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CASE NOTES

How Can New Scientific and Technical Knowledge Affect the Authorisation of Plant Protection Products at Member State Level? Some Clarifications from the Court of Justice

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Most reliable scientific knowledge and Member State authorisation of plant protection products (area of discussion)

Case C-308/22, PAN Europe (Closer) [2024] EU:C:2024:350.

Reference for a preliminary ruling – Approximation of laws – Regulation (EC) No 1107/2009 – Authorisation for placing plant protection products on the market – Examination for authorisation – Article 36 – Discretion of the Member State concerned, for the purposes of Article 36(2), with regard to the scientific risk assessment carried out by the Member State examining the application for authorisation under Article 36(1) – Article 44 – Withdrawal or amendment of an authorisation – Precautionary principle – Effective judicial remedy – Current scientific and technical knowledge.

Joined Cases C-309/22 and C-310/22, PAN Europe (Evaluation of Endocrine Perturbation Properties) [2024] EU:C:2024:356.

Reference for a preliminary ruling – Approximation of laws – Regulation (EC) No 1107/2009 – Authorisation for placing plant protection products on the market – Examination for authorisation – Article 4 – Article 29 – Conditions – No harmful effect – Criteria – Endocrine disrupting properties – Regulation (EU) 2018/605 – Precautionary principle – Current scientific and technical knowledge.

Articles 4(1), 29(1)(a) and (e), and 36(1), (2), and (3) of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market OJ L 309 of 24.11.2009, pp 1–50.

I. Facts

The disputes in the main proceedings stem from three separate complaints filed by Pesticide Action Network Europe (PAN Europe) against the authorisation by the Dutch national authority competent to enforce Regulation 1107/2009, the Plant Protection

Products and Biocides Approval Board (CTGB),[1] of three plant protection products (pesticides): Closer, Dagonis and Pitcher.

Case C-308/22 (Closer) refers to the extension by the Netherlands of the authorisation of the plant protection product Closer, which contains the approved active substance sulfoxaflor.[2] In 2015, the pesticide company Dow AgroScience BV applied for an extension of the authorisation of Closer in multiple countries belonging to the centre zone, including the Netherlands.[3] Ireland, as the designated Member State for the examination of the application under Article 36(1) of Regulation 1107/2009, conducted the risk assessment of the product and the evaluation of the dossier. The assessment was based on the 2002 Guidance Document on Terrestrial Ecotoxicology and not on the more recent 2013 EFSA Guidance Document on risks to bees.[4] Yet, the CTGB decided to extend Closer's authorisation in 2019 on the basis of Ireland's assessment.

Case C-309/22 relates to the authorisation by the CTGB of the fungicide crop protection product Pitcher containing the active substances fludioxonil and folpet, among others.[5] In 2015, the pesticide company Adama Registrations BV applied for marketing authorisation of Pitcher in the Netherlands. In 2019, the CTGB granted the authorisation for this product until 2021, without however assessing the endocrine disrupting properties of the substance fludioxonil in light of the new scientific criteria of Regulation 2018/605.[6]

Lastly, Case C-310/22 concerns the authorisation by the CTGB of the fungicide Dagonis, which contains the active substances difenoconazole and fluxapyroxad.[7] In 2016, the pesticide company BASF Nederland BV applied for marketing authorisation of Dagonis in various Member States, including the Netherlands. The United Kingdom, as the Member State designated to examine the application for the centre zone, carried out the scientific risk assessment of the fungicide. Considering the positive results of this assessment, the CTGB in 2019 authorised Dagonis for certain crops until December 2020. However, the Dutch authority did not examine the endocrine disrupting properties of that product in light of new criteria, such as Regulation 2018/605 and the EFSA guidance document for the identification of endocrine disruptors in the context of Regulation 1107/2009.[8]

Three separate references for a preliminary ruling were made by the Administrative Court of Appeal for Trade and Industry in the Netherlands, where PAN Europe had sought the annulment of the CTGB's decisions. The Court of Justice of the European Union (CJEU) joined the Cases C-309/22 and C-310/22 (Evaluation of Endocrine Perturbation Properties).

[1] 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 [2009] OJ L 309/1, Art 75.

