Reports of Cases

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

Joined Cases C-309/22 and C-310/22

Pesticide Action Network Europe (PAN Europe)
v
College voor de toelating van gewasbeschermingsmiddelen en biociden,
joined parties:
Adama Registrations BV (Adama),
BASF Nederland BV

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

(References 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 – Criteria – Endocrine disrupting properties – Regulation (EU) 2018/605 – Transitional regime – Application of criteria to pending procedures – Current state of scientific and technical knowledge – State of scientific and technical knowledge at the time of the application or of the decision – Precautionary principle)

1. The present references for a preliminary ruling from the College van Beroep voor het bedrijfsleven (Administrative Court of Appeal for Trade and Industry, Netherlands) seek an interpretation of Article 2 of Regulation (EU) 2018/605, [2] Article 4(1) and (3) and Article 29(1)(e) of Regulation (EC) No 1107/2009, [3] and Article 47 of the Charter of Fundamental Rights of the European Union ('the Charter').

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'. [4] The present cases are important in that they raise the question whether Member States should, in the context of authorising plant protection products, 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 Commission Regulation 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 (OJ 2018 L 101, p. 33).

3 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).

4 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 (pesticides) authorised and marketed across the European Union.[5] It is against this background that I will attempt to address the questions raised by the present references for a preliminary ruling.

4. The first action in the main proceedings (Case C-309/22) 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 authorise the placing of the plant protection product Pitcher – containing the active substance fludioxonil – on the Netherlands market.

5. The second action in the main proceedings (Case C-310/22) was brought by PAN Europe against the CTB in relation to the latter's rejection of PAN Europe's objection against the decision of the CTB to authorise the placing of the plant protection product Dagonis – containing the active substance difenoconazole – on the Netherlands market.

6. The background to the present cases is that the active substances in the plant protection products in both cases – Pitcher and Dagonis – allegedly have endocrine disrupting properties. Endocrine disruptors are currently a topic of much debate and concern. A large body of evidence has been accumulated indicating that some substances (both natural and manmade) interfere with the function of hormones in the body and have disruptive effects. Nevertheless, there remain significant challenges ahead, particularly since it is difficult to evaluate the precise effect that endocrine disrupting chemicals have as regards disease in humans or other organisms. These chemical substances, present in many products used in daily life, have a similar chemical structure to hormones naturally produced by the body; once in contact with the hormonal system, they can disrupt its proper functioning.[6]

7. Having regard to the foregoing, the Court is called upon to rule on the division of competences of the authorities involved in the authorisation of plant protection products, under Regulation No 1107/2009, in particular, in relation to the questions whether and how the most recent scientific and technical knowledge should be taken into consideration in that authorisation process.

8. Lastly, I would point out that the present cases are related to Case C-308/22, PAN Europe (Closer), which was referred by the same national court. My Opinion in that case is also being delivered today and the two Opinions should be read together.

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

[6] European Parliament (Dinu, A.), 'Endocrine Disruptors: An Overview of Latest Developments at European Level in the Context of Plant Protection Products', Brussels, European Parliamentary Research Service, 2019, pp. 5 and 42. See also Kalofiri, P., Balias, G., Tekos, F., 'The EU endocrine disruptors' regulation and the glyphosate controversy', *Toxicology Reports*, Vol. 8, 2021, pp. 1193 to 1199.

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

A. Case C-309/22 (concerning Pitcher)

9. Pitcher, a plant protection product, is a fungicide[7] for professional use intended for the immersion treatment of certain flower bulbs and tubers and for the treatment of certain perennial and floricultural crops. It is composed of a mixture of the active substances fludioxonil and folpet and seven formulation auxiliaries.

10. At the time the preliminary reference was made, the validity of the approval of fludioxonil as an active substance in the European Union had been extended until 31 October 2022.[8] The validity of the approval of folpet as an active substance in the European Union had also been extended until 31 July 2022.[9]

11. According to the referring court, *at the time of the facts in the main proceedings*, no decision had yet been taken on the requests for renewal of the approvals of those active substances.

12. A plant protection product 'shall only be authorised where [inter alia] its active substances … have been approved'.[10]

13. On 15 September 2015, Adama Registrations BV (Adama) applied in the Netherlands for a first marketing authorisation for Pitcher.

14. By decision of 4 October 2019, the CTB granted Pitcher's Netherlands marketing authorisation until 31 July 2021.

15. PAN Europe's objection against that decision was rejected by the CTB by decision of 2 September 2020.

16. PAN Europe therefore brought an action for annulment of that decision before the College van Beroep voor het bedrijfsleven (Administrative Court of Appeal for Trade and Industry), the referring court.

