Case C-616/17 Blaise and Others: The precautionary principle and its role in judicial review – Glyphosate and the regulatory framework for pesticides

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Abstract
The approval renewal of glyphosate as an active substance for pesticides in the EU has also kept the Court of Justice occupied. Within this line of case law, the Blaise case is the most recent one. In this preliminary reference procedure the Court was asked to review the validity of the Plant Protection Products Regulation 1107/2009, examined against the precautionary principle as benchmark. The case is relevant not only for the questions raised about the Regulation, but also as it sheds a light on the – albeit limited – use of the precautionary principle in the judicial review of EU legislative measure.

Keywords
Judicial review, precautionary principle, pesticides, glyphosate, validity

1. Introduction
The Blaise case is the most recent of a line of cases arising in the context of the intense debate surrounding the renewed approval of glyphosate as an active substance for plant protection products in December 2017.¹ Unlike previous cases, it does not concern access to documents and the

¹ Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011, (C/2017/8419), OJ L 333, p. 10–16. For an insight into the controversies see

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transparency of the procedure such as in the rulings of Tweedale and Hautala, 2 or applications for annulment of specific measures taken during the glyphosate approval renewal. 3 The preliminary questions referred to the Court in the case at hand raised fundamental issues regarding the regulatory framework applicable to plant protection products (PPPs) in the EU. Although the glyphosate approval procedure ultimately might have triggered the events that gave rise to this case, what is examined is not the contested procedure regarding one active substance (glyphosate), but the viability and validity of the whole regulatory framework of plant protection products examined against the precautionary principle as benchmark.

Ultimately, the Court of Justice in this case ruled that the issues identified in the preliminary questions did not violate the precautionary principle and, therefore, the validity of the Plant Protection Product Regulation 1107/2009 (PPP Regulation) was confirmed. However, the case provides very interesting insights into the role of the precautionary principle in the judicial review of the Court of Justice.

2. Relevant facts

As an introduction to the regulation of pesticides in the European Union, it should be clarified that plant protection products, commonly referred to as pesticides, have to be approved before being placed on the internal market. 4 An active substance, like glyphosate, is subject to approval at the EU level by the Commission after an assessment by the European Food Safety Authority (EFSA). However, the final plant protection products, that is, the commercial formulation of the active substance with other co-formulants, like the glyphosate-containing herbicide Roundup, have to be authorized in the Member States.

This reference for a preliminary ruling originates in the Criminal Court of Foix (France), as Mr. Blaise and 20 other persons belonging to an activist group were charged with damaging property...
after they had applied paint to containers of Roundup, a herbicide containing glyphosate, and defaced display cabinets.\textsuperscript{5} As part of their defence, they pleaded necessity and asked the French court to question the validity of the PPP Regulation,\textsuperscript{6} claiming that it fails to live up to the precautionary principle and thereby neglecting risks of PPPs to human health and the environment.\textsuperscript{7} The Court of Justice ruled the case in Grand Chamber and the ruling is largely congruent with the opinion of Advocate General Sharpston.\textsuperscript{8}

\section*{3. The reasoning of the Court}

The French court referred 4 questions, all asking for an assessment of the compatibility of Regulation 1107/2009 with the precautionary principle. In this regard, the Court first of all clarified the scope of the precautionary principle, especially in the context of the validity assessment of the PPP Regulation. The Court used its by now well-established formula to define the principle.\textsuperscript{9}

That principle entails 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. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because the results of studies conducted are inconclusive, but the likelihood of real harm to public health persists should the risk materialize, the precautionary principle justifies the adoption of restrictive measures.\textsuperscript{10}

The Court stressed that although in the Treaties the precautionary principle is only mentioned in Article 191(2) TFEU on environmental policy, it applies also to other policies, especially where they are aimed at the protection of public health and human health, such as the PPP Regulation.\textsuperscript{11} It emphasized that the mere fact that recital 8 and Article 1(4) of the Regulation declare that the PPP Regulation is based on the precautionary principle is not in itself sufficient to claim compliance of the legislation with the principle.\textsuperscript{12} It explained that the application of the principle with regard to the pesticides authorization requires first, the identification of the risks for human health of the use of active substances and plant protection products and second, a risk assessment based on ‘the most reliable scientific data available and the most recent results of international research’.\textsuperscript{13} This means that in the validity review of the PPP Regulation the benchmark laid precautionary principle for the validity of the Regulation is the question if the legislation at hand ensures that the competent authorities have enough information to adequately assess the risk of the active substances and PPPs.

