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ARTICLE

The Glyphosate Saga Continues: 'Dissenting' Member States and the European Way Forward

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Abstract
A decision will soon have to be taken regarding the renewal of approval of glyphosate at the European Union (EU) level; this pesticidal active substance, however, is more controversial than ever. This article critically assesses various strategies pursued by EU Member States and regional authorities which challenge the EU approach to glyphosate and aim to safeguard their higher levels of public health and environmental protection. It reflects on the prospects of success of these strategies, and their compatibility with EU law. The analysis includes the action for the annulment of glyphosate's 2017 reapproval brought by the Brussels-Capital Region, the Austrian attempt to enact a blanket ban on glyphosate-based pesticidal formulations, and the more sophisticated strategies pursued by Luxembourg and France. The article concludes that the French strategy is effective in risk regulation terms, and compatible with EU law. Nonetheless, adopting the French approach may prove rather difficult for other Member States, as a result of both structural-regulatory and practical constraints. Rather, an EU-wide strategy on glyphosate is urgently needed.

Keywords: Glyphosate, Pesticides, Court of Justice of the European Union (CJEU), Precautionary principle, Environmental public interest litigation, Access to justice

1. INTRODUCTION

In December 2022, the approval of glyphosate at the European Union (EU) level will expire.[1] This pesticidal active substance is more controversial than ever, and the re-authorization procedure is likely to be even more troubled than it was back in 2017. A considerable number of EU Member States are challenging the EU approach to the governance of the uncertain risks posed by glyphosate. Ultimately, these

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1 The active substance glyphosate is approved for use in the EU until 15 Dec. 2022 (Commission Implementing Regulation (EU) 2017/2324 Renewing the Approval of the Active Substance Glyphosate in Accordance with Regulation 1107/2009 concerning the Placing of Plant Protection Products on the Market, and Amending the Annex to Implementing Regulation (EU) 540/2011 [2017] OJ L 333/1). In May 2022, the European Food Safety Authority (EFSA) informed the institutions that there will be a delay in the delivery of its Conclusion on the risk assessment of glyphosate. Commissioner Kyriakides has thus announced that an extension to the current approval period will be necessary. For more information, see European Commission, 'Status of Glyphosate in the EU', available at: https://ec.europa.eu/food/plants/pesticides/approval-active-substances/renewal-approval/glyphosate_en.

Member States advocate the setting of a higher level of protection and lower threshold of acceptable risk at the EU level. As explained in further detail in the following section, two radically different approaches to scientific uncertainty and two diametrically opposed long-term visions for the agricultural and food production systems are clashing across the EU. In the face of persisting uncertainty, the risks posed by the use of glyphosate and their acceptability are evaluated differently by various stakeholders in the light of their diverse normative perspectives, value systems and goals.

This article critically assesses different strategies pursued by Member States and regional authorities to challenge the EU regulatory approach to glyphosate and safeguard their intended level of protection and threshold of acceptable risk. These national or regional measures call into question the EU determination that glyphosate is safe enough for use in pesticidal formulations, and seek to deviate from the EU's 2017 decision to renew the approval of this active substance. The article focuses on the prospects of success of these measures and their compatibility with EU law.

The remainder of this article is structured as follows. Section 2 sets the stage for the analysis. Section 3 takes a close look at the action for the annulment of glyphosate's EU-wide renewal of approval brought in the *Brussels-Capital Region* case,[2] laying particular emphasis on the obstacles to the admissibility of this action and the prospective limits in the assessment of the merits of this case. Section 4 focuses on the Austrian attempt to enact a legislative ban on the use of all pesticides containing the active substance glyphosate, as a class. The analysis is conducted against the backdrop of the unsuccessful challenge brought by Austria and the Upper Austria region in the *Upper Austria* case.[3] Section 5 evaluates the more complex strategies pursued by Luxembourg and France to challenge the reapproval of glyphosate. Upon suggesting that Luxembourg's measures are incompatible with EU law, this section highlights the overall strength and effectiveness of the French approach. The final section concludes that the French strategy is effective in terms of risk regulation, and is compatible with EU law. As such, it provides a viable way forward for other 'dissenting' Member States. Nonetheless, a unitary position at the EU level on the acceptability of the risks of glyphosate is urgently needed; this is all the more important in the light of the European Green Deal commitments and the Farm to Fork Strategy.[4]

2. THE GLYPHOSATE CONUNDRUM AND THE PLANT PROTECTION PRODUCTS REGULATION ARRANGEMENTS

The EU-wide renewal of approval of the pesticidal active substance glyphosate has sparked controversy across the region. Ever since the 2015 decision by the

[2] Case T-178/18, *Région de Bruxelles-Capital* v. *Commission*, EU:T:2019:130; Case C-352/19 P, *Région de Bruxelles-Capital* v. *Commission*, EU:C:2020:978 (*Brussels-Capital Region*).

[3] Case T-366/03, *Land Oberösterreich and Austria* v. *Commission*, EU:T:2005:347; and Joined Cases C-439/05 and C-454/05, *Land Oberösterreich and Austria* v. *Commission*, EU:C:2007:510 (*Upper Austria*).

[4] European Commission, Communication on the European Green Deal, COM(2019) 640 final, 11 Dec. 2019; European Commission, Communication on a Farm to Fork Strategy for a Fair, Healthy and Environmentally-friendly Foods System, COM(2020) 381 final, 20 May 2020.

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International Agency for Research on Cancer (IARC) to classify it as 'probably carcinogenic',[5] glyphosate has been the object of heated debate. The 'Ban Glyphosate' European Citizens' Initiative succeeded in mobilizing consumers, farmers, and stakeholders across the EU. The Commission, by contrast, struggled to build a qualified majority in Comitology in favour of glyphosate's re-authorization, and only managed to muster one at the very last minute in December 2017.[6]

Science can neither confirm nor categorically exclude the hazardousness (namely, the carcinogenicity) of this active substance. The 2021 Draft Assessment Report of the designated co-Rapporteurs for EU Member States has confirmed the absence of conclusive scientific proof of a causal link between exposure to glyphosate, on the one hand, and adverse (tumour-initiating and tumour-promoting) effects, on the other.[7] Nonetheless, in the wake of the 'Monsanto Papers' scandal,[8] and after successful class actions in the United States (US), the question of glyphosate's carcinogenicity is more controversial than ever. US courts have found that the available scientific evidence is solid enough to establish a causal link between exposure to glyphosate and the development of Non-Hodgkin lymphoma, awarding unprecedentedly high levels of damages to the plaintiffs.[9]

Far from being a mere scientific matter,[10] the assessment of the uncertain risks posed by glyphosate and the evaluation of their acceptability raise questions of a normative nature. Facts and values, scientific and non-scientific considerations are structurally intertwined in the field of risk regulation. The determination of the threshold of legally relevant adverse effects, which warrants regulatory intervention, results from three different factors.

The first consists of recourse to more or less prudential approaches to risk assessment: this results in a different *evidence base*. Risk assessment involves an evaluation and characterization of uncertain risks, conducted by technical-scientific experts. As

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5 IARC, *Some Organophosphate Insecticides and Herbicides* (IARC, 2015), available at: http://monographs.iarc.fr/ENG/Monographs/vol112/mono112.pdf.

6 For a detailed account of the glyphosate controversy, see G.C. Leonelli, 'The Glyphosate Saga and the Fading Democratic Legitimacy of European Union Risk Regulation' (2018) 25(5) *Maastricht Journal of European and Comparative Law*, pp. 582–606.

7 In May 2019, the Commission appointed 4 Member States (France, Hungary, the Netherlands, and Sweden) as co-Rapporteurs for the first stage of the glyphosate risk assessment. In Dec. 2019, the Glyphosate Renewal Group submitted an application for renewal of approval after Dec. 2022. In June 2021, the co-Rapporteurs finalized their Draft Assessment Report and a further Report on the (proposed) harmonized classification and labelling of this active substance; these will be reviewed by the European Food Safety Authority (EFSA) and the European Chemicals Agency; see European Commission, 'Status of Glyphosate in the EU', n. 1 above.

8 For access to the key documents produced before the US federal and state courts, see US Right to Know, 'Roundup (Glyphosate) Cancer Cases: Key Documents & Analysis', available at: https://usrtk.org/monsanto-papers.

9 Bayer AG has set aside more than USD 15 billion for glyphosate-related settlements and litigation: L. Burger, 'Bayer Loses Third Appeals Case over Glyphosate Weedkiller', *Reuters*, 10 Aug. 2021, available at: https://www.reuters.com/business/healthcare-pharmaceuticals/bayer-loses-third-appeals-case-over-glyphosate-weedkiller-2021-08-10.