[2] Case C-308/22, *PAN Europe (Closer)* [2024] EU:C:2024:350; and Commission Implementing Regulation (EU) 2015/1295 of 27 July 2015 approving the active substance sulfoxaflor [2015] OJ L 199/8.

[3] Regulation 1107/2009 (n 1), Annex I.

[4] European Commission, "Guidance Document on Terrestrial Ecotoxicology" SANCO/10329/2002 (17 October 2002); and European Food Safety Authority, "Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees" (2013) 11 EFSA Journal 3295.

[5] Joined Cases C-309/22 and C-310/22, *PAN Europe (Evaluation of Endocrine Perturbation Properties)* [2024] EU:C:2024:356. At the time of the application, the validity of the approval of the two active substances was already extended. Commission Implementing Regulation 2021/1449 extended the validity of fludioxonil until 31 October 2022, and Commission Implementing Regulation (EU) 2021/745 extended the validity of folpet until 31 July 2022.

[6] Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties [2018] C/2018/2229/33.

[7] Joined Cases C-309/22 and C-310/22 (n 5). Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances [2011] OJ L 153/1.

[8] Commission Regulation 2018/605 (n 6); and European Chemicals Agency et al., "Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009" (2018) 16 EFSA Journal 5311.

II. Judgments

In the three preliminary references to the Court of Justice, the central issue is the impact that new scientific and technical knowledge could have on the authorisation of a plant protection product at the Member States' level.

In the *Closer* case, the Court is initially asked whether Article 36 of Regulation 1107/2009 permits the Member State deciding on the authorisation for placing a plant protection product on the market (Member State concerned) under Article 36(2) and (3) to deviate from the scientific risk assessment of that product conducted by the Member State examining the application for such authorisation (reference Member State) under Article 36(1).[9] The Court clarifies that Regulation 1107/2009 allows for this possibility. A new assessment is specifically possible when the Member State concerned has access to "the most reliable scientific and technical data" not considered by the Member State examining the application for such authorisation under Article 36(1).[10] These data must indicate an unacceptable risk to human or animal health, or to the environment.

Another question is how to settle differences of opinion between Member States, specifically when one Member State believes that the scientific risk assessment conducted by the reference Member State does not adequately address its concerns regarding health or environmental issues specific to its territory. The Court clarifies that the concerned Member State may conduct a new risk assessment without the need to involve the Member State that carried out the initial examination of the product under Article 36(1).[11]

Finally, in the *Closer* case, the Court addresses two other additional elements. With the second question, the Court is specifically asked whether the national court of the Member State concerned reviewing the lawfulness of an authorisation decision made by that Member State can also evaluate the scientific assessment conducted by another Member State under Article 36(1), when this assessment is used for authorisation purposes in the concerned Member State. The Court examines this inquiry in light of the principle of effective judicial protection. It affirms that the national court has indeed the authority to review pesticide authorisations made under Article 36(2) and (3) of Regulation 1107/2009.[12] For that purpose, the national court can evaluate if these decisions comply with the substantive and procedural conditions outlined in that Regulation. It can also consider the conclusions of the evaluation carried out by the reference Member State under Article 36(1), subject to an important limitation: a national court cannot substitute its own assessment to the scientific assessment of a national competent authority.[13] Finally, the fourth and fifth questions concern the possibility of challenging pesticide authorisations through national courts or authorities. In this regard, the Court declares that Articles 29(1)(e) and 36(2) of Regulation 1107/2009 permit to submit the most reliable scientific and technical data available before these bodies in order to demonstrate that the scientific risk assessment of a plant protection product, conducted by the Member State evaluating the application under Article 36(1), may lack sufficient reasoning or justification.[14] This approach aligns with the precautionary principle that is at the foundation of Regulation 1107/2009.[15]

In the *Evaluation of Endocrine Perturbation Properties* case, the Court is called upon to clarify whether under Article 29(1)(a) and (e), and the second and third subparagraphs of

[9] Case C-308/22 (n 2), para 51.

[10] Ibid, 70. The Court follows the Advocate General's reasoning. Case C-308/22, *PAN Europe (Closer)* [2024] EU:C:2023:716, Opinion of Advocate General Medina, paras 55–57.

[11] Case C-308/22 (n 2), para 84.

[12] Ibid, para 76.

[13] Ibid, paras 75–76.

