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EU 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 organisms[2] 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 waters[6] and soils.[7] Furthermore, there are significant declines in insect populations and on 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 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.[11]

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[1] EEA (2023).
[2] Geiger (2010) p. 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, op.cit.,* pp. 103-104.
[8] EEA (2023).
[9] Pesticide pollution reduces natural pest control and encourages organisms to become resistant to pesticides.
[10] Pallemaerts (2023) p. 420.
[11] See below section 6.

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 that will be addressed in this chapter. 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.[12] 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.[13] 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. [14]' 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%.[15]After authorizing undertakings to place these active substances on the market,[16] the European Commission first issued restrictions in 2013,[17] and then prohibited the marketing and use of seeds treated with these active substances in 2018.[18] 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,[19] and the restrictions imposed by the European Commission.[20]

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.

[12] On the renewal of glyphosate by the European Commission, see de Sadeleer (2024) pp. 291-318.
[13] O'Connor et al. (2012) p. 351.
[14] Maxim and van der Sluijs (2013) p. 369-406; Hladik, Main, and Gouldson (2018), pp. 3329-3335; M Laure (2025) pp. 2794-2829
[15] Perrot (2025) p. 127132.
[16] 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.
[17] Commission Implementing Regulation (EU) 485/2013 (neonicotinoid).
[18] Commission Implementing Regulation (EU) 2018/784 (neonicotinoid); Commission Implementing Regulation (EU) 2018/785 (neonicotinoid).
[19] Case C-514/19 (*Union des industries de la protection des plantes*).
[20] Case C-449/18P (*Bayer CropScience and Bayer v Commission*).

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'.[21] 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.[22] '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'.[23] 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 existing scientific uncertainty.[24] Accordingly, risk management presupposes that the authorities determine from the outset 'the level of protection which they deem appropriate for society'.[25] Although Article 1(3) is unclear on this issue, it is settled case law that the health concerns take precedence over economic interests.[26]

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'.[27] 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.[28] A situation in which the principle is applied by definition coincides with one in which scientific uncertainty persists.[29]

Since the PP is binding on the EU institutions and on the Member States when their measures fall within the scope of secondary law, the EU courts may be called upon to review whether

[21] Article 1(3).
[22] Articles 114(3), 168(1), 169(3) and 191(2) of the TFEU as well as articles 35 and 37 of the EUCFR.
[23] Case T-31/07 (*Du Pont de Nemours and Others*), para 145.
[24] Case C-284/95 (*Safety Hi-Tech*), para 49.
[25] Case T-13/99 (*Pfizer*), para 151.
[26] Joined Cases T-74, 76, & 83/00 to T-85, 132, & 137/00 and T-141/00 (*Artegodan*), para. 184.
[27] Cases T-429/13 and T-451/13 (*Bayer*), para 109.
[28] Case 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 Article 60(4) of the REACH Regulation on the sole ground that there is no proof of control of the risk. Case T-108/17 (*ClientEarth*), para 139.
[29] Cases T-429/13 and T-451/13 (*Bayer*), para 116.

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.[30]

As we shall see below, judgements of the CJEU and the General Court on pesticides often refer to the precautionary principle. As recalled by the CJEU in *Blaise*, the principle is the cornerstone of the PPP Regulation. The recourse to the principle 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 European Union.[31]

Article 191 TFEU and the PPP Regulation make no distinction between the implementation of the precautionary principle by the Member State Rapporteur 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 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 CPA and adopted pursuant to former Article 43 EEC. In other words, in 2009 the EU

[30] For an overview of this case law, see de Sadeleer (2020) pp. 192-221.
[31] Para 45.
[32] Donati (2023), p. 6.
[33] Case C-616/17 (*Blaise and Others*), para 44.
[34] Article 288 TFEU.
[35] Case C-370/07 (*Commission v Council*), paras. 37, 39, 46, 48.

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 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) TFEU[38] 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

PPPs contain 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 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.

[36] See Case T-31/07 (*Du Pont de Nemours and Others*), *op.cit.*, para 203.
[37] de Sadeleer (2010) pp. 157-161, 291, 304, 353, and 358-382.
[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] Article 168(1) TFEU, read in combination with Article 35 EUCHR, requires that the protection of human health must be integrated into the definition and implementation of the Union policies and activities.
[40] Articles 7 to 13.
[41] Articles 33 to 39.
[42] Article 29(1)(a). Case C-616/17 (*Blaise and Others*), *op.cit.*, para 66.
[43] Case T-545/11 RENV (*Stichting Greenpeace Nederland*), para. 74.
[44] Articles 4 to 13.