7 The EEA defines it as: 'Chemicals used to kill or halt the development of fungi that cause plant disease, such as: storage rot; seedling diseases; root rots; vascular wilts; leaf blights, rusts, smuts and mildews, and viral diseases. These can be controlled by the early and continued application of selected fungicides that either kill the pathogens or restrict their development.'

8 Commission Implementing Regulation (EU) 2021/1449 of 3 September 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, etofenprox, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sulphur, tetraconazole, tri-allate, triflusulfuron and tritosulfuron (OJ 2021 L 313, p. 20).

9 Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, benthiavalicarb, bifenazate, boscalid, calcium carbonate, captan, carbon dioxide, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distilation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxyloglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils/rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/ sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea (OJ 2021 L 160, p. 89).

10 See Article 29(1)(a) of Regulation No 1107/2009.

17. Before the referring court, PAN Europe claims that the CTB made an error in granting Pitcher's Netherlands marketing authorisation because it did not assess Pitcher's endocrine disrupting properties, even though the active substance fludioxonil has such properties. According to PAN Europe, when deciding on the authorisation, the CTB must assess the endocrine disrupting properties of a plant protection product in the light of the state of scientific and technical knowledge at the time the decision on that application is being made.

18. Taking the view that resolution of the dispute before it requires an interpretation of Article 2 of Regulation 2018/605 and Article 4(3) and Article 29(1)(e) of Regulation No 1107/2009, 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 Article 2 of Regulation 2018/605 imply that the competent authority must also apply the new criteria for the determination of endocrine disrupting properties in the assessment and decision-making process relating to applications for authorisation which were still pending on 10 November 2018, also in view of Article 29(1)(e) in conjunction with Article 4(3) of Regulation No 1107/2009?

(2) If the answer to the first question is in the negative, is it incumbent on the competent authority to stay the assessment and decision-making process relating to applications for authorisation pending the findings of the European Commission on the effects of Regulation 2018/605 on any proceedings pending under Regulation No 1107/2009, having regard to recital 8 of the preamble to Regulation 2018/605?

(3) If the answer to that second question is in the negative, is it sufficient for the competent authority to make an assessment solely on the basis of data known at the time of the application, even if the scientific and technical knowledge reflected therein is no longer current at the time when the contested decision is taken?'

B. Case C-310/22 (concerning Dagonis)

19. Dagonis, a plant protection product, is a fungicide intended, inter alia, to combat powdery mildew and the septoria leaf spot. It contains the active substances difenoconazole and fluxapyroxad.

20. Difenoconazole was included in Annex I to Directive 91/414/EEC[11] by Directive 2008/69/EC,[12] with effect from 1 January 2009. After the entry into force of Regulation No 1107/2009, that inclusion of difenoconazole was converted into an approval of an active substance under that regulation by Regulation (EU) No 540/2011.[13] The period of validity of the approval of difenoconazole was extended several times, inter alia by Regulation 2021/1449, which extended that period of validity until 31 December 2022.

[11] Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1).

[12] Commission Directive of 1 July 2008 amending Council Directive 91/414 to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances (OJ 2008 L 172, p. 9).

[13] Commission Implementing Regulation of 25 May 2011 implementing Regulation No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ 2011 L 153, p. 1).

21. The referring court states that Regulation (EU) 2015/408 [14] designates the active substance difenoconazole as a candidate for substitution.

22. The active substance fluxapyroxad was approved as an active substance by Regulation (EU) No 589/2012, [15] with effect from 1 January 2013, with a period of validity until 31 December 2022.

23. BASF Nederland BV ('BASF') applied for authorisation of Dagonis in several Member States. The application for authorisation in the Netherlands was submitted on 22 January 2016.

24. The United Kingdom assessed the authorisation of Dagonis as the rapporteur Member State for the Central Zone (which includes the Netherlands). The Netherlands was a Member State concerned.

25. By decision of 3 May 2019, the CTB granted Dagonis marketing authorisation in the Netherlands until 31 December 2020 for the treatment of potatoes, strawberries and various vegetables, herbs and flowers.

26. PAN Europe lodged an objection against that decision before the CTB.

27. By decision of 13 November 2019, declaring that objection to be in part well founded and in part unfounded, the CTB confirmed the decision of 3 May 2019, while amending its grounds.

28. PAN Europe brought an action before the referring court, seeking annulment of the decision of 13 November 2019.

29. Before the referring court, PAN Europe claims that the CTB's decision to authorise Dagonis is vitiated by its failure to take into account its endocrine disrupting properties, even though it is known that the active substance difenoconazole has such properties, based on the dossier provided by BASF and six studies submitted by PAN Europe.

30. Taking the view that resolution of the dispute before it requires an interpretation of EU law, 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 it follow from the second paragraph of Article 4(1) of Regulation No 1107/2009, in conjunction with [point] 3.6.5 of Annex II thereto, that the potential endocrine disrupting properties of an active substance need no longer be assessed during the assessment at national level of an application for authorisation of a plant protection product?