\begin{thebibliography}{99}
\bibitem{5} C-616/17 Blaise, EU:C:2019:800, para. 27; Opinion of Advocate General Sharpston in Case C-616/17 Blaise, para. 32.
\bibitem{6} Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, p. 1–50.
\bibitem{7} Case C-616/17 Blaise, para. 28; Opinion of Advocate General Sharpston in Case C-616/17 Blaise, para. 33.
\bibitem{8} Opinion of Advocate General Sharpston in Case C-616/17 Blaise, para. 117.
\bibitem{9} E. Vos and K. de Smedt, Taking Stock as a Basis for the Effect of the Precautionary Principle Since 2000, RECIPES, p. 80 and 81, available at: https://recipes-project.eu/sites/default/files/2020-03/Report%20Taking%20stock%20asa%20basis%20for%20the%20effect%20of%20the%20precautionary%20principle%20since%202000.pdf.
\bibitem{10} Case C-616/17 Blaise, para. 43.
\bibitem{11} Ibid., para. 41 and 42.
\bibitem{12} Ibid., para. 42, 44 and 45.
\bibitem{13} Ibid., para 46.
\end{thebibliography}
under review. The Court then proceeded to address the four specific questions raised by the referring court.

In the first question, the referring court stated that the absence of a definition of what constitutes an ‘active substance’ means that an applicant is able to delimit the scientific assessment by strategically choosing which substance to identify as active substance(s). While the Court admitted the absence of a definition of the term active substance in Article 3 of the Regulation, it pointed to Article 2(2), which clarifies that: ‘This Regulation shall apply to substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as “active substances”.’ Together with the data requirements laid down in the Regulation, which require the applicant to provide information that must be sufficient to identify the active substance, the Court denies that the absence of a definition would allow the applicant to freely choose which part of a formulation constitutes the active ingredient.

The Court in this regard also points out that the Member States in their assessment are tasked with ensuring that each active substance in a PPP is approved, and that the authorization of a PPP where not all active substances are approved can be withdrawn.

With its second question, the referring court expressed concerns about an alleged lack of assessment of the cumulative effect where several active substances are used in a PPP, and whether not examining this so-called ‘cocktail effect’ would be in breach of the precautionary principle. The Court, however, clarified that the ‘cocktail effect’ is considered both in the assessment of active substances as well as in the authorization of plant protection products. The aim of the active substance assessment is to examine whether the substance or product has any immediate or delayed harmful effects on human health and the environment. In this regard, the Court points to Article 4(2) and (3) of the Regulation, requiring that in the approval procedure of the active substance ‘known cumulative and synergistic effects’ are taken into account with regard to the pesticide and its residues. With regard to the authorization of plant protection products, the Court stresses that Article 4(3) must also be complied with, the evaluation is carried out by harmonized principles, which ensures that in the Member States as well, ‘cocktail effects’ arising from the combination of active substances, safeners, synergists and co-formulants are taken into account.

The third question asked whether the rule that the scientific evidence required in the approval procedure is submitted by the applicant would not mean that the scientific data is susceptible to bias and undue influence, especially if the data is not subject to independent counter-analysis. The Court reasoned that the submission of the assessment data by the applicant is based on the principle that the applicant is responsible for proving the safety of the substance and showing

14. Ibid., para. 74.
15. Ibid., para. 52.
16. Ibid., para. 53.
17. Ibid., para. 54.
18. Ibid., para. 55 and 56.
19. Ibid., para. 57.
20. Ibid., para. 59.
21. Ibid., para. 60.
22. Ibid., para. 67.
23. Ibid., para. 68.
24. Ibid., para. 71.
25. Ibid., para. 71–76
26. Ibid., para. 77.
compliance with the legal requirements.\textsuperscript{27} This, according to the Court, ‘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’.\textsuperscript{28}

The Court is convinced that this does not lead to bias,\textsuperscript{29} as the tests that have to be submitted are regulated and standardized, through which the legislator ensures the quality of the scientific evidence.\textsuperscript{30} Furthermore, it is provided in Article 8(4) of the Regulation that the rules concerning the data requirements for both active substances and PPPs have to be adopted in accordance with ‘the current scientific and technical knowledge’.\textsuperscript{31} In addition, the Regulation provides that the Member State where authorization of the PPP is requested must carry out ‘an independent, objective and transparent assessment of that application in the light of current scientific and technical knowledge’.\textsuperscript{32} This also entails that the applicant is required to add scientific peer-reviewed literature to the dossier.\textsuperscript{33} The Member State authorities cannot take into account data submitted if there is no evidence that the data was generated in accordance with accepted scientific methodology,\textsuperscript{34} and must ask for additional information from the applicant if the evidence is insufficient.\textsuperscript{35} From this, the Court infers that the duty of the Member States is not in all cases to put pre-eminent emphasis on the data submitted by the applicant, but to rely on the most comprehensive and recent scientific findings available.