10 G.C. Leonelli, *Transnational Narratives and Regulation of GMO Risks* (Hart, 2021). For an examination of the point that the determination that a risk exists 'cannot be a matter of pure science', see V.R. Walker, 'The Myth of Science as a "Neutral Arbiter" for Triggering Precautions' (2003) 26(2) *Boston College International and Comparative Law Review*, pp. 197–228.

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openly acknowledged in the scientific community, different 'science-policy choices' are required throughout the risk assessment stage and will influence the final results of a risk assessment to a considerable extent.[11] Ideal 'sound scientific' approaches are premised on the assumption that uncertainty and variability are predictable, objectively quantifiable and manageable.[12] Adopting a cautious approach and referring to worst-case scenarios is thus unwarranted from a sound scientific perspective. By contrast, prudential approaches postulate a very cautious approach in the exercise of scientific judgement and in the selection of specific methods, data and default assumptions. In the context of the glyphosate controversy, the application of more or less prudential approaches to risk assessment has resulted in the coexistence of different data and different bodies of scientific research.[13]

The second factor is the varying extent to which regulators focus on conclusive scientific proof of the existence of a hazard and pathway for the materialization of a risk,[14] as opposed to persisting uncertainty surrounding the hazardous properties of a product or the potential materialization of a risk. This is the 'sound science' versus 'uncertainty' dichotomy.[15] The extent to which regulators adhere to 'sound science' or take into account persisting uncertainty and the perceived insufficiency of the available data influences the *inferences* that are drawn from the available scientific evidence.[16] This dichotomy is prominent in the glyphosate debate, as scientific research has neither established nor excluded glyphosate's carcinogenicity.

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[11] National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (National Academies Press, 1983) (the 'Red Book'), pp. 28 ff. See also S. Jasanoff, *The Fifth Branch: Science Advisers as Policy-makers* (Harvard University Press, 1990); S. Jasanoff (ed.), *States of Knowledge: The Co-production of Science and Social Order* (Routledge, 2004).

[12] For an analysis of 'sound scientific' and 'prudential' approaches through the lens of ideal 'evidence-based' and 'socially acceptable risk' paradigms, see Leonelli, n. 10 above. In a similar vein, albeit from the different (procedural) perspective of Rational-Instrumental and Deliberative-Constitutive paradigms, see E. Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart, 2007). The terminology of 'sound scientific' risk assessments (and 'sound science') has been traditionally employed by the denigrators of the precautionary principle. For an analysis see, e.g., W.E. Wagner, 'The Bad Science Fiction: Reclaiming the Debate over the Role of Science in Public Health and Environmental Regulation' (2003) 66(4) *Law and Contemporary Problems*, pp. 63–134.

[13] For an analysis of methodological questions in the context of the glyphosate debate see, e.g., Y. Hendlin et al., 'Like Oil and Water: the Politics of (Not) Assessing Glyphosate Concentrations in Aquatic Ecosystems' (2020) 11(3) *European Journal of Risk Regulation*, pp. 539–64. For a procedural analysis and a focus on the EU regulatory epistemology see M. Morvillo, 'Glyphosate Effect: Has the Glyphosate Controversy Affected the EU's Regulatory Epistemology?' (2020) 11(3) *European Journal of Risk Regulation*, pp. 422–35.

[14] A 'hazard' is defined as a biological, chemical or physical agent with the potential to cause adverse effects. A 'risk', on the other hand, is a function of the probability of occurrence of adverse effects and the severity of these effects, consequential on exposure to a hazard: Codex Alimentarius Commission, *Procedural Manual*, 27th edn (Joint FAO/WHO Food Standards Programme, 2019), p. 128.

[15] Leonelli, n. 10 above.

[16] This second dimension is distinct from that of recourse to 'sound scientific' or 'prudential' approaches to risk assessment. Firstly, the 'sound science' versus 'uncertainty' dichotomy does not centre on *scientific methodological questions* pertaining to the risk assessment stage, but on the *interpretation* of the available data by regulators. Secondly, it encompasses a focus on the different ways in which the 'same' evidence base may be interpreted by various regulators. Thirdly, in cases where hazards and risks have been conclusively established, the former dimension (recourse to 'sound scientific' or 'prudential' approaches) may result in regulatory divergencies; the latter dimension ('sound science' versus 'uncertainty'), by contrast, will not come into play.

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The third and final factor is the *level of protection* pursued by regulators. In this respect the extent to which regulators prioritize the economic cost-benefit effectiveness of risk governance, as opposed to pursuing enhanced protection and considering other legitimate factors, comes into play. This third factor is the normative frame that informs the entire risk regulation process.

In cases where hazards and risks have been conclusively established, this normative frame emerges *directly*.[17] In risk regulation systems characterized by reliance on 'sound scientific' approaches to risk assessment and regulatory adherence to 'sound science', economic cost-benefit analysis is employed to determine whether and to what extent conclusively established risks should be regulated. Hazardous products should be regulated only in so far as the public health and environmental benefits of regulatory intervention are expected to outweigh the economic costs of risk regulation and the economic benefits of the relevant product. Under different systems of risk regulation, regulators may choose to pursue enhanced (namely, higher than cost-benefit effective) levels of protection and take into account other legitimate factors. In either case, the normative frames informing the regulatory process will directly and expressly feed into the determination of the threshold of acceptable risk.

In cases where hazards and risks have *not* been conclusively established, by contrast, the normative frames informing the regulatory process will come into play only *indirectly*. In the glyphosate controversy, the point is not whether economic cost-benefit analysis, enhanced protection or other legitimate factors should inform regulatory responses, but rather whether regulators *should* act, despite the absence of conclusive proof of glyphosate's carcinogenicity. The answer to this question depends on the selection by regulators of a specific evidence base, and on their specific inferences. These regulatory determinations are still (albeit indirectly) informed by normative frames.

In the face of high levels of scientific complexity, 'sound science' will not necessarily yield any factually 'correct' answer: the boundaries between 'objective' facts and 'subjective' values thus fade in the field of risk regulation. Far from being neutral and objective, the assumption that 'sound scientific' approaches *must* be relied on and that 'sound science' *must* be adhered to is informed by considerations surrounding the economic cost-benefit effectiveness of risk regulation. Adherence to 'sound science' relieves market actors from the economic costs and regulatory burdens associated with precautionary measures. By contrast, prudential risk assessment policies and a focus on different forms of scientific uncertainty reflect the pursuit of enhanced levels of protection and consideration of other legitimate factors. In this sense, as famously argued, 'facts' and 'values', 'cognitive' and 'normative' evaluations, 'science' and 'social order' are co-produced.[18]

This sheds some light on the glyphosate controversy. The constituencies in favour of glyphosate's re-authorization have consistently pointed to sound scientific data,

[17] For an in-depth analysis of this and the following points, including the linkage between 'sound scientific' approaches to risk assessment, adherence to 'sound science' and the pursuit of cost-benefit effective levels of protection, see Leonelli, n. 10 above.

[18] On the notion of co-production, see Jasanoff (2004), n. 11 above.

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stressing that there is no conclusive scientific proof of glyphosate's carcinogenicity. The assumption that the uncertain risks posed by glyphosate must be taken because (and as long as) its hazardous properties have not been conclusively established is implicitly informed by economic considerations surrounding the important role of glyphosate-based pesticides in the agricultural sector.

Conversely, Member States and societal stakeholders in favour of a ban or stringent restrictions have drawn on prudential risk assessments and focused on persisting uncertainty. Reliance on this evidence base and this interpretation of the available data indirectly reflect the pursuit of enhanced levels of protection, precautionary evaluations, and consideration of other legitimate factors: these include a long-term vision for more sustainable agricultural approaches, and the potential development of less hazardous alternatives to glyphosate. Science can by no means resolve the conundrum; it can neither provide a single 'valid' answer, nor a universally agreeable one.

The 2017 EU-wide renewal of approval of glyphosate has caused considerable discontent among Member States, triggering the enactment of several national or regional measures. Through these measures, national or regional authorities have sought to safeguard their higher levels of protection. The measures under analysis in this article are connected with the exercise of specific Member State powers under the complex multi-level regulatory architecture of the Plant Protection Products Regulation (PPP Regulation).[19] As reconstructed throughout the next sections, the PPP Regulation provides for EU-wide approval of pesticidal active substances. When deciding on approval or renewal of approval, the Commission should take into account the results of risk assessment, the overarching tenets of the precautionary principle, and any other relevant legitimate factors.[20] Specific pesticides (plant protection products (PPPs)) containing an active substance, however, may be marketed or used at the national level only after the relevant Member State has authorized them. PPPs are made up of one or more active substances and a number of co-constituents; the same active substance will be present in a plurality of different PPPs. Specific criteria apply to the national authorization process, which takes place in the broader context of the 'zonal system'.[21] National regulators may also have recourse to the precautionary principle.[22]

Member States may refuse to grant authorizations for specific glyphosate-based pesticidal products, or subject them to specific risk management measures. Nonetheless, structural-regulatory as well as practical constraints come into play. The next section begins the examination by focusing on the first (unsuccessful) strategy: that pursued by the Brussels-Capital Region.

