By the same token, the Member State must carry out a RA of the effects of the products concerned.

According to the CJEU case law, the RA must be “as complete as possible given the particular circumstances of the individual case”.¹³³ Thanks to this assessment, the institutions should be able to examine, “carefully and impartially, all the relevant facts of the individual case”.¹³⁴ The “detailed assessment of the risk”,¹³⁵ “presupposes, in the first place, the identification of the potentially negative consequences for health” of the product or the substance.¹³⁶

¹³¹ ECJ T-178/18 (*Région de Bruxelles-Capitale v. Commission*) para. 61.

¹³² Art. 4(2) subpara. 2.

¹³³ ECJ C-236/01 (*Monsanto Agricoltura Italia*) para. 113; ECJ T-13/99 (*Pfizer*) paras. 155-156; EFTA Ct., E-3/00 (*EFTA Surveillance Authority v. Norway*), Rep. 73. In that regard, the incomplete analysis of the relevant scientific evidence is apt to vitiate the measure. See ECJ C-405/07 P (*Netherlands v. Commission*), para. 77.

¹³⁴ See, *inter alia*, ECJ C-269/90 (*Technische Universität München*), para. 14.

¹³⁵ ECJ C-192/01 (*Commission v. Denmark*), para. 47.

¹³⁶ ECJ E-3/00 (*EFTA Surveillance Authority v. Norway*) para. 30; ECJ C-236/01 (*Monsanto Agricoltura Italia*) para. 113; and ECJ C-192/01 (*Commission v. Denmark*) para. 51.

5.2. Reliability of the information submitted by the applicant

The information used as a basis for the approval is provided by the company submitting the application.¹³⁷ Should one be concerned that substance approvals and product authorisations are mainly based on data provided by the applicant without any real independent counter-analysis? In other words, could an applicant submit to the authorities tests or studies that are biased? In response to these questions, the CJEU emphasised in *Blaise* that the applicant bears the burden of proving that the active substance or the product “fulfils the relevant criteria laid down” in the Regulation.¹³⁸ The EU legislator has regulated the quality of the tests, studies and analyses to be submitted.¹³⁹ In addition, several provisions of the PPP Regulation emphasise the objectivity, transparency and independence of experts.¹⁴⁰ At European and national level, the competent authorities must take into account the most reliable scientific data and the latest results of international research, without giving preponderant weight to the studies provided by the applicant.¹⁴¹

At first sight, however, the confidentiality enjoyed by the applicant could prevent the public from challenging the results used in the authorisation application.¹⁴² As a result, the public concerned won’t be able to advance arguments opposing the granting of the approval or authorisation sought by an applicant. Nonetheless, according to the CJEU, the procedure for approving an active substance requires the authority to make the summary dossier immediately available to the public.¹⁴³ The same applies to the draft assessment report sent to the Commission by the rapporteur Member State for distribution to all EU countries.

5.3. Epistemological limits

As far as pesticides are concerned, I feel that the RA procedure can be subject to a number of criticisms.

First, the decision to approve the active substance is adopted by the European Commission based on recommendations made by EFSA, with the consultation of ECHA. However, due to budgetary constraints, these EU agencies must rely on external experts to formulate their opinions. These experts are renowned figures who are called upon to give their opinion on specific issues. Carrying out their research for the private sector, they are likely to work with undertakings that develop or manufacture products and substances subject to the

¹³⁷ ECJ C-616/17 (*Blaise and Others*) para. 78.

¹³⁸ ECJ C-616/17 (*Blaise and Others*) para. 79.

¹³⁹ Art. 36. See ECJ C-616/17 (*Blaise and Others*) paras. 82-86.

¹⁴⁰ Art. 11(2) and 36(1). ECJ C-616/17 (*Blaise and Others*) para. 88.

¹⁴¹ ECJ C-616/17 (*Blaise and Others*) para. 46.

¹⁴² Art. 7(3), 9, 12, 15(2), 63; Art. 8(1).