2.2.1. The identification of the 'active substance'

The PPPR does not contain any definition of the expression 'active substance'.[45] 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.[46] 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.[47]

The PPP Regulation introduced the concept of low-risk PPPs. To qualify as low-risk, a PPP can only contain active substances approved as low-risk[48] and may not contain any 'substances of concern'. 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.[49] 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).[50] 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 environment.[51] It prepares a Draft Assessment Report (DAR). The European Food Safety Authority (EFSA) performs a peer review[52] in consultation with the other Member States[53] and the European Chemicals Agency (ECHA). At the end of these consultations, the Agency finalises its opinion.[54]

The European Commission subsequently prepares an implementing act based on the EFSA's opinion.[55] It can take into consideration 'factors legitimate to the matter under consideration' and must pay heed to the precautionary principle.[56] In order to approve the substance, the Commission must consult the Standing Committee on Plants, Animals, Food and Feed on its draft implementing act.[57] Following discussions in the comitology committee, the Commission

[45] Case C-616/17 (*Blaise and Others*), *op.cit.*, para. 52.
[46] *Ibid.*, para. 57.
[47] *Ibid*.
[48] Point 5 of Annex II sets out the EU criteria for low-risk substances.
[49] Article 13(2).
[50] Article 7(2)-(3).
[51] Article 11.
[52] Article 8(5).
[53] Article 12(1).
[54] Article 12.
[55] Article 13(1).
[56] Article 13(2).
[57] 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 Case T-178/18 (*Région de Bruxelles-Capitale v Commission*), paras 66-67.

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,[58] 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.[59]

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.[60]

A new active substance is usually approved for a maximum of 10 years[61], or 15 years if classified as low risk.

The comitology procedure has been criticised insofar as it strengthens the powers of the Commission. Indeed, the latter adopts the decision when Member States fail to reach agreement within the committee in which they meet.[62] 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.[63]

2.2.3. Criteria to fulfil to approve an active substance

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.[64] Pursuant to Article 4(1) of the PPPR, 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. 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'.

The applicant must thus provide proof that the active substance does not have the harmful effects referred to.[65] Accordingly, he must submit a complete dossier alongside its application for authorisation demonstrating that the active substance satisfies the approval criteria.[66] The rapporteur Member State and then EFSA, with the participation of the other Member States and the public, evaluate that information. However, that evaluation is not limited to the information submitted as they must also take into account current scientific and technical knowledge.[67]

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[58] All approved active substances are listed in Commission Implementing Regulation (EU) 540/2011.
[59] Opinion AG Kokott, Case C-316/24 P (*PAN Europe v Commission*), para. 44.
[60] Case T-719/17 (*FMC Corporation v Commission*), paras 187-188.
[61] Article 15.
[62] Regulation (EU) 182/2011, Article 5(4).
[63] Nihoul (2024) p. 200.
[64] Recital 10; Article 4(2).
[65] Case C-616/17 (*Blaise and Others*), *op.cit.*, paras 78, 79, 95 and 114.
[66] Articles 7 and 8. See Commission Regulation (EU) 283/2013.
[67] Case C-616/17 (*Blaise and Others*), *op.cit.*, para 69.

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 disruptive[68]) cannot receive approval, or renewal of approval.[69] 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.[70] The probability of harm associated with the PBT, POP, vPvB characteristics is deemed to be too hight to authorise these substances. The procedure relying on cut-off hazard-based criteria is faster and less expensive,[71] 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).

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.[72]

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'.[73] 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.[74] 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.[75] In principle an active substance shall

[68] 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). By 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 528/2012 specifying the scientific criteria for determining EDS properties.

[69] 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 Commission Delegated Regulation (EU) 2017/2100 and Commission Regulation (EU) 2018/605. See Kuraj (2018) p. 299.

[70] Bozzini (2017) p. 30.

[71] *Ibid.*, pp. 32, 67.

[72] Article 6.

[73] Article 21(1).

[74] Recital 10, Article 14(1).

[75] Article 14(1).

only be approved where a complete dossier is submitted.[76] Specific implementing measures have been adopted by the Commission regarding the submission of the application for renewal and its contents and format.[77]

When applying for renewal, the producer of the active substance must identify new data he intends to submit and demonstrate their necessity, either because of data requirements or because criteria have changed since the last approval.[78] 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.[79]

At the end of the renewal procedure, the European Commission adopts a regulation in accordance with the comitology procedure.[80] The approval of the active substance is either renewed or not renewed.[81] 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.[82] Renewals may not exceed 15 years.[83] 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.[84]

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 judicature 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.[85]

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.[86] 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.[87] 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

[76] Point 2.2 of Annex II.
[77] See in particular Commission Implementing Regulation (EU) 844/2012.
[78] Article 15(2); Regulation (EC) 1107/2009, art. 6.
[79] Regulation (EC) 1107/2009, art. 7(1) d).
[80] Article 19.
[81] Article 20(1).
[82] Article 20(2), second subparagraph.
[83] Article 15(2).
[84] Article 43(1) and (2)
[85] See Case C-98/78 (*Racke*), para 5, and Case C-16/90 (*Nölle*), para 12 ; Case C-326/05 P (*Industrias Químicas del Vallés*), pare 76 ; Opinion AG Kokott, Case C-316/24 P (*PAN Europe v Commission*), *op.cit.*, para. 38.
[86] Case C-499/19 P (*Lupu*), para. 45; Case C-499/18 P (*Bayer CropScience et Bayer*), Opinion of AG Kokott, para. 74.
[87] Case C-499/19-P (*Lupu*), *op.cit* para. 55

further conditions.[88] 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.[89]

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.[90] It considered that a decision on whether approval criteria are still met[91] may be 'based on any new knowledge, in so far as it is scientific or technical' regardless of its source.[92] 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'.[93] 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.[94]