The referring Court had also alluded to a contradiction between the precautionary principle and the confidential nature of the dossier. The Court also did not find a manifest error of assessment in this regard.\textsuperscript{36} The Court noted that the PPP Regulation permits public access to the dossier to a great extent, but also noted that ‘it is not inconceivable that increased transparency may (…) permit an even better assessment of the risk (…), by enabling the public concerned to put forward arguments opposing the grant of the approval or authorisation’.\textsuperscript{37} In this regard it also confirmed the ruling in C-442/14 \textit{Bayer CropScience and Stichting De Bijenstichting}, which made clear that Directive 2003/4 on public access to environmental information applied to studies concerning the harm caused by the use of PPPs and residues in the environment.\textsuperscript{38}

According to the Court, the precautionary principle is safeguarded through the independent assessment of the dossier through the respective authorities, which review the presented evidence and can also ask for additional information by consulting experts or a Community reference laboratory.\textsuperscript{39} Thus, the Court concluded that the system established by the Regulation, which requires the applicant to submit the dossier that forms the basis of the assessment, is not vitiated

\begin{itemize}
\item \textsuperscript{27} Ibid., para. 79.
\item \textsuperscript{28} Ibid., para. 80.
\item \textsuperscript{29} Ibid., para. 81.
\item \textsuperscript{30} Ibid., para. 82–87.
\item \textsuperscript{31} Ibid., para. 86.
\item \textsuperscript{32} Ibid., para. 88.
\item \textsuperscript{33} Ibid., para. 89.
\item \textsuperscript{34} Ibid., para. 91.
\item \textsuperscript{35} Ibid., para 92.
\item \textsuperscript{36} Ibid., para. 109.
\item \textsuperscript{37} Ibid., para. 102.
\item \textsuperscript{38} Ibid., para. 108.
\item \textsuperscript{39} Ibid., para. 92 and 93.
\end{itemize}
by a manifest error of assessment, despite a systematic independent counter-analysis of the submitted studies not being required.40

Finally, in the fourth question, the referring court states that in the authorization of PPPs – as opposed to active substances – no carcinogenicity and toxicity studies are required and raises doubts on the compatibility of this lacuna with the precautionary principle.41 However, the Court pointed to Articles 4(3)(b) and 29(1) of the Regulation, which state that, in order to obtain authorization, the product cannot have immediate or delayed harmful effect on human health.42 According to the Court, a pesticide ‘cannot be considered to satisfy that condition where it exhibits any long-term carcinogenicity and toxicity’.43 Thus it is for the competent authorities to examine, taking into account current scientific and technical knowledge, that the submitted data sufficiently show that the product does not exhibit risks such as carcinogenicity or toxicity.44

Overall, the Court ruled that the questions raised by the referring court did not show any manifest error of assessment and revealed nothing capable of affecting the validity of the PPP Regulation.45

4. Comments

The Blaise case is interesting from two perspectives: first of all, it gave the Court the opportunity to take a position regarding some hotly debated issues with regard to the PPP Regulation. Moreover, the case is interesting from an EU law perspective, even for those that lack interest in the regulation of pesticides, as it sheds a light on the – albeit limited – use of the precautionary principle as a benchmark for the validity of an EU legislative measure. This case note will first pay attention to the latter, as it significantly influences the intensity of review of the PPP Regulation in this case.

A. The precautionary principle and the limits of validity review of legislative measures

First of all, one should note that Blaise is extraordinary in the sense that it is one of the rare occasions in which a citizen managed to challenge the validity of EU secondary legislation. This review was only made possible by using the vehicle of the preliminary ruling procedure, due to the limited standing in the act of annulment procedure.46 In this regard, the Blaise case is an example of the fact that in order to challenge the validity of European law, individuals – due to the strict standing requirements – have to essentially breach the law in order to get a chance to challenge the legal framework,47 as was also criticized by AG Jacobs in the UPA case.48

40. Ibid., para. 100.
41. Ibid., para. 110.
42. Ibid., para. 114.
43. Ibid., para. 115.
44. Ibid., para. 116.
45. Ibid., para. 118.
46. For example, the government of the Region Brussels failed to assure standing in an act of annulment procedure invoking the precautionary principle against the glyphosate renewal Implementing Regulation: Case T-178/18 Région de Bruxelles-Capitale v European Commission, EU:T:2019:130.
47. See a comment on the case by the NGO Client Earth: www.clientearth.org/environmental-activists-access-eu-court-by-breaking-the-law/.
48. Opinion of Advocate General Jacobs in case C-50/00 P UPA v. Council, EU:C:2002:197.
Even though this might be welcomed by advocates of enhanced access to judicial review in front of the CJEU, the Court’s ruling in *Blaise* has been criticized as legalistic and too deferential.\(^{49}\) In addition to the wording and scope of the referred questions, this has two contributing factors: the margin of discretion of the legislator with the resulting limited scope of judicial review; and the (limited) role of the precautionary principle in judicial review.

