COMMON MARKET LAW REVIEW

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Aims
The Common Market Law Review is designed to function as a medium for the understanding and implementation of European Union Law within the Member States and elsewhere, and for the dissemination of legal thinking on European Union Law matters. It thus aims to meet the needs of both the academic and the practitioner. For practical reasons, English is used as the language of communication.

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COMMON MARKET LAW REVIEW

Managing Editor: Alison McDonnell
Common Market Law Review
Europa Instituut
Steenschuur 25
2311 ES Leiden
The Netherlands
e-mail: a.m.mcdonnell@law.leidenuniv.nl
tel. + 31 71 5277549
fax: + 31 71 5277600

Establishment and Aims

The Common Market Law Review was established in 1963 in cooperation with the British Institute of International and Comparative Law and the Europa Instituut of the University of Leyden.The Common Market Law Review is designed to function as a medium for the understanding and analysis of European Union Law, and for the dissemination of legal thinking on all matters of European Union Law. It aims to meet the needs of both the academic and the practitioner. For practical reasons, English is used as the language of communication.

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The editors will consider for publication manuscripts by contributors from any country. Articles will be subjected to a review procedure. The author should ensure that the significance of the contribution will be apparent also to readers outside the specific expertise. Special terms and abbreviations should be clearly defined in the text or notes. Accepted manuscripts will be edited, if necessary, to improve the general effectiveness of communication. If editing should be extensive, with a consequent danger of altering the meaning, the manuscript will be returned to the author for approval before type is set.

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CASE LAW

A. Court of Justice

Don't judge a case by its cover: The pesticides Regulation survives judicial scrutiny but is given new teeth: *Blaise*

Case C-616/17, *Blaise and others*, Judgment of the Court (Grand Chamber) of 1 October 2019, EU:C:2019:800

1. Introduction

On 1 October 2019, the Grand Chamber of the European Court of Justice delivered a ruling regarding the validity of Regulation 1107/2009, which governs the procedure and conditions for the approval of active substances and the authorization of plant protection products (PPPs) in the EU. The judgment was handed down following a preliminary reference made by the French criminal court of Foix in a case where the defendants raised the dangerousness of the active substance glyphosate in order to justify the defacing of containers containing the famous Monsanto weed killer Roundup.

Unsurprisingly, the ECJ confirmed the validity of the legal regime set up by Regulation 1107/2009. However, by interpreting this Regulation in the light of the precautionary principle, it significantly clarified – and arguably extended – the obligations imposed on the Member States and the Commission when deciding on the approval of an active substance or on a PPP authorization.

This ruling is therefore of high relevance for the future of EU pesticides regulation and might have an impact on the current evaluation of Regulation 1107/2009 conducted by the Commission as part of its REFIT programme.[1] It also echoes certain concerns voiced by the European Parliament in its detailed resolution of 16 January 2019 on the Union's authorization procedure for pesticides.[2] Regarding glyphosate in particular, this judgment could bolster

1. The current status of this evaluation can be found at: <ec.europa.eu/food/plant/pesticides/refit_en> (all websites last visited 30 March 2020).
2. P8_TA(2019)0023.

pending judicial challenges[3] against Commission Regulation 2017/2324 renewing that substance's approval until 15 December 2022.[4] It will also put an additional burden on the Assessment Group on Glyphosate, a group of four Member States (France, Hungary, the Netherlands, and Sweden) appointed by the Commission to examine the application that a group of companies called the Glyphosate Renewal Group filed in December 2019 with a view to having glyphosate re-approved after 2022.

2. Background

In September 2016 and March 2017, members of an activist group called "Voluntary Reapers of GMOs" entered shops in Southern France and damaged cans of phytosanitary products containing glyphosate as well as glass display cases. They explained that their actions aimed to flag violations of the rules requiring glyphosate-based products to be kept locked in glass cabinets and to be accompanied by a vendor's warning regarding their carcinogenicity. They were criminally charged with degrading or deteriorating the property of another, acting in joint enterprise.

At their trial, the defendants justified their actions based on the "state of necessity" and the precautionary principle. They claimed that they wanted to draw attention to the danger associated with the use of products containing glyphosate. Upon the suggestion of the defendants' lawyer, the criminal court of Foix sent the ECJ four questions regarding the validity of Regulation 1107/2009 in the light of the precautionary principle.