¹⁴³ ECJ C-616/17 (*Blaise and Others*) para. 103.

Regulation's approval procedures. In such circumstances, the independence of these experts, the opinions they give, the recommendations made by the EU scientific bodies and the decision ultimately adopted by the Commission at the end of the "comitology" procedure may be perceived as lacking, wholly or partly, in objectivity.¹⁴⁴

Second, limitations in testing methods,¹⁴⁵ data availability and obligations to communicate approved pesticides' adverse effects (i.e. post-marketing surveillance) imply that such effects may only be recognised after many years.¹⁴⁶ The current RA paradigm fails to capture cumulative and combined exposure to pesticides, and the resulting impacts on human health and ecosystems.¹⁴⁷ Indeed, the RA mainly relies on the assessment of individual active substances. As a result, exposure to multiple chemicals is not really considered within the legislative framework. That being said, the quality and objectivity of the RAs have been strengthened by the EU courts. For instance, the authorities have to take into account the "known cumulative and synergistic effects" of residues having a harmful effect on human or animal health.¹⁴⁸ This entails that the cocktail effects caused by the interaction between glyphosate and, *inter alia*, other constituents of the product must also be considered.¹⁴⁹

Third, while RAs rely heavily on science, data are often incomplete, and results may be unclear or contradictory. Indeed, as it is difficult to establish causal links between exposure to chemicals and health or environmental effects, there is generally a significant degree of uncertainty in estimating the probability and magnitude of adverse effects associated with a chemical substance. The variety and complexity of environmental dispersion pathways and the bioaccumulation in the food chain are likely to exacerbate these uncertainties. In addition, chemical substances have different properties which may give rise to risks of a different nature.¹⁵⁰ As the result of limited knowledge, it is difficult to provide conclusive evidence of a threat to human health or to the environment. In particular, EDS mimicking hormones have challenged the scientific belief that high doses produce more serious effects than low ones.¹⁵¹ It follows that "where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken",¹⁵² even if "it proves impossible

¹⁴⁴ ECJ C-616/17 (Blaise and Others) para. 103.

¹⁴⁵ In most cases, the assessment for consumers or works is done by testing herbicides in laboratory animals according to standard methods.

¹⁴⁶ SAPEA, Authorisation for plant production products (2018).

¹⁴⁷ Bopp et al. (2018), pp. 544-562.

¹⁴⁸ Art. 4(2)(a)-4(3)(b).

¹⁴⁹ AG Sharpston' Opinion in ECJ C-616/17 (Blaise and Others) para. 58.

¹⁵⁰ ECJ C-419/17 P (Deza) para. 37.

¹⁵¹ See e.g., ECJ T-31/07 (Du Pont de Nemours and Others).

¹⁵² See ECJ C-157/96 (National Farmers' Union and Others) para. 63, and ECJ C-180/96 (UK v. Commission), para. 99.

to carry out as full a risk assessment as possible in the particular circumstances of a given case because of the inadequate nature of the available scientific data”.¹⁵³

5.4. The precautionary principle is not anti-scientific

It may thus be impossible to carry out a complete RA where such investigations operate at the frontiers of scientific knowledge. Decision-makers face a dilemma. On the one hand, they may be tempted to demand better RAs by requiring the experts to conduct additional research and by refining their techniques. On the other, the pursuit of sound science is likely to come at the price of continued exposure to hazardous substances as the implementing restrictive measures are deferred.

