Reports of Cases

OPINION OF ADVOCATE GENERAL
MEDINA
delivered on 28 September 2023 [1]

Case C-308/22

Pesticide Action Network Europe (PAN Europe)
v
College voor de toelating van gewasbeschermingsmiddelen en biociden,
joined parties:
Corteva Agriscience, formerly Dow AgroScience BV (Dow)

(Request for a preliminary ruling from the College van Beroep voor het bedrijfsleven (Netherlands))

(Reference for a preliminary ruling – Approximation of laws – Regulation (EC) No 1107/2009 – Placing of plant protection products on the market – Assessment for the purposes of authorisation – Article 36 – Article 44 – Discretion of the Member State concerned as regards the assessment of the zonal rapporteur Member State that examined the application – Obligation to take account of current state of scientific and technical knowledge, even outside of guidance documents – Precautionary principle)

1. The present reference for a preliminary ruling from the College van Beroep voor het bedrijfsleven (Administrative Court of Appeal for Trade and Industry, Netherlands) seeks an interpretation of, in particular, Article 36 of Regulation (EC) No 1107/2009. [2] The action in the main proceedings was brought by Pesticide Action Network Europe (PAN Europe) against the College voor de toelating van gewasbeschermingsmiddelen en biociden (Plant Protection Products and Biocides Approval Board, Netherlands; 'the CTB') in relation to the latter's rejection of PAN Europe's objection against the decision of the CTB to extend the authorisation of the plant protection product Closer, which contains the active substance sulfoxaflor.

2. As the European Environment Agency (EEA) has pointed out, '[plant protection product (pesticide)] pollution drives biodiversity loss in Europe. It causes significant declines in insect populations, threatening the critical role they play in food production' and 'human exposure to chemical pesticides is linked to chronic illnesses such as cancer, and heart, respiratory and neurological diseases'. [3] The present case is important in that it raises the question whether Member States, when taking a decision as to whether grant or refuse authorisation of plant protection products, should be able to take account of the most recent scientific and technical knowledge in relation to the impact that plant protection products have on our lives.

1 Original language: English.

2 Regulation 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 2009 L 309, p. 1).

3 EEA Briefing 'How pesticides impact human health and ecosystems in Europe', 26 April 2023.

3. In that connection, under the EU Green Deal agenda (in particular, the Farm to Fork Strategy), the European Union aims to reduce the use of chemical plant protection products by 50% by 2030 in order to 'secure a fair, healthy and environmentally friendly food system'. It should be noted in that regard that, in 2018, the European Parliament estimated that there were as many as 500 different plant protection products authorised and marketed across the European Union.[4] It is against this background that I will attempt to address the questions raised by the present reference for a preliminary ruling.

4. The present case is related to Joined Cases C-309/22 and C-310/22, *PAN Europe (Assessment of endocrine disrupting properties)*, which were referred by the same national court. My Opinion in those cases is also being delivered today and the two Opinions should be read together.

I. Legal framework

A. Regulation No 1107/2009

5. Article 1 of that regulation, entitled 'Subject matter and purpose', provides, in paragraphs 3 and 4, as follows:

'3. The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.

4. The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.'

6. Article 4 of Regulation No 1107/2009, which is entitled 'Approval criteria for active substances', provides, in paragraphs 1 to 4, as follows:

'1. An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3.

The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.

[4] European Parliament, Report on the Union's authorisation procedure for pesticides, (2018/2153 (INI)), p. 14 (18 December 2018).

2. The residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

(a) they shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by [the European Food Safety Authority (EFSA)] to assess such effects are available, or on groundwater;

(b) they shall not have any unacceptable effect on the environment.

For residues which are of toxicological, ecotoxicological, environmental or drinking water relevance, there shall be methods in general use for measuring them. Analytical standards shall be commonly available.

3. A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

(a) it shall be sufficiently effective;

(b) it shall have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by [EFSA] to assess such effects are available; or on groundwater;

(c) it shall not have any unacceptable effects on plants or plant products;

(d) it shall not cause unnecessary suffering and pain to vertebrates to be controlled;

(e) it shall have no unacceptable effects on the environment, having particular regard to the following considerations where the scientific methods accepted by [EFSA] to assess such effects are available:

…

4. The requirements of paragraphs 2 and 3 shall be evaluated in the light of uniform principles as referred to in Article 29(6).'

7. Chapter III of Regulation No 1107/2009, entitled 'Plant protection products', contains a Section 1 relating to 'Authorisation', Subsection 1 of which concerns 'Requirements and contents'.

8. Article 29 of that regulation, which appears in that subsection, is entitled 'Requirements for the authorisation for placing on the market' and provides as follows:

'1. Without prejudice to Article 50 a plant protection product shall only be authorised where following the uniform principles referred to in paragraph 6 it complies with the following requirements:

(a) its active substances, safeners and synergists have been approved;

…

(c) its co-formulants are not included in Annex III;

…

(e) in the light of current scientific and technical knowledge, it complies with the requirements provided for in Article 4(3);

…

2. The applicant shall demonstrate that the requirements provided for in points (a) to (h) of paragraph 1 are met.

3. Compliance with the requirements set out in point (b) and points (e) to (h) of paragraph 1 shall be established by official or officially recognised tests and analyses carried out under agricultural, plant health and environmental conditions relevant to the use of the plant protection product in question and representative of the conditions prevailing in the zone where the product is intended to be used.

…'

9. Subsection 2, entitled 'Procedure', of the same Section 1 of Chapter III of Regulation No 1107/2009 contains, in particular, Article 36.

10. According to Article 36 of that regulation, entitled 'Examination for authorisation':

'1. The Member State examining the application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application. It shall give all Member States in the same zone the opportunity to submit comments to be considered in the assessment.