[14] Commission Implementing Regulation of 11 March 2015 on implementing Article 80(7) of Regulation No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution (OJ 2015 L 67, p. 18).

[15] Commission Implementing Regulation of 4 July 2012 approving the active substance fluxapyroxad, 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 No 540/2011 (OJ 2012 L 175, p. 7).

(2) If the answer to the first question is in the affirmative, does it mean that the scientific insights and technical knowledge relating to endocrine disrupting properties, which, for example, underpin Regulations No 283/2013 and 2018/605, need not be taken into account when assessing the authorisation of a plant protection product? How does that relate to the requirement of Article 29(1)(e) of Regulation No 1107/2009 that such an assessment must be conducted on the basis of current scientific and technical knowledge?

(3) If the answer to the first question is in the affirmative, how can a non-governmental organisation such as [PAN Europe] be said to have an effective remedy under Article 47 of the Charter to refer the approval of an active substance to a court of law?

(4) If the answer to the first question is in the negative, does it mean that, when assessing an application for authorisation, the state of scientific and technical knowledge about that endocrine disrupting property at that time is decisive?'

II. Procedure before the Court of Justice

31. Written observations were submitted by PAN Europe, BASF, the Czech, Greek and Netherlands Governments as well as by the Commission. No hearing was held.

III. Assessment

32. As requested by the Court of Justice, the present Opinion will focus only on Question 1 in each of these Joined Cases.

A. Introduction

33. The referring court points out in Case C-309/22 that, in order to resolve the case in the main proceedings, it is necessary first of all to answer a preliminary question, that being whether endocrine disrupting properties must be assessed when an application for authorisation of a plant protection product is examined at national level. The referring court notes that it has already referred that question to the Court in Case C-310/22.

34. If the answer to the preliminary question is in the affirmative, the referring court seeks to know whether Article 2 of Regulation 2018/605 implies that the competent authority must also apply the new criteria for the determination of endocrine disrupting properties in the assessment and decision-making process relating to applications for authorisation which were still pending on 10 November 2018 (the date from which that regulation applied), also in view of Article 29(1)(e) in conjunction with Article 4(3) of Regulation No 1107/2009. Indeed, the application for authorisation of Pitcher was submitted before that date (on 15 September 2015) and the CTB adopted a decision thereon after that date (on 4 October 2019). Therefore, Regulation 2018/605 became applicable whilst that application was still pending.

35. I consider that the above 'preliminary' question in Case C-309/22 – which corresponds to Question 1 in Case C-310/22 – and Question 1 in Case C-309/22 must be analysed together.

36. That being said, Article 2 of Regulation 2018/605, raised in Question 1 of Case C-309/22, does not need to be interpreted by the Court for the purposes of the resolution of the present case. [16]

37. First, that provision states that 'points 3.6.5 and 3.8.2 of Annex II to Regulation [No 1107/2009], as amended by … Regulation [2018/605], shall apply as of [10 November] 2018, except for procedures where the Committee has voted on a draft Regulation by [10 November] 2018'. According to a generally accepted principle, the laws amending a legislative provision apply, unless otherwise provided, to the future consequences of situations which arose under the former law. [17] Since the conditions of the exception in the last clause of Article 2 of Regulation 2018/605 are not met in the present case and do not apply to the authorisation procedure for Pitcher (which does not provide for such a vote), the new criteria are liable to be taken into account.

38. Secondly, the abovementioned Annex II is devoted to the 'Procedure and criteria for the approval of *active substances*, safeners and synergists pursuant to Chapter II' of Regulation No 1107/2009 (in other words, Annex II and Chapter II deal, in particular, with the approval of active substances and not with the authorisation of plant protection products, which are instead addressed in Chapter III of that regulation). Therefore, that exception is intended to concern the *identification of active substances* with endocrine disrupting properties for the purposes of approving an active substance. It is not intended to concern the *consideration of the risk of harmful effects that a plant protection product* is liable to have because it contains a certain active substance; nor does it concern the assessment of such a risk for the purposes of adopting a decision to place such a product on the market.

39. Therefore, in order to give the referring court a useful answer, Questions 1 in Cases C-309/22 and C-310/22 should be answered together and construed as asking, essentially, whether Article 29(1)(e) read in conjunction with Article 4(1), second subparagraph, and (3) of Regulation No 1107/2009, and point 3.6.5 of Annex II to that regulation, must be interpreted as meaning that the competent authority of the Member State must assess the potential endocrine disrupting properties, including by applying new criteria for the determination of endocrine disrupting properties, in the assessment and decision-making process relating to applications for authorisation of a plant protection product.