These questions related to: (i) the lack of definition of the notion of active substance and the ensuing discretion of the applicants (i.e. the companies applying for the approval of such substances) to determine what they designate as the active substance in their PPPs; (ii) the fact that it is the applicants themselves that conduct all the tests and analyses used by the competent authorities to evaluate their dossier, without any independent counter-analysis or publication of their results; (iii) the lack of provision imposing a comprehensive analysis of the cumulative effect of multiple active substances within a single product; and (iv) the fact that long-term toxicity tests (including carcinogenicity) need not be submitted in support of PPP authorization applications.

3. See Case C-352/19 P, *Brussels Region* v. *Commission*, pending. The author represents the Brussels Region in that case. The request for annulment was rejected at first instance on admissibility grounds (Case T-178/18, *Brussels Region* v. *Commission*, EU:T:2019:130).

4. Commission Regulation 2017/2324 of 12 Dec. 2017, O.J. 2017, L 333/10.

These questions were raised in a context of deep scientific uncertainty regarding the effect of glyphosate (and of glyphosate-based PPPs) on human health and the environment. On 20 March 2015, the International Agency for Research on Cancer (IARC) issued a monograph classifying glyphosate among the substances "probably carcinogenic to humans".[5] A few months later, the European Food Safety Authority (EFSA) reached the opposite conclusion, declaring that glyphosate is "unlikely to pose a carcinogenic hazard to humans".[6] On 15 March 2017, the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) sided with the EFSA, finding *inter alia* that "no classification for carcinogenicity is warranted".[7]

These reports – and others – led the Commission to propose the renewal of glyphosate's approval, but only for a period of five years. The Commission proposal did not garner the support of a qualified majority of Member States in the so-called SCoPAFF Committee.[8] However, the bill was finally adopted at the appellate committee level thanks to an unexpected reversal from the German minister for agriculture, apparently acting without his government's sign-off.[9] Since this renewal, several Member States (namely Austria and Luxembourg) and regions (such as Brussels) have decided to impose a total ban on the use of glyphosate-based phytosanitary products, whilst other governments (such as France and Germany) have announced a phasing-out schedule. The Commission might question the legality of such unilateral moves and consider launching infringement proceedings against the rebellious States.

3. Opinion of the Advocate General

In her Opinion delivered on 1 October 2019, Advocate General Sharpston concluded that none of the questions referred for preliminary ruling had disclosed elements affecting the validity of Regulation 1107/2009.

As a preliminary note, the Advocate General pointed out that the questions referred to the Court were in no way targeted at the Commission Regulation

5. *Some Organophosphate Insecticides and Herbicides*, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 112.

6. "Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate", 13 EFSA Journal (2015), 4302.

7. Opinion proposing harmonized classification and labelling at EU level of glyphosate (ISO); N-(phosphonomethyl)glycine, available at <echa.europa.eu/documents/10162/2f8b5c7f-030f-5d3a-e87e-0262fb392f38>.

8. The Standing Committee on Plants, Animals, Food and Feed.

9. This episode attracted massive media coverage. See e.g. <www.euractiv.com/section/agriculture-food/news/merkel-angry-with-agriculture-minister-who-voted-in-favour-of-glyphosate/>.

renewing the approval of glyphosate. In other words, these questions do not inquire into whether Regulation 1107/2009 was correctly *applied* in the case of glyphosate. They had a much wider scope since they cast doubt on the validity of the legal regime established by Regulation 1107/2009 itself. The Advocate General went on to explain that whilst that Regulation was based on the precautionary principle, it covered a technically and scientifically complex area of law. As a result, the EU institutions enjoyed a "particularly wide discretion" in regulating that field.[10]

Advocate General Sharpston started her analysis by addressing together the two questions regarding the notion of "active substance" and the (alleged lack of) obligation to take into account the "cocktail effect" of multiple active substances contained in a single PPP for the purpose of evaluating it. The Advocate General roundly dismissed the assumptions underpinning these two questions.