It shall apply the uniform principles for evaluation and authorisation of plant protection products, referred to in Article 29(6), to establish, as far as possible, whether the plant protection product meets the requirements provided for in Article 29 in the same zone, where used in accordance with Article 55, and under realistic conditions of use.

The Member State examining the application shall make available its assessment to the other Member States within the same zone. The format of the assessment report shall be established in accordance with the advisory procedure referred to in Article 79(2).

2. The Member States concerned shall grant or refuse authorisations accordingly on the basis of the conclusions of the assessment of the Member State examining the application as provided for in Articles 31 and 32.

3. By way of derogation from paragraph 2 and subject to [EU] law, appropriate conditions may be imposed with respect to the requirements referred to in Article 31(3) and (4) and other risk mitigation measures deriving from specific conditions of use.

Where the concerns of a Member State relating to human or animal health or the environment cannot be controlled by the establishment of the national risk mitigation measures referred to in the first subparagraph, a Member State may refuse authorisation of the plant protection product in its territory if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment.

That Member State shall immediately inform the applicant and the Commission of its decision and provide a technical or scientific justification therefor.

Member States shall provide for the possibility of challenging a decision refusing the authorisation of such products before national courts or other instances of appeal.'

11. Subsection 4, entitled 'Renewal, withdrawal and amendment', of Section 1 of Chapter III of Regulation No 1107/2009 contains, in particular, Article 44.

12. According to Article 44 of that regulation, entitled 'Withdrawal or amendment of an authorisation':

'1. Member States may review an authorisation at any time where there are indications that a requirement referred to in Article 29 is no longer satisfied.

…

2. Where a Member State intends to withdraw or amend an authorisation, it shall inform the authorisation holder and give him the possibility to submit comments or further information.

3. The Member State shall withdraw or amend the authorisation, as appropriate, where:

(a) the requirements referred to in Article 29 are not or are no longer satisfied;

(b) false or misleading information was supplied concerning the facts on the basis of which the authorisation was granted;

(c) a condition included in the authorisation has not been met;

(d) on the basis of developments in scientific and technical knowledge, the manner of use and amounts used can be modified; or

(e) the authorisation holder fails to comply with the obligations resulting from this Regulation.

4. Where a Member State withdraws or amends an authorisation in accordance with paragraph 3, it shall immediately inform the holder of the authorisation, the other Member States, the [European] Commission and [EFSA]. The other Member States belonging to the same zone shall withdraw or amend the authorisation accordingly taking into account national conditions and risk mitigation measures except for cases where the second, third or fourth subparagraphs of Article 36(3) have been applied. Article 46 shall apply where appropriate.'

II. Succinct presentation of the facts and procedure in the main proceedings and the questions referred for a preliminary ruling

13. Closer is a plant protection product containing the active substance sulfoxaflor. Sulfoxaflor was approved in the European Union as an active substance under Regulation No 1107/2009 by way of Implementing Regulation (EU) 2015/1295. [5]

14. On 30 April 2015, Dow AgroScience BV ('Dow') lodged an application in the Netherlands for Closer's authorisation to be extended to use in the open cultivation of cabbages and potatoes. It also lodged the same application, as regards the central zone (which includes the Netherlands), in Belgium, the Czech Republic, Germany, Ireland, Hungary, Austria, Poland, Romania, Slovakia and the United Kingdom.

15. As the zonal rapporteur Member State, Ireland assessed the application on the basis of the EFSA 2002 guidance document [6] and completed this assessment in 2016. However, Ireland did not use (what was, at that time,) the 'new' 2013 guidance document for the risk assessment relating to bees, [7] which was drawn up by EFSA at the behest of the Commission in order to assess the risks to bees.

16. Based on the risk assessment carried out by Ireland, the CTB decided, by decision of 5 April 2019, to extend the authorisation of Closer to include the requested use, whilst adding the following restrictive phrase: 'Dangerous for bees and bumblebees. In order to protect bees and other pollinating insects, do not apply this product during flowering of crops or on crops that are not in flower, when these are actively visited by bees and bumblebees. Application is only allowed after the flowering of potato crops. Do not use this product in the proximity of self-propagating plants. Eliminate self-propagating plants before they flower'.

17. PAN Europe lodged an objection against the decision of 5 April 2019. By decision of 5 February 2020 ('the contested decision'), the CTB rejected the objection as unfounded. It is against that decision that PAN Europe brought an action before the referring court, seeking its annulment.

18. Before the referring court, PAN Europe claims that the CTB should not have extended Closer's authorisation to the use requested in the Netherlands market. It maintains that Ireland's assessment, which was followed by the CTB, was not based on current scientific and technical

[5] Commission Implementing Regulation of 27 July 2015 approving the active substance sulfoxaflor, in accordance with Regulation 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 (OJ 2015 L 199, p. 8).

[6] Guidance Document on Terrestrial Ecotoxicology, SANCO/10329/2002 rev. 2, 17 October 2002 ('the 2002 guidance document').

[7] EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees), *EFSA Journal*, 2013; 11(7):3295, published on 4 July 2013 ('the 2013 guidance document'). Indeed, EFSA has since (on 11 May 2023) published a new 'Revised guidance on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees)'. EFSA Journal.

knowledge. The 2002 guidance document is out of date and does not address sublethal effects, chronic effects, exposure through weeds, effects on reproduction and effects on bumblebees and solitary bees. According to PAN Europe, given that the 2002 guidance document is obsolete – as attested by the fact that there was a need to update that document and issue the 2013 guidance document, which contains new scientific knowledge – the assessment should have been based on the latter document. It argues that, in practice, the 2013 guidance document is not accepted by several Member States, due to the possibility of certain plant protection products being banned as a consequence.

