Glyphosate as an active substance authorized under EU pesticide regulations: Regulatory principles and procedures

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Introduction

Aiming at reducing health and environmental risks, the chemical policy has historically been related to a general preference for a certainty-seeking regulatory style in which a formal, science-based, and standardized risk assessment has been singled out as the predominant tool for decision-making. However, while risk assessments draw extensively 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 estimates of the probability and magnitude of adverse effects associated with a chemical agent. The variety and complexity of the pathways of dispersion in the environment compound these uncertainties. As the result of limitations on knowledge, it is difficult to provide conclusive evidence of a threat to human health or to the environment. Nature does not reveal its secrets quickly: long latency periods may conceal hazards for decades.[1]

The implementation of Council directive 91/414/EEC of 15 July 1991, concerning the placing of plant protection products on the market proved so problematic that the European Union (EU) institutions decided to abrogate and replace it with a regulation. The adoption in 2009 of the EU pesticide regulations brought about a radical change in terms of legal bases, goals, risk assessment, and risk management. Moreover, this regulation was complemented by Directive 2009/128/EC of 21 October 2009, that requires the member states to achieve a reduction in pesticide-related risks.

Glyphosate is found in Roundup, the most widely used herbicide in the world. Its impacts on health and the environment have sparked much controversy, particularly in the EU. The active substance was approved under Council directive 91/414/EEC and later under the EU pesticide regulations. In spite of the opposition of several member states and parts of civil society, the European Commission (hereafter EC) renewed the approval of glyphosate as an active substance in 2017. To understand the scope of this approval, which will last until 2022, this chapter explores the intricacies of the 2009 EU pesticide regulations and attempts to shed light on their significance in the context of analogous chemical regulatory regimes.

The chapter is structured as follows. The EU pesticide regulations principles and procedures must be understood against the broader EU constitutional background, where the authors of EU treaties constantly strike a balance between economic integration (the functioning of the internal market) and nonmercantile interests (health and environmental protection in the case of glyphosate). The procedure for the approval of active substances must be distinguished from the procedure for authorization of plant protection products. The procedure under which the approval of glyphosate has been renewed is examined in detail. The core of the chapter discusses the consistency of the EU pesticide regulations with the precautionary principle.

In accordance with the recent European Court of Justice (hereafter CJEU) *Blaise* judgment, applicants are obligated to submit to the public authorities, in accordance with the precautionary principle, tests on the cocktail effects of active substances and the long-term carcinogenicity and toxicity of pesticide products.

Last but not least, the chapter is written for a broad scientific audience.

The pesticide regulations embedded in an economic common playing field

Glyphosate is authorized under Regulation (EC) No. 1107/2009 concerning the placing of plant protection products on the market (PPPR),[a] an EU act that is at the juncture of different and sometimes apposite policies.

It is settled case law that each piece of EU legislation must be founded on one or more legal bases set out in the founding EU treaties. The byzantine structure of EU treaty law, with its diversification of legal bases likely to provide for specific competences to address issues as complex as the marketing and the use of pesticides, remains the subject of an ongoing debate.[2] The choice of the relevant legal base for legislation aimed at enhancing the free circulation of pesticides while achieving a high level of environmental and health protection represents a critical juncture in relations between institutions as well as the relations between member states and the EU. The choice of legal base is not a purely formal question, but rather one of substance, being a matter of "constitutional significance"[b] that is regularly ruled on by the CJEU. It is settled case law that "the choice of the legal base for a measure may not depend simply on an institution's conviction as to the object pursued."[c] Instead, the determination of the legal base is amenable to judicial review, which includes in particular the aim and the content of the measure.[d]

If it is established that the act simultaneously pursues different objectives or has several components that are indissociably linked (e.g., agricultural production, internal market, environmental protection), and if one of these is identifiable as the main or predominant purpose or component whereas the others are merely incidental, it will have to be founded on a single legal base, namely, that required by the main or predominant purpose or component–the center of gravity of the act–rather than its effects.[e] Accordingly, the act concerned should be adopted in principle on a sole legal base, namely that required by the main or predominant purpose or component.

[a] Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, *OJ L 309, 1*.

[b] Opinion 2/00 [2001] ECR I-9713, para. 5.

[c] Case C-300/89 *Commission v. Council* (Titanium dioxide) [1991] ECR I-2867, para. 10.

[d] See, *inter alia*, Case C-300/89 *Titanium Dioxide*, cited above, para. 10; Case C-269/97 *Commission v. Council* [2000] ECRI-2257, para. 43; and Case C-211/01 *Commission v. Council* [2003] ECR I-3651, para. 38; and Case C-338/01 *Commission v Council* [2004] ECR I-4829, para. 54.

[e] See, *inter alia*, Case C-155/91 *Commission v. Council* [1993] ECR I-939, paras. 19 and 21, Case C-36/98 *Spain v. Council* [2001] ECR I-779, para. 59; and Case C-211/01 *Commission v. Council*, cited above, para. 39; and Case C-281/01 *Commission v. Council* [2002] ECR I-12049, para. 57; Case C-338/01 *Commission v. Council*, cited above, para. 55; and Case C-91/05 *Commission v. Council* [2008] EU:C:2008:288, para. 73.

However, it may be the case that the twin objectives and the two constituent parts of the act are "inseparably" or inextricably linked without one being secondary and indirect in relation to the other. In such a case, it is impossible to apply the predominant aim and content test. Exceptionally, the CJEU accepts that such a measure must be founded on the corresponding legal bases and the applicable legislative procedures respected.[f] In this connection, the 2009 EU pesticide regulations are a case in point.

Given that the marketing of pesticides intermingles with a swath of policy issues, the EU lawmaker (the European Parliament and the Council) based this regulation on three provisions of the Treaty on the Functioning of the European Union (hereafter TFEU):

- Article 43(2) with respect to the Common Agricultural Policy.
- Article 114 with respect to the internal market.
- Article 168(4)(b) with respect to health protection.

This choice amounted to a significant departure from the previous regulatory approach, as Council directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market was related to the Common Agricultural Policy as it was adopted in virtue of former Article 43 EEC. In other words, the lawmaker abandoned the traditional agricultural base in favor of a mixed approach combining agriculture, the internal market, and health protection. Being based on the internal market legal base, the PPPR came closer to the other regulatory regimes related to chemical substances, which are mainly based on Article 114 TFEU, a treaty provision fostering the functioning of the internal market. The importance afforded by the EU lawmaker in 2009 to internal market integration requires a few words of explanation.

The EU policy for the placing on the market of chemical substances was established in the early days of the environmental debate. It consists of a complex regulatory system made up of an intricate network of regulations. Several features of this risk regulatory framework need to be explained before focusing on the legal status of glyphosate in EU law.

The EU institutions have been producing a web of varied, fragmented, and complex regulations that harmonize the procedures related to the placing on the market of chemical substances. Given that all these sectors are product-related, the EU institutions have favored regulations adopted pursuant to Article 114 TFEU. In sharp contrast with other environmental sectors (air, water, waste, nature, listed installations), these regulations increase the centralization of the decision-making process. The preference for regulations based on Article 114 could be explained by the fact that the more flexible nature of a directive entails a genuine risk of market fragmentation.