First, she considered that Article 2(2) of Regulation 1107/2009 indeed provides a definition of the notion of "active substance", which covers "substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products". Therefore, contrary to what the referring court seemed to suggest, the applicant is not at liberty to determine which element in his product is an active substance – and must therefore undergo a detailed examination at EU level – and which are not.[11]

The Advocate General reached the same conclusion regarding the "cocktail effect" evaluation. She pointed out that under Article 4(2) and (3) of Regulation 1107/2009, the evaluation of an active substance (at EU level) and of a PPP (at Member State level) must take into account the "cumulative" and "synergistic" effects of both active substances and PPPs.[12] She noted further that Article 29(6) of the same Regulation provides that the evaluation of PPPs shall consider the "interaction between the active substance" and the "safeners, synergists and co-formulants" contained in the product.[13]

Advocate General Sharpston turned next to the question regarding the lack of independence and transparency in the collection and evaluation of the scientific data for the purpose of approving an active substance or authorizing a PPP. She once again considered that this question relied on a number of ill-founded premises.

10. Opinion of A.G. Sharpston in Case C-616/17, *Blaise*, EU:C:2019:190, para 52.
11. Ibid., para 55.
12. Ibid., paras. 56–57.
13. Ibid., para 58.

First, Regulation 1107/2009 requires the applicant to submit a summary of "all relevant data from the scientific peer-reviewed open literature"[14] and only to use, in support of their applications, "official or officially recognized tests and analyses",[15] namely tests conducted in accordance with good laboratory practice as defined by Directive 2004/10.[16] Furthermore, the applicant's dossier must be reviewed by both Member States and the EFSA. The Advocate General concluded that such substantive and procedural requirements not only ensure the quality and objectivity of the data collected, but also provide "systemic independent analysis of the material submitted by the industry applicant".[17]

Advocate General Sharpston also rejected the assumption that such material should necessarily be treated as confidential and, therefore, would not be available for scrutiny by third parties. In that respect, she noted that the confidentiality regime laid down in Article 63 of Regulation 1107/2009 is without prejudice to Directive 2003/4 on public access to environmental information[18] (the Aarhus Directive) and does not detract from the well-established principle of widest possible access and narrowly interpreted exceptions. In addition, Articles 10 and 12 of Regulation 1107/2009 provide for the public dissemination of the applicant's summary dossier and of the Rapporteur Member State's draft assessment report.[19]

Advocate General Sharpston considered the fourth question to be equally based on a wrong assumption. She disputed the view that Regulation 1107/2009 dispenses applicants of the need to submit long-term toxicity data (including data on genotoxicity, carcinogenicity and endocrine disruption) in support of their request for PPP authorization. Although such data is not explicitly mandated, the EU legislation makes the marketing of PPPs conditional on the absence of any "delayed harmful effect on human health". It also allows Member States to ask for additional studies, and even to reject an

14. Art. 8(5) Reg. 1107/2009. See also Commission Regulation 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, O.J. 2013, L 93/1, Annex, 1.4 and 9; and Commission Regulation 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, O.J. 2013, L 93/85, Annex, 1.4 and 11.

15. Art. 29(3) Reg. 1107/2009.

16. Directive 2004/10/EC of the European Parliament and of the Council of 11 Feb. 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances, O.J. 2004, L 50/44.

17. Opinion, para 67.

18. O.J. 2003, L 41/26.

19. Opinion, para 74.

application for authorization if "there is a risk to human health due (for example) to long-term toxicity but it is not clear how serious that risk is".[20]

4. Judgment of the Court

The Court largely followed the reasoning of its Advocate General, only adding a few bold statements.

For the sake of completeness, it should be noted that the Court first examined the Commission's and European Parliament's claim that the French court's preliminary reference was inadmissible because, insofar as it questioned the validity of Regulation 1107/2009 (and not the lawfulness of the approval granted to glyphosate), it could not have any impact on the classification as criminal offences of the acts committed by the accused. Following long-standing case law, the ECJ dismissed this objection on the ground that it falls to the national court to assess the need for preliminary guidance and that the questions submitted to the Court enjoy a presumption of relevance – a presumption that was not rebutted *in casu*.