Generally, the Court has been known for its deferential approach to review in the face of discretion, whereas one can draw a distinction between ‘political’ and ‘technical’ discretion.\(^{50}\) While political discretion concerns the freedom of the legislator to make political choices weighting diverse interests, technical discretion concerns the wide margin of appreciation granted to administrative bodies where they have to take decisions in the face of complexity. In the *Blaise* judgment, the deferential approach in the face of political discretion finds expression in para. 50: ‘( . . . ) in view of the need to strike a balance between several objectives and principles, and of the complexity of the relevant criteria, judicial review by the Court must necessarily limited to whether the EU legislature, in adopting Regulation No 1107/2009, committed a manifest error of assessment.’

Although the questions referred by the French court concerned the PPP Regulation as such, the elephant in the room was of course the glyphosate renewal. The Court, as well as AG Sharpston, however stressed, that a finding of non-compliance of the Regulation with the precautionary principle could not be based – solely – on the circumstances of a particular case, such as the glyphosate approval procedure.\(^{51}\) This is based on the principle that ‘the validity of a provision of EU law is to be assessed according to the characteristics of those provisions themselves and cannot depend on the particular circumstances of a given case’.\(^{52}\) Thus, the Court was prevented from examining how the Regulation was applied in practice in the context of the glyphosate renewal, and whether this renewal is in accordance with the precautionary principle.\(^{53}\) This, however, has to be nuanced, as was also clarified by AG Sharpston stating that the validity of the Regulation could be questioned where ‘concerns relating to glyphosate are shown to be representative of a systemic and fundamental failure undermining the PPP Regulation’.\(^{54}\) Nonetheless, this was not argued in the questions referred to the Court and not discussed in the judgment. It remains debateable whether – in a case as highly politicized as glyphosate, concerning the world’s most used pesticide,\(^{55}\) and where all institutional actors were very aware of the significance of the procedure – an (allegedly) flawed risk assessment would not indicate systemic flaws in the regulatory framework.\(^{56}\)

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49. A. Donati, ‘The Glyphosate Saga, A Further but Not a Final Step: The CJEU Confirms the Validity of the Regulation on Plant Protection Products in Light of the Precautionary Principle’, forthcoming *European Journal of Risk Regulation* (2020), doi:10.1017/err.2019.72.; S. Paulini, ‘Fact or Fiction? Case C-616/17 and the Compatibility of the EU Authorisation Procedure for Pesticides with the Precautionary Principle’, forthcoming *European Journal of Risk Regulation* (2020), doi:10.1017/err.2020.19.

50. A. Fritsche, ‘Discretion, Scope of Judicial Review and Institutional Balance in European Law’, 47 *Common Market Law Review* (2010), p. 361–403. For a criticism of this distinction see: J. Mendes, ‘Bounded Discretion in EU Law: A Limited Judicial Paradigm in a Changing EU’, 80 *The Modern Law Review* (2017), p. 443–472.

51. Case C-616/17 Blaise, para. 48 and 49; Opinion of Advocate General Sharpston in Case C-616/17 *Blaise*, para. 45.

52. Case C-616/17 Blaise, para. 48. The Court refers to: C-426/16 *Liga van Moskéen*, C:2018:335, paragraph 72.

53. For a discussion on how the glyphosate renewal could be reviewed see: A. Donati, forthcoming *European Journal of Risk Regulation* (2020), doi:10.1017/err.2019.72.

54. Opinion of Advocate General Sharpston in Case C-616/17 *Blaise*, para. 44.

55. C. Benbrook, ‘Trends in glyphosate herbicide use in the United States and globally’, 28(3) *Environmental Sciences Europe* (2016).

56. See also: Paulini, forthcoming *European Journal of Risk Regulation* (2020), doi:10.1017/err.2020.19, p. 16.
Thus, the Court was limited to review the validity of the PPP Regulation in the abstract, without taking into account how it was applied in practice in approval and authorization procedures, being restrained to only declare it invalid in the face of ‘manifest errors of assessment’. The question is therefore not if there is room for improvement, but if there are fundamental problems that would call into question the validity of the Regulation. As also AG Sharpston stated: ‘Most laws are capable of improvement; and the PPP Regulation is probably no exception to that general rule.’

The benchmark set by the referred questions is the assessment of alleged manifest errors of assessment in securing the adherence to the precautionary principle, which again set certain boundaries to the judicial review.

In this regard, one of the main criticisms voiced with regard to the precautionary principle is that it is not sufficiently defined in EU law and, therefore, is claimed to be of limited use for application in practice. A certain ‘vagueness’ should not be surprising given that it is a principle, not a rule. However, as explained before, the Court used its established definition of the principle. Still it was faced with determining which requirements the precautionary principle sets for legislation, and in which cases those where manifestly violated. This is not an easy task as generally the precautionary principle is invoked in cases where either the EU institutions or the Member States have adopted measures to preventing a specific risk from manifesting, like the ban on British beef in the BSE crisis. In such case the Court is tasked with reviewing a concrete risk assessment process or risk management measure, as opposed to the whole regulatory framework. In such cases the definition of the precautionary principle as established by the Court is used to review whether the measure taken is based on an appropriate risk assessment and whether it is proportionate. These cases often revolve around the standard of proof and how much or which type of evidence of risk is required to apply the precautionary principle.