19. PAN Europe considers that, by failing to take account of the 2013 guidance document, the CTB undermined the high level of protection of human and animal health and the environment sought by Regulation No 1107/2009. It points out that that document has been available since its publication in 2013 and that that regulation does not require there to be a majority position among the Member States in order for a guidance document to be applied. PAN Europe notes that Belgium has been applying the 2013 guidance document since November 2016.

20. Unlike the extension of the authorisation of the plant protection product Closer, the approval of the active substance sulfoxaflor in 2015 was based on the 2013 guidance document. A high risk to bees was identified on the basis of the data submitted by Dow. That data was not taken into account in the assessment at issue. Had the CTB taken it into account, it would have found the same risks. The restriction imposed is insufficient and, moreover, inapplicable, impracticable and unenforceable. It follows from the precautionary principle that, in the event of uncertainty as to effects, further research is necessary before a plant protection product can be authorised.

21. Taking the view that the resolution of the case in the main proceedings requires an interpretation of Article 36 of Regulation No 1107/2009 and of Article 47 of the Charter of Fundamental Rights of the European Union, the College van Beroep voor het bedrijfsleven (Administrative Court of Appeal for Trade and Industry) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

‘(1) Does the Member State concerned, which decides on the authorisation of a plant protection product under Article 36(2) of Regulation No 1107/2009, have any discretion to depart from the assessment of the zonal rapporteur Member State that examined the application under Article 36(1) of [that regulation] and, if so, what is the margin of that discretion?

(2) If the answer to the first question is that the Member State concerned has no or limited discretion, how is the right to an effective remedy under Article 47 of the Charter given effect? Is it then possible for the correctness of the zonal rapporteur Member State’s assessment to be fully challenged before the national court of the Member State concerned?

(3) If the Member State concerned, or the court of that Member State, concludes that the zonal rapporteur Member State’s assessment is based on insufficient grounds, to what extent is the Member State concerned required to involve the zonal rapporteur Member State in preparing an adequately reasoned assessment?

(4) Can the zonal rapporteur Member State confine itself to an assessment based exclusively on adopted guidance documents, even if the scientific and technical knowledge contained therein is no longer fully up to date?

(5) If the answer to the previous question is in the negative, can the Member State carrying out the zonal assessment additionally rely on scientific and technical knowledge contained in guidance documents which have already been drawn up but [have] not yet [been] adopted, or must the Member State carrying out the zonal assessment take account of all scientific and technical knowledge available even outside of the guidance documents?'

III. Procedure before the Court of Justice

22. Written observations were submitted by PAN Europe, Corteva Agriscience (formerly Dow AgroScience BV), the German and Greek Governments, Ireland and the Netherlands Government as well as by the Commission. No hearing was held.

IV. Assessment

23. As requested by the Court of Justice, the present Opinion will address the first, fourth and fifth questions referred only.

A. Introduction

24. By Question 1, the referring court seeks to know whether the Member State concerned, when deciding whether or not to authorise a plant protection product, has any discretion to depart from the risk assessment carried out by the zonal rapporteur Member State ('rapporteur Member State') in cooperation with the other Member States of the zone, under Article 36(2) of Regulation No 1107/2009. Questions 4 and 5 seek to determine what type of guidance documents and scientific and technical knowledge must be taken into account, under Article 36(1) of Regulation No 1107/2009, in the risk assessment by the rapporteur Member State.

25. Within the framework of these questions the Court is called upon to provide guidance on the tension that has become apparent between the purpose of Regulation No 1107/2009 'to ensure a high level of protection of both human and animal health and the environment' and the strict application of procedures by Member States under that regulation. Moreover, the present case is not an isolated one. In other Member States (in France, for instance) the same issues relating to the same active substance and plant protection product have given rise to disputes. In 2017, the *tribunal administratif de Nice* (Administrative Court, Nice, France) suspended the authorisation for two plant protection products made by Dow Chemical, citing uncertainty over environmental risks including their effects on bees. [8] The interlocutory ruling by that court overturned a decision by France's Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Agency for Food, Environmental and Occupational Health and Safety; ANSES) to grant authorisation for Closer (the very product at issue in the present case) and Transform plant protection products, which contain the active substance sulfoxaflor (also at issue in the present case). The case arose because environmental protection groups argued that authorisation of the above products was being phased out in France because they were potentially a factor in declining bee populations. As mentioned earlier, the European Union approved sulfoxaflor in 2015. Subsequently, ANSES authorised Closer, which contains sulfoxaflor, for use on straw

[8] See https://www.reuters.com/article/us-france-pesticides-idUSKBN1DO1M9.

cereals like wheat as well as fruit and vegetable crops, but prohibited it for crops that attract pollinating insects and for all crops during flowering periods, noting its potential toxic effects for bees.

B. Question 1

26. In view of the issues raised in points 18 to 20 of the present Opinion, the referring court wishes to know whether the Member State concerned (here, the Netherlands), when deciding on the authorisation of a plant protection product, is competent to depart from the rapporteur Member State's (here, Ireland) assessment carried out under Article 36(1) of Regulation No 1107/2009.

27. The referring court indicates that Article 36(2) of that regulation seems to maintain that the Member State concerned must, in principle, take the conclusions of the assessment of the rapporteur Member State as a basis for its own authorisation decision.