40. BASF, the Netherlands and Greek Governments and the Commission submit, in essence, that the endocrine disrupting effects that an active substance may have are not to be assessed when considering – at national level – an application for authorisation of a plant protection product containing this active substance. Any other approach would disregard the scheme of Regulation No 1107/2009, the distinction between the assessment of the intrinsic properties of active substances at EU level and the assessment of authorisations of plant protection products at Member State level as well as the division of powers established by that regulation. In addition, the EU legislature provided for a specific mandatory regime for the consequences of a decision rejecting the application to renew the approval of an active substance and the impact on the authorisations of plant protection products based on that active substance.

[16] See, nevertheless, my remarks on Regulation 2018/605 in point 86 et seq. of the present Opinion.

[17] As established in the judgment of 4 July 1973, *Westzucker* (1/73, EU:C:1973:78, paragraph 5). This legal principle implied, in that case, that the amended provisions of the regulation at issue should be applied *not only* to advance fixing certificates for the exportation of sugar *issued after the entry into force* of those provisions, *but also to those certificates issued before such date inasmuch as the intended exportation had not yet taken place and an adjustment of the intervention price had not been made.*

41. By contrast, the referring court considers (and is supported by PAN Europe and the Czech Government) that when the competent authority deciding on an application for authorisation of a plant protection product has at its disposal current and relevant scientific and technical knowledge from which it appears that there is a risk of harmful effects from the active substance contained in that product, that competent authority of the Member State cannot stand idly by but is required to assess the risk of such effects and to draw appropriate conclusions from that assessment.

42. It is true that Regulation No 1107/2009 makes a distinction between the approval of active substances at EU level, by way of regulations adopted by the Commission, and the authorisations to place on the market plant protection products which contain approved active substances, taken by Member States.

43. It is, therefore, necessary to examine whether national competent authorities should, in the context of assessing an application for authorisation to place on the market a plant protection product, appraise the endocrine disrupting properties of an approved active substance contained in that product. If such an appraisal is not excluded, the question arises whether those authorities should carry out that appraisal on the basis of the scientific and technical knowledge that was available at the time the active substance in question was approved or on the basis of the knowledge available at the time of the assessment of the application for authorisation of the plant protection product was made.

44. It should be borne in mind at the outset that, in accordance with settled case-law, for the purpose of interpreting a provision of EU law, it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part. [18]

B. The wording of the relevant provisions of Regulation No 1107/2009

45. Article 29(1)(a) of Regulation No 1107/2009 provides 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: … *its active substances*, safeners and synergists *have been approved*' (emphasis added).

46. However, the same Article 29(1), under point (e), also provides that a plant protection product is to be authorised only where 'in the light of current scientific and technical knowledge, it complies with the requirements provided for in Article 4(3)' of the regulation.

47. In relation to the wording of that provision, the Court already confirmed in the judgment in *Blaise* [19] that 'as regards the procedure for the authorisation of a plant protection product, taking into account the known cumulative and synergistic effects of the constituents of that product is again required, since, 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'.

[18] Judgment of 19 January 2023, *Pesticide Action Network Europe* (C-162/21, EU:C:2023:30, paragraph 35 and the case-law cited; 'the judgment in *Pesticide Action Network Europe*').

[19] Judgment of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraph 71; 'the judgment in *Blaise*').

48. Article 4 of Regulation No 1107/2009, entitled 'Approval criteria for active substances', provides, in paragraph 3 thereof, that a plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, is to meet, inter alia, under point (b), the requirement that 'it shall have no immediate or delayed harmful effect on human 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 …'. The terms 'it *shall* have *no* … harmful effect on human health' clearly indicate that the EU legislature opted for a 'no risk' requirement in this regard.

49. In that connection, I note that the importance of taking account of 'current' or 'new' scientific and technical knowledge pervades the whole of Regulation No 1107/2009 in so far as it is stressed in the wording of a great number of provisions: Article 4(1) (Approval criteria for active substances), Article 6(f) (Conditions and restrictions), Article 11(2) (Draft assessment report), Article 12(2) (Conclusion by EFSA), Article 21(1) (Review of approval), Article 29(1)(e) (Requirements for the authorisation for placing on the market), Article 36(1) (Examination for authorisation), Article 44(3)(d) (Withdrawal or amendment of an authorisation), Article 78(1) (Amendments and implementing measures), and Annex IV (Comparative assessment pursuant to Article 50).

50. Indeed, in the judgment in *Blaise* (paragraph 94), the Court stressed 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*' (emphasis added).