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 of Regulation are based on the precautionary principle.[95] It follows that the Commission can invoke the principle where there is scientific uncertainty concerning risks posed by active substances.[96] 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.[97] In its 2018 peer review of the risk assessment of the active substance cypermetrhin,[98] EFSA underscored the missing information as being required by the regulatory framework and identified four critical areas of concern ('*domaines critiques de préoccupation'*): high risk to aquatic organisms, bees and non-target arthropods, and uncertainty as to whether batches used in the (eco)toxicological studies were representative of the technical specification. 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.[99] It was therefore not possible for the Commission to renew the authorisation for the active substance. Admittedly, the renewal of

[88] Case C-352/19 P (*Région de Bruxelles-Capitale v Commission*), para. 50.
[89] Case C-616/17 (*Blaise and Others*), *op.cit.*, para 99.
[90] Article 21(1).
[91] Article 4.
[92] Case C-499/18 P (*Bayer CropScience et Bayer*), *op.cit.*, para. 69.
[93] Jennings (20122).
[94] Maxim and van der Sluijs (2013) p. 389.
[95] Case C-499/18 P (Bayer CropScience et Bayer), *op.cit.*, para 79.
[96] *Ibid.*
[97] 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.
[98] EFSA et al. (2018) p. 5402.
[99] Article 75.

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 authorizations for PPPs. 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.[100] 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. [101] In her opinion of 5 June 2025, AG Kokott proposed that the Court of Justice should set aside the judgment of the General Court.[102]

2.3.Granting of product authorisations

2.3.1. 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 authority, but from a Member State authority.[103] 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 Court, to conclude that the applicant is directly affected.[104] The Member States examining the application to place the pesticide on the market grants or refuses authorisations.[105]

2.3.2. 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'.[106] 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

[100] Article 146.
[101] Case T–536/22 (*PAN Europe v Commission*). See N de Sadeleer (2024) pp. 304-311.
[102] Opinion AG Kokott, Case C-316/24 P.
[103] Articles 33 and 35.
[104] Case T-178/18 (*Région de Bruxelles-Capitale v Commission*), *op.cit.*, para 66.
[105] Article 36(2).
[106] Case C-616/17 (*Blaise and Others*), *op.cit.*, para. 73.

examination of that application.[107] He is not exempted from submitting tests on long-term carcinogenicity and toxicity relating to the PPP that is the subject of an application for authorisation.[108] 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'.[109] 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.[110] Ultimately, the Member State concerned shall grant or refuse authorisations accordingly on the basis of the conclusions of the risk assessment.[111]

2.3.3. Comparative assessment' of pesticides containing particularly hazardous substances

The PPP Regulation represents a watershed in the development of the substitution principle,[112] 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 alternatives.[113] 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

[107] *Ibid.,* para. 57.
[108] *Ibid.,* para. 113.
[109] *Ibid.*, para. 115.
[110] Article 36(1).
[111] Article 36(1).
[112] Winter (2007) pp. 313-329.
[113] Article 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 criticized the Commission forhttps://www.ombudsman.europa.eu/en/decision/en/191432 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).

substances in pesticides considered to be 'Candidates for Substitution' which must undergo a comparative assessment.[114]

2.4.Principle of mutual recognition

The principle of mutual recognition is one of the means of ensuring the free movement of goods within the EU.[115] 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.[116] 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 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.[117]

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.

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

3.1.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.[118] By the same token, the Member State must carry out a RA of the effects of the products concerned.

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[114] The candidates for substitution, are listed in Part E of the Commission Implementing Regulation (EU) 540/2011.
[115] Recital 29.
[116] See PPPR, recital 23, art 40 and Annex IV.
[117] Case T-178/18 (*Région de Bruxelles-Capitale v Commission*), *op.cit.*, para 61.
[118] Article 4(2) subparagraph 2.

According to the CJEU case law, the RA must be 'as complete as possible given the particular circumstances of the individual case'.[119] Thanks to this assessment, the institutions should be able to examine, 'carefully and impartially, all the relevant facts of the individual case'.[120] The 'detailed assessment of the risk',[121] 'presupposes, in the first place, the identification of the potentially negative consequences for health' of the product or the substance.[122]

3.2.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.[123] 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.[124] The EU legislator has regulated the quality of the tests, studies and analyses to be submitted.[125] In addition, several provisions of the PPP Regulation emphasise the objectivity, transparency and independence of experts.[126] 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.[127]

At first sight, however, the confidentiality enjoyed by the applicant could prevent the public from challenging the results used in the authorisation application.[128] 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.[129] The same applies to the draft assessment report sent to the Commission by the rapporteur Member State for distribution to all EU countries.