[f] Case C-300/89 "*Titanium dioxide*," cited above, para. 13; Case C-336/00 *Huber* [2002] ECR I-7699, para. 31; Case C-281/01 *Commission v. Council* [2002] ECR I-12049, para. 35, Case C-211/01 *Commission v. Council*, cited above, para. 40; Case C-211/01 *Commission v. Council* [2003] ECR I-8913, paragraph 40, Case C-91/05 *Commission v. Council*, cited above, para. 75; and Opinion 2/00 [2001] ECR I-9713, para. 23.

For instance, in spite of the significant environmental and health concerns they give rise to, both Regulation 528/2012 concerning making available on the market and the use of biocidal products and the PPPR have been based on Article 114 TFEU. What is more, this harmonization confers an exclusive competence on the EU authorities for the assessment of the active substances found in these products. Given the completeness of their procedures,[g] this regulation led to a complete harmonization that constrains the member states' room for maneuvering.[3]

Although it was not mentioned in the 1957 Treaty of Rome, environmental and health concerns have, through the various treaty reforms, gradually been able to establish themselves among the greatest values enshrined in the EU treaties. Needless to say, internal market and environmental and health policies have traditionally focused on opposite, albeit entangled, objectives: the abolition of unilateral national measures hindering free trade, and protection of individuals and vulnerable populations as well as natural resources. In other words, whereas the internal market is about facilitating the free circulation of products and substances, environmental and health policies encourage the adoption of regulatory measures that are likely to jeopardize free trade. Besides, the internal market favors economic integration through total harmonization while environmental law allows for differentiation.[4]

Does it mean that the environmental and health concerns are absent from the internal market harmonization process? Several TFEU provisions oblige EU lawmakers to take into account, as part of the decision-making process, not only the full range of the interests affected by the harmonization process (freedom of enterprise, confidentiality of private data, etc.) but also a number of interests that received a lesser degree of priority at the earlier stage of the European integration.[4]

First, pursuant to Article 114(3) TFEU, the EC's proposals, which have as their object the establishment and functioning of the internal market, must pursue a high level of protection while addressing the concerns about health, safety, environmental protection, and consumer protection. These concerns have to be fully integrated into the internal market harmonization process.

Second, Article 168(1) TFEU, read in combination with Article 35 EUCHR, requires that the protection of human health be integrated into the definition and implementation of EU policies and activities. In accordance with this integration clause, the PPPR is also based on Article 168(4)(b).

Third, by the same token, Article 11 TFEU, read in combination with Article 37 EUCHR, requires that environmental protection requirements be integrated into the definition and implementation of EU policies and activities. However, the environmental legal base–Article 192TFEU–has not been added to the other legal bases of the PPPR.

In light of these treaty provisions, the EU institutions must display particular sensitivity to nonmercantile concerns and must reconcile the various objectives laid down in the TFEU. The internal market's goals are thus not solely economic, but also social

[g] Case T-31/07, *Du Pont de Nemours* [2013] T:2013:167, para. 203.

and environmental. Prioritizing one objective should not render the achievement of the other objectives impossible.[h]

These various integration clauses are not devoid of legal consequences. In accordance with treaty law, the internal market regulations of hazardous substances seek to strike a balance between a high level of protection of human health and the environment and the free circulation of substances in the internal market. The objectives of the PPPR are testament to such a conciliatory approach. Article 1(3) is worded as follows[i]:

> *The purpose of this 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.*

The combination of these different objectives has legal effects. It was settled case law that former Directive 91/414 (replaced by the PPPR) sought to enhance the internal market (removal of barriers to intra-EU trade in plant products) while maintaining a high level of protection of the environment and of human and animal health. The CJEU held in this respect that the EC was enjoying broad discretion to effectively pursue the objective assigned to it.[j] However, the exercise of that discretion does not escape judicial review. As a result, the EU judicature must determine whether the relevant procedural rules have been complied with, whether the facts established by the Commission are correct, and whether there has been a manifest error of appraisal of those facts or a misuse of powers.[k]

It is also settled case law that health requirements take precedence over economic interests.[l]

The pesticide regulations epitomizing specific features of EU regulatory governance

The regulations on hazardous substances display specific features of EU governance. On the one hand, they empower the Commission to adopt implementing acts in accordance with the comitology procedure; on the other hand, they delegate significant

[h] See in particular the CJEU case law on CAP objectives. Joined Cases 197-200/80 *Ludwigshafener Walzmühle v. Council and Commission* [1981] ECR 3211, para. 41; Case 59/83 *Biovilac v. Commission* [1984] ECR 4057, para. 16; Case C-280/93 *Germany v Council* [1994] ECR I-4973, paras. 47 and 51; Case C-122/94 *Commission v Council* [1996] ECR I-881, para. 24.

[i] Along the same lines, see Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals [2006] OJ L396/1, Art 1(3); and the Biocide Regulation, Art 1. It must be noted that the European Commission is not empowered to undermine the equilibrium sought by the EU lawmaker. See Case T-521/14 *Sweden v Commission* [2015] T:2015:976, para. 72.

[j] Case C-326/05 P *Industrias Químicas del Vallés v Commission* [2007] ECR I-6557, paras. 74 and 75; Case T-31/07, *Du Pont de Nemours* [2013] T:2013:167, para. 155.

[k] Case C-326/05 P *Industrias Químicas del Vallés v Commission* [2007] ECR I-6557, para.106; Case T-326/07 *Cheminova* [2009] II-2685, para 107.

[l] Joined Cases T-74, 76, & 83/00 to T-85, 132, & 137/00 and T-141/00 *Artegodan* [2002] ECR II-4945, para. 184.

administrative tasks, in particular in the realm of risk assessment, to two EU agencies. In effect, the regulatory decisions on chemicals policy, such as those relating to registration, authorization, restriction, classification, and labelling under the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), are backed by the opinions of the European Chemicals Agency (ECHA), whereas the assessment of the active substances in pesticides is subject to the opinions of the European Food Safety Agency (EFSA). The interaction among these two agencies (risk assessment), the regulatory committees, and the Commission (risk management) is testament to the principle of institutional balance enshrined in Article 4(3) of the treaty on the EU. In this connection, the PPPR straddles risk assessment and risk management alike.

Additional precautionary features of the pesticide regulations: Cut-off hazard-based criteria and substitution

In contrast to former Directive 91/414/EEC, the PPPR represents a real step forward for health and environmental protection. In shifting the risk-based approach to the hazard-based approach, in providing new regulatory mechanisms such as substitution, the PPPR not only fleshed out the precautionary principle but also allocated more clearly the responsibilities for safety and improved the risk assessment requirements.[5]

Lately, the EU regulatory approach has been shifting from risk to hazard: substances that do not meet the EU's predetermined cut-off hazard-based criteria (persistent bioaccumulative and toxic, persistent organic pollutants, very persistent very bioaccumulative, or endocrine disruptive) cannot receive approval or renewal of approval.[m] Whenever one of these properties is ascertained, the substance is deemed to be intrinsically dangerous and its use must be forbidden.[7] These cut-off criteria do not require any additional risk exposure assessment. It follows that the EC 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).

In avoiding the need to perform an entire risk assessment on a case-by-case basis, which can be time and resource consuming, relying on cut-off hazard-based criteria reduces considerably the administrative burden entailed by full risk-assessment procedures. As a result, it is faster and less expensive.[8] In practical terms, this means that experts are not called on to fully perform the additional steps of the assessment procedure (hazard characterization, risk identification, and risk characterization). It comes as no surprise that this regulatory approach has been championed by different EU institutions and several member states and strongly resisted by others. So far, few substances have been regulated in relation to their hazard.