This limited review due to a wide margin of discretion, which is not only to be found in EU law but also for example in common law courts, leads to a review that places substantive matters largely outside the remit of the review, while it focuses on procedural matters. As was identified in a review of the case law of the Court on the precautionary principle since

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57. Opinion of Advocate General Sharpston in Case C-616/17 Blaise, para. 83.
58. See e.g.: R. Löfstedt, ‘The Precautionary Principle in the EU: Why a Formal Review is Long Overdue’, 16 Risk Management (2014), p. 137–163; G. Majone, ‘What Price Safety? The Precautionary Principle and its Policy Implications’, 40 Journal of Common Market Studies (2002), p. 89–109.
59. E. Fisher, ‘Is the Precautionary Principle Justiciable?’, 13(3) Journal of Environmental Law (2001), p. 315–334.
60. See e.g.: E. Vos, ‘EU Food Safety Regulation in the Aftermath of the BSE Crisis’, 23 Journal of Consumer Policy (2000), p. 227–255.
61. N. de Sadeleer, ‘The Precautionary Principle in EC Health and Environmental Law’, 12 European Law Journal (2006), p. 139–172; E. Vos and J. Scott, ‘The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO’, in C. Joerges and R. Dehousse (eds.), Good Governance in Europe’s Integrated Market (Oxford University Press, 2002), p. 253–286; A. Alemanno, ‘The Shaping of the Precautionary Principle by European Courts: From Scientific Uncertainty to Legal Certainty’, in L. Cuocolo and L. Luparia (eds.), Valori Costituzionali e Nuove Politiche del Diritto – Scritti raccolti in occasione del decennale della rivista ‘Cahiers Européens’ (Halley, 2007).
62. K. Garnett and D. Parsons, ‘Multi-Case Review of the Application of the Precautionary Principle in European Union Law and Case Law’, 37 Risk Analysis (2017), pp. 502–516.
63. Fisher, 13 Journal of Environmental Law (2001), p. 322; J. Zander, The Application of the Precautionary Principle in Practice. Comparative Dimensions (Cambridge University Press, 2010), p. 110.
2000 in the context of the EU Horizon 2020 REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders (RECIPES) project, in cases where the Commission or a Member State took a measure based on the precautionary principle, a challenge of the validity of such measure in the large majority of cases was not successful.\(^{64}\)

In the rare cases where the challenge was successful, this was due to procedural matters, such as a missing impact assessment.\(^{65}\) The opinion of AG Sharpston in the *Blaise* case seems to confirm this, as she explained that the principle can be used ‘to challenge an act that is deemed too restrictive, as opposed to an act that is deemed not to be restrictive enough’.\(^{66}\) In essence AG Sharpston argues that the precautionary principle can be used to challenge measures that are ‘too precautionary’ in the sense of being disproportionally strict, while it cannot be used – at least on its own – to challenge measures that are ‘not precautionary enough’. This deferential review is criticized for example by Alemanno in his annotation to the *Gowan* case concerning the approval of the pesticide active substance fenarimol, criticized the Court for ‘failing to surround the invocation of the precautionary principle with a set of procedural guarantees’\(^{67}\) and called for a ‘predictable heightened scrutiny aimed at counterbalancing the broadening of discretionary powers inherent in precautionary action’.\(^{68}\)

As elaborated previously, the task of the Court in *Blaise*, however, was not related to one specific risk or substance of concern, but asked for judicial review of a general regulatory framework. Although the adoption of a pre-authorization scheme itself and the requirements this imposes on applicants constitute a precautionary measure,\(^{69}\) the question in the *Blaise* case was whether the Regulation is ‘precautious enough’, looking at certain concrete regulatory features that the questions referred to.

At this point, it becomes clear that the political discretion of the legislator and the technical discretion of the administration, and how they are reviewed by the Court, are connected. The review standard that the Court used in the *Blaise* case to review the validity of the PPP Regulation in essence asks whether the regulatory framework established by the PPP Regulation facilitates that in concrete risk assessment and risk management processes the precautionary principle is safeguarded. The Court established that in single case decisions in the approval and authorization procedures a comprehensive risk assessment, based on the latest and most reliable international scientific data,\(^{70}\) has to be carried out. Generally, in cases involving administrative decision making in the face of technically complex assessments, while the substance of the decision is not subject to judicial review, the Court compensates this with the review of sound administration and the duty of care, focusing on reviewing if the assessment was based on complete and accurate information.\(^{71}\) This is also how the General Court approached a claim that the EU ban on

\(^{64}\) Vos and de Smedt, Taking Stock as a Basis for the Effect of the Precautionary Principle Since 2000, RECIPES, p. 81.