3.3.Epistemological limits

As far as pesticides are concerned, the RA procedure is subject to several 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

[119] Case C- 236/01 (*Monsanto Agricoltura Italia*), para 113; Case T-13/99 (*Pfizer*), *op.cit.*, paras 155-156; EFTA Ct., Case 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 Case C-405/07 P (*Netherlands v Commission*), para 77.
[120] See, inter alia, Case C-269/90 (*Technische Universität München*), para 14.
[121] Case C-192/01 (*Commission v. Denmark*), para 47.
[122] Case E-3/00 (*EFTA Surveillance Authority v Norway*), *op.cit.,* para 30; Case C-236/01 (*Monsanto Agricoltura Italia*), *op.cit.*, para 113; and Case C-192/01 (*Commission v Denmark*), *op.cit.,* para 51.
[123] Case C-616/17 (*Blaise and Others*), *op.cit.*, para. 78.
[124] *Ibid.*, para. 79.
[125] Article 36. See Case C-616/17 (*Blaise and Others*), *op.cit.*, paras. 82-86.
[126] Articles 11(2) and 36(1). Case C-616/17 (*Blaise and Others*), *op.cit.*, para. 88.
[127] Case C-616/17 (*Blaise and Others*), *op.cit.*, para. 46.
[128] Articles 7(3), 9, 12, 15(2), 63 ; Article 8(1).
[129] Case C-616/17 (*Blaise and Others*), *op.cit.*, para. 103.

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 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.[130]

Second, limitations in testing methods,[131] 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.[132] The current RA paradigm fails to capture cumulative and combined exposure to pesticides, and the resulting impacts on human health and ecosystems.[133] 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.[134] This entails that the cocktail effects caused by the interaction between glyphosate and, inter alia, other constituents of the product must also be considered.[135]

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.[136] 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.[137] It follows that 'where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken',[138] even if 'it proves impossible 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'.[139]

3.4. 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

[130] Case C-616/17 (*Blaise and Others*), *op.cit.*, para. 103.
[131] In most cases, the assessment for consumers or works is done by testing herbicides in laboratory animals according to standard methods.
[132] SAPEA, Authorisation for plant production products (2018).
[133] Bopp et al (2018), pp. 544-562.
[134] Articles 4(2)(a)- 4(3)(b).
[135] AG Sharpston' Opinion in Case C-616/17 (*Blaise and Others*), *op.cit.*, para. 58.
[136] Case C-419/17 P (*Deza*), para 37.
[137] See e.g., Case T-31/07 (*Du Pont de Nemours and Others*).
[138] See Case C-157/96 (*National Farmers' Union and Others*), para 63, and Case C-180/96 (*UK v Commission*), para 99.
[139] Case C-236/01 (*Monsanto Agricoltura Italia*), paras 111 and 112.

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.[140] 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'.[141]

Although the European Commission, as a risk manager, must 'take into account' the conclusions of the RA,[142] 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.[143]

4. Access to information

The solitary exercise of power linked to the administrative tradition of secrecy has long been reflected in the considerable inertia that arises when it comes to disclosing information about technical choices relating to environmental issues. Yet information constitutes the core of the struggle to protect the environment, since ignorance renders rights to participation and access to justice ineffective. The right to information is therefore central among procedural rights.[144] Furthermore, access to environmental information plays an important role as a procedural aspect of a substantive right such as a right to a clean environment. The openness enables the EU institutions to have greater legitimacy and to be more effective and more accountable to EU citizens in a democratic system and that, by allowing divergences between various points of view to be openly debated. It also contributes to increasing those citizens' confidence in those institutions.[145]

4.1. Access to the information held by the EU institutions

Access to the information held by the EU institutions is regulated by two regulations, the second of which implements the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (hereafter the Aarhus Convention):

[140] Case T-31/07 (*Du Pont de Nemours and Others*), *op.cit.*, para 140.
[141] Case C-343/09 (*Afton*), para 171.
[142] Article 14(1), 2nd indent of Implementing Regulation 844/2012.
[143] Case C-616/17 (*Blaise and Others*), *op.cit.*, para 94.
[144] N de Sadeleer, (2020), *op.cit.*, p. 425.
[145] Case C-57/16 P (*ClientEarth v Commission*), para 75.

- Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents,[146]

- Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (hereafter the Aarhus Regulation).[147]

At the outset, the EU institutions could refuse to grant access to the information on data related to active substances in invoking the exception in Article 4(2), first indent, of Regulation No 1049/2001, namely the protection of the commercial interests of the company producing the substance.

However, the Aarhus Regulation is a *lex specialis* that derogates from Regulation No 1049/2001. Indeed, its aim is to ensure the widest possible systematic availability and dissemination of the environmental information held by the EU institutions and bodies.[148] As a result, exceptions to that principle must be interpreted and applied strictly. Furthermore, account must be taken of the Aarhus Convention for the purposes of interpreting the Aarhus Regulation.[149]

The fact that the EU institutions are obliged under the Aarhus Regulation to ensure the dissemination of environmental information has significant consequences. The rule laid down in Article 4(2) of Regulation 1049/2001 requires the weighing up of the interests. In contrast, the Aarhus Regulation derogates from that rule by establishing a presumption in favour of the disclosure of information that 'relates to emissions into the environment'.[150] It follows that the Aarhus Regulation requires the disclosure of a document where the information requested relates to 'emissions into the environment', even if there is a risk of undermining the protection of the commercial interests of the company.[151]

The question arose as to whether the concept of 'information relating to emissions into the environment' must be interpreted broadly or restrictively.