Turning to the issues raised by the referring court, the ECJ started by making some general statements on the relationship between Regulation 1107/2009 and the precautionary principle. It noted that this Regulation is expressly based on the precautionary principle and allows Member States to apply this principle where there is scientific uncertainty as to the risks for health or the environment.[21] However, the Court added that this finding was not enough for Regulation 1107/2009 to comply with the precautionary principle. In order to pass muster, the EU pesticides legislation must "establish a normative framework that ensures that the competent authorities have . . . sufficient information in order adequately to assess . . . the risks to health resulting from the use of [active substances and PPPs]".[22] Just like its Advocate General, the Court made clear that the validity of the Regulation could not be appraised based on its specific application in the case of glyphosate. Furthermore, the need to "strike a balance" between competing objectives and the complexity of the matter warranted a hands-off type of judicial review limited to the "manifest error of assessment" standard.[23]

Regarding the first question, the Court concluded from Articles 2(2) and 33(b) of Regulation 1107/2009 and from Commission Regulation 283/2013 that "an applicant does not have the option of choosing at his discretion which

20. Ibid., para 78.
21. Judgment, para 44.
22. Ibid., para 47.
23. Ibid., para 50.

constituent of that product is to be considered to be an active substance".[24] In a rather clumsy statement, the Court considered further that "it is not clearly evident that the criteria set out in [Article 2(2)] are insufficient to permit an objective determination of the substances concerned".[25] However, the Court went on, the onus is on the Member States to make sure that the application complies with the obligation to identify the active substances contained in the plant protection product. Should it appear at a later stage that this requirement was not met, the authorization could be immediately withdrawn.

Moving on to the "cocktail effect" issue, the Court noted that any assessment of the harmful effect of an active substance – which must include the assessment of one or more representative uses of at least one protection product containing that substance – simply "cannot be carried out while failing to take into account the effects deriving from a possible combination of various constituents of a plant protection product".[26] The reference to "known cumulative and synergistic effects" in Article 4(2) and (3) of Regulation 1107/2009 buttressed that conclusion. According to the Court, the same holds true for the PPP authorizations at Member State level. On the one hand, Article 29(1)(e) extends the condition of Article 4(3) to such an authorization process. On the other hand, Article 29(6) provides more broadly that "interaction between the active substance, safeners, synergists and co-formulants shall be taken into account in the evaluation of plant protection products".[27] As a result, the premise of the French court's question appeared to be incorrect.

The Court reached the same conclusion for the third question regarding the alleged biased character of the dossiers submitted by the applicants and the lack of transparency of the whole process.

Just like its Advocate General, the Court started by enumerating the various provisions that secure the objectivity of the data submitted in support of an application for a PPP authorization, as well as the independence and quality of the review performed by the Member States and the EFSA. Importantly, and departing from a literal reading of the Regulation, the ECJ added that in the course of this assessment, those authorities "are of necessity bound to take into account relevant evidence other than the tests, analyses and studies submitted by the applicant that might contradict the latter".[28] Driving the point home, the Court held further that "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

24. Ibid., para 57.
25. Ibid., para 58.
26. Ibid., para 68.
27. Ibid., para 72.
28. Ibid., para 93.

preponderant weight to the studies provided by the applicant".[29] Finally, the possibility for the Commission to submit samples to a Community reference laboratory and the fact the relevant authorities are at liberty to withdraw approvals or authorizations at any time confirmed the quality and seriousness of the procedural system laid down by Regulation 1107/2009.[30]

Regarding the claim relating to the lack of transparency, the Court noted that, "while it is not inconceivable that increased transparency in those procedures may be such as to permit an even better assessment of the risk to health", Regulation 1107/2009 already allows, to a large extent, public access to the applicant's dossier.[31] Following Advocate General Sharpston, the Court pointed out not only the obligation to make public the "summary dossier" (Art. 10) and the Rapporteur Member State's draft assessment report (Art. 12(1)), but also the wording of the provision on confidentiality (Art. 63). In line with earlier case law, it confirmed that the studies designed to assess the harm to the environment must be regarded as "information on emissions into the environment" within the meaning of the Aarhus Directive.[32] As a result, Member States cannot refuse access to such studies "on grounds based on protection of the confidentiality of commercial or industrial information".[33]

Turning finally to the alleged exemption of long-term toxicity and carcinogenicity tests, the Court acknowledged that Regulation 1107/2009 does not explicitly impose such tests as part of the PPP authorization process.[34] It considered, however, that it results from a combined reading of Article 4(3)(b), Article 29(1)(e) and Article 29(2) that the applicant must prove that his product has no delayed harmful effect. As a consequence, "a plant protection product cannot be considered to satisfy that condition where it exhibits any long-term carcinogenicity and toxicity".[35] More specifically, the competent authorities must verify that the material submitted by the applicant is sufficient to "exclude" a risk of carcinogenicity or toxicity. In that respect, "cursory tests" would not suffice.[36]

The Court logically concludes that none of the questions raised by the French court has revealed elements capable of affecting the validity of Regulation 1107/2009.