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19 Regulation (EC) No. 1107/2009 concerning the Placing of Plant Protection Products on the Market and Repealing Directives 79/117/EEC and 91/414/EEC [2009] OJ L 309/1 (PPP Regulation).

20 Ibid., Recital 8 and Art. 13(2).

21 Annex I of the PPP Regulation identifies three zones for the assessment of PPPs: these are Zone A (North), Zone B (Centre), and Zone C (South). The three zones are characterized by specific agricultural, plant health, environmental and climatic conditions.

22 PPP Regulation, n. 19 above, Recital 8 and Art. 1(4).

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3. THE ZONAL SYSTEM AND THE FIRST UNSUCCESSFUL STRATEGY: SEEKING THE ANNULMENT OF GLYPHOSATE'S REAPPROVAL

The factual and legal background to *Brussels-Capital Region* sheds some light on a few problematic aspects associated with the institutional architecture of the PPP Regulation zonal system. The discretion of Member States and their margins of manoeuvre in the evaluation of the risks posed by PPPs are limited by the specificities of the zonal system arrangements.

Where approval of an active substance has been renewed at the EU level, the applicants for authorization of specific PPPs containing that active substance shall apply to each Member State where they are seeking re-authorization of the relevant pesticidal formulations.[23] Just as in the case of the first authorization of a PPP, each application will be examined by a Rapporteur Member State in the relevant zone.[24] Every Zonal Steering Committee will take the final decision as to which Member State should act as zonal Rapporteur.[25] Where applications for the renewal of approval of different PPPs containing the same active substance are pending in a zone, the Zonal Steering Committee is encouraged to appoint a single Rapporteur;[26] nonetheless, this may not occur in practice.[27] The other Member States in the zone will be involved in the procedure and will submit their comments; however, they must refrain from taking any decision pending the Rapporteur's examination of the dossiers.[28] Once the Rapporteur's assessment is ready, the Member States will 'grant or refuse authorizations [for the specific PPP] accordingly on the basis of the conclusions of the assessment of the [Rapporteur]'.[29]

If the Rapporteur and other Member States in the zone diverge in their evaluation of the uncertain risks posed by a pesticidal product and their acceptability, the margins of discretion for the latter not to re-authorize a PPP are ultimately curtailed. There are two exceptions. Firstly, a Member State may in its authorization set additional risk mitigation measures.[30] Secondly, where the concerns of a Member State cannot be controlled through these additional measures, the relevant Member State may refuse authorization if, 'due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the [PPP] still poses an unacceptable risk to human or animal health or the environment'.[31] The latter exception may be employed by 'dissenting' Member States in circumstances where the acceptability of the uncertain risks

[23] Ibid., Art. 43(1), (2).
[24] Ibid., Arts 43(3)–(6), 35, 36.
[25] European Commission, 'Guidance Document on the Renewal of Authorisations According to Article 43 of Regulation (EC) No. 1107/2009', SANCO/2010/13170 rev. 14, 7 Oct. 2016, p. 6.
[26] Ibid.
[27] Ibid., p. 13.
[28] PPP Regulation, n. 19 above, Art. 35.
[29] Ibid., Arts 36(2), (3).
[30] Ibid., Art. 36(3).
[31] Ibid.

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posed by a PPP lies at the heart of zonal disagreements. However, as a matter of law, this exception enables a Member State to refuse authorization only if it can point to specific national 'environmental or agricultural circumstances'.[32]

Similar considerations apply to the mutual recognition procedure. This involves an applicant's request to a Member State to recognize the authorization for a PPP that has been granted in another Member State. If the two Member States are part of the same zone, the Member State that has received the request cannot refuse mutual recognition; the only applicable exceptions are the two provided for in Article 36(3), as illustrated above.[33] Clearly, the mutual recognition procedure erodes the discretionary powers of Member States to a greater extent than authorizations in the zonal system. In the case of mutual recognition, Member States can only recognize a pre-existing authorization granted by a different national authority, without being involved in the risk assessment stage.

Delays and disagreements among Member States in the zonal assessment of glyphosate-based PPPs[34] prompted the Brussels-Capital Region to bring an action for the annulment of Implementing Regulation (EU) 2017/2324,[35] by which the Commission had re-authorized the active substance glyphosate at the EU level. The Brussels-Capital Region sought the annulment of this reapproval by alleging, inter alia, an infringement of the principle that a high level of protection is to be pursued in the EU and an infringement of the precautionary principle.[36] The Region raised a number of points surrounding the admissibility of the action. For the purposes of the present enquiry, two specific points deserve particular attention. These relate to the assessment of the Region's direct concern within the meaning of the second limb of Article 263(4) of the Treaty on the Functioning of the European Union (TFEU),[37] and the interpretation of PPP authorizations as implementing acts. The following subsections address these points. They illustrate why the Region's challenge overall was very likely to be deemed inadmissible and why, even if considered admissible, the action would have been unlikely to succeed on the merits.

3.1. *Interpretation of Direct Effect* in Concreto: *Not Impossible, but Unlikely To Succeed*

The Brussels-Capital Region argued that it was directly and individually concerned by the reapproval of glyphosate under the second limb of Article 263(4) TFEU.[38] The

[32] A refusal to authorize a PPP must also be notified to the Commission with a specific technical-scientific justification: ibid., Art. 36(2).

[33] PPP Regulation, n. 19 above, Arts 40(1), 41(1).

[34] See the express references in Case T-178/18, *Brussels-Capital Region*, n. 2 above, paras 45–6; and in the Opinion of AG Bobek in Case C-352/19 P, *Brussels-Capital Region*, EU:C:2020:588, paras 88–98 and 99–104.

[35] N. 1 above.

[36] Opinion in Case C-352/19 P, *Brussels-Capital Region*, n. 34 above, paras 25–6.

[37] Lisbon (Portugal), 13 Dec. 2007, in force 1 Dec. 2009 [2012] OJ C 326/47, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2012:326:FULL:EN:PDF.

[38] Case T-178/18, *Brussels-Capital Region*, n. 2 above, para. 44.

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Region claimed that it was individually concerned by the renewal of approval of glyphosate in so far as this compromised the exercise of its environmental competences under national law. Importantly, the Region also maintained that it was directly concerned by the Implementing Regulation of 2017,[39] in the specific circumstances of the case.

In accordance with settled case law, the Court will find that an applicant is directly concerned within the meaning of the second limb of Article 263(4) TFEU if two conditions are met. Firstly, the act must directly affect the legal position of the applicant. Secondly, the implementation of the act must be automatic and exclude the exercise of discretion by other authorities.[40] In the case under analysis, the Region pointed to the specific dynamics underlying the re-authorization of PPPs in the zonal system to advance the argument that it was directly concerned.

Pursuant to Article 43(5) and (6) of the PPP Regulation, Member States that have received an application for the re-authorization of PPPs must adopt their decision at the latest 12 months after renewal of the approval of the relevant active substance. Where this proves impossible in the zonal system, Member States are to extend the authorization for the period necessary to complete the examination. In this case, the Region claimed that the reapproval of glyphosate at the EU level *automatically* affected its own legal position (exercise of environmental competences) in so far as all Member States in the zone were *pro tempore* bound to extend the authorizations of glyphosate-based PPPs.

The General Court (GC) rejected this argument, finding that it was based on a misinterpretation of the PPP Regulation. It noted that the renewal of approval of an active substance does not automatically cause the confirmation, extension or renewal of marketing authorizations for PPPs. Rather, the holders of national authorizations for PPPs must request renewal of their authorizations at Member State level.[41] The GC indirectly suggested that the temporary extension referred to by the applicant did not automatically result from glyphosate's renewal of approval, but from delays in the context of the zonal system.[42] It thus concluded that the Region was not directly concerned.

Advocate General (AG) Bobek, by contrast, embraced a substantive reading and developed a teleological interpretation of the standing criteria. The opinion emphasizes that the EU Courts have increasingly assessed the ways in which EU acts may alter the applicant's legal situation *in concreto*. The AG focused on both the EU Courts' evaluation of direct concern in the light of the specific purpose of the contested measure, and their assessment of the margins of discretion that could be exercised in practice.[43] He underlined that the existing national PPP authorizations were automatically maintained as a direct consequence of the adoption of the act under challenge.[44]

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39 N. 1 above.

40 See, e.g., Case C-622/16 P, *Scuola Elementare Maria Montessori* v. *Commission*, EU:C:2018:873, para. 42; and Case C-663/17 P, *ECB* v. *Trasta Komercbanka and Others*, EU:C:2019:923, para. 103.