28. The referring court notes that, although Article 36(3) of Regulation No 1107/2009 provides that, by way of derogation from paragraph 2, appropriate conditions with respect to the requirements referred to in paragraphs 3 and 4 of Article 31 of that regulation and other risk mitigation measures may be imposed, those requirements must derive from specific conditions of use. However, in the case in the main proceedings, the question is whether the Member State concerned is allowed, in the context of examining an application for authorisation of the plant protection product on its territory, to carry out its assessment on the basis of other relevant scientific and technical knowledge (in particular, a newer guidance document than the one used by the rapporteur Member State). It follows from the order for reference that the referring court considered that an obligation to take into account the assessment of the rapporteur Member State as a fait accompli would not be compatible with the precautionary principle. It therefore took the view that it would be logical for the Member State concerned not to be automatically required to follow the rapporteur Member State's assessment.

29. In my view, it is useful briefly to recall the zonal authorisation procedure for plant protection products, as it is set out under Article 33 et seq. of Regulation No 1107/2009.

30. Under that procedure, the applicant makes a proposal as to which Member State it expects to act as the rapporteur. Once the proposal is accepted, the applicant submits to the rapporteur Member State an application for zonal authorisation, indicating in which other Member States in that zone it wishes to apply as well.[9] The applicant submits the application to all the Member States concerned in parallel. The necessary documentation is indicated in Article 33 of Regulation No 1107/2009.

31. Next, the rapporteur Member State assesses the application under Article 35 of that regulation. It is required to carry out 'an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application'.[10]

[9] Article 35 of Regulation No 1107/2009. See the explanation of the procedure in Verwaltungsgericht Braunschweig (Administrative Court, Braunschweig, Germany) (Ninth Chamber), judgment of 12 April 2018, 9 A 44/16 (paragraph 66 et seq.) ('the judgment of the *VG Braunschweig*'), which essentially concerned the grounds on which a Member State concerned is permitted to refuse authorisation of the plant protection product under Article 36(3) of Regulation No 1107/2009.

[10] Article 36(1) of Regulation No 1107/2009.

32. The rapporteur Member State is required to apply uniform principles for evaluation and authorisation of plant protection products [11] in order to establish, as far as possible, whether the plant protection product meets the requirements provided for in Article 29 in the same zone, where used in accordance with Article 55, and under realistic conditions of use. [12]

33. The Member States concerned suspend their assessment of the application until the rapporteur Member State has finished its assessment. [13]

34. In the course of its assessment, the rapporteur Member State prepares a draft assessment report and sends it for comment to the Member States in that zone. [14] Once the deadline for comments expires, the rapporteur Member State decides, for its territory, whether to grant or refuse authorisation for the plant protection product at issue and adopts the assessment report. Then it transmits that report and the copy of the authorisation to the other Member States of the zone.

35. Next, the Member States concerned will decide on the application in accordance with Article 36(2) and (3) of Regulation No 1107/2009 within 120 days of the receipt of that report and the copy of the authorisation. [15]

36. In the context of the authorisation system, as explained above, I will now turn to the interpretation of Article 36 of that regulation, at issue in the present case.

37. Recital 12 of Regulation No 1107/2009 clarifies that EFSA 'performs a risk assessment' whilst the Commission 'should perform the risk management role and take the final decision on an active substance'. The wording of Article 36 of that regulation suggests that there is a similar division of roles in relation to the plant protection product authorisation procedure: this time it is the rapporteur Member State which 'performs a risk assessment' and the Member State concerned which 'performs[s] the risk management role and take[s] the final decision [on such a product]' vis-à-vis its own territory. In order to answer the question of the referring court, first, the nature of the relationship between those two roles needs to be established.

38. Article 36(2) of Regulation No 1107/2009 provides that a Member State concerned is to grant or refuse authorisations 'on the basis of the conclusions of the assessment' carried out by the rapporteur Member State. The term 'on the basis of' connects the two procedural steps and characterises the relationship between the role of a risk assessor and that of a risk manager by indicating that the two tasks are interlinked, but at the same time, each has its own specific purpose.

39. It is true that the system for the authorisation of plant protection products is based on mutual trust among Member States and aims to avoid duplication of work by Member States. To achieve that goal, the above regulation provides for a careful and purposeful step-by-step procedure with a clear division of tasks among the authorities involved. It follows from that procedure that the rapporteur Member State undertakes the first mandatory procedural step in that administrative

[11] Referred to in Article 29(6) of Regulation No 1107/2009 'uniform principles for evaluation and authorisation of plant protection products shall contain the requirements set out in Annex VI to Directive 91/414/EEC and shall be laid down in Regulations adopted in accordance with the advisory procedure referred to in Article 79(2) without any substantial modifications'. See point 71 of the present Opinion.

[12] Second subparagraph of Article 36(1) of Regulation No 1107/2009.

[13] Third paragraph of Article 35 of Regulation No 1107/2009.

[14] Third subparagraph of Article 36(1) of Regulation No 1107/2009.

[15] Article 37(4) of Regulation No 1107/2009.

process and delivers an assessment on the authorisation of the plant protection product in the zone. It is then followed by the next intrinsically connected procedural step, which is executed by a Member State concerned. Thus, the rapporteur Member State's assessment serves as a prerequisite for a Member State concerned to exercise its own powers within the system, that is, to take a final decision as to the authorisation of that plant protection product in its own territory. Clearly the step taken by a rapporteur Member State and the step taken by a Member State concerned are connected.

40. Second, on the basis of the established nature of the relationship, the powers of a Member State concerned need to be clarified. First, the connection between the two steps indicates that the rapporteur Member State and each Member State concerned intervene, at different stages, in a single administrative process initiated by the applicant. The Member State concerned, which completes that process, therefore does not have a power of review of the conclusions of the assessment carried out by the rapporteur Member State. As a result, it cannot review the legality of those conclusions of the rapporteur Member State,[16] as that would go against the mutual trust and completeness of the process built into the system established under Regulation No 1107/2009.