\(^{65}\) Ibid., p. 82.

\(^{66}\) Opinion of Advocate General Sharpston in Case C-616/17 *Blaise*, para. 48.

\(^{67}\) A. Alemanno, ‘Case C-79/09, *Gowan Comércio Internacional e Serviços Lda v. Ministro della Salute*, Judgment of the Court of Justice (Second Chamber) of 22 December 2010, nyr.’, 48 Common Market Law Review (2011), p. 1329–1348 at 1347.

\(^{68}\) Ibid., p. 1348.

\(^{69}\) Case C-616/17 Blaise, para. 50.

\(^{70}\) Ibid., para 46. See also: C-77/09 *Gowan Comércio Internacional e Serviços Lda v Ministero della Salute*, EU:C:2010:803, para.75.

\(^{71}\) Mendes, 80 The Modern Law Review (2017), p. 466. See also: Case C-269/90 *Technische Universität München*, EU:C:1991:438.
neonicotinoid pesticides would violate the precautionary principle.72 These review standards applied by the Court to individual decisions in the context of the application of the precautionary principle, shape the validity assessment of the legislation as carried out in the Blaise case. Concretely the judicial review boils down to examining if the PPP Regulation facilitates the risk assessment of pesticides and their active substance based on sufficient and high-quality scientific evidence.73

To summarize, given the margin of discretion of the legislator in drafting the PPP Regulation and the resulting limited scope of judicial review, as well as the – mostly procedural – benchmark set by the precautionary principle, the review of the Court remained relatively abstract. This approach to judicial review meant that the Court resorted to analysing the legislative text and not looking much further into the application of the legislation in practice, limiting itself to manifest flaws. However, the ruling was bound to disappoint anyone who awaited revolutionary findings from the Court, especially those who had hoped for an assessment of the glyphosate approval.74

B. A confirmation of the regulatory framework for pesticides in the EU?

As far as the actual review of the validity of the PPP Regulation is concerned, the Court’s position on the issues raised is very relevant, as some of the questioned provisions were also subject to criticisms in the legal literature,75 in a European Citizens Initiative76 and also by EU bodies.77

In the assessment of the ‘cocktail effect’, the Court’s stance is quite theoretical. While the Court is correct to state that, in the approval of active substances and especially in the authorization of PPPs on national level, the cocktail effect of a formulation is assessed, it should also be acknowledged that such an assessment is not easily carried out in practice: EFSA, for instance, has tried to establish harmonized risk assessment methodologies for chemical mixtures since 2006 and only finalized its guideline containing the harmonized framework for such assessment in 2019.78 Moreover, while the intentional mixing of chemicals in plant protection products may be covered by the Regulation, this is different with regard to unintentional and coincidental mixtures. Where the question referred to the Court only covered the mixture of active substance(s) and further chemicals in one pesticide, in the practical application on the fields, a variety of pesticides is used

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72. T-429/13 Bayer CropScience AG and Others v European Commission, EU:T:2018:280. See further: E. Bozzini and E. Stokes, ‘Court Upholds Restrictions on Neonicotinoids – A Precautionary Approach to Evidence’, 9 European Journal of Risk Regulation (2018), p. 585–593.
73. Case C-616/17 Blaise, para. 74.
74. See: Donati, forthcoming European Journal of Risk Regulation (2020), doi:10.1017/err.2019.72.
75. See e.g. the literature referred to in footnote 1.
76. European Citizens’ Initiative, Ban Glyphosate and Protect People and the Environment from Toxic Pesticides. Available at: http://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2017/000002.
77. European Parliament resolution of 13 April 2016 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate (D044281/01 – 2016/2624(RSP)), P8_TA(2016)0119; European Parliament resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate (D053565-01 – 2017/2904(RSP)), P8_TA(2017)0395; Scientific Advice Mechanism (SAM), Group of Chief Scientific Advisors, ‘EU Authorisation Processes of Plant Protection Products – From a Scientific Point of View’, Scientific Opinion 5/2018.
78. EFSA, ‘Guidance on Harmonised Methodologies for Human Health, Animal Health and Ecological Risk Assessment of Combined Exposure to Multiple Chemicals’, 17 EFSA Journal (2019).
in one area, and this is much harder to assess and not sufficiently taken into account. Thus, the Court remained quite legalistic and did not examine whether, beyond the legislation, the risk assessment procedures foresee an examination of the cocktail effect. This would not have required the review of concrete assessments (like the one for glyphosate), which was deemed outside the scope of review, but an examination of the implementation of the legislation in scientific and technical guidance on the level of EFSA or the national regulatory bodies. This is arguably not necessarily included in the validity review; however, it would allow the Court to examine the regulatory framework more comprehensively, while still reviewing the general rules rather than individual cases.