29. Ibid., para 94.
30. Ibid., para 98.
31. Ibid., para 102.
32. Ibid., para 108.
33. Ibid., para 107.
34. Ibid., paras. 111–112.
35. Ibid., para 115.
36. Ibid., para 116.

5. Comments

Considering the conclusion reached by the ECJ, it may come as a surprise that the accused's lawyer, who had drafted the questions with a view to challenging the EU legal framework's validity, hailed this judgment as a milestone in the evolution of pesticides legislation.[37] This reaction is however understandable upon a closer reading of the judgment. The Court may have kept up legislative appearances, but its extensive reading of Regulation 1107/2009 will undoubtedly impact on the latter's day-to-day application and probably trigger a number of judicial challenges both at national (for PPP authorizations) and EU (for active substances approvals) levels.

5.1. *A matter of principle(s): The preliminary statements*

Before examining the practical fall-out of this faux-naïf interpretation of Regulation 1107/2009, attention should be drawn to some preliminary statements made by the Court and Advocate General Sharpston. It is not surprising that both the ruling and the Opinion grant the EU legislature significant regulatory leeway. More interesting is their reference to the "balance" that the legislature has to strike between competing objectives and principles.[38] The notion of balance might convey the impression that the objectives and principles at stake are of equal value.[39] Yet, it is a distinctive feature of Regulation 1107/2009 that it does not put on a par the protection of health and the environment on the one hand and the enhancement of plant productivity on the other. Recital 24 to the preamble, for instance, states that "when granting authorizations of plant protection products, the objective of protecting human and animal health and the environment *should take priority* over the objective of improving plant production. Therefore, it should be demonstrated, before PPPs are placed on the market, that they present a *clear* benefit for plant production and do not have *any* harmful effect on human or animal health …". This principled imbalance in favour of environment-related

37. Tumerelle, "Un arrêt de la Cour de justice de l'union européenne qui fait évoluer la législation sur les pesticides", available at <www.avocats-tumerelle.fr/2019/10/01/cjue-01102019-un-arret-qui-fait-evoluer-la-legislation-sur-les-pesticides/>. See also "Pesticide formulations as sold and used must be tested for long-term toxicity and carcinogenicity", available at <www.gmwatch.org/en/news/latest-news/19158>.

38. See judgment, para 50, and Opinion, para 29.

39. Although the use of this notion by the Court is not always consistent, a pattern seems to emerge from cases featuring conflicts between fundamental rights, or conflicts between fundamental rights and free movement rights. Faced with such hard cases, the Court usually refers to the necessity to "strike a fair balance" between the rights at stake. See e.g. Case C-112/00, *Schmidberger*, EU:C:2003:333, para 81; Case C-283/11, *Sky ÖSterreich*, EU:C:2013:28, para 60; Case C-752/18, *Deutsche Umwelthilfe eV*, EU:C:2019:1114, para 50.

and health-related concerns is supported by the fact that Regulation 1107/2009 is based on the precautionary principle, which requires "giving precedence to the requirements related to the protection of those interests over economic interests".[40]

Also noteworthy is Advocate General Sharpston's contention that the precautionary principle has thus far only been relied upon to challenge acts allegedly too protective of health and the environment, as opposed to potentially overly business-friendly measures.[41] While it is true that statistically, most pleas based on the precautionary principle are made by corporations against restrictive measures concerning their products, there are notable – albeit unsuccessful – exceptions which feature an environment-minded use of that principle.[42] But the Advocate General's statement and these statistics deserve attention because they reflect a deep inequality in the admissibility treatment of challenges mounted by economic actors and actions filed by simple "stakeholders", be they public entities or NGOs. Whereas the former are presumed to be directly and individually concerned by an act that affects their activities, the latter's concern for the environment or public health does not suffice to demonstrate *locus standi* under Article 263(4) TFEU.[43] Arguably, this fact sheds new light on the offences committed by the environmental activists at the origin of this case. Whether or not these actions were intended as part of a legal strategy, it is safe to say that they were probably the most straightforward way[44] for the accused to obtain such a wide-ranging ruling on the validity of Regulation 1107/2009.