Greenpeace and PAN Europe have been attempting to gain access to the records concerning the authorisation of glyphosate for use in pesticides. The European Commission disclosed some of the documents in question, but withheld others on grounds of protection of the commercial interests of the undertakings concerned. The General Court, on the other hand, ruled that the withheld documents also relate to emissions into the environment and an overriding interest in their disclosure must therefore be presumed to exist. On appeal, the CJEU held that the concept of 'information [which] relates to emissions into the environment' must not be interpreted strictly.[152] Consequently, an EU institution cannot justify its refusal to divulge it on the basis

[146] Regulation (EC) No 1049/2001, *OJ 2001 L 145*, p. 43.
[147] Regulation (EC) No 1367/2006, *OJ 2006 L 264*, p. 13.
[148] Art. 1. See Case C-673/13 P (*Commission v Stichting Greenpeace Nederland and PAN Europe*), para. 52; Case T-222/23 (*Arysta Lifescience*), para 33.
[149] Case C-673/13 P (*Commission v Stichting Greenpeace Nederland*), *op.cit.*, para. 61
[150] Article 6(1) first sentence.
[151] Case T-222/23 (*Arysta Lifescience*), para 36.
[152] C-673/13 P (*Commission v Stichting Greenpeace Nederland*), *op.cit.*, paras 49 and 53.

of the exception relating to the protection of the commercial interests of a particular natural or legal person for the purposes of Article 4(2), first indent, of Regulation No 1049/2001, where the information contained in that document constitutes information which 'relates to emissions into the environment' within the meaning of Article 6(1) of the Aarhus Regulation.[153]

The CJEU concluded that it was necessary to include in the concept of information which 'relates to emissions into the environment' information enabling the public to check whether the assessment of actual or foreseeable emissions, on the basis of which the competent authority authorised the product or substance in question, was correct, and the data relating to the effects of those emissions on the environment.[154] Accordingly, the Court endorsed a broad interpretation of the notion of the concept of 'emissions'.

The CJUE judgment in *Commission* v *Stichting Greenpeace Nederland and PAN Europe* left a number of questions unanswered on the account that an active substance such as glyphosate is inevitably released into the environment at some stage of its life cycle.

In that case, the CJEU referred the case back to the General Court. The parties disagree on whether that information is covered by the concept of 'information relating to emissions into the environment' as defined by the CJUE in the judgment on appeal.

The NGOs requesting the information (Stichting Greenpeace Nederland and PAN Europe) supported by Sweden argued that the information concerns all the substances released into the environment when the authorised substance 'glyphosate' is used and applied in pesticides. In particular, the NGOs sought access to information relating to the 'identity' and quantity of impurities present in the glyphosate, the analytical profile of the batches, in particular their composition, the 'identity' and quantity of chemical substances added during the tests, the duration of those tests and the actual effects on the active substance.[155] In their view, that information could allow the determination of the level of emission of those impurities into the environment.[156]

In contrast, the European Commission argued that this information relates to the manufacturing processes used by the various operators that notified glyphosate for the purpose of its inclusion in Annex I to Directive 91/414 and was thus not directly linked to of emission into the environment. In particular, the disclosure of such information would make it possible to reconstitute the manufacturing process of the glyphosate and the related business secrets.[157]

The General Court held that:
'while it is not necessary to apply a restrictive interpretation of the concept of 'information [which] relates to emissions into the environment', that concept may not, in any event, include information containing any kind of link, even direct, to emissions into the environment. If that concept were interpreted as covering such information, it would to a large extent deprive the concept of 'environmental information' as defined in Article 2(1)(d) of Regulation No 1367/2006 of any meaning. Such an interpretation would deprive of any practical effect the possibility, laid down in the first indent of Article 4(2) of Regulation No 1049/2001, for the institutions to refuse to disclose environmental information on the ground, inter alia, that such

[153] Case T-716/14 (*Tweedale*), para. 58.
[154] Case C-673/13 P (*Commission v Stichting Greenpeace Nederland*), *op.cit.*, para. 80
[155] *Ibid*., para. 60.
[156] *Ibid*., paras. 62-64.
[157] *Ibid*., para. 65.

disclosure would have an adverse effect on the protection of the commercial interests of a particular natural or legal person and would jeopardise the balance which the EU legislature intended to maintain between the objective of transparency and the protection of those interests. It would also constitute a disproportionate interference with the protection of business secrecy ensured by Article 339 TFEU (judgment on appeal, paragraph 81)'.[158]

The General Court drew a distinction between:

- on the one hand, 'the use and conditions of use of the plant protection product covered by authorisation in a Member State' that 'may be very different from those which have been subject to the theoretical assessment at EU level',[159]

- on the other, the plant protection product for which authorisation is requested that is often produced, by a different undertaking than that which requested approval for the active substance at EU level.[160]

It concluded that

'it is only at the stage of the national authorisation procedure to place a specific plant protection product on the market that the Member State assesses any emissions into the environment and that specific information emerges concerning the nature, composition, quantity, date and place of the actual or foreseeable emissions, under such conditions, from the active substance and the specific plant protection product containing it,…'.[161]

As a result, the Commission did not commit an error of assessment in considering that the draft report, drawn up in the course of the approval procedure at EU level, does not contain information relating to emissions into the environment. This narrow interpretation has been criticized by E. Brosset who argues that the CJEU judgment allowed a case-by-case approach whilst the General Court endorses a global approach ('*une approche d'ensemble'*).[162]