51. It follows from the wording of Article 29(1)(e) read in conjunction with Article 4(3)(b) of Regulation No 1107/2009 that, in order to be authorised, it is necessary: (i) that a plant protection product has no harmful effects, in particular, on human health or animal health (indeed, the reference, in the wording of Article 29(1)(e), to Article 4(3) confirms the importance of the protection of human health and animal health); which, in turn, entails (ii) basing that authorisation on *current* scientific and technical knowledge. In that connection, the terms 'current scientific and technical knowledge' in Article 29(1)(e) imply that that knowledge must be the 'most recent' or 'latest', which is justified by the rapid pace of new scientific and technical (as well as technological) development.

52. I will now consider the objectives of Regulation No 1107/2009 and then the context of that regulation.

C. The objectives of Regulation No 1107/2009 and the importance of the precautionary principle

53. The Court has already had an opportunity to rule on the objective of Regulation No 1107/2009 as well as on the precautionary principle, which underpins it.[20] I shall recall that case-law below.

[20] Article 1(4) of Regulation No 1107/2009. See De Grove-Valdeyron, N., 'Le principe de précaution, nouvel instrument du droit communautaire de la santé', *Revue des Affaires Européennes*, No 2, 2003, p. 265.

54. In the first place, the objective of Regulation No 1107/2009 is, as stated in Article 1(3) and (4) and reflected in recital 8 thereof, in particular to ensure a high level of protection of human and animal health and the environment. [21]

55. In that regard, the Court has 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'. [22]

56. Indeed, the Court has stressed on numerous occasions that 'a correct application of [the precautionary] principle in the area covered by Regulation No 1107/2009 presupposes, first, identification of the potentially negative consequences for health 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 based on the most reliable scientific data available and the most recent results of international research'. [23]

57. In the second place, the Court has stated that 'consequently, since the purpose of Regulation No 1107/2009 is, as provided in Article 1(1) and (2) thereof, to lay down rules for the authorisation of plant protection products and the approval of active substances contained in those products, for their placing on the market, the EU legislature ought to establish a normative framework that ensures that the competent authorities have available to them, when they decide on that authorisation and that approval, sufficient information in order adequately to assess [24], the risks to health resulting from the use of those active substances and those plant protection products'. [25]

58. To my mind, it follows that while that regulation *prevents* a Member State from granting an authorisation for a plant protection product containing an active substance which has *not been approved*, the fact remains that a Member State is *not obliged* to authorise a plant protection product containing active substances *all of which have been approved*, if there is scientific or technical knowledge that identifies negative risks to human or animal health or the environment from the use of those plant protection products.

59. Indeed, recital 24 of Regulation No 1107/2009 makes clear 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 other objective of that regulation, which seeks to improve plant production. [26]

[21] See the judgment in *Pesticide Action Network Europe* (paragraph 46). See, for a critical assessment, Robinson, C., Portier, C.J., Čavoški, A., Mesnage, R., Roger, A., Clausing, P., Whaley, P., Muilerman, H., Lyssimachou, A., 'Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions', *European Journal of Risk Regulation* (EJRR), Vol. 11, No 3, 2020, p. 450. See also Villaverde, J.J., Sevilla-Morán, B., Sandín-España, P., López-Goti, C., Alonso-Prados, J.L., 'Challenges of Biopesticides Under … Regulation (EC) No 1107/2009: An Overview of New Trends in Residue Analysis', *Studies in Natural Products Chemistry*, Vol. 43, 2014, p. 437.

[22] See the judgment in *Pesticide Action Network Europe* (paragraph 47).

[23] Emphasis added. See the judgment in *Blaise* (paragraph 46 and the case-law cited).

[24] In accordance with what is recalled in point 56 of the present Opinion and with the case-law, which states that the precautionary principle 'entails that, where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because the results of studies conducted are inconclusive, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures' (the judgment in *Blaise*, paragraph 43).

[25] See the judgment in *Blaise* (paragraph 47).

[26] See the judgment in *Pesticide Action Network Europe* (paragraph 48).

60. Consequently, 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 above all that they do not have any harmful effect on human or animal health. [27]

61. As pointed out by the Czech Government, if the competent authority of the Member State did not take into account this current scientific and technical knowledge on the sole ground that the active substance concerned had previously been approved according to the procedure laid down in Chapter II of Regulation No 1107/2009, then the Member State would be in breach of the requirement to take into account the current state of scientific and technical knowledge under Article 29(1)(e) of that regulation. Moreover, such an interpretation would be contrary to the objective of guaranteeing a high level of protection of human health and to the very nature of the precautionary principle.