The third question concerned a core feature of the regulatory framework: in accordance with the precautionary principle, the burden of proof has been shifted and producers of pesticides will have to prove the safety of their product. Such prior-approval schemes are used in several policy areas in the EU, including food, chemicals and pharmaceuticals. In accordance with the Commission Communication on the precautionary principle, such authorization schemes are used exceptionally with regard to ‘substances deemed “a priori” hazardous’. This also based on the logic that public money should not be spend on commissioning studies that will be commercially beneficial for an industry marketing a product, especially given the very high costs involved. However, it also leads to an information asymmetry between the applying companies and the risk assessing public authorities. The Blaise ruling confirms the validity of the choice of the legislator to base the risk assessment on industry funded studies and strengthens the arguments of the Commission and EFSA, proving that this practice is not only in accordance with the precautionary principle, but actually part of the application of it.

Here, in addition to discussing the ruling in Blaise, one should note that concerns were raised over whether this shift of the burden of proof sufficiently guarantees correct data and an independent and transparent risk assessment. These doubts were fuelled in the glyphosate assessment by the Monsanto papers scandal, which showed that Monsanto actively interfered in the supposedly objective scientific debate by ghost-writing scientific articles and intruding in peer review process. In the wake of this scandal, the Commission and also EFSA, very much in accordance with the Court’s analysis in the Blaise case, stated that in the risk assessment process the studies submitted by industry are verified through peer review, and note that their correctness or interpretation is not

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79. E. Bozzini, Study ‘Assessing criteria and capacity for reliable and harmonised “hazard identification” of active substances’, in European Parliamentary Research Service, European Implementation Assessment Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market, April 2018, Annex II, p. II-8.
80. See also: European Commission, Communication from the Commission on the European Citizens’ Initiative ‘Ban Glyphosate and Protect People and the Environment from Toxic Pesticides’, C(2017) 8414 final, p. 11.
81. European Commission, Communication from the Commission on the precautionary principle, COM/2000/0001 final, p. 20.
82. European Commission, C(2017) 8414 final, p. 11.
83. EFSA, Statement regarding the EU assessment of glyphosate and the so-called ‘Monsanto papers’. Available at: www.efsa.europa.eu/sites/default/files/topic/20170608_glyphosate_statement.pdf, last accessed 29/03/2020; European Commission, C(2017) 8414 final.
84. European Parliamentary Research Service, European Implementation Assessment Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market, April 2018, p. 40–41.
85. L. McHenry, ‘The Monsanto Papers: Poisoning the Scientific Well’ 29 International Journal of Risk and Safety in Medicine (2018), p. 193–205.
taken for granted. Moreover, both emphasized that these studies have to conform to up-to-date legal data requirements and comply with test guidelines developed by the Organisation for Economic Co-operation and Development (OECD) as well as with Good Laboratory Practice (GLP) standards, which ensures the quality and reliability of industry commissioned studies.

What is remarkable in this regard in the Blaise ruling is the statement the Court makes in paragraph 94: ‘(....) it is the duty of the competent authorities, in particular, 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.’ At first sight, this paragraph follows logically from the previous paragraphs, in which the Court sets out the obligation to carry out the assessment on the basis of the state of the art scientific knowledge. However, upon closer inspection, the obligation to take into account international research might in practice be delimited by the previously mentioned standardization of scientific studies. In the risk assessment of pesticides, the authorities use the so-called ‘weight of evidence’ approach, which focuses on whether the studies are reproducible, how many studies support a conclusion and also how these studies are designed and conducted. A big emphasis is placed on the studies submitted by the applicant as those comply with the Good Laboratory Practice (GLP), while academic studies are often designed and carried out according to more original and less standardized designs, usually without GLP certification. Thus, although the Court confirms the duty to take into account international research beyond the industry studies, in practice the ‘trade-off between “regulatory science” and “research science”’ might stand in the way of independent studies counterbalancing the studies submitted by the applicant. However, this is a problem that is difficult to address in the abstract review of the regulatory framework, as opposed to the judicial review of a concrete authorization or approval decision, where it could be easier to question if all relevant studies have been sufficiently taken into account.

Of course in some regards, the Court’s confirmation of the validity of the Regulation constitutes more of an afterthought, as changes have already been introduced through the adoption of Regulation 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain. This reform addresses concerns regarding the transparency of the dossier submitted through making it publicly available – subject to certain delimited exceptions for commercially confidential information – and enables closer examination of the industry studies by third parties in...