[14] Ibid, paras 88 and 110.

[15] Ibid, paras 103–107.

Article 4(1) of Regulation 1107/2009, read in conjunction with point 3.6.5 of Annex II to that Regulation, a national competent authority is required to conduct its own evaluation of the potential health risks associated with the endocrine disruptors of an approved active substance during the product authorisation process, even though this assessment has already been performed at the EU level. In that regard, the Court explains that while the Member States cannot reassess the Commission's approval of an active substance when evaluating an application for a product containing that substance, the authorisation of such a product cannot be reduced to a mere automatic extension of the EU approval of the active substance it contains.[16] The Court clarifies that Article 29(1)(a) and (e), read in conjunction with Article 4(1), must be interpreted as requiring national competent authorities when assessing an application for authorisation to place a plant protection product on the market, to take into account the adverse effects of the endocrine disrupting properties of an active substance.[17] This interpretation aligns with both the literal text of these provisions and the precautionary principle.[18]

III. Comments

The *Closer* and *Evaluation of Endocrine Perturbation Properties* cases represent important additions to the Court of Justice's case law regarding the procedures to place pesticides on the market. However, unlike earlier cases that have primarily concerned the authorisation of active substances at the EU level,[19] the very specificity of the cases commented on here is that they relate to the Member State level authorisation of plant protection products after the risk assessment of the products has been already done in another Member State and the active substances have been already approved at EU level. In this regard, a similar parallel development is the *PAN Europe v État belge* case, where the main dispute refers to national emergency authorisations under Article 53 of Regulation 1107/2009 of plant protection products containing active substances prohibited at EU level.[20] In this context, the Court clarifies that these national practices contradict the Regulation's primary objective of prioritising health and environmental protection over enhancing plant production.

Despite their specificity, the *Closer* and *Evaluation of Endocrine Perturbation Properties* cases should not be viewed in isolation from the previous Court's case law on pesticide authorisation. In this regard, an important common denominator is the reference to the precautionary principle and the interest in health and environmental protection.

While Regulation 1107/2009 declares to be underpinned by the precautionary principle in its entirety,[21] the practical application of this principle by risk managers at both EU and

[16] Joined Cases C-309/22 and C-310/22 (n 5) 82. Also, Case T-600/15, *PAN Europe and Others v Commission* [2016] EU:T:2016:601, para 33.

[17] Joined Cases C-309/22 and C-310/22 (n 5), para 100. The Court follows the reasoning of AG Medina. Joined Cases C-309/22 and C-310/22, *PAN Europe (Evaluation of Endocrine Perturbation Properties)* [2024] EU:C:2023:717, Opinion of Advocate General Medina, paras 68–75.

[18] Joined Cases C-309/22 and C-310/22 (n 5), para 88–93.

[19] Case T-229/04, *Kingdom of Sweden v Commission of the European Communities* [2007] ECR II-02437; Case C-499/18 P, *Bayer CropScience AG and Bayer AG v European Commission* [2021] EU:C:2021:367; and Case C-374/20 P, *Agrochem-Maks d.o.o. v European Commission* [2021] EU:C:2021:990.

[20] Case C-162/21, *Pesticide Action Network Europe ASBL and Others v État belge* [2023] EU:C:2023:30.

[21] Regulation 1107/2009 (n 1) Art 1(4). The EU has also integrated the precautionary principle into other EU policies. Again, the Court has helped to clarify how the principle operates. K De Smedt, and E Vos, "The Application of the Precautionary Principle in the EU" in HA Mieg (eds) The Responsibility of Science. Studies in History and Philosophy of Science, (Springer, 2022) 175–176.

Member State levels remains largely undefined within the framework of that Regulation.[22] The role of the Court in clarifying this ambiguity has been crucial so far.[23]

Fundamentally, the Court has established that before an active substance can be approved or a product can be authorised, it must be established beyond reasonable doubt that their use does not present any hazard or risk to health and the environment.[24] In that regard, the existence of evidence that casts doubt on the safety of a substance or product justifies, in principle, the refusal to authorise them.[25] However, this precautionary measure cannot be based on hypotheses that have not been scientifically proven. Instead, this measure should be based on an evaluation of the potential health risks associated with the substance and product as well as on a rigorous health risk assessment based on the most reliable and up-to-date scientific evidence.[26] Once one of these criteria is met, the precautionary principle allows protective measures to be taken without waiting for the full extent of the risks to be understood.[27] Moreover, the Court has also clarified that any such measures must align with the principle of proportionality, ensuring that the response is proportionate to the identified level of risk.[28]