Furthermore, the adoption in 2009 of the PPPR represented a watershed in the development of the substitution principle, according to which the mere existence

[m] PPPR, Annex II, 3.6.2 to 3.6.5; Biocides Regulation, preamble recital 12. 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 (OJ L 301, 17.11.17, p. 1) and Commission Regulation (EU) 2018/605 (OJ L 101, p. 33). See also Kuraj.[6]

of an alternative substance that appears to be less dangerous than the substance in question constitutes a sufficient basis for restriction or prohibition. This principle has been enshrined in the PPPR (Article 50). The EC is required to define a list of active substances in pesticides considered to be "Candidates for Substitution" (CfS) that go through a comparative assessment.

Procedures for approval of active substances and for authorization of plant protection products

Plant protection products containing active substances[n] 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.[o]

The approval procedure for active substances (Articles 7 to 13 PPPR) such as glyphosate is separated from the authorization procedure for the formulated plant protection product, such as Roundup, that is then used by operators (Articles 33 to 39 PPPR). In so doing, the EU lawmakers have been endorsing a two-pronged approach:

- In the first stage, the active substance such as glyphosate must be assessed and approved by the EC "in order to achieve the same level of protection in all member states" (Preamble, recital 10; Articles 7 to 13 PPPR).
- In the second stage, the pesticide containing the active substances approved by the EU cannot be placed on the market or used unless it has been assessed and authorized in one of the member states (Articles 28 to 39 PPPR). Consequently, the applicant who wishes to place a pesticide on the market is obligated to apply for an authorization to each member state where the pesticide is intended to be placed on the market (Article 33 PPPR). As a result, the national authorities and not the EC have to authorize the placing on the market of products such as Roundup containing the active substance glyphosate.

The procedure for the approval of active substances and the procedure for authorization of plant protection products are not waterproof. In this connection, two examples will suffice to highlight how the two procedures are closely linked.[p]

- As stressed above, the authorization of a plant protection product presupposes that its active substances have previously been approved by the EC.
- The EU lawmakers have obliged the authorities to take into account the potential effects of a combination of the various constituents of a plant protection product both in the procedure for the approval of the active substances and in the procedure for the authorization of the plant protection products.

[n] Although the PPPR does not contain any definition of the expression "active substance," it is clear from Article 2(2) of Regulation No 1107/2009 that substances, including micro-organisms, having general or specific action against harmful organisms or on plants, parts of plants or plant products are to be regarded as active substances, for the purposes of that regulation. See Case C-616/17 *Blaise* [2019] C:2019:800, paras. 53-54.

[o] Case T-545/11 RENV *Stichting Greenpeace Nederland* [2016] EU:T:2018:817, para. 74.

[p] Case C-616/17 *Blaise* [2019] C:2019:800, para. 64. See case note Bailleux A. Common Market Law Review; 2020; 57: 861–876.

Level of harm

"It is for the [EU] institutions to determine the level of protection (that) they deem appropriate for society."[q] Accordingly, it is by reference to that level of protection that the institutions may require preventive measures in spite of any existing scientific uncertainty. Therefore, determining the level of risk deemed unacceptable involves "the [EU] institutions in defining the political objectives to be pursued under the powers conferred on them by the treaty."[r] Is it possible for EU lawmakers to pursue an absolute level of protection? It is settled case law that precautionary measures "must not aim at zero risk," for they may be deemed disproportionate.[s] That being said, nothing precludes the EU institutions from endorsing a zero tolerance policy with regard to certain risk factors for which the producer of the substance cannot adduce proof that they are acceptable.[t] In particular, the concept of zero tolerance may through the precautionary principle result in the total ban of a substance provided that its potential risk is supported by scientific data.[u]

Against this background, the determination of the illicit level of harm varies significantly from one regulation to another.[9, 10] Whereas several chemical regulations prohibit squarely the use of chemical substances such as persistent organic pollutants,[v] companies may under the PPPR seek authorization for placing on the market hazardous active substances if their risks can be "adequately controlled."[w]

The preamble of the PPPR stresses that "when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production. Therefore, it should be demonstrated, before plant protection products are placed on the market, that they present a clear benefit for plant production and do not have any harmful effect on human or animal health, including that of vulnerable groups, or any unacceptable effects on the environment" (Preamble, recital 24). Against this background, the PPPR requires that an active substance can only be included in a pesticide product if it has been demonstrated to present a clear benefit for plant production and is not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment [Preamble, recitals 10, 24, Article 4(2)b, Article 4 (3)c and e]. This requirement is not devoid of legal consequences. "Determining the

[q] Case T-13/99 *Pfizer*, *cited above*, para. 151.

[r] Case T-13/99 *Pfizer*, *cited above*, para. 151.

[s] Communication of the European Commission, n° 6.3.1, para. 18. See Case T-13/99 *Pfizer,* cited above, para. 145.

[t] Case C-121/00 *Hahn* [2002] ECR I-9193, para. 93; Case T-392/02 *Solvay Chemicals*, cited above, para. 97.

[u] Taking account of the genuine risk that the intake of fluoride in food supplements will exceed the upper safe limit established for that mineral, a Member State may set the maximum amount of fluoride which may be used in the manufacture of food supplements at a zero level. Case C-446/08 *Solgar Vitamin's France* [2010] ECR I-03973, para. 47.

[v] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants [2019] *JO L 169, 45*.

[w] See also REACH, Art. 57(2).

level of risk deemed unacceptable involves the [EU] institutions in defining the political objectives to be pursued under the powers conferred on them by the Treaty."[x] It is by reference to that level of protection–absence of harmful effect on human or animal health–that the EU institutions and national authorities may be required to take preventive measures.

The General Court and the CJEU alike have been endorsing lately a harder look at the Commission's attempts to relax somewhat the level of safety requirements in the area of active substances found in plant protection products and chemicals. In this respect, the *Paraquat* judgment handed down by the General Court on 11 July 2007 is a case in point. Under the former Directive 91/414,[y] the Commission could list such a substance under Annex I inasmuch as the use of the products "in the light of current scientific and technical knowledge" will not have any harmful effects on animal health. Adjudicating an action for annulment brought by Sweden against the decision listing paraquat under Annex I, the General Court stressed that the safety requirement had to be interpreted "in combination with the precautionary principle." It follows that "in the domain of human health, the existence of solid evidence which, while not resolving scientific uncertainty, may reasonably raise doubts as to the safety of a substance, justifies, in principle, the refusal to include that substance in Annex I to Directive 91/414."[z]

However, in *Blaise* the CJEU stresses the "need to strike a balance between several objectives and principles."[aa] This paragraph conveys the feeling that the competing interests have been placed on equal footing. But a closer reading of the PPPR indicates that the EU lawmakers clearly departed from a traditional weighing of interests in highlighting the prevalence of health and environmental protection over plant production (Preamble, recital 24). The high level of health and environmental protection pursued by the EU institutions limits their room for maneuvering in implementing the regulation.[ab]

Burden of proof

While in the past regulators had to prove that particular substances were hazardous,[ac] under EU secondary law the applicants who wish to place a hazardous substance on the market must provide evidence that it is safe for health and the environment.[11] The

[x] Case T-13/99 *Pfizer Animal Health v Council* [2002] ECR II-3305, para. 151.