41 Case T-178/18, *Brussels-Capital Region*, n. 2 above, para. 53.

42 Ibid., para. 54.

43 Opinion in Case C-352/19 P, *Brussels-Capital Region*, n. 34 above, paras 49–55.

44 Ibid., paras 83–6, and all the case law cited therein.

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It is hard to disagree with the AG on this point. If a substantive, rather than a formal, perspective is taken, the Region would certainly qualify as being directly concerned. Still, in his opinion, the AG chose to focus on the EU Courts' alleged 'regional blindness'.[45] He neither engaged with the specificities of judicial review of EU environmental and public health law, nor elaborated on the EU Courts' (different) interpretation of direct concern in actions brought in this area by market actors. Yet, raising the question of the equality of arms[46] might have proved helpful to underpin the AG's substantive-teleological interpretation of direct concern.

EU refusals to authorize active substances, EU authorizations subject to specific restrictions, and EU withdrawals of or amendments to pre-existing authorizations of active substances have been the object of several challenges by market actors. The notifiers of an active substance have consistently been held to be individually concerned. Further, the Courts have repeatedly found notifiers to be directly concerned in that these EU measures do not leave any margins of discretion to Member States.[47] This is unproblematic in the context of EU refusals to authorize active substances or EU withdrawals of authorizations. However, the picture changes in the case of EU authorizations that are subject to specific restrictions or EU amendments to existing authorizations.[48] In these cases the GC has still found that implementation is automatic, thus granting standing to market actors. However, the question is more complex than it may seem at first sight.

On the one hand, it is certainly true that Member States do not enjoy any discretion as regards the implementation of the EU-wide restrictive measures enshrined in the authorizations of active substances. On the other hand, it is equally true that Member States may add further restrictions and requirements, or choose not to authorize specific PPPs containing an active substance. From this perspective, Member States enjoy discretion, and the implementation of EU measures is not automatic. Thus, the notifiers' direct concern becomes questionable.

The Court's non-restrictive interpretation of the TFEU standing criteria in challenges brought by market actors in the field of pesticidal products, and the question of the equality of arms in public health and environmental litigation, could have strengthened the AG's assessment of direct effect *in concreto*. Nonetheless, it is still worth noting that a substantive-teleological interpretation of direct effect was overall quite unlikely to be successful in the specific circumstances of this case. The European Court of Justice (ECJ) straightforwardly adhered to the formalistic, yet perfectly tenable, interpretation of the GC. The Region's ground of appeal was dismissed.

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[45] Ibid., paras 97, 141.

[46] For an express reference to this principle, see the applicants' arguments in Case T-236/04, *EEB and Stichting Natuur en Milieu* v. *Commission*, EU:T:2005:426, para. 47.

[47] With the only exception of challenges against a decision to have recourse to the comparative assessment procedure: Case C-244/16 P, *IQV* v. *Commission*, EU:C:2018:177; Case C-384/16 P, *Copper* v. *Commission*, EU:C:2018:176.

[48] Case T-429/13, *Bayer CropScience* v. *Commission*; Case T-584/13, *BASF Agro and Others* v. *Commission*, EU:T:2018:279.

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3.2 *A Bold but Unsuccessful Argument: The Absence of Implementing Measures*

Besides laying emphasis on the automaticity of Belgium's extension of the authorizations for glyphosate-based PPPs, the AG put forward a much bolder argument to establish the Region's standing. He contended that the reapproval of glyphosate impacted on the Region's environmental competences *by its very existence*. From this perspective, the contested act did *not* entail *implementing measures* at all; thus, the appellant could also be held to have standing under the third limb of Article 263(4) TFEU.

To begin with, the AG argued that the authorization of an active substance, despite being a preliminary step in the authorization of PPPs, 'produces *significant legal effects on its own*, independently of any national decision authorizing specific products'.[49] Thus, 'the fact that decisions on the renewal of the specific authorizations [for glyphosate-based PPPs] are not automatic … does not detract from the fact that the determination as to the safety of that [active] substance does not need any implementing measure to deploy legal effects'.[50] Further, he emphasized that non-substantive or ancillary measures should not qualify as implementing measures where an EU act is 'fully and autonomously operational in the light of its purpose, content and effects on the applicant's legal situation'.[51]

Building on this premise, he noted that the Region was not contesting any specific authorizations of PPPs, but the *safety* of the *active substance as such*. This is 'an aspect on which the contested act provides a final determination [and] *no measure of implementation* is necessary or provided for in that respect'.[52] On these grounds he argued that the Region had standing under the third limb of Article 263(4) TFEU.

This point in the opinion raises the complex issue of the relationship between EU approvals of active substances and national authorizations of PPPs that contain them, the nature of the latter measures, and the extent to which they may qualify as *stricto sensu* implementing acts. While national measures automatically incorporate some provisions enshrined in the EU approval of active substances, they may expand the scope of the relevant restrictions. Member State authorizations are thus located on a spectrum from automatic implementation to the point where national discretion is so broad that the national measures cease to be implementing measures at all. From this perspective, *both EU approvals* of active substances and *national authorizations* of PPPs that contain them qualify as *self-standing*, *self-contained* acts.

It is indeed possible to make a case that national authorizations of PPPs differ from EU approvals of active substances in their scope *ratione materiae* and *ratione personae* to such an extent that they do not qualify as proper implementing measures.[53] In the

[49] Opinion in Case C-352/19 P, *Brussels-Capital Region*, n. 34 above, para. 77 (emphasis added).

[50] Ibid.

[51] Ibid., paras 172–3 (citing, inter alia, the Opinion of AG Cruz Villalón in Case C-456/13 P, *T&L Sugars and Sidul Açucares* v. *Commission*, EU:C:2014:2283, para. 32).

[52] Ibid., para. 163 (emphasis added).

[53] G.C. Leonelli, 'A Threefold Blow to Environmental Public Interest Litigation: The Urgent Need to Reform the Aarhus Regulation' (2020) 45(3) *European Law Review*, pp. 324–47, at 331–3.

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former respect, the authorization of an active substance as present in representative PPPs is structurally different from the authorization of a plurality of different pesticidal products containing the active substance *and* different co-constituents. The relevant approval criteria also differ. Symmetrically, challenging the legal determination that an active substance is safe enough for representative PPPs that contain it to be authorized at the national level is structurally different from challenging national authorizations of specific PPPs. In the latter respect, the approval of an active substance and the authorization of PPPs produce different legal effects for different constituencies.

In *Brussels-Capital Region*, paradoxically, the acknowledgement that EU approvals of active substances are self-contained acts could not underpin the argument on the Region's direct concern. The reason is that Member States (or regional and local authorities) can only regulate *PPPs*; they have no competence in the exhaustively harmonized area of regulation of *active substances*, and cannot exercise their powers in this respect. This point is illustrated in the following sections.

On these grounds the EU finding that glyphosate is safe enough to meet the approval criteria of the PPP Regulation could not alter the *legal sphere* of the Region; the regulatory powers of the latter may be exercised only in respect of glyphosate-based PPPs, the authorizations for which qualify as self-standing acts and encroach on the Region's legal position. However, recognition that the approval of an active substance may be challenged as a self-contained act and that national authorizations do not qualify as *stricto sensu* implementing measures would be extremely helpful for environmental non-governmental organizations (NGOs). The reference to 'regulatory acts which do not entail implementation' in the third limb of Article 263(4) TFEU is one of the main obstacles to direct access to the EU Courts for this category of non-privileged applicants.[54]

Against this backdrop, the strategy pursued by the Brussels-Capital Region was unlikely to be successful. As the analysis has demonstrated, the finding of inadmissibility overall was predictable.

3.3. *The Merits of the Case: Regrettably, Unlikely to Succeed*

As anticipated at the beginning of this section, the Brussels-Capital Region alleged an infringement of the precautionary principle and an infringement of the principle that a high level of protection will be pursued in the EU. This triggers the question whether, had the action been deemed admissible, the Region's challenge stood any chances of being successful on the merits.

Over the years, market actors have challenged several EU acts adopted in the field of risk regulation; some of the complaints raised by the applicants relate to an alleged

[54] The 2021 reform of the Aarhus Regulation, however, has now enabled NGOs and specific categories of stakeholders to request an internal review of provisions of non-legislative acts which entail implementation, and challenge the refusal to grant review before the CJEU. This finally resolves the problems associated with the third limb of Art. 263(4) TFEU. For an in-depth analysis, see G.C. Leonelli, 'Access to the EU Courts in Environmental and Public Health Cases and the Reform of the Aarhus Regulation: Systemic Vision, Pragmatism, and a Happy Ending' (2021) 40 *Yearbook of European Law*, pp. 230–64.