40. Joined Cases T-429 & 451/13, *Bayer CropScience e.a.* v. *Commission*, EU:T:2018:280, para 109. In the context of food surplus characterizing the current EU market, it is safe to consider that the "enhancement of plant production" objective exclusively serves economic interests (of farmers, consumers and, of course, plant protection producers).

41. Opinion, para 49.

42. See e.g. Case T-257/07, *France* v. *Commission*, EU:T:2011:444; Case C-528/16, *Confédération paysanne e.a.*, EU:C:2018:583.

43. Examples of this restrictive approach regarding actions for annulment of the Commission Regulation renewing the approval of glyphosate can be found in Case T-178/18, *Brussels Region*, appeal pending, and in Case T-125/18, *Associazione GranoSalus*, EU:T:2019:92, appeal pending.

44. Admittedly, they could have sought the annulment of the French authorization of glyphosate before domestic administrative courts. But the time limit for such an action had probably elapsed at the time of the offence. In addition, it appears from the ECJ's ruling in Case C-416/17, *Commission* v. *France*, EU:C:2018:811, that they might have experienced difficulties in obtaining a preliminary reference through that channel. It should be recalled that in this judgment, the ECJ found that France infringed Art. 267(3) TFEU because the Council of State refused to make a preliminary reference in a case where the conditions of the *acte clair* doctrine were manifestly not met.

5.2. *The first question: The vague definition of "active substance"*

The first question put to the Court regarding the notion of "active substance" uncovers a real problem. It is probably no coincidence that Article 3, which defines most technical concepts used in Regulation 1107/2009, does not say anything about that notion. It is true, as both the Court and the Advocate General pointed out, that Article 2(2) characterizes active substances as "substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products". But it is doubtful – as the Court implicitly acknowledges[45] – whether this very broad description was intended to serve as an operational definition with a view to identifying the components of a PPP that must be subject to approval as active substances. For example, it does not exclude an overlap with the notion of "synergist", which includes substances showing "weak activity" on undesired plants or harmful organisms (Art. 2(3)(b)). There are currently 13 types of synergists used in plant protection products in the EU.[46] By silencing the detoxification mechanisms of the targeted organism, they prevent the "pest" from working off the poisonous substances, thereby enhancing the effectiveness of the plant protection products.

In theory, this lack of clear-cut distinction between synergists and active substance should not be problematic because, according to Article 25 of Regulation 1107/2009, synergists are subject to the same approval conditions and procedure as active substances. However, the Commission has never implemented Article 25, as a result of which synergists are currently not evaluated at EU level – and neither are they in a number of Member States. The *Blaise* ruling might provide an opportunity to close this gap by leading the Commission to approve at least some synergists as active substances under Article 4 et seq. of Regulation 1107/2009. It can, indeed, be argued that by thwarting the harmful organism's detoxification mechanisms, synergists have an "action against harmful organism" within the meaning of Article 2(2), bringing them within the category of active substances.

More importantly, the broad definition of active substance taken on board in *Blaise*, combined with the obligation imposed on Member States to track down potentially undeclared active substances in commercial formulations,

45. "[I]t is not clearly evident that the criteria set out in [Article 2(2)] are insufficient to permit an objective determination of the substances concerned" (para 58).