86. EFSA, Statement regarding the EU assessment of glyphosate and the so-called ‘Monsanto papers’.
87. The data requirements are to be found in Commission Regulation (EU) No 283/2013 as well as Commission Regulation (EU) No 284/2013. The GLP is to be found in Council Directive 2004/10/EC. See also: European Commission, C(2017) 8414 final, p. 10.
88. L. Maxim and J. van der Sluijs, ‘Seed-dressing Systemic Insecticides and Honeybees’, in European Environmental Agency, Late Lessons From Early Warnings: Science, Precaution, Innovation, EEA Report 1/2013, p. 369–406. Available at: www.eea.europa.eu/publications/late-lessons-2/late-lessons-2-full-report/part-b-emerging-lessons-from-ecosystems-1/view. J. Myers et al., ‘Why Public Health Agencies Cannot Depend on Good Laboratory Practices as a Criterion for Selecting Data: The Case of Bisphenol A’, 117 Environmental Health Perspectives (2009), p. 309–315; C. Robinson et al., ‘Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions’, forthcoming European Journal of Risk Regulation (2020), doi:10.1017/err.2020.18.
89. Bozzini, Pesticide Policy and Politics in the European Union Regulatory Assessment, Implementation and Enforcement, p. 90.
90. Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain, OJ L 231, p. 1–28.
Moreover, it allows the Commission to ask EFSA to commission additional studies in exceptional cases. In some ways, this Regulation even closes gaps that the Court did not identify in Blaise, such as the possibility that applicants might stop or not submit their studies where they would provide evidence for risk to human health or the environment. This is now addressed by a mandatory register for studies commissioned for regulatory purposes. However, as noted also by other scholars, it does not change the fundamental choice to place the burden – and also opportunity – to prove the safety of a pesticide on the industry, which always means that the industry data is in a certain sense privileged and to large degree shapes the risk assessment. In this regard, the Blaise case is relevant as a confirmation of this regulatory choice and its compliance with the precautionary principle.

Finally, the clarification provided by the Court to the fourth question – that PPPs are not exempted from long-term toxicological studies – was welcomed by some, although doubts are voiced as to whether this will be sufficiently implemented in the Member States. However, overall, the Blaise case is certainly not the catalyst for a radical reform in the regulatory approach to pesticides that might have been desired by some actors.

5. Conclusion

The Court in Blaise declared the PPP Regulation valid and did not identify manifest errors of assessment regarding its compliance with the precautionary principle. Whether this will appease the critical voices, however, is very questionable. Overall, the Court exercised a limited review and the arguments used by the Court to declare the regulatory choices valid have already been raised by other EU actors, without being able to divert the debate surrounding the regulation of pesticides in the EU. However, the Court through this deferential approach aims to safeguard the discretion of the legislator in setting the regulatory and scientific requirements for approval or authorization, where the legislator has to safeguard a high level of protection of human and animal health as well as environmental protection, while also facilitating the marketing of pesticides to increase agricultural productivity.

It is questionable whether the increasingly voiced criticisms towards the regulation of pesticides is indeed due to flaws in the Regulation, which could have been addressed in the Blaise case, or if gaps might be found in the administrative guidance that further implement the Regulation, or the risk assessment and risk management in concrete cases like glyphosate. Those were not addressed due to the questions referred, the limited review and the choice of using the precautionary principle as the benchmark for validity. This deferential approach will thus not satisfy those that had hoped for the Court to critically examine the EU’s approach to pesticides or the specific risk governance process in the glyphosate approval. Nevertheless, it is also questionable whether the Court is the right forum to resolve the controversies surrounding glyphosate. Ultimately, although many of the

91. Article 1(6) Regulation 2019/1381.
92. Ibid.
93. Ibid. See also: Morvillo, forthcoming European Journal of Risk Regulation (2020), https://doi.org/10.1017/err.2020.11, p. 10.
94. Morvillo, forthcoming European Journal of Risk Regulation (2020), https://doi.org/10.1017/err.2020.11, p. 11.
95. Robinson et al., forthcoming European Journal of Risk Regulation (2020), doi:10.1017/err.2020.18, p. 17.
96. Opinion of Advocate General Sharpston in Case C-616/17 Blaise, para. 89.
97. Robinson et al., forthcoming European Journal of Risk Regulation (2020), doi:10.1017/err.2020.18.
concerns raised with regard to glyphosate concern the scientific risk assessment, which in concrete cases like the glyphosate renewal would be reviewable by the Court, provided the claimant has standing.

It is also quite apparent that the debate surrounding glyphosate is fuelled by broader societal and political questions on the future of agriculture and its impact on human health and the environment. These questions, in my view, cannot and should not be solved by a Court, but through broader societal debate in the remit of the democratic process. However, the *Blaise* case is certainly not the endpoint of the debate surrounding pesticides in the EU, as the political pressure for further reforms is very high and the European Green Deal proposed by the Commission promises changes. Moreover, the currently awaited REFIT Evaluation will provide an opportunity for political rather than judicial contestation of the PPP Regulation.

**Case note**

*C-616/17 Criminal proceedings against Mathieu Blaise and Others*, EU:C:2019:800

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98. *See* B. Url, ‘Don’t Attack Science Agencies for Political Gain’, 553 *Nature* (2018), p. 381.

99. European Commission, Communication – The European Green Deal, COM(2019) 640 final.