62. Indeed, the Court has already recalled that 'the provisions of [that regulation] are based on the precautionary principle and do not prevent Member States from applying that principle where there is scientific uncertainty as to the risks to human or animal health or the environment posed by plant protection products to be authorised in their territory'. [28]

63. In relation to the issue of scientific uncertainty in particular, I agree with Advocate General Mischo when he argued, in a case relating to Article 36 TFEU, that 'a plausible public-health risk is enough, according to the precautionary principle, to allow a Member State to adopt [necessary] measures .... Moreover, *the greater the scientific uncertainty, the broader the discretion of the Member States, which are responsible for protecting public health*'. [29]

64. In that connection, it is relevant to address the time frame within which the active substances at issue in the main proceedings were approved. In relation to the product Pitcher (Case C-309/22), the active substances at issue are fludioxonil and folpet. Fludioxonil was first approved on 1 November 2008 [30] and folpet on 1 October 2007. [31] As far as the product Dagonis is concerned (Case C-310/22), the active substances at issue are difenoconazole and fluxapyroxad. Difenoconazole was first approved on 1 January 2009 [32] and fluxapyroxad on 1 January 2013. [33]

65. Therefore, between 10 and 16 years have elapsed since those approvals. It is clear that in such a long period of time the scientific and technical knowledge – in relation to the endocrine disrupting properties and effects of such active substances (and the plant protection products containing those substances) as well as other effects – will necessarily have advanced. Even if those approvals were reassessed under the cyclical approach, that does not detract from the argument that it is important for the protection, in particular, of human and animal health and the

27 See the judgment in *Pesticide Action Network Europe* (paragraph 49).

28 Judgment of 6 May 2021, *Bayer CropScience and Bayer* v *Commission* (C-499/18 P, EU:C:2021:367, paragraph 79 and the case-law cited).

29 See his Opinion in *Commission* v *Denmark* (C-192/01, EU:C:2002:760, point 102 in the English version of the Opinion and point 103 in the original French version). The precautionary principle is by definition (as a principle) not a hard legal rule, but a supple one. As a result, it must be applied in a rigorous manner on a case-by-case basis (De Sadeleer, N., 'Grandeur et servitudes du principe de précaution en matière de sécurité alimentaire et de santé publique', dans Nihoul, P., Mahieu, S. (dir.), *La Sécurité alimentaire et la réglementation des OGM*, Brussels, Larcier, 2005, p. 344. See also De Sadeleer, N., 'The Precautionary Principle in EC Health and Environmental Law', *European Law Journal*, Vol. 12, No 2, 2006, p. 139).

30 See https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/37; the approval expires on 31 October 2023.

31 See https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/742; the approval expires on 15 February 2025.

32 See https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/631; the approval expires on 31 December 2023.

33 See https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/989; the approval expires on 31 May 2025.

environment, and is required under the precautionary principle, to take account of current (that is to say the most recent) scientific and technical knowledge when Member States are deciding on the authorisation of plant protection products such as Pitcher and Dagonis.

66. It follows from the foregoing considerations that, just like the wording of Article 29(1)(e) read in conjunction with Article 4 of Regulation No 1107/2009, that regulation's objectives and the precautionary principle which underpins it confirm that in order to be authorised it is necessary that the plant protection product has no harmful effects on human and animal health. In turn, that implies that the authorisation must be based on current scientific or technical knowledge and not on knowledge which is obsolete or no longer up to date.

D. The context of Regulation No 1107/2009 and the impact of full harmonisation of the approval of active substances on the authorisation of plant protection products by Member States

67. The Commission contends that an assessment of the endocrine disrupting properties of an active substance in the context of the national procedure for the authorisation of plant protection products would run counter to the full harmonisation of the approval of active substances at EU level (which results in the adoption of Commission implementing regulations applicable throughout the European Union). It submits that an independent review of the intrinsic properties of an active substance at Member State level would jeopardise that system.

68. It is true that Article 4 and Article 29 fall under different chapters of Regulation No 1107/2009. The former is in Chapter II and the latter in Chapter III. Indeed, the procedure for the authorisation of plant protection products under the regulation involves separate approval of active substances at EU level (under Chapter II), on the one hand, and authorisation of plant protection products at national level (under Chapter III of that regulation), on the other.

69. However, as the Court has already made clear, while these procedures are distinct and should not be confused, the fact remains that the EU legislature established them both in Regulation No 1107/2009 and they are closely linked,[34] a fact which is confirmed also by a clear reference in Article 29(1)(e) to Article 4(3).

70. It is sufficient to rely on the *GranoSalus* case-law, given that the Court has already addressed therein the relationship between the approval of an active substance by the Commission and the authorisation of a plant protection product containing that substance by Member State authorities.

[34] See the judgment in Blaise (paragraph 64), and the judgment of 28 October 2020, *Associazione GranoSalus* v *Commission* (C-313/19 P, EU:C:2020:869, paragraph 35; 'the judgment in *GranoSalus*').

71. Similarly to that judgment,[35] in the first place, I note that it follows from Regulation No 1107/2009 that, before granting an application for authorisation of a plant protection product, the Member States are required to *carry out an independent, objective and transparent assessment of that application*, with a view, in particular, to establishing the absence of harmfulness of that product, in the light of the *most reliable* scientific data available as well as the *most recent* results of international research.