46. Ecorys, "Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005)", Final report, 10 Oct. 2018, 218, available at <op.europa.eu/en/publication-detail/-/publication/7244480c-d34d-11e8-9424-01aa75ed71a1/language-en>.

will preclude applicants from presenting as mere "co-formulants"[47] – and therefore dispensed from any long-term toxicity tests[48] and, in practice,[49] from any harmonized examination at EU level[50] – components which are sometimes more toxic than the component officially presented as the active substance. This is arguably the case for POE-tallowamine, for example, which is included in some glyphosate-based total herbicides.[51]

5.3. *The second question: The "cocktail effect" assessment*

The second question, regarding the "cocktail effect" assessment of active substances and PPPs, also exposes glaring failures in the current application of Regulation 1107/2009. The Court is right to say that the EU legislation imposes the assessment of such effects as regards both the approval of an active substance and the authorization of a PPP. However, it conveniently fails to mention that the cumulative and synergistic effects of a substance's residues and of a PPP must only be taken into account "where the scientific methods accepted by the Authority [namely, the EFSA] to assess such effects are available" (Art. 4 (2)(a) and 4(3)(b)). Yet, the EFSA has been struggling for at least 15 years[52] to provide such a methodology – so far to no avail. As a consequence, such cumulative and synergistic effects are currently not (or hardly) assessed, whether at EU or national level. The *Blaise* judgment will probably boost the EFSA's efforts in that respect. But insofar as it *immediately* – and arguably retrospectively – imposes an obligation to assess the cocktail effects of active substances and PPPs, it might prompt challenges against current and future authorizations and approvals, but also other types of lawsuits such as actions for failure to act or liability proceedings.

47. This notion refers to a residual category covering "substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists" (Art. 2(3)(c) Reg.1107/2009).

48. See Art. 27 of Reg. 1107/2009.

49. Art. 27(2) provides that the Commission should draw up a list of unacceptable co-formulants. The Commission has not yet done so, but has started working on it: <ec.europa.eu/food/sites/food/files/safety/docs/adv-grp_plenary_20160429_pres09-ppp-discuss.pdf>.

50. In principle, co-formulants will be assessed under the REACH and CLP legislation, but based on differing requirements and standards as under Regulation 1107/2009.

51. Annex II of the aforementioned Commission Regulation 2017/2324 renewing the approval of glyphosate now prohibits Member States from authorizing glyphosate-based PPPs containing such co-formulant.

52. See Art. 14(2)(b) of Regulation 396/2005 of the European Parliament and of the Council of 23 Feb. 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, O.J. 2005 L70/1.

5.4. *The third question: The impartiality and publicity of the approval and authorization procedures*

The third question is also spot-on insofar as it questions the impartiality and publicity of the approval and authorization procedures. And again, the Court is right to say that, on paper, Regulation 1107/2009 erects a number of bulwarks against any kind of abuse or regulatory capture. Reality, however, is more complex. First, neither the EFSA nor the Rapporteur Member State do always perform a careful examination of the list of "scientific peer-reviewed open literature" to be provided by the applicant. In the case of glyphosate, even though stakeholders adduced evidence that many peer-reviewed articles had been left out of the applicant's dossier,[53] this does not seem to have triggered any further scrutiny by the competent authorities. In the same vein, and as is well known, it turned out that substantial parts of Germany's risk assessment report on glyphosate had actually been copy-pasted from the application itself.[54]

The same is true for the – *prima facie* self-evident – statement that competent authorities should "not give in all cases preponderant weight to the studies provided by the applicant" (para 93). In reality, most university studies are dismissed or underrated (based on the so-called Klimisch score, created by former members of a well-known chemical company) on the grounds that they are not carried out according to costly and narrow OECD protocols, which place the emphasis on the reliability rather than the sensitivity of the tests. Here again, the *Blaise* ruling might lead to some changes in the practice of the competent authorities.

In the same vein, the Court and Advocate General Sharpston are right to consider that the tests and analyses submitted by the applicant must be performed by a reliable institution according to the so-called good laboratory practices. However, they overlook the fact that these analyses are the sole property of the applicants. Therefore, the laboratories which perform the analyses at the applicants' request are not at liberty to communicate the results to the competent authorities. Only the applicants can. As a result, the applicants are *de facto* in a position to submit only the tests showing the most favourable results and to keep to themselves more unwelcome studies.

The divorce between theory and practice is further illuminated by the Court's reference to the possibility for the EFSA to seek the advice of a

53. See <www.pan-europe.info/old/Resources/Reports/PANE%20-%202014%20-%20Missed%20and%20dismissed.pdf>.

54. Weber, "Detailed Expert Report on Plagiarism and superordinated Copy Paste in the Renewal Assessment Report (RAR) on Glyphosate", available at <www.greens-efa.eu/files/doc/docs/298ff6ed5d6a686ec799e641082cdb63.pdf>.