41. However, the fact that the stage of the procedure involving the rapporteur Member State and the stage of the procedure involving the Member State concerned are connected, and the fact that the latter cannot review the conclusions of the assessment carried out by the former does not mean that the discretion of a Member State concerned is completely eliminated. Quite the opposite, as the wording of Article 36(2) of Regulation No 1107/2009 'grant or refuse … *on the basis of the conclusions* of the assessment carried out by [the rapporteur] Member State' itself indicates, that assessment, although important, is only one of the documents that the Member State concerned must consult; it is not a final decision on the authorisation of that plant protection product in all the Member States of the zone. As the German Government rightly pointed out, given that the Member State concerned takes its decision 'on the basis of the conclusions', the above provision foresees a certain *possibility of departing*, in justified cases, from the decision of the rapporteur Member State. It therefore seems clear to me that the language adopted by the EU legislature does not require the Member State concerned to grant or refuse authorisations *by automatically following the approach taken by the rapporteur Member State*.

42. In fact, a departure from the conclusions of the assessment of the rapporteur Member State is already expressly provided for in Regulation No 1107/2009 in Article 36(3), showing that the metaphorical hands of a Member State concerned are not completely tied by the assessment of a rapporteur Member State.

43. Article 36(3) states in the first subparagraph that 'by way of derogation from [Article 36(2)] and subject to [EU] law, appropriate conditions may be imposed with respect to the requirements referred to in Article 31(3) and (4) and other risk mitigation measures deriving from specific conditions of use'.

44. Then, in the second subparagraph of Article 36(3), it explains that 'where the concerns of a Member State relating to human or animal health or the environment cannot be controlled by the establishment of the national risk mitigation measures referred to in the first subparagraph, a Member State may refuse authorisation of the plant protection product in its territory if, due to its

[16] This is also the view defended in national case-law. See the judgment of the *VG Braunschweig* (paragraph 74).

specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment'.

45. The second subparagraph of Article 36(3) uses the terms 'may refuse', which implies a margin of discretion on the part of the Member State concerned. However, there are certain limits imposed by that article: 'if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment'.

46. Therefore, according to the wording of Article 36(3), the Member State concerned is allowed to depart from the assessment of the rapporteur Member State. Such explicit recognition of the rights of a Member State concerned sheds light on the context in which the EU legislature sees the role of risk management to be carried out by that Member State in the authorisation process.

47. Therefore, it is important that Article 36(2) not be interpreted in isolation.[17] It is apposite to apply a systemic approach and interpret that provision in the context in which it occurs, that is by considering its place within a complete set of rights accorded to a Member State concerned in order to control which plant protection products are allowed to be placed and maintained on the market of the Member State in question.

48. Such control involves not only allowing plant protection products to be placed on the market but also the review and withdrawal of any authorisation granted. Article 44 of Regulation No 1107/2009 stipulates the procedure and conditions for the withdrawal or amendment of an authorisation of a plant protection product, thus completing the set of powers accorded to a Member State concerned. It is therefore in the context of those provisions that Article 36(2) should be interpreted. It is evident that the two articles are interlinked elements of the system of authorisation, as Article 44(4) makes an explicit reference to Article 36(3) and provides for an analogous derogation, but in a situation where an authorisation has already been given and it is now subject to being amended or withdrawn.

49. However, the essence of the authorisation and control system of plant protection products and the scope of rights accorded to a Member State concerned become evident from reading Article 44(1) and (3) of Regulation No 1107/2009. Under those provisions, Member States may review an authorisation at any time, in particular, where there are indications that any of 'the requirements referred to in Article 29 [of that regulation] are not or are no longer satisfied'.[18] If the Member State concludes that those requirements are no longer met, it is to withdraw or amend an authorisation.

50. Moreover, Article 44 states that it is a 'Member State' that is to review, withdraw or amend the authorisation, and sets out exhaustive conditions for using those rights. It does not provide that such a review, withdrawal or amendment is conditional upon prior changes to the assessment having been made by the rapporteur Member State. It follows that that right of a 'Member State' constitutes an autonomous right, which a Member State concerned exercises independently of the rapporteur Member State. For the purposes of the present case it is important to note that one of

[17] Indeed, for the purpose of interpreting provisions, it is necessary to consider not only their wording but also the context in which they occur and the objectives pursued by the rules of which they form part (judgment of 2 March 2023, *Staatsanwaltschaft Graz (Düsseldorf tax office for criminal tax matters)* (C-16/22, EU:C:2023:148, paragraph 25 and the case-law cited).

[18] Article 44(3)(a) of Regulation No 1107/2009.

the conditions for the mandatory withdrawal of an authorisation is set out in Article 44(3)(a) and requires the Member State to review and withdraw or amend the authorisation if 'the requirements referred to in Article 29 are not or are no longer satisfied'.

51. As the Court recalled in the judgment in *Blaise*,[19] 'it follows from Article 44(1) and (3) of [Regulation No 1107/2009] that the authorisation of a plant protection product may be reviewed, then amended or withdrawn, where, inter alia, it is apparent from developments in scientific and technical knowledge that the product does not satisfy or no longer satisfies the requirements for a marketing authorisation laid down in Article 29 of that regulation, including the requirement that it has no immediate or delayed harmful effect on human health'.

52. Therefore, Article 36(2) read in the context of the whole system of authorisation, amendment and withdrawal of plant protection products under Regulation No 1107/2009, and of Article 44 in particular, calls for the rights of Member States concerned under Article 36(2) to be interpreted sufficiently broadly so as to allow such a Member State to observe Article 29 of that regulation when deciding upon an application for the authorisation of a plant protection product. If it is possible to *withdraw* an authorisation,[20] when scientific and technical knowledge available to a Member State indicates that there may be harmful effects on human or animal health or unacceptable effects on the environment, the same power should be available to a Member State concerned when it assesses a request for a new authorisation, in order to avoid such harmful effects in the first place. Such a right is, however, conditional upon the existence of current scientific or technical knowledge of harmful effects, referred to above, which a rapporteur Member State had not taken into consideration during its assessment procedure.