72. In the second place,[36] it is important to point out that the *prior approval by the Commission of the active substances* at issue, which are contained in the plant protection products in question, constitutes *only one of the cumulative conditions that must be verified by the Member State* to which an application for authorisation of a plant protection product is submitted, before granting the authorisation.

73. In the third place,[37] I note that, while it is true that the Commission's approval of active substances, such as those at issue in the present cases, *cannot be reconsidered* by the Member State concerned, the fact remains that it is *for that Member State*, before granting the authorisation of the plant protection products in question, *to first assess whether the other conditions set out in Article 29(1)* of Regulation No 1107/2009 are met.

74. As mentioned in points 46 and 47 above, the reference in Article 29(1)(e) of Regulation No 1107/2009 establishes a clear link, thus requiring the consideration of the conditions laid down in Article 4(3) of the regulation. Therefore, first, Article 29(1)(e) must be interpreted in conjunction with Article 4(3) and, secondly, it must be read in the light of Article 1(4) of that regulation.[38]

75. It follows that the authorisation of a plant protection product and the renewal or extension of such authorisation cannot be regarded as constituting a purely automatic implementation of the approval by the Commission of an active substance contained in that product.[39] As a result, the judgment in *GranoSalus* shows that the Commission's argument in the present case is unfounded as Regulation No 1107/2009 requires the Member State concerned to protect human and animal health. That judgment also makes clear that Regulation No 1107/2009, and the competences and duties of the Commission and of the Member States under that regulation, must be interpreted in a manner that ensures a high level of protection of human and animal health and the environment as an overriding objective of that regulation and the aim established under the first subparagraph of Article 191(2) TFEU.

[35] See the judgments in *GranoSalus* (paragraph 53), and in *Blaise* (paragraphs 66 and 94). On this case-law and on the precautionary principle, see Leonelli, G.C., 'Judicial review of compliance with the precautionary principle from *Paraquat* to *Blaise*: "Quantitative thresholds", risk assessment, and the gap between regulation and regulatory implementation', *German Law Journal*, 2021, no 22, p. 184. The author concludes that 'EU governance of pesticides does not always live up to the overarching tenets of the precautionary principle. The implementation of the regulatory arrangements for risk assessment of [plant protection products], as laid out in [Regulation No 1107/2009], does not always comply with the precautionary principle … the implementation of this system may not provide an exhaustive assessment of the relevant risks, enabling precautionary risk management. This sheds some light on the interplay of complex regulatory arrangements and their implementation across different territorial levels; … the analysis of the [that regulation] shows the gap between the provisions of a regulatory framework and their implementation' (p. 213).

[36] See the judgment in *GranoSalus* (paragraph 54).

[37] See the judgment in *GranoSalus* (paragraph 55).

[38] '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.'

[39] See also the judgment in *GranoSalus* (paragraph 58).

76. In that connection, the Netherlands Government submits that Article 29(1)(e) of Regulation No 1107/2009 refers to the *effects* of the plant protection product on humans and not to the endocrine disrupting *properties* of an active substance. Therefore, it argues, a competent authority is not required to take account of scientific and technical knowledge on endocrine disrupting properties when it is assessing an application for authorisation of a plant protection product and such an obligation does not follow from Article 29(1)(e).

77. I do not find that reasoning convincing. Indeed, it is artificial to divide properties and their effects in such a manner in so far as the EU legislature considered them to be two sides of the same coin. As regards the assessment of endocrine disrupting properties under Regulation No 1107/2009, as the Commission pointed out, Article 4 of that regulation, read in conjunction with Annex II thereto, provides, inter alia, that an active substance may be considered to have no harmful *effect* on human or animal health only if it is not considered to have endocrine disrupting *properties*. [40]

78. The argument of the Netherlands Government also contradicts the very aim of the assessment procedure. The aim of establishing that an active substance has such *properties* is precisely in order to prevent that substance from causing harmful *effects*, in particular, on human and animal health and on the environment. Therefore, if the active substances at issue in these cases possess endocrine disrupting properties, those substances may be approved, and the plant protection products containing them may be authorised, only if there is no negative risk to human or animal health or the environment. [41]

79. In other words, independently of the fact that an active substance is approved at EU level by a regulation adopted by the Commission and that the validity of this approval is not (yet) formally called into question, the competent authority of a Member State is to, on the basis of current and reliable information indicating that this active substance could have endocrine disrupting *properties*: (i) take into account the risk of harmful *effects* of the plant protection product which contains this active substance; and (ii) assess this risk, in accordance with Article 29(1)(e) and Article 4(3) of that regulation, for the purposes of adopting its decision on the placing of that product on the market of that Member State.