In 2009, in *Tweedale* and *Hautala*, the General Court endorsed an interpretation that was more consistent with the *Stichting Greenpeace Nederland and PAN Europe* CJEU judgment. The General Court ruled that key studies intended to determine the effects of exposure to glyphosate on human health (determining, inter alia, the acceptable daily intake (ADI) and 'acute reference dose' (ARfD) for glyphosate) and used in the renewal dossier amount to an information on foreseeable emissions into the environment. What is more, 'an active substance contained in plant protection products, such as glyphosate, in the course of normal use, is intended to be discharged into the environment by virtue of its function, and its foreseeable emissions cannot, therefore, be regarded as purely hypothetical'.[163]

In *Arysta Lifescience***,** the General Court held that co-formulants contained in a PPP were akin to active substances, given that they are discharged into the environment in the course of its normal or realistic use.[164] Where EFSA correctly finds that a list of co-formulants contained 'information [relating] to emissions into the environment', it was not necessary to carry out

[158] Case T-545/11 (*RENV Stichting Greenpeace Nederland*), para. 58
[159] *Ibid*., para. 83.
[160] *Ibid*., para. 84.
[161] *Ibid*., para. 88.
[162] Brosset (2019).
[163] Case T-716/14 (*Tweedale*) ; Case T-329/17 (*Hautala*).
[164] Case T-222/23 (*Arysta Lifescience*), para 47.

such an assessment of the commercial harm this information will cause to the applicant on the basis of Article 4(2) of Regulation No 1049/2001.[165]

4.2.Access to environmental information held by the Member States

In adopting the PPPR, the EU lawmaker sought to balance the confidential nature of the information submitted by the applicant and the right of the public to access to environmental information. This led to a political compromise, as Article 63 of the PPPR is worded as follows:

> '1. A person requesting that information submitted under this Regulation is to be treated as confidential shall provide verifiable evidence to show that the disclosure of the information might undermine his commercial interests, or the protection of privacy and the integrity of the individual.
>
> 2. Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests or of privacy and the integrity of the individuals concerned:
>
> (a) the method of manufacture;
>
> …
>
> (f) information on the complete composition of a plant protection product;
>
> …

The third paragraph of this provision states expressly that that the right to keep some information confidential is to be without prejudice to the application of Directive 2003/4, which means that requests for access by third parties to the information contained in authorisation application dossiers are subject to the general provisions of that directive.[166]

In virtue of Directive 2003/4 EC on public access to environmental information, Member States have to ensure that public authorities make the environmental information they hold available to any legal or natural person on request. Account must be taken of the Aarhus Convention for the purposes of interpreting Directive 2003/4.[167]

The CJEU has provided guidelines in its interpretation of the concept of 'information on emissions into the environment' for the purposes of the second subparagraph of Article 4(2) of Directive 2003/4/EC.[168]

In *Bayer CropScience,* the CJEU had to assess whether the information regarding the foreseeable emissions into the environment of the residues of the active substance glyphosate could be disclosed in accordance with Directive 2003/4/EC. Studies of residues and reports of field trials submitted in connection with a procedure for extending the authorisation of a product in accordance with the legislation of plant protection products are deemed to be 'environmental information' for the purpose of Art 2 of Directive 2003/4 on access to environmental

[165] Case T-222/23, (*Arysta Lifescience*), *op.cit*., para 56.
[166] Case C-616/17 (*Blaise and Others*), para. 106.
[167] Case C-442/14 (*Bayer CropScience and Stichting De Bijenstichting*), para. 54.
[168] Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information.

information. In effect, this information 'concerns elements of the environment which may affect human health if excess levels of those residues are present'[169].

The Court took the view that the information to be communicated encompasses 'studies which seek to establish the toxicity, effects and other aspects of a product or substance under the most unfavourable realistic conditions which could possibly occur, and studies carried out in conditions as close as possible to normal agricultural practice and conditions which prevail in the area where that product or substance is to be used'.[170]

5. 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 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.[171] 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 production[172] but also that they do not have any harmful effect on human or animal health.[173] Despite its exceptional character, this derogation seems to be successful. In 2020, over 13000 tonnes of non-approved substances were marketed in the EU.[174]

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

[169] Case C-266/09 (*Stichting Natuur en Milieu*), paras 42 and 43.
[170] Case C-442/14 (*Bayer CropScience and Stichting De Bijenstichting*), para. 91.
[171] Recital 32.
[172] Recital 24.
[173] Case C-162/21 (*Pesticide Action Network Europe*), paras 48 and 49.
[174] Eurostat, 2022b.

Commission but also the use of approved neonicotinoids that had been restricted by the Commission.[175]

However, reckoning upon the principle of strict interpretation of derogations, the CJEU did not follow her opinion.[176] 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,[177] consistent with the precautionary principle.[178] 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,[179] 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' scientific assessment.[180]

6. Validity of the restrictions placed by the Member States on the use of plant protection products and their substances

6.1. Total harmonisation

As far as pesticides are concerned, prior to the adoption of Directive 91/414/EEC on the placing of PPPs on the market , there were no common harmonized rules governing the production and marketing of PPPs. In the absence of harmonisation, it was therefore 'for the Member States to decide what degree of protection of the health and life of humans they intended to assure… having regard to the fact that their freedom of action is itself restricted by the Treaty'.[181] Since the entry into force of that Directive (replaced in 2009 by the PPP Regulation) this field has become fully harmonised. Member States may thus no longer rely on Article 36 TFEU or on mandatory requirement.[182]

Nevertheless, State authorities still keep room for manoeuvre.