53. Indeed, a Member State cannot have more rights to withdraw an authorisation than it had to grant or refuse it.[21] If the EU legislature has explicitly obliged the Member State to act in order to eliminate any harmful effects that an authorised plant protection product may have on human or animal health or any unacceptable effect such a product may have on the environment where current scientific or technical knowledge indicates such effects, the same obligation is implied in the authorisation process so as to avoid such effects from appearing. As noted in the introductory part of the present Opinion, plant protection product pollution causes loss of biodiversity and significant decline in insect populations, threatening the critical role they play in food production. It is further acknowledged that exposure to chemical plant protection products is linked to chronic illnesses such as cancer and heart, respiratory and neurological diseases.[22] Therefore, it should be within the powers of a Member State concerned to prevent such effects from happening or to minimise them.

54. It follows from these considerations that the wording in Article 36(2) 'on the basis of the conclusions of the assessment' must be interpreted as including the power of a Member State concerned to *refuse* to grant an authorisation if – on the basis of developments in scientific or technical knowledge – it is apparent that the plant protection product does not satisfy the requirements laid down in Article 29 and Article 4(3) of that regulation, including the requirement that there should be no harmful effect on human or animal health or unacceptable effect on the environment.

[19] Judgment of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraph 99; 'the judgment in *Blaise*').

[20] Article 44(3) of Regulation No 1107/2009.

[21] The same argument is used in national case-law. See the judgment of the tribunal administratif (Administrative Court, Luxembourg), No 44377, in the Glyphosate case, p. 37 (upheld on appeal by the judgment of the Cour administrative (Higher Administrative Court, Luxembourg), No 47873C, 30 March 2023).

[22] See point 2 of the present Opinion.

55. In other words, the fact that Regulation No 1107/2009 explicitly makes it possible for a Member State to take away or change an authorisation, based on scientific or technical knowledge, implies that it must be entitled also not to grant such authorisation in the first place.

56. Therefore, a Member State concerned can refuse an authorisation within the meaning of Article 36(2) of Regulation No 1107/2009 *in a situation where current scientific or technical knowledge indicates that 'the requirements referred to in Article 29 [of that regulation] are not or are no longer satisfied'* [23] in relation to the plant protection product in question.

57. Furthermore, the above interpretation follows from the very nature of the precautionary principle, according to which it is necessary to take preventive action in order to avoid potential risks to human or animal health or the environment.

58. Indeed, Article 1(4) of Regulation No 1107/2009 states that that regulation's provisions 'are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory'. [24]

59. In relation to the precautionary principle, the Court has already held on several occasions that 'a correct application of that principle in the area covered by Regulation No 1107/2009 presupposes, first, identification of the potentially negative consequences for health [or the environment] of the use of the active substances and plant protection products falling within its scope, and, second, a comprehensive assessment of the risk to health [or the environment] based on the *most reliable scientific data available* and the *most recent results of international research*'. [25]

60. I agree with the referring court [26] that to accept the argument that the Member State concerned must do little more than systematically follow the conclusions of the assessment of the rapporteur Member State would be incompatible with the precautionary principle.

61. It may be pointed out in that connection that the General Court has already had an opportunity to rule – in relation to the same active substance as the one at issue in the present case (sulfoxaflor) – essentially that Member States enjoy considerable discretion, in particular with regard to complex technical assessments and the determination of authorisation conditions specific to the situation prevailing in their territory. [27]

[23] The cited terms are from Article 44(3) of that regulation. Emphasis added.

[24] See also the judgment in *Blaise* (paragraph 44).

[25] Emphasis added. See the judgment in *Blaise* (paragraph 46 and the case-law cited) and judgment of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C-77/09, EU:C:2010:803, paragraph 75).

[26] See points 11.3 to 13 of the original language version of the order for reference.

[27] Order of 28 September 2016, *PAN Europe and Others* v *Commission* (T-600/15, EU:T:2016:601, paragraph 33) (not appealed to the Court of Justice).

62. As the Court confirmed in a recent judgment,[28] 'it is clear, as stated in recital 24 of Regulation No 1107/2009, that the provisions governing authorisations must ensure a high standard of protection and that, in particular, when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should "take priority" over the objective of improving plant production'.

63. It follows from the foregoing considerations that Question 1 must be answered as follows: Article 36(2) of Regulation No 1107/2009 must be interpreted as allowing the Member State concerned, when examining an application for authorisation of a plant protection product, to depart from the assessment of the rapporteur Member State, and as giving it a right to refuse a requested authorisation in a situation where current scientific or technical knowledge indicates that the requirement that there should be no harmful effect on human or animal health or unacceptable effect on the environment is not or is no longer satisfied in relation to the plant protection product in question.

C. Questions 4 and 5

64. According to Question 4, the referring court is uncertain how the phrase 'current scientific and technical knowledge using guidance documents available at the time of application' should be interpreted. According to the CTB, relying on Article 77 and Article 79(2) of Regulation No 1107/2009, that wording requires the rapporteur Member State to carry out its assessment taking into account the guidance document *adopted* by the Commission. PAN Europe, on the other hand, considers that it is sufficient that the guidance document has been *published* without it having to have been adopted by the Commission, and that the 2013 guidance document contains the most recent scientific and technical knowledge relevant to the present case.