[y] Directive 91/414/EEC concerning the placing of plant protection products on the market [1991] OJ L 230/1. This directive has been replaced by Regulation (EC) 1107/2009.

[z] Case T-229/04 *Sweden v Commission* [2007] ECR I-2437, paras. 161 and 224.

[aa] Case C-616/17 *Blaise* [2019] C:2019:800, para. 50.

[ab] In sharp contrast, the choice of the Commission to authorize the chemical substance DEHP under the REACH "socio-economic procedure" (Article 60(4)) does not constitute a breach of the precautionary principle on the ground that this authorization procedure 'was precisely conceived to enable undertakings to place on the market substances which pose in particular a risk to human health but whose socio-economic advantages prevail'. See Case T-108/17 *ClientEarth* [2019] EU:T:2019:215, para. 287. Under such a procedure, the weighing of interest tilts in favour of the socio-economic interests.

[ac] By way of illustration, Council Regulation (EEC) 793/93 required the Member States to carry out the risk assessment of priority substances because of their potential impacts on man or the environment. The implementation of that regulation has been so laborious that it has paralyzed regulatory action.

PPPR is testament to this shift. In effect, it is for the applicant and not for the authorities to prove that the active substance or the plant protection product that is the subject of an application for approval or authorization fulfills the relevant criteria laid down by the PPPR. As a result, the tests, studies, and analyses must be provided by the applicant to permit approval of the active substance [Article 7(1) and from Article 8(1) and (2)] and authorization of the product [Article 33(3)(a) and (b)]. Placing the obligation on the applicant "contributes to achieving compliance with the precautionary principle by ensuring that there is no presumption that active substances and plant protection products have no harmful effects."[ad]

In *Blaise*, the French criminal referring court was uncertain whether the tests, studies, and analyses required in the procedures for the approval of glyphosate submitted by the applicant, with no independent counteranalysis, were contrary to the precautionary principle. As the studies performed by the applicant are confidential, there is a risk that the applicant submits only studies showing no potential health and environmental risks. In particular, the absence of counteranalysis could imply that the applicant's tests, studies, and analyses might be biased.

The CJEU held that the EU legislature provided a number of safeguards to control the quality of the tests, studies, and analyses submitted by the applicant.[ae] To enhance transparency, the PPPR requires, for instance, that the applicant submit a summary dossier that contains, in respect to each point of the data requirements that apply to the active substances and the plant protection products, the summaries and results of tests and studies and the name of their owner and of the person or institute that carried out the tests and studies [Article 8(1)].[af]

However, the authorities are not totally dependent upon the scientific assessment submitted by the applicant. Their duty is "to take account of the most reliable scientific data available and the most recent results of international research and not to give in all cases preponderant weight to the studies provided by the applicant."[ag] Accordingly, the authorities can rely on information other than merely the tests, analyses, and studies submitted by the applicant.[ah] Nothing precludes these studies contradicting the data gathered by the applicant.[ai] In acknowledging the possibility for the authorities to take into consideration dissenting opinions, the CJEU *Blaise* judgment takes full stock of the precautionary principle.

In addition, the authorities are allowed to organize a consultation of experts and to ask the Commission to consult a community reference laboratory, to which the applicant may be required to submit samples and analytical standards.[aj] So far, the reference laboratories appointed by the EC in 2019 have played no role in the assessment of glyphosate.[ak]

[ad] Case C-616/17 *Blaise* [2019] C:2019:800, paras. 79-80.

[ae] Case C-616/17 *Blaise* [2019] C:2019:800, para. 82.

[af] Case C-616/17 *Blaise* [2019] C:2019:800, para. 83.

[ag] Case C-616/17 *Blaise* [2019] C:2019:800, para. 94.

[ah] Case C-616/17 *Blaise* [2019] C:2019:800, para. 96.

[ai] Case C-616/17 *Blaise* [2019] C:2019:800, para. 93.

[aj] Case C-616/17 *Blaise* [2019] C:2019:800, para. 98.

[ak] Bailleux A. Case note on Blaise, *cited above*, 874.

These various safeguards preclude biased risk assessments breaching the precautionary principle. Accordingly, the PPPR is vitiated by a manifest error of assessment.[al]

Inclusion of glyphosate as an active substance in EU pesticide legislation

As discussed above, glyphosate had to be approved at the EU level before being included in various pesticide products. The EC adopted Directive 2001/99/EC on 20 November 2001, with a view to amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, to include glyphosate as an active substance.

Pursuant to Directive 2001/99, glyphosate was approved from 1 July 2002 to 30 June 2012. Since 2002, it has been authorized in member states and is one of the most widely used herbicides in the EU.[am]

The EC received a renewal request for glyphosate before the expiration of the approval. As the information necessary for the renewal of active substances had yet to be adopted at that time, the inclusion of glyphosate was extended until 31 December 2015.[an]

Subsequently, in 2009, Directive 91/414 was repealed, with effect from 14 June 2011, by the PPPR. As active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No. 1107/2009, glyphosate was listed in the annex to the Implementing Regulation No. 540/2011.[ao] Under that regulation, the expiry date of the approval period was fixed at 31 December 2015.

Renewal of the authorization of glyphosate as an active substance

On 20 December 2013, the Federal Republic of Germany, as the rapporteur member state, submitted, in collaboration with the Slovak Republic as the corapporteur, the renewal assessment report for glyphosate. The EFSA forwarded it to the applicant and to the other member states for comments. Assessment of the carcinogenicity of glyphosate has been a matter of controversy ever since. In March 2015, the International Agency for Research on Cancer (IARC) of the World Health Organization published its monograph on glyphosate, concluding that it should be classified as "probably carcinogenic to humans."[ap] In the wake of this international assessment,

[al] Bailleux A. Case note on Blaise, *cited above*, 874. para. 100.

[am] Implementing Regulation 2017/2324, recital 19.

[an] Commission Directive 2010/77/EU of 10 November 2010 amending Directive 91/414 as regards the expiry dates for inclusion in Annex I of certain active substances (OJ 2010 L 293, p. 48).

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

[ap] In *Pilliod et al. c Monsanto Company et al.,* the California Superior Court held that Roundup's alleged risk of NHL was "known or knowable in light of the generally recognized and prevailing scientific and medical knowledge." *Alva and Alberta Pilliod v. Monsanto Co.* (Case No. RG17862702, JCCP No. 4953) Cal.1d.

the Commission mandated EFSA to review the information in the IARC's findings. The EFSA stated that "glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence [did] not support classification [of that active substance] with regard to its carcinogenic potential" according to REACH.

Doubtful of the EFSA's risk assessment, several member states of the Standing Committee on Plants, Animals, Food and Feed decided to seek the opinion of the Committee for Risk Assessment of the ECHA. In 2017, ECHA concluded by consensus that, on the basis of the information currently available, no hazard classification for carcinogenicity was justified for glyphosate.