Firstly, harmonisation does not equate to uniformity. For instance, Directive 91/414 did not contain any provision which specifically governed the conditions for granting marketing authorisation for PPPs in the context of parallel imports.[183] As this area was not harmonized, a

[175] Para 59.
[176] Case C-162/21 (Pesticide Action Network Europe), *op.cit*.
[177] Article 1(3) and (4) and recital 8
[178] Para 50.
[179] de Sadeleer (2010) pp. 308-318.
[180] *Ibid*., para 52.
[181] Case C-104/75 (*De Peijper*) ; Case C-272/80 (*Biologishe Produkten*), para. 12.
[182] See among others Case C-5/77 (*Tedeschi*), para. 35; Case C-148/78 (*Ratti*), para. 36; Case C-251/78 (*Denkavit Futtermittel*), para. 14; Case C-190/87 (*Moormann*), para. 10; Case C-215/87 (*Schumacher*), para. 15; Case C-369/88 (*Delattre*), para. 48; Case C-62/90 (*Commission v Germany*), para. 10; Case C-323/93 (*Centre d'insémination de la Crespelle*), para. 30; and Case C-320/93 (*Ortscheit*), para. 14. Regarding the non-exhaustive character of food additives see Case C-121/00 (*Walter Hahn*).
[183] Advocate General Trstenjak's Opinion delivered on 10 July 2007 in Joined Cases C-260/06 and C-261/06 (*Escalier and Bonnarel*), para. 8.

Member State was entitled, pursuant to Article 36 TFEU, to subject farmers importing a PPP as a parallel import solely for their own needs to a simplified authorisation procedure.[184]

Secondly, the PPP Regulation does not prevent the Member States from applying the precautionary principle where there is scientific uncertainty regarding risks to human or animal health or the environment posed by the pesticides to be authorised in their territory.[185]

Thirdly, the PPP Regulation provides a mechanism for domestic interim protective measures 'where a Member State officially informs the Commission of the need to take emergency measures and no action has been taken in accordance with the Regulation'.[186]

Fourthly, in implementing Directive 2009/128/EC[187] Member States are empowered to regulate the use of pesticides containing glyphosate.

The reauthorisation of glyphosate as safe and risk-free triggered one of the most acute crises in EU food governance in the last decade, and mobilised a variety of avenues of contestation. This approval raises the question of the extent to which national or even regional authorities still have the power to prohibit the marketing or use of the product on grounds contrary to those adopted by the Commission.

6.2. The standing of the Brussels-Capital Region to obtain the nullification of the reapproval of glyphosate

The Brussels-Capital Region had adopted an order prohibiting the use of pesticides containing glyphosate on its territory, due to the risks that it believed this substance posed to human health and the environment. The Region argued before the General Court that the exercise of its powers regarding the use of the product was affected by the Commission's decision to renew the approval of the active substance glyphosate, on the grounds that it did not pose a risk to human health or the environment. Followed by the CJEU, the General Court held that the Commission's approval of glyphosate does not, in itself, imply an obligation on Member States to authorise the use of products containing that substance.[188] According to the Court, the PPP regulation allows Member States to determine such use based on the policy choices made within their territory.[189] However, the General Court held that this uncertainty is insufficient to establish the existence of a direct effect.[190]

6.3. National cases regarding the validity of restrictions placed on the use of glyphosate

The following judgments exemplify to some extent the room for manoeuvre left to the Member States.

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[184] Joined Cases C-260/06 and C-261/06 (*Escalier and Bonnarel*), *op.cit.*, paras. 34 and 36.
[185] Case C-616/17 (*Blaise and Others*), *op.cit.*, para. 44.
[186] Article 71.
[187] See below section 7.
[188] Case T-178/18 (*Région de Bruxelles-Capitale v Commissio*n), *op.cit.*, para 60-61 ; C-352/19 P (*Région de Bruxelles-Capitale*), *op.cit.*
[189] *Ibid.*, para 61.
[190] Case T-178/18 (*Région de Bruxelles-Capitale v Commission*), *op.cit.*

In its judgment of 15 January 2019, the Administrative Court of Lyon struck the authorisation granted by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) for the marketing of Round Up Pro 360.[191] It criticised ANSES for failing to produce a risk assessment making it possible to establish that Round Up Pro 360 was neither carcinogenic nor toxic to reproduction, even though the EFSA considered that glyphosate preparations may not be carcinogenic. Indeed, the court stressed that Roundup Pro 360 is a preparation that is more toxic than glyphosate. In other words, the product at issue is likely to prove to be carcinogenic without the active substance it contains being carcinogenic as such. Despite the restrictions placed on the use of Round Up Pro 360, the marketing authorisation granted by ANSES is 'likely to cause serious damage to health'. On the basis of that conclusion, the Court annulled the marketing authorisation on the ground that, by authorising that herbicide, ANSES had committed a manifest error of appraisal in light of the precautionary principle enshrined in Article 5 of the Constitutional Charter on the Environment. That principle is to be implemented by the public authorities where there is a risk of serious and irreversible damage to the environment or damage to the environment likely to cause serious harm to health. By omitting to take into consideration serious health risks, ANSES could not grant such a marketing authorisation. This reasoning seems to us to be in line with EU law, since the PPP Regulation only allows the marketing of safe PPPs.