65. As regards Question 5, assuming that the rapporteur Member State cannot limit its assessment solely to the guidance documents *adopted*, the referring court wishes to know whether it is sufficient for it to carry out that assessment on the basis of the guidance documents available, or whether it must take account of all scientific and technical knowledge, even beyond the guidance documents available.

66. It should be noted, as a preliminary point that in Questions 4 and 5 the referring court does not identify the specific articles of Regulation No 1107/2009 it seeks to have interpreted and which stipulate the duty to consider the relevant guidance documents referred to in those questions. Nevertheless, according to the Court's case-law, 'under the cooperation procedure provided for in Article 267 TFEU, even if, formally, the referring court has limited its question to the interpretation of a particular provision of EU law, that does not prevent the Court from providing the referring court with all the elements of interpretation of EU law which may be of assistance in adjudicating in the case pending before it, whether or not the referring court has referred to them in the wording of its questions. It is, in this regard, for the Court to extract from all the information provided by the national court, in particular from the grounds of the decision to make the reference, the points of EU law which require interpretation in view of the subject matter of the dispute in the main proceedings'.[29] It is clear from the order for reference that these

[28] Judgment of 19 January 2023, *Pesticide Action Network Europe* (C-162/21, EU:C:2023:30, paragraph 48 and the case-law cited).

[29] Judgment of 1 August 2022, *TL (Absence of an interpreter and of translation)* (C-242/22 PPU, EU:C:2022:611, paragraph 37 and the case-law cited).

two questions referred concern the interpretation of Article 36(1) of that regulation and in particular the wording 'current scientific and technical knowledge using guidance documents available at the time of application' contained therein.

67. In those circumstances, it must be considered that, by Questions 4 and 5, which must be answered together, the referring court asks the Court of Justice to determine whether the rapporteur Member State can, under Article 36(1) of Regulation No 1107/2009, confine itself to an assessment based exclusively on adopted guidance documents, even if the scientific and technical knowledge contained therein is no longer up to date, or whether that Member State must take account of all scientific and technical knowledge available even outside of those guidance documents.

68. First, Article 29, entitled 'Requirements for the authorisation for placing on the market', provides in paragraph (1)(e) that 'without prejudice to Article 50 a plant protection product shall only be authorised where following the uniform principles referred to in paragraph 6 it complies with the following requirements: … in the light of current scientific and technical knowledge, it complies with the requirements provided for in Article 4(3)'.

69. In relation to that wording, the Court clarified in the judgment in *Blaise* (paragraph 71) that 'pursuant to Article 29(1)(e) of Regulation No 1107/2009, one of the requirements imposed if a plant protection product is to be authorised is that it must, in the light of current scientific and technical knowledge, comply with the conditions laid down in Article 4(3) of that regulation'.

70. As the referring court pointed out, the precautionary principle also militates in favour of taking into account all available scientific and technical knowledge, since that principle requires an overall assessment based on the most reliable scientific data available and the most recent results of international research. [30]

71. Second, as regards the 'uniform principles', these have been set out in Regulation (EU) No 546/2011, [31] which implements Regulation No 1107/2009. The former regulation's Annex ('Uniform principles for evaluation and authorisation of plant protection products, as provided for in Article 29(6) of Regulation [No 1107/2009]'), Part I ('Uniform principles for evaluation and authorisation of chemical plant protection products'), Part A ('Introduction'), point 2, provides that 'in evaluating applications and granting authorisations Member States shall: … (c) *take into consideration other relevant technical or scientific information they can reasonably possess with regard to the performance of the plant protection product or to the potentially adverse effects* of the plant protection product, its components or its residues' (emphasis added). Moreover, Part B of Part I of that annex ('Evaluation'), point 1 ('General principles'), under point 1.1, provides that '*having regard to current* scientific and technical knowledge, Member States *shall evaluate* the information referred to in point 2 of Part A …' (emphasis added).

72. I would underline also the applicant's obligation under Article 33 of Regulation No 1107/2009 to furnish information, evidence and documentation underlying its application for the authorisation of a plant protection product (including any information on potentially harmful effects of the product on human and animal health or on the environment, as well as known and

[30] See the judgment in *Blaise* (paragraphs 46 and 94).

[31] Commission Regulation of 10 June 2011 implementing Regulation No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ 2011 L 155, p. 127). Regulation No 546/2011 was amended in 2022, but the changes do not appear pertinent or decisive for the purposes of the present case.

expected cumulative and synergistic effects caused by such interaction)[32] and the possibility, under Article 37 of that regulation, for the rapporteur Member State, during its examination of the application, which is not limited to an examination of the information and evidence submitted by the applicant, to request additional information.

73. As pointed out by the German Government, in view of the wording in Article 36(1) of that regulation that 'the Member State … shall make an … assessment in the light of current scientific and technical knowledge *using* guidance documents available at the time of application' (emphasis added), that provision should be interpreted as meaning that, in addition to the available guidance documents (that is to say both adopted guidance and published but not yet adopted guidance), other more recent information must also be taken into account in the authorisation decision-making process. In that regard, it is necessary to take into account the fact that Article 36(1) envisages not only the use of guidance documents, but also the consideration of 'current scientific and technical knowledge'. Article 44(3) (on the withdrawal or amendment of an authorisation) refers to that knowledge as well.

74. Importantly, one should bear in mind that the guidance documents are what their name suggests: they seek to provide guidance, but they are as such not established by Regulation No 1107/2009 as a *conditio sine qua non*. They constitute soft law that exists in order to help Member States apply applicable rules and principles (for instance, in the context of the assessment and authorisation of plant protection products) in a consistent, uniform and transparent manner. This is confirmed by Article 77 of that regulation, which provides explicitly that the Commission 'may' adopt such guidance documents. It follows that if there are no guidance documents or if the existing guidance documents are obsolete (that is to say they no longer represent 'current scientific and technical knowledge'), then the Member States are obliged under that regulation to carry out the assessment and adopt authorisation decisions based on other available sources that do contain most recent scientific and technical knowledge.