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misapplication of the precautionary principle by the EU institutions.[55] The Court of Justice of the EU (CJEU) has always acknowledged that EU institutions enjoy a broad administrative discretion in cases involving complex technical-scientific evaluations. Consequently, in challenges against acts that are deemed *too restrictive*, the CJEU has confined itself to 'examining whether [an act] contains a manifest error or constitutes a misuse of power or whether the authority [clearly exceeded] the bounds of its discretion'.[56] The CJEU has thus employed a deferential, procedural standard of review. This is connected with a more or less explicit acknowledgement by the EU Courts that the EU risk managers exercised their administrative discretion in precautionary risk management.[57] In these cases, the *power* of the EU institutions to have recourse to the precautionary principle goes hand in hand with *procedural* review by the EU Courts.

An analysis of actions against EU risk regulation acts challenged for being *insufficiently protective* offers a different picture. With regard to regulatory (non-legislative) acts, the EU Courts have ruled on alleged infringements of the precautionary principle *stricto sensu* on two occasions: in *Paraquat* and in *France* v. *Commission*.[58] In these cases, the relevant point is not whether the EU risk managers incurred a manifest error of assessment in the exercise of precautionary risk management. Rather, the applicants' complaints relate to the EU institutions' *failure to comply* with the overarching tenets of the precautionary principle. As a result, the EU Courts have employed a more intense standard of scrutiny. Rather than focusing on the *procedural* conditions for the exercise of administrative discretion in precautionary risk management, the EU Courts have ultimately sought to review *substantive* compliance with the tenets of the precautionary principle. In this sense, the precautionary principle operates as an inner limit to the EU institutions' broad administrative discretion in the field of risk regulation.

Firstly, in *Paraquat* and *France* v. *Commission*, procedural questions as to whether the EU institutions incurred a manifest error of assessment or took all relevant factors into account are either not prominent, or not dealt with at all.[59] The applicants

[55] For a detailed analysis, see G.C. Leonelli, 'Acknowledging the Centrality of the Precautionary Principle in Judicial Review of EU Risk Regulation: Why It Matters' (2020) 57(6) *Common Market Law Review*, pp. 1773–818.

[56] See, e.g., Case T-13/99, *Pfizer Animal Health SA* v. *Council*, EU:T:2002:209, para. 166; and Case T-70/99, *Alpharma* v. *Council*, EU:T:2002:210, para. 177.

[57] In a limited number of cases, the CJEU has instead employed a quasi-substantive standard. For an analysis of different strands of procedural review see Leonelli, n. 55 above.

[58] Reference here is made to actions for annulment or preliminary rulings on the validity of EU non-legislative acts adopted in the field of risk regulation (rather than in the broader field of environmental law) and challenged for being insufficiently protective on the grounds of an infringement of the precautionary principle (*stricto sensu*). *Paraquat*, to date, is the only successful action: Case T-229/04, *Sweden* v. *Commission*, EU:T:2007:217 (*Paraquat*). In Case T-257/07, *France* v. *Commission*, EU:T:2011:444, unsuccessfully appealed (Case C-601/11 P, *France* v. *Commission*, EU:C:2013:465), the EU Courts assessed and rejected France's claims on alleged breaches of the precautionary principle.

[59] The former applies to *France* v. *Commission*, where the GC applied the manifest error of assessment test in a very different way from the 'traditional' application in challenges to acts that are deemed too restrictive. The latter applies to *Paraquat*, in which the application of a procedural standard of review would not have justified the annulment of the challenged act; see G.C. Leonelli, 'Judicial Review of Compliance with

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straightforwardly alleged a substantive infringement of the precautionary principle and of the principle that a high level of protection is to be pursued in the EU. Secondly, in these cases the EU Courts have exercised a more intrusive review of the scientific evidence relied upon by the Commission. Procedural questions are not salient. In dealing with the applicant's points in *Paraquat*, for instance, the Court of First Instance (CFI) famously found that an interpretation of the pre-2009 framework for the governance of pesticidal active substances in the light of the precautionary principle implies that '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 [approve an active substance]'.[60] In a similar vein, referring to the tenets of the precautionary principle, the CFI held that in order to approve an active substance, the EU institutions must establish '*beyond a reasonable doubt* that the restrictions on the use of the substance involved make it possible to ensure that use of that substance will be in accordance with the [legislative requirements]'.[61]

Undeniably, judicial review of compliance with the precautionary principle poses several challenges for the CJEU. In the face of high levels of complexity and scientific pluralism, the level of protection pursued by regulators could always be challenged for not being high enough. Furthermore, the complete definition of the precautionary principle stipulates that when scientific evidence is incomplete, inconclusive or insufficient, and a risk may be too high to meet the intended level of protection, EU risk managers may take precautionary action.[62] This entails the exercise of administrative discretion in three respects: (i) in the determination that the available evidence is incomplete, inconclusive or insufficient; (ii) in the setting of the intended level of protection in a specific regulatory area; and (iii) in the final determination that the relevant risk may be too high to meet the intended level of protection. A balance must then be struck between the acknowledgement that the EU institutions are *bound to comply* with the precautionary principle, and recognition of their margins of *administrative discretion in complying* with the principle.[63]

A close examination of *Paraquat* and *France* v. *Commission* suggests that, in challenges against acts deemed to be insufficiently protective, the EU Courts have sought to carve out a 'quantitative threshold' standard of review.[64] A set of indicators can be inferred from these two cases. If the challenge brought in *Brussels-Capital Region* is assessed against these indicators, it is reasonable to suggest that the action for annulment was unlikely to succeed on the merits.

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the Precautionary Principle from *Paraquat* to *Blaise*: Quantitative Thresholds, Risk Assessment and the Gap between Regulation and Regulatory Implementation' (2021) 22(2) *German Law Journal*, pp. 184–215.

60 Case T-229/04, *Paraquat*, n. 58 above, para. 161 (emphasis added).

61 Ibid., para. 170 (emphasis added).

62 European Commission, Communication on the Precautionary Principle, COM(2000)1 final, 2 Feb. 2000, pp. 7, 12, Section 5.

63 Leonelli, n. 59 above.

64 Ibid.

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Firstly, an action brought on the grounds of the precautionary principle will be more likely to succeed where, persisting uncertainty and scientific complexity notwithstanding, the applicants can make a case that the probability that a risk will materialize and that the relevant adverse effects will occur is high.[65] This occurred in *Paraquat*: the applicant pointed to scientific evidence showing that, under realistic conditions of use, risks would materialize and adverse effects would occur as a result of specific operator exposures to paraquat-based PPPs. In *France* v. *Commission*, by contrast, the GC expressly and repeatedly referred to the finding that the probability that the relevant risks would materialize was 'low', 'very low' or 'extremely low'.[66] In the case of glyphosate, the absence of conclusive scientific proof of carcinogenicity acts as an obstacle to a finding that specific risks will materialize.

Secondly, the prospects of success will be considerably higher where the applicants can point to a specific evidence base to substantiate their claims, rather than merely focus on a diverging interpretation of the evidence relied upon by the EU institutions. Different evaluations as to the acceptability of a risk will not make a convincing case. This emerges from a comparison of *Paraquat*, in which the applicant pointed to specific data, and *France* v. *Commission*, in which the disagreements centred largely on a diverging interpretation of the EFSA evidence base. For this reason, the applicants should invoke prudential risk assessments to substantiate their claim. In the case of glyphosate, the Brussels-Capital Region could have referred to the IARC monograph[67] and other studies that highlight persisting uncertainty surrounding glyphosate's carcinogenicity.

Nonetheless, this would probably not have been sufficient; this point brings us to the third indicator. Persisting uncertainty and scientific complexity notwithstanding, the evidence relied upon by the applicants should be as cogent and as specific as possible to the claims that they are making. To borrow the words of the CFI, the relevant evidence should be 'solid' and, 'while not resolving scientific uncertainty, [it should] reasonably raise doubts as to the safety [of a product or process]'.[68] In *Paraquat*, Sweden relied on studies on exposure to paraquat-based PPPs that cast serious doubts on the EU institutions' determination that the acceptable operator exposure level (AOEL) established for paraquat would be met.[69] In the case of glyphosate, by contrast, scientific proof of carcinogenic effects is missing. If minority scientific opinion could establish a potential mechanism of action associated with the tumour-initiating or tumour-promoting effects of glyphosate, the scenario would be different. However, at the current stage of technical-scientific knowledge, applicants in a potential challenge could point only to *persisting uncertainty* and the *insufficiency* of the available evidence,

[65] Whether the severity of the relevant potential adverse effects also plays a role, on the other hand, is less clear-cut.

[66] *France* v. *Commission*, n. 58 above, paras 96, 98, 100, 104, 107–9, 137, 149–51, 155, 159, 163–71, 219, 229, 230, 250, 240, 251, 261, 265.

[67] N. 5 above.

[68] *Paraquat*, n. 58 above, para. 161.

[69] Ibid., paras 70–1 and 172–92.

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which would most probably not suffice to meet the criterion of 'solid' scientific evidence.