"Community reference laboratory" on samples and analytical standards submitted by an applicant. In reality, the Commission only appointed the first five "Community reference laboratories" in the field of PPP regulation in March 2019. Whether this decision has something to do with the (at the time) pending judgment of the Court in *Blaise* is left to everyone's guess. But there is little doubt that these laboratories have not played any role so far in the approval or authorization processes organized by Regulation 1107/2009.

Although remarkable, the part of the judgment regarding transparency is less innovative. The Court confirms its holding in *Bayer CropScience*[55] that most studies designed to assess the harmful effect of PPPs are covered by the Aarhus Directive and should in principle be accessible on request notwithstanding the confidentiality of commercial or industrial information. Through this ruling, the ECJ also indirectly approves the General Court's judgments annulling EFSA's refusals to grant a number of individuals (including MEPs) access to toxicity and carcinogenicity studies submitted in the glyphosate case.[56]

5.5. *The fourth question: The performance of long-term carcinogenicity and toxicity studies*

In cauda venenum. The Court's answer to the last question is probably the most spectacular. The ECJ holds in substance that regardless of any explicit obligation to that effect in Regulation 1107/2009, long-term carcinogenicity and toxicity studies must be submitted (or requested) in support of PPP authorization applications if they are necessary to exclude the risk of carcinogenicity or toxicity.

This obligation, which is logically derived from Articles 4(3)(b) and 29(1)(e) of Regulation 1107/2009, makes a lot of sense from an environmental and public health perspective. In the case of glyphosate-based PPPs, for example, many scientific authorities consider that the formulations are more likely to be carcinogenic than glyphosate alone.

But the Court's interpretation will also significantly burden the task of the applicants – long-term studies are costly and lengthy. In that respect, it does not derive clearly from the Court's judgment that PPP authorization applications should *always* be supported by long-term toxicity studies. It might be argued that such studies would be necessary only in such cases where credible doubts have been raised in the scientific literature.

55. Case C-442/14, *Bayer Cropscience and Stichting De Bijenstichting*, EU:C:2016:890.

56. Case T-716/14, *Tweedale* v. *EFSA*, EU:T:2019:141; and Case T-329/17, *Hautala and others* v. *EFSA*, EU:T:2019:142.

Finally, although the Court only refers to the PPP authorization process at Member States level, its holding indisputably extends to active substance approval procedures at EU level. The reason is that such approvals can only be granted where it has been demonstrated that at least one representative use of a PPP containing the active substance concerned complies with the health-related and environment-related requirements of Regulation 1107/2009.[57] Turning back to the glyphosate renewal case, and to the best of this author's knowledge, no such long-term toxicity study had been submitted by the applicant regarding the glyphosate-based PPP examined in the framework of the approval procedure. If confirmed, this lack of data regarding a product whose long-term carcinogenicity is fiercely debated would seem hardly compatible with the Court's interpretation of Regulation 1107/2009.

6. Conclusion

As this comment sought to demonstrate, there is more to the *Blaise* judgment than meets the (uninformed) eye. It is not the first time that the Court of Justice uses seemingly innocent findings of validity to undermine the practice and interpretations adopted by other EU institutions and the Member States.[58] Such judgments reveal that the consistent interpretation technique may put a strain on the balance of powers just as surely – and even more effectively[59] – as an outright annulment. In this case, however, it is this author's view that the Court did not exceed the boundaries of its competences. It steered clear of any daring teleological reasoning or lofty statement. It simply took the precautionary principle and the provisions of Regulation 1107/2009 seriously. The Union's pesticides legislation is one of the world's most ambitious; the Court has simply called upon the Commission and the Member States to live up to its standards.

Antoine Bailleux*

57. Art. 4(5) Reg. 1107/2009.

58. See e.g. Case C-266/16, *Western Sahara Campaign*, EU:C:2018:118.

59. Because they do not strike down the legislation at stake, such rulings do not automatically result in handing the matter back to the legislature. Therefore, if the latter does not take the initiative to revise the text, the Court's interpretation will continue to prevail.

* Université Saint-Louis – Bruxelles, Belgium.

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