The opposing views of the IARC and the two EU agencies can be explained by their diverging methodologies. First, while the IARC looked at both glyphosate–the active substance–and the plant protection products (e.g., Roundup), the EU risk assessments considered only glyphosate, on the grounds that member states are responsible for authorizing each plant protection product that is marketed in their territories. Second, while the IARC considered only published studies, the EU agencies also took into consideration studies submitted by applicants as part of their dossiers that were not in the public domain. These divergent methodologies explain the differences in how EFSA/ECHA and IARC weighed the available data.[aq]

In light of the diverging view between EFSA/ECHA and IARC, the Commission extended the period of the validity of the approval of glyphosate in amending the Implementing Regulation No. 540/2011. Since then, the approval period for glyphosate has been extended several times.

In 2017, the EFSA communicated to the Commission its report on the potential endocrine-disrupting properties of glyphosate, confirming that the weight of evidence indicates that glyphosate does not have endocrine-disrupting properties.

In 2016 and 2017, the European Parliament adopted several resolutions on the different draft Commission Implementing Regulations renewing the approval of the active substance glyphosate.

Considering that the approval of glyphosate was going to expire on 15 December 2017, the Commission presented in 2016 a draft implementing regulation to renew the approval of the substance for a period of 10 years to the Standing Committee on Plants, Animals, Food and Feed. As the Standing Committee did not manage to deliver an opinion within the time limit (Comitology Regulation 182/2011), the draft implementing act was submitted to the Appeal Committee. Finally, the Appeal Committee delivered a favorable opinion by qualified majority (Article 4 Rules of Procedure 182/2012), which enabled the EC to adopt its implementing regulation (EU) 2017/2324 on 12 December 2017.

The quorum of 65% provided for in Article 278 TFEU was narrowly reached (65.71%). The Commission's success was due to Germany's about-face in the Appeal Committee. During the previous vote on 6 October 2007, this quorum was not

[aq] Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides" C(2017) 8414 final.

reached, as the 16 member states in favor of the measure represented only 47.46% of the EU population.

The 2017 Commission Implementing Regulation renewed the approval of the active substance until 15 December 2022.[ar] Shorter than the maximum duration of 15 years provided for in Article 14.2 of Regulation No.1107/2009, the 5-year renewal period was justified by the EC on the grounds that it had to take into account the opinions of the European Parliament and "future scientific and technological developments." It is important to note that the implementing regulation itself contains the maintenance of the marketing authorizations for the pesticides containing the active substance "glyphosate."

European citizens' initiative

In allowing one million citizens residing in one-quarter of the member states to invite the Commission to submit a proposal for a legal act to implement the EU treaties, the European Citizens' Initiative (ECI) mirrors participatory democracy in the EU.[as] It allows the citizens to apply directly to the Commission to submit a request inviting it to submit a proposal for a legal act of the EU, for the purposes of the application of the treaties.[at]

On 6 October 2017, the EC officially received a successful ECI referring specifically to glyphosate. On 23 October, 2017, the Commission responded to the ECI stating that "as regards the first aim seeking to ban glyphosate-based herbicides it [took] the view that there [was] no scientific or legal grounds for a ban on glyphosate and [did] not intend to introduce legislative proposals to that effect." It added that "in particular, the scientific evidence [did] not support the conclusion that glyphosate could cause cancer" and "therefore, the decision adopted … to renew the approval of glyphosate (for a period of five years) [was] completely justified."

Actions for annulment of Commission implementing regulation (EU) 2017/23241

The CJEU guarantees rule of law[au] in reviewing the conformity of EU legislative acts, regulatory acts, and individual acts against the superior rules of the EU legal order. An action can be brought within 2 months of the publication. Applicants are divided into three categories: privileged, semiprivileged, and nonprivileged. Although they are considered privileged applicants, neither the member states nor the European

[ar] Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate [2017] *JO* L 333, 10.

[as] Art. 11(4) and Art. 24(1) TFEU. See Regulation (EU) No 2019/788.

[at] Case C-589/15 P *Anagnostakis/Commission* [2017] EU:C:2017:663, para. 24

[au] Art. 2 TEU.

Parliament lodged within 2 months of the publication of the Commission implementing regulation an action for annulment.

Nonprivileged applicants, including regional and local governments, may bring an action for annulment only if they prove that the contested regulation infringes upon their interests. In particular, they may bring an action against an act provided that it is of direct and individual concern to them as well as against a regulatory act that is of direct concern to them and does not entail implementing measures.[12]

The first action for annulment of the Commission implementing regulation was lodged by an Italian association of wheat producers. The General Court held that the renewal of the approval of glyphosate "is not, in itself, the confirmation, extension, or renewal of the marketing authorisation granted by the Member States for a phytopharmaceutical product containing that active substance."[av] It concluded that the renewals of marketing authorizations constitute implementing measures of the contested act, within the meaning of the fourth paragraph of Article 263 TFEU.[aw] The existence of implementing measures precluded the claimants from demonstrating that they were "directly" affected by the contested implementing regulation.[ax] Accordingly, the applicants also had to demonstrate that they were "individually" affected. Although the applicants claim that the continued use of glyphosate gives rise to material damage for some of its members who are wheat producers, the General Court held that the harm relied on by the applicants was "no different from that which could be relied on by any farmer who, for his own reasons, abstains from using glyphosate in favour of other solutions which give rise to certain costs for him."[ay] The action was thus dismissed as inadmissible.

Another case must be mentioned. With a view to protecting its own regulatory prerogatives, the Brussels Capital Region brought an action for annulment of the Commission implementing regulation. The region alleged an infringement of the obligation to ensure a high level of protection of human health and of the environment. It argued that the implementing regulation is based on a scientific assessment of risks to health and the environment that does not meet the requirements of the precautionary principle. The region also alleged an infringement of the general principle of sound administration. With respect to standing, the region argued that the Commission implementing regulation prevents it from exercising its regulatory competences as it sees fit.

The General Court did not rule on the merit of the case as, on 28 February 2019, it declared the action inadmissible on the ground of lack of standing to bring proceedings.[az] Specifically, the General Court held that the Brussels Capital Region was not "directly concerned" within the meaning of Article 263 fourth paragraph TFUE by the regulation at issue. On appeal, Advocate General Michal Bobek found

[av] Case T-125/18, *Associazione GranoSalus* [2019] T:2019:92, para. 83.

[aw] Case T-125/18, *Associazione GranoSalus* [2019] T:2019:92, para. 85.

[ax] Case T-125/18, *Associazione GranoSalus* [2019] T:2019:92, para. 96.

[ay] Case T-125/18, *Associazione GranoSalus* [2019] T:2019:92, para. 59.

[az] Case T-178/18 *Région de Bruxelles-Capitale v Commission* [2019] EU:T:2019:130.

recently that by denying standing to the Brussels Capital Region, the General Court erred in law, misinterpreting the fourth paragraph of article 263 TFEU as well as a number of provisions of applicable secondary law.[ba]

Validity of the pesticide regulations in light of the precautionary principle

Enshrined in Article 192(2) TFEU–a provision declaring the principles underpinning EU action in the field of environmental protection–the precautionary principle was not defined by the treaty framers. The CJEU filled this gap in 1998 by asserting that "where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent."[bb] The precautionary principle quickly developed into one of the foundations of the high level of environmental protection in the EU.[bc] While the CJEU has been more careful in speculating about the nature of that principle, the General Court has classified precaution as a general principle of EU law. According to the General Court, the precautionary principle empowers the EU institutions "to take appropriate measures to prevent specific potential risks to public health and safety."[bd]

The precautionary principle is explicitly mentioned in the PPPR [Article 1(4)]. In this connection, EU institutions as well as national authorities are called on to conduct risk assessments of pesticide products and their substances considering the extent of lingering uncertainties.