Rather than rendering the precautionary principle nugatory, the EU courts consider the need to take preventive measures with a view to protecting the environment and human health despite lingering uncertainties. Indeed, the scientific RA is not required to provide the EU institutions with conclusive scientific evidence of the reality of the adverse effects of the hazardous substances being released into the environment or their seriousness.¹⁵⁴ Both the CJEU and the General Court have held that “where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the PP justifies the adoption of restrictive measures”.¹⁵⁵ It follows from the case law of the Court that, to ensure compliance with the precautionary principle, the safety of a PPP cannot be presumed.¹⁵⁶

Although the European Commission, as a risk manager, must “take into account” the conclusions of the RA,¹⁵⁷ it is not obliged to follow experts’ conclusions. In *Blaise*, the CJEU indicated that greater weight should not systematically be given to official studies and that the most recent studies should be taken into account.¹⁵⁸

6. Emergency powers of the Member States

“In exceptional cases”, pursuant to Article 53, Member States are permitted to authorise PPPs that are, in principle, not yet authorised, for limited and controlled use. They must demonstrate that such authorisation is necessary due to a danger or threat to plant production or ecosystems which

¹⁵³ ECJ C-236/01 (*Monsanto Agricoltura Italia*) paras. 111 and 112.

¹⁵⁴ ECJ T-31/07 (*Du Pont de Nemours and Others*) para. 140.

¹⁵⁵ ECJ C-343/09 (*Afton*) para. 171.

¹⁵⁶ Case C-616/17 (*Blaise and others*) para. 80.

¹⁵⁷ Art. 14(1), 2nd indent of Implementing Regulation 844/2012.

¹⁵⁸ ECJ C-616/17 (*Blaise and Others*) para. 94.

cannot be contained by any other reasonable means. The temporary derogations last for a period not exceeding 120 days and are reviewed at EU level.¹⁵⁹ It follows that the national authorities must demonstrate, before the PPPs are placed on the market, not only that they present a clear benefit for plant production¹⁶⁰ but also that they do not have any harmful effect on human or animal health.¹⁶¹ Despite its exceptional character, this derogation seems to be successful. In 2020, over 13,000 tonnes of non-approved substances were marketed in the EU.¹⁶²

In 2020-2021, the invasion of aphid colonies in sugar beet plantations had major economic consequences for the sugar beet industry. Around ten Member States applied to activate the derogation provided for in Article 53(1). In 2018, the Belgian authorities, relying on the temporary derogation regime provided for in Article 53(1), temporarily authorised the placing on the market of PPPs containing two NNIs – clothianidin and thiamethoxam – for the treatment of sugar beet seeds.

Although NNIs in PPPs have been expressly prohibited, the question arose as to whether a Member State may nevertheless derogate from such restrictions by way of the “emergency authorisation” provided for under Article 53. In an annulment case against these measures, the Belgian Council of State referred questions to the CJEU for a preliminary ruling on the conformity of such a derogation. In particular, the referring Court expressed doubts as to the scope of the derogation for substances that have already been banned.

In her opinion, AG Kokott proposed that a balance should be struck between protecting animal health and the environment, on the one hand, and ensuring pest control and agricultural competitiveness, on the other. This led the AG to accept the possibility of derogating from the Commission’s ban, provided that the benefits and risks of the products in question were weighed against one another. She concluded that Member States were authorised, in principle, to allow the use not only of active substances which have not yet been approved by the Commission but also the use of approved neonicotinoids that had been restricted by the Commission.¹⁶³

However, reckoning upon the principle of strict interpretation of derogations, the CJEU did not follow her opinion.¹⁶⁴ It held that Article 53 does not allow Member States to derogate from a Regulation that aims at prohibiting the placing on the market and use of seeds treated with such products. The Court’s interpretation is based on the wording of Article 53 and the objective of the PPP Regulation, which is to ensure a high level of protection of human and animal health and the environment,¹⁶⁵ consistent with the precautionary princi-

¹⁵⁹ Recital 32.

¹⁶⁰ Recital 24.

¹⁶¹ ECJ C-162/21 (Pesticide Action Network Europe) paras. 48 and 49.

¹⁶² Eurostat (2022b).

¹⁶³ ECJ C-162/21 (Pesticide Action Network Europe) para. 59.

¹⁶⁴ ECJ C-162/21 (Pesticide Action Network Europe).

¹⁶⁵ Art. 1(3) and (4) and recital 8.

ple.¹⁶⁶ The opposite reasoning would render the European Commission ban on NNIs nugatory.