On 28 February 2019, the Belgian Constitutional Court dismissed a claim lodged by the Belgian association of the pesticide industry against a Flemish decree restricting the use of glyphosate.[192] The Court held that the decree implemented Directive 2009/128/EC which allows Member States to regulate the use of pesticides. The Court further emphasized that the restrictions placed on the use of pesticides containing glyphosate are authorised in virtue of Article 12 of that Directive.[193]

In Sweden, the Supreme Administrative Court has overturned a decision taken by the chemicals agency (KemI) and, on appeal by the government restricting the use of the active substance glyphosate on the ground that the substance was authorised under former Directive 91/414 on pesticides.[194] The Supreme Court held that a concrete risk assessment of the impact of the substance into ground water was missing.

Finally, although several regions and municipalities had partially banned the use of glyphosate-based products, Luxembourg became, in 2022, the first European country to ban all personal and professional use of such products. The governmental decisions were annulled by the administrative courts for a breach of the adversarial principle. In addition, the Administrative Tribunal pointed out that Luxembourg breached EU law by withdrawing glyphosate-based products from the market solely on the ground of Article 44(3) of the PPPR Regulation.[195] For the Administrative Tribunal and the Court of Appeal, Luxembourg should have proved that, due to specific environmental or agricultural circumstances, it had substantiated reasons to consider that glyphosate-based products posed an unacceptable risk to human or animal health or the environment. In the case at stake, Luxembourg was not entitled to invoke the precautionary principle insofar as it did not examine directly the application for the

[191] Administrative Court of Lyon, 15 January 2019.
[192] Case No 38/2019. Under Belgian law, the regions are competent to regulate the use of PPPs on their territory, whereas the Belgian federal authority is competent to adopt decisions on the grant and renewal of authorisations to place a PPP on the market in accordance with the regulation.
[193] *Ibid*., B.5.
[194] Case Raa 2005.
[195] Donati (2023) pp. 1–7.

authorisation of glyphosate-based products but authorised them following the authorisation granted by Belgium, acting as a Member State Rapporteur.

7. The sustainable use of pesticides

So far, data on pesticide use are not yet available at EU level.[196] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (SUD)[197] promotes low pesticide-input pest management, giving priority wherever possible to non-chemical methods.[198] Low pesticide-input pest management includes integrated pest management as well as organic farming. The SUD provides for a range of actions to achieve a sustainable use of pesticides by promoting the use of Integrated Pest Management (IPM)[199] and alternative approaches or techniques, such as non-chemical substitutes to pesticides. The CAP framework Regulation encompasses several instruments, which support implementation of IPM by users.[200]

In contrast to the PPP Regulation, the SUD is largely subject to the principle of subsidiarity and relies on actions to be taken at Member State level, given the variation given the variation in agriculture across the EU. Accordingly, Member States have drawn up national action plans to implement the measures set out in the Directive. The SUD requires the States, among others, to train users, advisors and distributors of pesticides, to inspect pesticide application equipment, to prohibit aerial spraying and to limit pesticide use in sensitive areas. However, it appears that several Member States are dragging their feet in implementing these measures. [201]

The Court of Auditors published a report on the "Sustainable use of plant protection products" which assessed whether the actions of the Commission and Member States had led to a reduction in the risks related to pesticide use, and whether the relevant legislation provided effective incentives to reduce dependency on pesticides.[202] The Court recommended that the Commission should ensure that the Member States convert the IPM general principles into practical criteria and that they verify them at farm level, allowing them to be linked to payments under the common agricultural policy in the post-2020 period.

Article 55 of the PPP Regulation states that use of PPPs must comply with the Directive and, in particular, the general principles of IPM as referred to in Article 14 of and Annex III to the SUD.

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[196] In accordance with Article 10(5) of the Regulation (EU) 2022/2379.
[197] OJ, 2009 L 309 79
[198] Article 14(1).
[199] IPM includes rotating different crops and selecting pest resistant seeds, monitoring of pests and setting sound threshold values that help to decide whether and when pest control is needed.
[200] Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013, *OJ* L 435, 6.12.2021, pp. 1–186.
[201] Report from the Commission On the experience gained by Member States on the implementation of national targets established in their National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides ; COM(2020) 204 final.
[202] European Court of Auditors (2020).

In the context of the European Green Deal,[203] the farm to fork strategy[204] identified the need to reduce pesticide dependency. The European Commission has committed to revising the Directive. However, on 6 February 2024 the Commission announced the withdrawal of its proposal seeking to reduce the spraying of pesticides by half.[205] The urge of further simplification measures (Omnibus) may be the death knell of improving this regulatory scheme.

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' 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.

[203] de Sadeleer (2025) pp. 1-32.
[204] Commission communication, A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system, COM/2020/381 final.
[205] Proposal for a of regulation the European Parliament and of the Council on the sustainable use of plant protection products and amending Regulation (EU) 2021/2115 COM/2022/305 final.

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