Because the principle is binding on the EU institutions and on the member states when their measures fall within the scope of secondary law, EU courts may be called on to review the consistency of measures on hazardous substances with the principle. This happened in *Blaise*, when the CJEU was called on to review the consistency of the PPPR substances with the environmental principle.[be] All the questions referred by the French criminal court inquire as to the conformity of the EU pesticide regulations with the principle. In answering these questions, the CJEU stressed that there is "an obligation"[bf] on the EU legislature, when it adopts rules governing the placing on the market of pesticides, to comply with the principle in order to ensure a high level of

[ba] Advocate General's Opinion in Case C-352/19 P *Région de Bruxelles-Capitale v Commission*.

[bb] See Case C-157/96 *NFU* [1998] ECR I-2211, para. 63; Case C-180/96 *UK v Commission* [1998] ECR I-2265, para. 99. This interpretation of the PP has become settled case law: Case C-236/01 *Monsanto Agricoltura Italia* [2003] ECR I-8105, para. 111; Case C-77/09 *Gowan* [2010] C:2010:803, para. 73; Case C-333/08 *Commission v France* [2010] ECR I-757, para. 91; Case C-343/09 *Afton* [2010] C:2010:419, para. 62. See also Case T-13/99 *Pfizer* [2002] ECR II-3305, para. 139.

[bc] Case C-127/02 *Waddenzee* [2004] ECR I-7405, para. 44; Case T-125/17, *BASF Grenzach GmbH* [2019] T:2019:638, para. 272. See de Sadeleer.[13, 14]

[bd] Cases T-429/13 and T-451/13 *Bayer* [2018] T:2018:624, para. 109.

[be] Case C-616/17 *Blaise*, cited above, C:2019:800.

[bf] Case C-616/17 *Blaise*, cited above, C:2019:800.para. 42.

protection of human health.[bg] As a result, the Court ruled on the validity of the PPPR in light of the precautionary principle.

At the outset, the CJEU stresses that the normative framework stemming from the PPPR "ensures that the competent authorities …, when they decide on that authorisation and that approval, sufficient information in order adequately to assess, …, the risks to health resulting from the use of those active substances and those plant protection products."[bh]

However, "in view of the need to strike a balance between several objectives and principles, and of the complexity of the application of the relevant criteria," judicial review was limited to whether the EU legislature, in adopting the PPPR, committed a manifest error of assessment.[bi] As a result of the rather limited scope of review, the Article 191(2) TFEU principle grants wide discretion as to the measures that can be taken by the EU institutions.

This restrained judicial review of the internal legality of EU legislation is testament to a rather classical reasoning. Traditionally, the EU judiciary has shown judicial restraint, as it is not entitled to substitute its assessment of the facts for that of the EU institutions on which the treaty confers sole responsibility for that duty.[bj] Where the EU institutions are called upon to make "complex assessments," they enjoy a wide measure of discretion when they adopt risk management measures.[bk] In this respect, when invoking the principle of precaution, the CJEU[bl] and the General Court[bm] have on various occasions in the past rejected lawsuits founded on manifest errors of appraisal committed by the institutions when taking decisions that were not fully justified in the light of prevailing scientific knowledge. In any case, a court is no substitute for legislative power.

Although the CJEU confirmed the validity of the PPPR, it interpreted that regulation in light of the precautionary principle. In so doing, the Court enhanced the precautionary obligations placed on the authorities when approving an active substance.

In particular, it must be noted that in the course of risk assessment, the authorities have to take into account the "known cumulative and synergistic effects" of the residues having a harmful effect on human or animal health [Articles 4(2)(a)–4(3)(b)]. This entails that the cocktail effects caused by the interaction between glyphosate

[bg] CFR, Art 35 and TFEU, Art 9 and Art 168(1).

[bh] Case C-616/17 *Blaise*, cited above, para. 47.

[bi] Case C-616/17 *Blaise*, cited above, para. 50.

[bj] See Case T-13/99 *Pfizer*, above, para. 169.

[bk] Case C-180/96 *UK v Commission* [1998] ECR I-2269, para. 97; Case T-74/00 *Artegodan* [2002] ECR II-4945, para. 201; Case T-392/02 *Solvay Chemicals* [2003] para. 126; Case C-77/09 *Gowan* [2010] ECR I-13533, paras 55 and 82; Case C-343/09 *Afton* [2010] ECR I-7027, para. 28.

[bl] See Case 174/82 *Sandoz* [1983] ECR 2445, para. 17; Case C-331/88 *Fedesa* [1990] ECR I-4023, para. 9; Case C-180/96 *UK v Commission* [1998] ECR I-2269, paras 99 and 100; and Case C-127/95 *Norbrook Laboratories Ltd* [1998] ECR I-1531.

[bm] See Case T-199/96 *Laboratoires pharmaceutiques Bergaderm S.A.* [1998] ECR II-2805, paras. 66 and 67; cases T-13/99 *Pfizer Animal Health v Council* [2002] ECR II-3305 and T-70/99 *Alpharma v Council* [2002] ECR II-3495.

and, inter alia, the other constituents of the product must be taken into consideration.[bn] However, EFSA has found providing such a methodology difficult. The CJEU judgment should boost the agency's effort in that respect.[bo]

Furthermore, in order to obtain the authorization of plant protection products, the applicants must submit to the national authorities, in addition to the "known cumulative and synergistic effects," "any information on potentially harmful effects of the plant protection product on human and animal health or on the environment."[bp] In other words, an information duty applies whenever the impacts are potential and not yet fully demonstrated.

By the same token, the CJEU ruled that the applicant is not exempted from submitting tests of long-term carcinogenicity and toxicity relating to the plant protection product that is the subject of an application for authorization.[bq] In effect, a plant protection product cannot be considered to satisfy the safety requirement laid down by the EU lawmaker "where it exhibits any long-term carcinogenicity and toxicity."[br] As a result, the applicants would be required to submit tests of long-term carcinogenicity and toxicity relating to their plant protection products. Whether such tests will be submitted with respect to the renewal of the approval of pesticides containing glyphosate remains to be seen.

Validity of the restrictions placed by the member states on the use of glyphosate

At the outset, the interactions between the free movement of goods, enshrined in the TFEU, and the national restrictive measures placed on the marketing and use of pesticides are at odds with one another. Thus far, scant attention has been paid to the scope of these restrictive measures.

Total harmonization

As far as pesticides are concerned, until the entry into force of former directive 91/414/EEC, there were no common harmonized rules relating to the production and marketing of plant protection. In the absence of harmonization, 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."[bs]

[bn] Advocate General Sharpston' Opinion in Case C-616/17 *Blaise*, cited above, para. 58.

[bo] Bailleux A. Case note on Blaise, cited above, 872.

[bp] Case C-616/17 *Blaise*, cited above, para. 73.

[bq] Case C-616/17 *Blaise*, cited above, para. 113.

[br] Case C-616/17 *Blaise*, cited above, para. 115.

[bs] Case 104/75 *De Peijper* [1981] ECR 613; Case 272/80 *Biologishe Produkten* [1981] ECR 3277, para. 12.