Accordingly, the objectives of protecting human and animal health and the environment must take precedence over the aim of improving plant production. It follows that the traditional weighing of competing interests which a proportionality test would provoke,¹⁶⁷ should be discarded in such cases. This conclusion was all the more justified given that the marketing and use of the products concerned had been the subject of very clear prohibition measures following the EFSA's scientific assessment.¹⁶⁸

7. Conclusions

The difficulties in implementing the PPP Regulation are symptomatic of the tensions between the imperatives of free trade and those of health and environmental protection. By shifting from a risk-based to a hazard-based approach, in providing new regulatory mechanisms, such as substitution, the PPP Regulation not only fleshes out the precautionary principle but also clarifies the allocation of responsibilities for ensuring safety and improves the risk assessment requirements. The EU's prioritisation of health or environmental protection over economic considerations has been paving new ways in the reduction of health and environmental risks stemming from pesticides. As a result, the Union's goals are not only solely economic, they are also social and environmental. The proper functioning of the internal market must be accommodated with the protection of non-market values, whose legal protection is essential.

Post-scriptum

Shortly after we submitted our manuscript, on December 16th, 2025, the European Commission published as part of the cross-cutting legislative simplification package a "food/feed omnibus" (Omnibus X) that aims to increase the competitiveness and resilience of EU farmers and the food and feed industry, as well as to reduce the administrative burden on Member States authorities. Among the different food and feed regulations that the Commission proposes to simplify,¹⁶⁹ the PPP Regulation seems to be particularly targeted. We will limit ourselves to summarising the proposed amendments to several regulatory schemes discussed above.

Although, the number of approved basic and low-risk substances (section 2.2.1) is steadily increasing, stakeholders have been complaining about the absence of

¹⁶⁶ Para. 50.

¹⁶⁷ De Sadeleer (2010), pp. 308-318.

¹⁶⁸ ECJ C-162/21 (Pesticide Action Network Europe) para. 52.

¹⁶⁹ Proposal for an amending regulation as regards the simplification and strengthening of food and feed safety requirements, COM(2025) 1030 final.

a mechanism to speed-up the approval process for these substances. Therefore, the Commission proposes to simplify the criteria for identifying low-risk active substances to only refer to their intrinsic properties.

The proposed suppression of the renewal procedure for active substances that have already been authorised is undoubtedly the most radical and controversial modification envisioned by the Commission (section 2.2.5). Considering that most approved active substances have gone through at least one renewal process and that new active substances are expected to have better toxicological and ecotoxicological properties, the Commission proposes that approvals of active substances become unlimited in duration,¹⁷⁰ except in the following cases:¹⁷¹

- (a) active substances that are identified as candidates for substitution in accordance with Article 24;
- (b) active substances that are approved under Article 4(7) on the account that they are not meeting the approval criteria in Article 4 and Annex II;
- (c) active substances for which a limited period of approval is set in accordance with Article 6(j) in particular in the light of relevant uncertainties emerging from the risk assessment, including as a result of data gaps.

Attention should be drawn to the fact that the renewal procedure has already led to the ban of around 20 substances, such as Imidacloprid, a bee-killing neonicotinoid, and the organophosphate insecticide Chlorpyrifos, due to its potential genotoxicity and neurodevelopmental effects in children. Due to fears that such an elimination could cause among the public, the Commission is considering several safeguards in its proposal.

- taking into account national requests, it may identify active substances with unlimited approval for which a full renewal procedure will be carried out or identify active substances with unlimited or limited approval periods for targeted reassessment;
- the possibility for ad-hoc reviews already foreseen in Article 21 is maintained.

The fact remains that the Commission will be the sole authority to decide whether these safeguards should apply. In contrast, the current procedure is straightforward. Active substances that have already been authorised must be renewed every 15 years.

¹⁷⁰ Art. 15(2) of the proposal.

¹⁷¹ Art. 5 of the proposal.

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