75. The doubts of the referring court could also follow in part from the fact that the Dutch language version of Article 36(1) of Regulation No 1107/2009 seems to be incorrect or, in any case, imprecise, when compared to other language versions. Indeed, it says 'van de stand van de wetenschappelijke en technische kennis' ('in the state of scientific and technical knowledge') omitting an equivalent word to 'current', whereas, for instance, the French, Italian, German and English versions talk respectively about 'à la lumière des connaissances scientifiques et techniques *actuelles*' ('current'), 'conoscenze scientifiche e techniche *attuali*' ('current'), 'des *neuesten* Stands von Wissenschaft und Technik' ('newest') and '*current* scientific and technical knowledge'.

76. Therefore, I am of the view that while it is true that 'available' guidance documents (see point 73 of the present Opinion) are a reference point for scientific and technical knowledge which the Member States should consider when assessing the application for the authorisation of a plant protection product, *neither the rapporteur Member State* which prepares the risk assessment, *nor the Member States concerned*, which examine the application for authorisation, *are limited to that source of information when evaluating 'current scientific and technical knowledge', on the basis, in particular, of Article 36(1) and (2) and Article 29(1)(e) of Regulation No 1107/2009.*[33]

77. It follows that all the information considered to be current and relevant 'scientific and technical knowledge' should be taken into consideration.

[32] See, in this regard, the judgment in *Blaise* (paragraphs 73, 74 and 78 to 88).

[33] See Regulation No 546/2011, as cited in point 71 of the present Opinion.

78. This approach is confirmed by the objectives of Regulation No 1107/2009. The Court has recalled these objectives already in the judgment in *Pesticide Action Network Europe*.[34]

79. It held in that judgment that 'the objective of Regulation No 1107/2009 … is, as stated in Article 1(3) and (4) of that regulation and reflected in recital 8 thereof, in particular to ensure a high level of protection of human and animal health and the environment' (paragraph 46).

80. In that regard, it pointed out that 'those provisions are based on the precautionary principle, which is one of the bases of the policy of a high level of protection pursued by the European Union in the field of the environment, in accordance with the first subparagraph of Article 191(2) TFEU, in order to prevent active substances or products placed on the market from harming human or animal health or the environment' (paragraph 47).

81. Furthermore, it recalled that 'as stated in recital 24 of Regulation No 1107/2009, … the provisions governing authorisations must ensure a high standard of protection and that, in particular, when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should "take priority" over the objective of improving plant production' (paragraph 48).

82. Consequently, the Court ruled that 'as stated in that recital, it should be demonstrated, before they are placed on the market, not only that plant protection products present a clear benefit for plant production but also that they do not have any harmful effect on human or animal health' (paragraph 49).

83. The aforementioned goal can be achieved only where current (that is to say the most recent) scientific and technical knowledge is taken into account when the rapporteur Member State is carrying out its assessment and when the Member State concerned is deciding whether to grant or refuse authorisation for the plant protection product. It is the only way in which a Member State can demonstrate that, to its best knowledge, there is no harmful effect on human or animal health or the environment as far as the plant protection product in question is concerned.

84. As pointed out by the referring court, such an interpretation is confirmed by the Court's existing case-law.

85. In the judgment in *Bayer CropScience and Bayer* v *Commission*,[35] the Court held that 'in the context of the review of the approval of an active substance, the conclusion that the approval criteria laid down in Article 4 of Regulation No 1107/2009 are no longer satisfied *may be based on any new knowledge, in so far as it is scientific or technical, regardless of the source or document from which it comes*' (emphasis added).

86. As Ireland rightly pointed out, the fact that that case dealt with the reassessment of the authorisation of an *active substance* is not decisive. Indeed, there is no reason to consider that the same conclusion would not apply to the assessment of an application for authorisation of a *plant protection product*, as a contrary interpretation would not be in line with the precautionary principle, which underpins Regulation No 1107/2009.

[34] Judgment of 19 January 2023 (C-162/21, EU:C:2023:30, paragraphs 46 to 49).

[35] Judgment of 6 May 2021 (C-499/18 P, EU:C:2021:367, paragraph 69).

87. It follows from the foregoing considerations that the answer to Questions 4 and 5 should be that, in examining an application for authorisation of a plant protection product, under Article 36(1) of Regulation No 1107/2009, a Member State should take into account any pertinent and reliable current (that is to say the most recent) scientific and technical knowledge regardless of the source or document from which it comes.

V. Conclusion

88. I propose that the Court of Justice answer the first, fourth and fifth questions referred for a preliminary ruling by the College van Beroep voor het bedrijfsleven (Administrative Court of Appeal for Trade and Industry) as follows:

Question 1:

Article 36(2) of 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,

must be interpreted as allowing the Member State concerned, when examining an application for authorisation of a plant protection product, to depart from the assessment of the zonal rapporteur Member State, and as giving it a right to refuse a requested authorisation in a situation where current scientific or technical knowledge indicates that the requirement that there should be no harmful effect on human or animal health or unacceptable effect on the environment is not or is no longer satisfied in relation to the plant protection product in question.

Questions 4 and 5:

Article 36(1) of Regulation No 1107/2009

must be interpreted as follows: in examining an application for authorisation of a plant protection product, under that provision, a Member State should take into account any pertinent and reliable current (that is to say the most recent) scientific and technical knowledge regardless of the source or document from which it comes.