Finally, specific legal underpinnings and the applicants' reliance on robust references in the relevant regulatory frameworks will be crucial to assist the EU Courts in judicial review. In *Paraquat*, Sweden could rely on two express legislative requirements.[70] In the case of glyphosate, legal underpinnings are not entirely missing. The PPP Regulation's hazard-based cut-off criteria set a rebuttable presumption that carcinogenic active substances will not be approved.[71] However, evidence of a potential mechanism of action by which glyphosate could exert tumour-initiating and tumour-promoting effects is currently missing. Against this overall backdrop, even assuming that the Courts had found the action to be admissible, the annulment of glyphosate's reapproval on balance was unlikely to succeed on the merits.

4. THE SECOND UNSUCCESSFUL STRATEGY AND THE *UPPER AUSTRIA* DÉJÀ-VU

In July 2019, the Austrian Parliament passed a legislative measure enshrining a national ban on all glyphosate-based pesticides, on precautionary grounds. In May 2020, Austria provided the correct formal notification under Directive (EU) 2015/1535 Laying Down a Procedure for the Provision of Information in the Field of Technical Regulations and of Rules on Information Society Services.[72] The standstill period ended in August 2020. Regrettably, the comments and objections of the Commission and the Member States throughout the 2015 Directive procedures are not public. According to leaked documents publicized by the media, however, the Commission objected that 'in an area governed by directly applicable EU law, Member States may not adopt national provisions that would affect the correct and full application of EU law'.[73] It also noted that the Austrian measure would be irreconcilable with the Commission's 2017 Implementing Regulation renewing the approval of glyphosate[74] and that 'problems linking pesticides to biodiversity decline [are] not unique to Austria'.[75]

An analysis of the Austrian strategy begs the question whether a national, general legislative ban on *all* glyphosate-based PPPs, *as a class*, is compatible with EU law. The multi-level authorization procedure provided for under the PPP Regulation allocates exclusive authority to EU institutions as regards the approval of active

[70] The relevant requirements were enshrined in Art. 5 and Annex VI of Directive 91/414/EC concerning the Placing of Plant Protection Products on the Market [1991] OJ L 230/1 (the predecessor of the PPP Regulation).

[71] PPP Regulation, n. 19 above, Annex II, point 3.6.3, and Art. 4(7).

[72] [2015] OJ L 241/1. In June 2021, after the failed attempts to enact a total ban, the Austrian pesticide law was amended to prohibit specific uses of glyphosate-based PPPs, including private use.

[73] E. Wax, 'EU Blocks Austria's Planned Glyphosate Ban, Rejecting Claim that Weedkiller Harms Human Health', *Genetic Literacy Project*, 20 Aug. 2020, available at: https://geneticliteracyproject.org/2020/08/20/eu-blocks-austrias-planned-glyphosate-ban-rejecting-claim-that-weedkiller-harms-human-health.

[74] N. 1 above.

[75] Wax, n. 73 above.

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substances. Final decision making rests with the Commission and harmonization is exhaustive.[76] Member States, by contrast, have exclusive authority as regards the authorization of PPPs.[77]

The relevant approval criteria are analyzed in further detail below (Section 5). However, it is worth noting that the procedure for the EU-wide approval of an active substance involves an assessment of *representative uses* of *representative PPPs* containing the active substance. This is because active substances are never used on their own, but rather in specific pesticidal formulations. Pursuant to Article 4(5), the criteria for the approval of an active substance enshrined in Article 4(1), (2) and (3) 'shall be deemed to be satisfied where [compliance with these criteria] has been established with respect to one or more representative uses of at least one [PPP] containing that active substance'.[78] Symmetrically, the criteria of Article 4 will be considered as complied with where authorization is expected to be possible for at least one of the representative uses of at least one pesticidal formulation containing that active substance.[79] In sum, EU-wide approval of an active substance implies a finding by the EU institutions that the relevant active substance is *safe for use* in *at least some* pesticidal formulations that contain it.

These points trigger some considerations. A national blanket ban on *all* glyphosate-based PPPs, *as a class*, is tantamount to a finding that glyphosate is not safe for *any* use in *any* pesticidal formulations. Such a determination, however, could only be made at the EU level by means of a refusal to re-authorize glyphosate.

A connected point was raised in the public comments submitted by market stakeholders in the context of the 2015 notification procedure. As rightly noted, Member State 'evaluations [on PPPs] should be specific to the end products, comprising co-formulants and the overall formulation';[80] the PPP Regulation allows only 'for a case-by-case refusal or withdrawal of authorizations of products'.[81] Member States are to assess the risks associated with specific pesticidal formulations, made up of active substances and several co-constituents; particular attention should be paid to the risks posed by the interactions between the relevant active substance(s) and any co-formulants present in specific PPPs. Clearly, a blanket ban on all glyphosate-based PPPs does not respond to this rationale.[82]

Another salient point raised in the public comments relates to the impossibility for Austria to invoke Article 114(5) TFEU, on the introduction of national measures derogating from a (pre-existing) harmonization measure. Article 114(5) stipulates that the

[76] PPP Regulation, n. 19 above, Recital (10) and Ch. II, Section 1, Arts 4–24.

[77] Ibid., Recital (23) and Ch. III, Arts 28–57.

[78] See also the references in ibid., Arts 8(1)(a), 8(1)(c), 14(1), 29(3), and Annex II.

[79] Ibid., Annex II, para. 2.1.

[80] See the comments submitted by COCERAL on 6 Aug. 2020. Public comments are available on the Commission's TRIS database, available at: https://ec.europa.eu/growth/tools-databases/tris/en/search.

[81] See the comments submitted by Nufarm Europe GmbH on 5 Aug. 2020, available ibid.

[82] Ultimately, national discretion must be exercised within the specific boundaries of the PPP Regulation; if a Member State wishes to challenge the EU regulatory approach to a specific active substance, it must have recourse to the Regulation's specific procedures (PPP Regulation, Arts 21, 36, 43, 40–41, 44, 69–71).

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national measures must be based on new scientific evidence relating to the protection of the environment or the working environment, on the grounds of a problem specific to that Member State and which arose after the adoption of the harmonization measure. As in the famous *Upper Austria* case, Austria sought to invoke this Article in its comments during the notification procedure. This was bound to be an unsuccessful strategy.

The reference in the Article to new scientific evidence does not allow for national justifications on the grounds of a different (precautionary) interpretation of existing data. Whether Member States have drawn different scientific inferences in the face of persisting uncertainty, by taking into account a higher level of protection and a lower threshold of acceptable risk, is completely irrelevant.[83] As regards the requirement of a problem specific to the Member State, both the AG and the ECJ in *Upper Austria* accepted that the word 'specific' does not mean the same as 'unique'; rather, this terminology refers to situations that are particular, exceptional or unusual, and that distinguish the situation of the Member State from that of other Member States.[84] This condition is rather difficult to meet. Finally, the requirement that the problem must have arisen after the adoption of the harmonization measure is the most difficult to comply with.

In *Upper Austria*, the Republic of Austria and the Upper Austria region sought the annulment of a 2003 Decision of the Commission,[85] by which the latter had rejected Austria's request for a derogation from Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC,[86] on the grounds of (what is now) Article 114(5) TFEU. As the AG noted, the evidence that they had produced on hybridization and crop-to-crop gene flow did not constitute new scientific evidence within the meaning of (what is now) Article 114(5) TFEU.[87] As regards the specificity of the problem, the evidence could not point to unusual or specific ecosystems in the Region that would justify the adoption of the measure.[88] The applicants had also failed to establish that the specific problem had arisen after the adoption of the harmonization measure.[89]

A potential Austrian challenge in the case of glyphosate-based PPPs would have met exactly the same fate. Firstly, it is unlikely that Austria would have been able to point to *new* diverging scientific evidence surrounding glyphosate's carcinogenicity. As regards the second requirement, Austria invoked the risks posed by glyphosate-based PPPs to human health, groundwater and biodiversity. It is not impossible but rather difficult to imagine how Austria could identify peculiar or unusual characteristics that could

[83] Joined Cases C-439/05 and C-454/05, *Upper Austria*, n. 3 above, paras 61–4.

[84] Opinion of AG Sharpston in Joined Cases C-439/05 and C-454/05, *Upper Austria*, EU:C:2007:285, para. 109; and judgment, para. 64.

[85] Commission Decision 2003/653/EC relating to National Provisions on Banning the Use of Genetically Modified Organisms in the Region of Upper Austria Notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty [2003] OJ L 230/34.

[86] [2001] OJ L 106/1.

[87] Opinion, n. 84 above, para. 122.

[88] Ibid., paras 114–23.

[89] Ibid., paras 127–34.

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render this problem *specific* to it. Even if Austria managed to do this, it would still face the hurdle of explaining how such specific problems materialized only *after* the adoption of the 2017 Implementing Regulation reapproving glyphosate.