Since the entry into force of directive 91/414/EEC (replaced by the PPPR), this field is fully harmonized. As a result, member states may thus no longer rely upon Article 36 TFEU or a mandatory requirement.[bt]

The PPPR enshrines the principle of mutual recognition with the aim of ensuring the free movement of pesticides within the EU (PPPR Preamble, recital 2), albeit imperfectly.[15] To avoid the duplication of administrative burden for the application, the authorization to place the pesticide on the market granted by one member state has to be accepted by other member states where agricultural, plant health, and environmental (including climatic) conditions are comparable. To facilitate such mutual recognition, the EU has been divided into zones.

The renewal of glyphosate approval had the immediate effect of preserving the validity of existing authorizations to place pesticides containing glyphosate on the market.[bu] In the absence of a renewal, those authorizations would ipso facto have lapsed.

However, state authorities still keep room for maneuvering. First, harmonization does not equate with uniformity. By way of illustration, Directive 91/414 concerning the placing of plant protection products on the market did not contain any provision that specifically governed the conditions for the granting of marketing authorization for plant protection products in the context of parallel imports.[bv] As this area was not harmonized, the CJEU ruled that a member state is entitled pursuant to Article 36 TFEU to subject a farmer who imports a plant protection product as a parallel import solely for the needs of his farm to a simplified authorization procedure.[bw]

The PPPR safeguard clauses

The TFEU empowers the EU lawmaker to allow the EC and member states, subject to an EU control procedure, to adopt temporary measures in the event of a sudden and unforeseen danger to health, life, etc. [Article 114(10) TFEU]. Along the same lines of the majority of regulations founded on Article 114 that contain safeguard clauses encompassing health and environmental risks, the PPPR provides for such safeguard clauses. A detailed examination of the manner in which such mechanisms are implemented should be made.

[bt] See among others Case 5/77 *Tedeschi* [1977] ECR 1555, para. 35; Case 148/78 *Ratti* [1979] ECR 1629, para. 36; Case 251/78 *Denkavit Futtermittel* [1979] ECR 3369, para. 14; Case 190/87 *Moormann* [1988] ECR 4689, para. 10; Case 215/87 *Schumacher* [1989] ECR 617, para. 15; Case C-369/88 *Delattre* [1991] ECR I-1487, para. 48; Case C-62/90 *Commission v Germany* [1992] ECR I-2575, para. 10; Case C-323/93 *Centre d'insémination de la Crespelle* [1994] ECR I-5077, para. 30; and Case C-320/93 *Ortscheit* [1994] ECR I-5243, para. 14. Regarding the non-exhaustive character of food additives see Case C-121/00 *Walter Hahn* ECR I-9193.

[bu] Advocate General Bolbek's Opinion in Case C-352/19 P *Région de Bruxelles-Capitale v Commission,* para. 38.

[bv] Advocate General Trstenjak's Opinion delivered on 10 July 2007 in Joined Cases C-260/06 and C-261/06 *Escalier and Bonnarel* [2007] ECR I-9717, para. 8.

[bw] Joined Cases C-260/06 and C-261/06 *Escalier and Bonnarel*, above, paras. 34 and 36.

At the outset, a member state may request the Commission "to restrict or prohibit the use and/or sale" of a substance or product (that) has been authorized in accordance with the Regulation (Article 69), provided that the following conditions are fulfilled:

- It is "likely to constitute a serious risk to human or animal health or the environment."
- This risk cannot be contained satisfactorily by means of measures taken by the member state (s) concerned.
- The evidence must be examined by the Commission with the possibility to request the EFSA's opinion.

Moreover, in cases of extreme urgency, the Commission may provisionally adopt emergency measures after consulting the member states concerned and informing the other member states (Article 70).

However, the Commission has full discretion to adopt either the restrictive measures or the provisional measures requested by the member state.

In case no action has been taken in accordance with Article 69 or 70, the member state may adopt interim protective measures without obtaining the prior authorization of the Commission. In this event, it shall immediately inform the other member states and the Commission [Article 71(1)]. In such a case, within 30 working days of the notification, the Commission shall put the matter before the regulatory Committee "with a view to the extension, amendment, or repeal of the national interim protective measure" [Article 71(2)].

Meanwhile, the member state may maintain its national interim protective measures. When the EU measures have been adopted, it must comply with them. Accordingly, if the Commission backed up by the regulatory committee decides to repeal the unilateral domestic measure, the member state is obliged to repeal it.

This analysis prompts several observations.

- First, the Article 71 safeguard clause allows the member states to deal with exceptional situations of limited duration. In other words, the measures of prohibition or limitation taken by national authorities are only authorized for as long as is necessary for a new decision to be taken by the EU authorities.
- Second, precautionary provisions of the PPPR [Article 1(4)] do not prevent the member states from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the pesticides to be authorized in their territory.[bx] Accordingly, the condition that the substance or the product is "likely to constitute a serious risk to human or animal health or the environment" (Article 69) must be interpreted in light of the precautionary principle.
- Third, the member state must justify the ban or restriction in the light of the noneconomic reasons mentioned in Article 69, such as human or animal health or the environment.
- Fourth, regarding the burden of proof, the member state must provide the relevant evidence demonstrating the existence of a risk. In this connection, the CJEU ruled in *Monsanto Agricultura Italia* that "protective measures, notwithstanding their temporary character and even if they are preventive in nature, can be adopted only if they are based on a risk assessment which is as complete as possible in the particular circumstances of an individual case" [Case C-236/01, *Monsanto Agricoltura Italia* (2003) C:2003:431, para 107].

[bx] *Blaise*, para. 44.

- Finally, in accordance with principles traditionally applicable to safeguard clauses, the application of a safeguard clause is subject to a "control procedure" undertaken by the Commission. The member state is thus obligated to notify the Commission of the derogating measure taken in order to enable the latter to ascertain whether it is consistent with the PPPR. Generally speaking, the Commission shall either authorize the provisional measure for a time period defined or require the member state to revoke the provisional measure. As a result, the interim national measure is temporary.

The restrictive measures authorized by Directive 2009/128/EC

In implementing 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 (hereafter Directive 2009/128/EC), member states are empowered to regulate the use of pesticides containing glyphosate. In this connection, the following provisions are illustrative of the preventive measures that member states should enact.

- Integrated Pest Management: "professional users of pesticides [ought to] switch to practices and products with the lowest risk to human health and the environment among those available for the same pest problem" (Article 14.1).
- Use nonchemical alternatives: "Member states shall take all necessary measures to promote low pesticide-input pest management, giving wherever possible priority to non-chemical methods" (Article 14).
- Minimization or prohibition of pesticide use in specific areas (Article 12) and the establishment of appropriately sized buffer zones to protect nontarget aquatic organisms and safeguard zones for surface and groundwater used for the abstraction of drinking water (Article 11).

Review by national courts of restrictive measures placed on the use of glyphosate

The following judgments exemplify to some extent the room for maneuvering left to member states.