The Court has essentially referred to the precautionary principle as a mechanism to guide the discretion of both the Commission and national competent authorities and ground their decisions in comprehensive scientific analyses. The two rulings commented in this note represent an important development in this area. The Court explains that in compliance with the precautionary principle, national competent authorities are required to withdraw the authorisation of a plant protection product in the event that new data should emerge demonstrating that the product has a harmful effect on health or the environment.[29] For that purpose, new scientific evidence may also be brought before the authorities or courts of the Member States making the final evaluation of the product under Article 36(2) to prove the existence of risks that were not considered by the previous risk assessment conducted by the Member States under article 36(1).[30] Moreover, the Court also establishes that national authorities must conduct their own independent assessments when making decisions on pesticide approvals, taking into account the most reliable scientific and technical data available. This requirement goes beyond automatically relying on the EU level active substance approvals or evaluations from other Member States.[31]

Under these circumstances, the Court introduces additional layers of scrutiny for pesticides in the interest of health and environmental protection. However, the trade-off for this increased protection is the potential erosion of other established legal principles.

[22] E Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart Publishing 2007) 211–212; and M Weimer and G. Pisani, "Expertise as Justification: The Contested Legitimation of the EU 'Risk Administration'" in M Weimer and A de Ruijter (eds) *Regulating Risks in the European Union* (Hart Publishing 2017).

[23] Most recently, the Court has also confirmed the compatibility of Regulation 1107/2009 with the precautionary principle in Case C-616/17, *Criminal Proceedings against Mathieu Blaise and Others* [2020] EU:C:2019:800. Leonelli, "Judicial Review of Compliance with the Precautionary Principle from Paraquat to Blaise: 'Quantitative Thresholds,' Risk Assessment, and the Gap Between Regulation and Regulatory Implementation" (2021) 22 German Law Journal 184, 195–196.

[24] Case T-229/04 (n 18), paras 161 and 170.

[25] Case C-333/08, *European Commission v French Republic* [2010] ECR-I-00757, para 91 and case law mentioned.

[26] Case C-616/17 (n 23) para 46 and case law mentioned.

[27] Case C-616/17 Blaise and Others [2019] EU:C:2019:190, Opinion of Advocate General Sharpston, para 48.

[28] Joined Cases C-78/16 and C-79/16, Giovanni Pesce and Others v Presidenza del Consiglio dei Ministri – Dipartimento della Protezione Civile and Others [2016] EU:C:2016:428, para 48.

[29] Case C-308/22 (n 2) 107; and Joined Cases C-309/22 and C-310/22 (n 3), para 97.

[30] Case C-308/22 (n 2) para 110.

[31] Ibid, paras 68–70. Case C-308/22 (n 2) 107. To a certain degree, the Court extends the boundaries beyond what was previously established in Case C-313/19 P, *Associazione Nazionale GranoSalus – Liberi Cerealicoltori & Consumatori (Associazione GranoSalus) v European Commission* [2020] EU:C:2020:869, para 55.

These rulings highlight the complex interplay between safeguarding health and environmental protection through the application of the precautionary principle, on the one hand, and improving the functioning of the internal market through the principle of mutual recognition, on the other hand. Regulation 1107/2009 tries to balance these competing interests. In this regard, Article 40 of this Regulation introduces a mutual recognition procedure. This system enables the holder of an authorisation for a product in one Member State to apply for authorisation for the same product in another Member States.[32] To facilitate this process, Regulation 1107/2009 also identifies three geographical zones (North, Centre, and South) based on similar agricultural and environmental conditions.[33] The zonal procedure generally enables applicants to submit multiple applications across Member States within the same zone while designating one country for dossier evaluation.[34] When deciding, the Member States concerned must base their decision on the conclusions of the assessment by the reference Member State under Article 36(1).[35] While these procedures intend to streamline the authorisation process, they also cautiously balance this interest with that of health and environmental protection allowing concerned Member States to take mitigation measures or refuse to grant authorisation under specific circumstances.[36]

However, mutual recognition has not achieved its intended success in improving the functioning of the internal market, as many Member States have shown reluctance to cooperate within this framework.[37] In this respect, the Court's judgment in the *Closer* case has the potential to further undermine the principle of mutual recognition, since it allows Member States to conduct independent risk assessments when new scientific knowledge is available, going beyond the evaluation of the reference Member State.