The conditions of Article 114(5) TFEU are exceedingly stringent and cannot possibly accommodate diverging, precautionary national evaluations of uncertain risks vis-à-vis a higher national intended level of protection. The Austrian strategy was bound to be both incompatible with EU law and unsuccessful.

5. THE SUCCESSFUL STRATEGIES OF LUXEMBOURG AND FRANCE: THE QUESTION OF COMPATIBILITY WITH EU LAW

In January 2020, the Minister of Agriculture of Luxembourg announced that all national marketing authorizations of glyphosate-based PPPs would be withdrawn from 1 February 2020. The grace period for use of these products expired on 31 December 2020; from 1 January 2021, the use of any glyphosate-based PPPs is prohibited in Luxembourg.[90] Luxembourg thus became the first EU Member State to prohibit glyphosate.

The Commission's reaction to Austria's planned ban, analyzed above (Section 4), begs the question of how Luxembourg managed to take this course of action without any objections from the EU institutions. The answer can be evinced from the declarations of Luxembourg's Minister of Agriculture. In October 2020, a Member of the Luxembourg Parliament addressed a written question to the Minister of Agriculture regarding the compatibility of Luxembourg's measures with EU law. This question made express reference to the Commission's response to the Austrian notification of its legislative ban. The Minister's official answer states that 'unlike Austria, which [tried to] ban the introduction of glyphosate-based plant protection products by law, Luxembourg has withdrawn the authorizations for all plant protection products containing glyphosate'.[91] According to the official answer, the Commission was simply informed of these withdrawals under the procedure provided for in Article 44(4) of the PPP Regulation.

Article 44 regulates the withdrawal or amendment of pre-existing authorizations for PPPs in the context of the zonal system. Pursuant to Article 44(1), Member States may review an authorization at any time where there are indications that a requirement for authorization is no longer met. The authorization will be amended or withdrawn when, inter alia, the Member State finds that any requirements for authorization are no longer satisfied. Article 44(4) stipulates that where a Member State proceeds to withdraw or amend an authorization, it will immediately inform the authorization holder, the other Member States, the Commission and the EFSA. The other Member States in

[90] See the press release 'Luxembourg, the First EU Country to Ban Glyphosate', 16 Jan. 2020, available at: https://gouvernement.lu/en/actualites/toutes_actualites/communiques/2020/01-janvier/16-interdiction-glyphosate.html.

[91] Question parlementaire n. 2742 de l'honorable Députée Madame Martine Hansen, 6 Oct. 2020, Ref: 436/2020. See also the database of Administration of Technical Agricultural Services (ASTA), Luxembourg's national regulator, available at: https://ma.gouvernement.lu/en/administrations/asta.html.

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the same zone will withdraw or amend the authorization accordingly, taking into account national conditions and risk mitigation measures, except for the cases where they had previously refused authorization for the product on grounds of national specificities.

Taking the text of this Article into consideration, the reasons behind the Commission's silence become clearer. The review and withdrawal procedure of Article 44 does not provide the Commission with any opportunity to submit specific objections; nor does it enable the Commission to submit the national measure to Comitology for a vote on extension, amendment or repeal.[92] From this perspective, Luxembourg's choice to have recourse to this specific procedure was undoubtedly effective; so far, these measures have not been challenged. What remains to be seen is whether these measures are compatible with EU law.

Firstly, starting from the text of Article 44(4) of the PPP Regulation, it is worth emphasizing that the Article employs the singular and refers to the review, withdrawal or amendment of 'an authorization'. This shows that the rationale of this procedure was to enable a Member State to take action on an ad hoc, case-by-case basis and in respect of specific pesticidal formulations. This responds to the institutional architecture of the PPP Regulation, as explained in Section 4 above. The relevant question then becomes whether the Luxembourgish authorities have proceeded on a case-by-case basis, providing a specific scientific justification for the withdrawal of *each and every* glyphosate-based PPP on the grounds of its specific formulation. This is not impossible, but quite unlikely to be the case.

Secondly, as concerns the delicate balance between the competences allocated to the EU and the Member State levels, the effects of the Luxembourgish strategy do not differ from the Austrian legislative ban. While different in their form, the two measures are identical in their substance. As in the case of the Austrian ban, the Luxembourgish withdrawal of *all* glyphosate-based PPPs, *as a class*, is tantamount to a finding that glyphosate is not safe for *any* use in *any* pesticidal formulation. Such a determination, however, rests with the EU institutions, and any measure that deviates from it is incompatible with directly applicable EU law. In the specific circumstances of Luxembourg's measures, it is also worth underscoring that the withdrawals will have targeted some of the representative glyphosate-based pesticidal formulations assessed by the EFSA throughout the EU-wide risk assessment of glyphosate. This is hardly reconcilable with the provisions of the PPP Regulation. Therefore, while Luxembourg's strategy has so far proven successful, it may still be open to challenge by the EU institutions.

The French strategy appears to be the only one that is both satisfactory in public health and environmental protection terms, and compatible with EU law. After considering a national legislative ban, France started to focus on specific glyphosate-based PPPs on a case-by-case basis. Throughout 2018 and 2019, the French public health and environmental regulator (ANSES) re-evaluated the authorizations for 69 glyphosate-based PPPs in the context of the procedure for their renewal of approval,

[92] Unlike the emergency procedure of the PPP Regulation: cf. Art. 44(4) and Art. 71(1), (2) and (3).

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and assessed 11 applications for new glyphosate-based products. The agency refused authorization for four of the new products. It also refused to renew the authorization for 36 previously approved glyphosate-based PPPs, with effect from January 2021. The products account for 75% of the volume of glyphosate-based pesticides sold in France in 2018.[93]

These decisions were taken in the context of the zonal system. It is legitimate to presume that, within its zone, France acts as Rapporteur Member State for a considerable number of PPPs; in these cases it simply proposed and enacted a decision to refuse the renewal of approval.[94] It is likely, in other cases, that it proposed a withdrawal of authorization of specific pesticidal formulations, again in the context of the zonal system. In some cases it may have also resorted to the narrow exceptions of Articles 36(3) (zonal system) and 41(1) (mutual recognition) of the PPP Regulation.

Crucially, the ANSES has consistently followed a prudential approach to risk assessment; it has taken persisting uncertainty into due consideration in its scientific inferences, and it has set enhanced levels of protection and a very low threshold of acceptable risk as the relevant benchmark. The decisions of the ANSES reflect a precautionary stance on the uncertain risks posed by glyphosate-based PPPs. This is fully consistent with the PPP Regulation, pursuant to which Member States are to take into account the precautionary principle when authorizing PPPs.[95] Since 2016, the ANSES has advocated a reclassification of glyphosate as a category 2 substance (substances suspected of being carcinogenic to humans) under the CLP Regulation.[96] Throughout the 2017–19 re-evaluation of glyphosate-based PPPs, it has consistently affirmed that the genotoxicity of glyphosate cannot be ruled out because of the insufficiency of the available data:[97] if glyphosate's genotoxic properties were scientifically established, they would demonstrate its carcinogenic effects. Most importantly, the ANSES has conducted thorough assessments and focused closely on the uncertain risks posed by the interaction of glyphosate and the co-constituents that are present (in different quantities) in various pesticidal formulations. This has resulted in the withdrawal of specific PPPs.

The close focus of the ANSES on the risks posed by the interaction of the active substance (glyphosate) and co-formulants in PPPs should be an example for all national regulatory agencies. Such a focus would be the only way to remedy the '*Blaise* conundrum' and fill in the missing gap in the multi-level arrangements of the PPP

[93] G. Trompiz & S. de la Hamaide, 'France to Ban Dozens of Glyphosate Weedkillers amid Health Risk Debate', *Reuters*, 9 Dec. 2019, available at: https://www.reuters.com/article/us-france-glyphosate-idUSKBN1YD1BG.

[94] France is part of Zone C (South).

[95] PPP Regulation, n. 19 above, Recitals (8), (23), (24) and Arts 1(4), 29.

[96] Avis de l'agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail relatif à la saisine glyphosate n. 2015-SA-0093, available at: https://www.anses.fr. See Regulation (EC) No. 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures, Amending and Repealing Directives 67/548/EEC and 1999/45/EC, and Amending Regulation (EC) No. 1907/2006 [2008] OJ L 353 (CLP Regulation).

[97] Trompiz & de la Hamaide, n. 93 above.

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Regulation.[98] This would be of fundamental importance. Indeed, the assessment of active substances at the EU level encompasses highly complex evaluations and can set only a *presumption* that different pesticidal formulations containing an active substance should be safe.