In its judgment of 15 January 2019, the Administrative Court of Lyon struck the authorization granted by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) with respect to the marketing of Roundup Pro 360.[by] It criticized ANSES for failing to produce a risk assessment making it possible to establish that Roundup 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 Roundup Pro 360, the marketing authorization granted by ANSES is "likely to cause serious damage to health." On the basis of that

[by] Administrative Court of Lyon, 15 January 2019.

conclusion, the Court annulled the marketing authorization on the ground that, by authorizing that herbicide, ANSES had committed a manifest error of appraisal in the light of the precautionary principle, which is 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 authorization. This reasoning seems to us to be in line with EU law because the PPPR only allows the marketing of safe plant protection products.

On 28 February 2019, the Belgian Constitutional Court dismissed a claim lodged by the Belgian association of the plant protection products industry against a decree of the Flemish region restricting the use of glyphosate (judgment No. 38/2019). The Court held that the Flemish decree implements Directive 2009/128/EC that allows member states to regulate the use of pesticides. Furthermore, the Court emphasized that the restrictions placed on the use of pesticides containing glyphosate are authorized in virtue of Article 12 of that directive.[bz]

The Swedish Supreme Administrative Court reversed a decision taken by the Swedish Chemicals Agency (KemI) and, on appeal by the government, restricting the use of the active substance glyphosate, on the ground that the substance was authorized under former Directive 91/414 on pesticides.[ca] The Supreme Court held that a concrete risk assessment of the impact of the substance on ground water was missing.

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 because ignorance renders rights to participation and access to justice ineffective. The right to information is therefore central among procedural rights.[16] 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.[17]

Information held by EU institutions

Access to information held by EU institutions is covered by two regulations, the second of which implements the 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):

[bz] B.5.

[ca] Case Raa 2005.

- 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.[cb]
- 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).[cc]

At the outset, the EU institutions could refuse to grant access to the information on glyphosate by 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 glyphosate.

However, the Aarhus Regulation is a *lex specialis* that derogates from Regulation No. 1049/2001. Indeed, the aim of the Aarhus Regulation is to ensure the widest possible systematic availability and dissemination of the environmental information held by the institutions and bodies of the EU.[cd] 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.[ce]

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 of the interests. In contrast, the Aarhus Regulation derogates from that rule by establishing a presumption in favor of the disclosure of information that "relates to emissions into the environment" [Article 6(1) first sentence]. It follows that Article 6(1) of 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.

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

Greenpeace and the Pesticide Action Network Europe (PAN Europe) have been attempting to gain access to the records concerning the authorization of glyphosate for use in pesticides. The EC disclosed some of the documents in question, but withheld others on the 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.[cf] Consequently, an EU institution cannot justify its refusal

[cb] OJ 2001 L 145, p. 43.

[cc] OJ 2006 L 264, p. 13.

[cd] Art. 1. See Case C-673/13 P, *Commission v Stichting Greenpeace Nederland and PAN Europe* [2016] EU:C:2016:889, para. 52.

[ce] Case C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe* [2016] EU:C:2016:889, para. 61.

[cf] C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe* [2016] EU:C:2016:889, paras. 49 and 53.

to divulge it on the basis 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 that "relates to emissions into the environment" within the meaning of Article 6(1) of the Aarhus Regulation.[cg]

The CJEU concluded that it was necessary to include in the concept of information that "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 authorized the product or substance in question, was correct, and the data relating to the effects of those emissions on the environment.[ch] Accordingly, the Court endorsed a broad interpretation of the notion of the concept of "emissions."

Overriding public interest in disclosing information relating to emissions into the environment

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. They 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 nongovernmental organizations requesting the information [Stichting Greenpeace Nederland and Pesticide Action Network Europe (PAN Europe)], supported by Sweden, argued that the information concerns all the substances released into the environment when the authorized substance glyphosate is used and applied in pesticides. In particular, the nongovernmental organizations 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.[ci] In their view, that information could allow the determination of the level of emission of those impurities into the environment.[cj]

In contrast, the EC 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 emission into the environment. In particular, the disclosure of such information would make it possible to reconstitute the manufacturing process of glyphosate and the related business secrets.[ck]

[cg] Case T-716/14, *Tweedale* [2019] T:2019:141, para. 58.

[ch] C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe*, cited above, para. 80.

[ci] C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe*, cited above, para. 60.

[cj] C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe*, cited above, paras. 62–64.

[ck] C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe*, cited above, para. 65.

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 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).*[cl]

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."[cm]
- On the other, the plant protection product for which authorization is requested that is often produced by a different undertaking than that which requested approval for the active substance at the EU level.[cn]

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.*[co]

and further that 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 the 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 while the General Court endorses a global approach (*une approche d'ensemble*).[18]

In 2009, in *Tweedale* and *Hautala*, the General Court endorsed an interpretation that was more consistent with the *Stichting Greenpeace Nederland and PAN Europe*

[cl] Case T-545/11 *RENV Stichting Greenpeace Nederland* [2016] EU:T:2018:817, para. 58.

[cm] Case T-545/11 *RENV Stichting Greenpeace Nederland* [2016] EU:T:2018:817, para. 83.

[cn] Case T-545/11 *RENV Stichting Greenpeace Nederland* [2016] EU:T:2018:817, para. 84.

[co] Case T-545/11 *RENV Stichting Greenpeace Nederland* [2016] EU:T:2018:817, para. 88.

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 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."[cp]

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 (the) 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 the right to keep some information confidential is to be without prejudice to the application of Directive 2003/4/EC, which means that requests for access by third parties to the information contained in authorization application dossiers are subject to the general provisions of that directive.[cq]

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/EC.[cr]

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.[cs]

[cp] Case T-716/14 *Tweedale* [2019] T:2019:141; Case T-329/17 *Hautala* [2019] T:2019:142.

[cq] Blaise, para. 106.

[cr] Case C-442/14 *Bayer CropScience and Stichting De Bijenstichting* [2016] EU:C:2016:890, para. 54.

[cs] Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information.

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 authorization of a product in accordance with the legislation of plant protection products are deemed to be "environmental information" for the purpose of Article 2 of Directive 2003/4/EC on access to environmental information. In effect, this information "concerns elements of the environment which may affect human health if excess levels of those residues are present."[ct]

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."[cu]

Conclusions

The EC has always claimed that EU environmental laws, and in particular the PPPR, are among the most ambitious environmental regulations. This level of ambition should be buttressed by the constitutional obligations laid down in the EU founding treaties (high level of environmental and health protection). In particular, the PPPR has to be interpreted in light of the key objectives set forth under treaty law as well as the general principles of EU law, such as precaution. Moreover, in adopting the PPPR, the EU lawmaker has been favoring environmental and health interests over plant production. Therefore, one has to take seriously the place occupied by environmental and health interests in both primary and secondary law.

As it is underpinned by the principles of hazard identification, precaution, and substitution, the PPPR has been paving new ways in the reduction of health and environmental risks. As a result, the EU's goals are not solely economic, but also social and environmental. The proper functioning of the internal market must be accommodated with these nonmarket values, the legal protection of which is nonetheless essential.

The approval of glyphosate as an active substance has been subject to significant tension between the member states and the EU institutions. To understand this tension, this chapter has explored the key features of the regulatory framework empowering the EC to approve glyphosate and the member states' restrictions placed on its use. The understanding of this framework is indispensable, as a new approval procedure has just commenced.

[ct] Case C-266/09 *Stichting Natuur en Milieu* [2010] C:2010:779, paras 42-43.

[cu] Case C-442/14 *Bayer CropScience and Stichting De Bijenstichting* [2015] C:2016:890, para. 91.

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