Moreover, the Court seems to reduce the legal certainty of substance and product authorisations by warning the applicants that they "may expect that the state of scientific and technical knowledge will change during the authorisation procedure or during the period for which an active substance is approved or a plant protection product is authorised."[38] As already mentioned, the Court not only allows national competent authorities to review the assessment of the endocrine disrupting properties of an active substance, even if an assessment has already been made at EU level but also allows them to withdraw a product authorisation or take emergency measures in the light of new scientific evidence.

While jeopardising mutual recognition and legal certainty, these recent judgments have the potential to lead to an enhanced evaluation and scrutiny of decisions taken by national competent authorities, ensuring higher health and environmental protection standards for when plant protection products enter the market. However, in order to effectively implement the Court's vision of more rigorous scientific assessment, it is crucial that national competent authorities carry out objective and impartial assessments, taking concrete account of new scientific data, and that they make transparent decisions

[32] Regulation 1107/2009 (n 1), Art 40(1).
[33] Ibid, Annex I.
[34] Ibid, Arts 33(1) and 35.
[35] Ibid, Art 36(2).
[36] Ibid, Art 36(3).
[37] European Parliamentary Research Service (EPRS), European Implementation Assessment: Regulation (EC) 1107/2009 on the placing of plant protection products on the market' (2018) <https://www.europarl.europa.eu/thinktank/en/document/EPRS_STU(2018)615668> accessed 20 November 2024, 26; and W de Braal, "National responses to great uncertainty in EU authorisation of pesticides and industrial chemicals" (2023) 3 Review of European Administrative Law 33, 46–47.
[38] Case C-308/22 (n 2) 108; and Joined Cases C-309/22 and C-310/22 (n 5) para 98.

throughout the authorisation process, allowing for public scrutiny and potential review.[39] These conditions are essential to guarantee that national authorities act in the public interest and an essential condition for the legitimacy of their action.[40] However, national competent authorities have demonstrated serious deficiencies in terms of independence and transparency when authorising plant protection products,[41] making it very unlikely that the Court's judgments will be effectively implemented. Under these circumstances, the effectiveness of these rulings depends on the EU, or alternatively each Member State, taking action. Therefore, as already suggested elsewhere,[42] the EU should intervene to strengthen the transparency and independence requirements of these authorities when acting under Regulation 1107/2009.

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[39] In this regard, the glyphosate saga has highlighted the limited access to information and the possibility to scrutiny in relation to the procedures to approve active substances. Case T-716/14, *Anthony C Tweedale v European Food Safety Authority* [2019] EU:T:2019:141; and Case T-329/17, *Heidi Hautala and Others v European Food Safety Authority* [2019] EU:T:2019:142. In more detail, M Morvillo, "The General Court Orders Disclosure of Glyphosate-related Scientific Studies: Tweedale, Hautala, and the Concept of Environmental Information in the Context of Plant Protection Products" (2019) 10 European Journal of Risk Regulation 419, 426–427; and M Morvillo, "Glyphosate Effect: Has the Glyphosate Controversy Affected the EU's Regulatory Epistemology?" (2020) 11 European Journal of Risk Regulation 422.

[40] Case C-616/17 (n 23) para 102; and A de Boer, M Morvillo, and S Röttger-Wirtz, "Fragmented Transparency: The Visibility of Agency Science in European Union Risk Regulation" (2023) 14 European Journal of Risk Regulation (2023) 313, 317–319.

[41] EPRS (n 37), 55–56 and Annex III-79 et seq. Case C-442/14, *Bayer CropScience SA-NV and Stichting De Bijenstichting v Board for the Authorisation of Plant Protection Products and Biocides* [2016] EU:C:2016:890.

[42] EPRS (n 367), Annex III-79 et seq.; Morvillo, "The General Court Orders Disclosure of Glyphosate-related Scientific Studies" (n 39) 426–427.

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