Once the EFSA has determined that an active substance meets the Regulation's hazard-based cut-off criteria,[99] compliance with the requirements enshrined in Articles 4(2) and 4(3) must be assessed; specific reference values for such an assessment will be set.[100] The criteria of Article 4(2) refer to the *residues* of representative pesticidal formulations containing the relevant active substance, whereas the criteria of Article 4(3) relate to the *representative pesticidal formulations* in and of themselves.[101] As already mentioned, an active substance may be approved when these criteria have been met in respect of 'one or more representative uses of at least one plant protection product containing that active substance'.[102] However, this limited preliminary assessment cannot provide a guarantee that *any* pesticidal formulation containing the active substance will be safe enough to meet the PPP Regulation criteria. This should be for Member States to assess when authorizing PPPs. This is the missing gap of the PPP Regulation, and the real point raised in the famous *Blaise* case: the EU assessment of active substances cannot provide the full picture of their risks, and the determination that an active substance is safe enough to be approved at the EU level by no means implies that *all* pesticidal products containing it will also be safe enough to meet the relevant criteria. This largely overlooked aspect lay at the heart of the *Blaise* challenge to the PPP Regulation, on the grounds of the precautionary principle.[103]

Regrettably, as highlighted by the European Parliament, national authorities do not conduct sufficiently thorough risk assessments of PPPs and do not pay due consideration to the interactions between active substances and PPP co-constituents.[104] In this sense they have largely failed to fill in the missing gap of the PPP Regulation. From this perspective, the approach followed by the ANSES in its assessment of glyphosate-based PPPs should set an example for other national authorities, especially in highly controversial cases.

Finally, the choice of ANSES in 2020 to have recourse to the Article 50(2) procedure, conduct a comparative evaluation of non-chemical alternatives to glyphosate, and

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98 Case C-616/17, *Blaise and Others*, EU:C:2019:800; Case C-616/17, *Blaise and Others*, EU:C:2019:190, Opinion of AG Sharpston. For a detailed analysis of *Blaise*, see Leonelli, n. 59 above.

99 As mandated by Art. 4(1) and Annex II of the PPP Regulation, n. 19 above..

100 See ibid., point 3.6.1 of Annex II.

101 The 'cumulative and synergistic effects' of the interaction between active substance and co-constituents in the representative pesticides must also be taken into account.

102 PPP Regulation, n. 19 above, Art. 4(1) and (5).

103 Leonelli, n. 59 above, pp. 202–14. Despite their odd framing and imprecise formulation, the first and the third questions of the referring court pointed to this specific aspect and to the missing gap in the multi-level dynamics of the PPP Regulation.

104 European Parliament, 'Report on the Union's Authorization Procedure for Pesticides', 2018/2135 (INI), pp. 7, 14, 15, 22, 26; available at: https://www.europarl.europa.eu/doceo/document/A-8-2018-0475_EN.html. See also European Parliament, Resolution of 13 Sept. 2018 on the Implementation of the Plant Protection Products Regulation (EC) No. 1107/2009, 2017/2128 (INI), point 38, available at: https://www.europarl.europa.eu/doceo/document/TA-8-2018-0356_EN.html.

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integrate its results in the conditions for use of glyphosate-based PPPs is proving successful.[105] Upon identifying the specific situations in which glyphosate-based PPPs can be substituted by non-chemical alternatives, the agency has amended the authorizations for these PPPs to prohibit or restrict their use in those circumstances. This should also set an example for national authorities, and is fully compliant with the Commission's Farm to Fork Strategy and new approach to the sustainable use of pesticides.

Against this overall backdrop, to draw a summary, the French strategy is both compatible with EU law and successful from a public health and environmental protection perspective. The ANSES approach to glyphosate-based PPPs illustrates how national authorities may help to resolve the '*Blaise* conundrum' and make effective use of the procedure of Article 50(2) of the PPP Regulation. Nonetheless, adopting the French approach may prove rather difficult for some Member States, because of both structural-regulatory and practical constraints. In the former respect, it is worth stressing again that both the zonal system and the mutual recognition system arrangements limit the regulatory authority of Member States. This clearly emerges from the factual background of *Brussels-Capital Region*. In the latter respect, specific practical constraints come into play; as the European Parliament has noted throughout the years, national regulatory authorities too often lack institutional capacity, sufficient technical-scientific expertise, as well as economic and staff resources. For this reason an EU-wide strategy on the active substance glyphosate is urgently needed.

6. FROM MEMBER STATE REACTIONS TO AN EU-LEVEL STRATEGY

This article has critically assessed responses by EU Member States and regional authorities to the EU-wide reapproval of glyphosate in 2017. These measures are the result of far-reaching disagreements surrounding the level of public health and environmental protection and the threshold of acceptable risk set by EU institutions in this area. A clash between different perspectives on scientific uncertainty and different long-term visions for the agricultural and food system has led to high levels of controversy within and between EU Member States.

The article has evaluated various national and regional strategies and assessed their compatibility with EU law. Section 3 showed that the Brussels-Capital Region's attempt to challenge the EU reapproval of glyphosate was highly likely to fail, on admissibility grounds as well as on the merits. Section 4 highlighted the specific reasons why the Austrian strategy was also bound to fail. Section 5 focused on the strategy pursued by Luxembourg, showing that, although so far successful, such a strategy is incompatible with the institutional architecture of the PPP Regulation. The same section

[105] In Oct. 2020, the ANSES finalized its research on the existence of available alternatives to glyphosate-based PPPs. All relevant data is available at: https://www.anses.fr. Taking this data into consideration, it relied on the procedure of Art. 50(2) of the PPP Regulation to further restrict the use of the glyphosate-based PPPs that it had re-authorized.

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illustrated the more sophisticated approach followed by France. The focus of the ANSES on the synergistic and combinatorial effects of the interactions of glyphosate and co-formulants, and its reliance on the comparative assessment procedure, are fully compliant with EU law and can remedy the '*Blaise* conundrum'. The French approach offers a way forward; nonetheless, it may prove difficult to implement for many Member States.

Against this backdrop, the development of a European strategy on glyphosate is urgently needed. As the EU institutions implement their European Green Deal agenda and the Farm to Fork strategy, their plan of action on glyphosate should be consistent with their declared public health and environmental goals. The institutions should live up to the high expectations that they themselves have set.

The European strategy on glyphosate should be ambitious, long-term, and pursue a high level of public health and environmental protection. The Commission should take seriously the disagreements within and between the EU Member States surrounding the acceptability of the uncertain risks posed by glyphosate; it should not merely reiterate that the scientific community has not conclusively established glyphosate's tumour-initiating or promoting effects. As already mentioned, this has recently been confirmed by the Draft Assessment Report of the four appointed co-Rapporteur Member States for the glyphosate dossier. However, in the face of persisting uncertainty and high levels of complexity, these scientific findings do not categorically exclude that the active substance glyphosate is carcinogenic; nor can they, by any means, settle the thorny question of whether the uncertain risks that glyphosate may pose are acceptable for civil society in the EU. This is a normative question involving consideration of the *intended EU level of protection*, the value of the *precautionary principle* in the EU system of risk regulation, and *other legitimate factors* such as public opinion, the overarching tenets of the substitution principle, and an EU-wide long-term vision for the development of a sustainable agricultural and food system: a question that science cannot possibly address.

If the controversy reaches the levels of 2017, the Commission should consider refusing to reapprove glyphosate. It would be neither the first nor the last time that the EU institutions disregard the positive results of a risk assessment, invoking the precautionary principle and pointing to persisting uncertainty and the insufficiency of the available evidence at the current stage of technical-scientific knowledge. Alternatively, the Commission could reapprove it for a limited period and include stringent EU-wide restrictions in its act of reapproval; these could include limitations on the co-constituents allowed for use in glyphosate-based PPPs, and limitations on the conditions of application, categories of user, and areas where the PPPs containing the active substance may be used. These measures, like those adopted by the French authorities, could reduce the use of glyphosate-based PPPs and promote the use of alternative PPPs, whenever feasible.[106]

[106] Regrettably, at the current stage of technical-scientific knowledge, the preconditions to classify glyphosate as a candidate for substitution and to activate the comparative assessment procedure are not likely to be met (Recital (19), Art. 50, point 4 of Annex II, and Annex IV to the PPP Regulation).

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The identification of a European way forward would also be of crucial importance for the EU institutions not to disavow their political responsibilities in setting a European level of protection and European threshold of acceptable risk. This could breathe new life into the democratic component of EU risk regulation.[107] The Commission should not leave allegedly 'political' questions to Member States. This would further undermine the democratic legitimacy of EU risk regulation.

EU risk governance is grounded on a prudential approach to risk assessment, a focus on persisting uncertainty, the pursuit of enhanced levels of protection, and due consideration of the precautionary principle and other legitimate factors. Facts and values are intertwined in risk governance, and determining the intended level of protection and threshold of acceptable risk is never a mere 'scientific' matter. Normative frames are always, directly or indirectly, at stake. In the case of glyphosate, the EU institutions should take the overarching tenets of the precautionary principle into due consideration and learn from the mistakes that they made in 2017. This would finally bring the glyphosate saga to an end.

[107] Leonelli, n. 6 above.

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