80. In the main proceedings of Case C-310/22, it appears that PAN Europe provided a non-exhaustive list of at least six independent academic studies concerning the active substance difenoconazole, which show worrying results in terms of endocrine disrupting effects of that substance. Dagonis, which contains difenoconazole as well as another active substance (fluxapyroxad), and a series of (unknown) chemicals that serve as coformulants, may cause even more damage than difenoconazole alone, due to a potential mutually reinforcing effect.

81. Therefore, as PAN Europe rightly pointed out, if significant potential harm is likely to be caused to humans or animals or the environment by the authorisation of, for instance, Dagonis, in so far as it contains difenoconazole, the CTB should not be able to choose to disregard these effects and simply authorise the plant protection product. This is all the more so valid, given that difenoconazole was evaluated in 2008 (15 years ago). Moreover, the endocrine disrupting properties of difenoconazole were not assessed at that time. The competent authority's assessment should be based on the most up-to-date scientific and technical knowledge. As stated above, Article 29(1)(e) of Regulation No 1107/2009 provides that account must be taken of the current scientific and technical knowledge when evaluating a plant protection product.

[40] See, in particular, point 3.6.5 of Annex II.

[41] Or, at most, only if that risk is negligible (point 3.6.5 of Annex II).

82. In this regard, recital 1 of Regulation 2018/605 expresses the need to ensure in particular that the substances or products placed on the market do not have any harmful effect on human or animal health or unacceptable effects on the environment.

83. If the competent authority of the Member State has at its disposal current and relevant scientific and technical knowledge (including data) from which it appears that there is a risk that the active substance concerned may have harmful effects – for example, as in the present cases, it may disrupt the endocrine system – it is required to take into account the risk of harmful effects of the plant protection product which contains that active substance and assess that risk, as follows from Article 29(1)(e) in conjunction with Article 4(3) of Regulation No 1107/2009, read in the light of Article 1(4) thereof, and to draw appropriate conclusions from that assessment for the purposes of adopting a decision on the authorisation to place that product on the market in that Member State.

84. Therefore, it follows from the foregoing considerations that the context of Article 29(1)(e) of Regulation No 1107/2009 confirms that, in order to be authorised, (i) a plant protection product should not have any harmful effect, in particular, on human health; and (ii) its authorisation must be based on current (that is to say the most recent) scientific and technical knowledge.

85. As the Czech Government rightly pointed out, that interpretation is a fortiori to be followed when the 'current state of scientific knowledge' in question has already been reflected in EU legislation, by way of an amendment of Annex II to Regulation No 1107/2009. One cannot reasonably argue that there is a necessity to apply new scientific and technical knowledge, which the Commission considers sufficiently serious to justify adopting a new regulation, at EU level (that is to say in relation to active substances), but that at Member State level (that is to say in relation to plant protection products containing those substances) one should turn a blind eye to that knowledge and continue applying guidance that is obsolete.

E. Regulation 2018/605 and the transitional regime

86. In order to provide the referring court with a full answer, I will now address the issue of the impact of the transitional regime. As from 10 November 2018, the criteria in the Annex to Regulation 2018/605 for determining the endocrine disrupting properties that may have harmful effects on humans have applied, except in procedures in respect of which the draft regulation was voted on before 10 November 2018. Recital 8 of that regulation shows that the Commission will examine implications of Regulation 2018/605 for any proceedings under Regulation No 1107/2009. The referring court seeks to know whether the entry into force of Regulation 2018/605 has consequences for pending assessments of applications for authorisation, and therefore should have been taken into consideration with regard to the applications at issue in the main proceedings. In particular, the referring court considers that the question arises as to whether the CTB should have applied the new criteria for determining endocrine disrupting properties which reflect the (new) state of scientific and technical knowledge at the time when the decision was taken (and not the state of that knowledge at the time the application was made).

87. In that connection, the Commission submits that applying the new criteria for determining endocrine disrupting properties which reflect the new state of scientific and technical knowledge would run counter to the transitional regime established by Regulation 2018/605.

88. In that regard, I would note, first, that recitals 1 [42] and 8 [43] of Regulation 2018/605 show that there is some urgency to act quickly and to take account of recent scientific developments. Indeed, as pointed out in point 82 of the present Opinion, recital 1 of Regulation 2018/605 expresses the need to ensure in particular that the active substances or products placed on the market do not have any harmful effect on human or animal health or unacceptable effects on the environment and, it is in order precisely to guarantee this, that Regulation No 1107/2009 is based on the precautionary principle. Therefore, the CTB's position that the new endocrine disrupting criteria should be disregarded until the approval of the active substances is reviewed in the context of renewal of the approval appears to be contrary to the objective of Regulation No 1107/2009 to ensure a high level of protection of human and animal health and the environment. Moreover, it appears to be contrary to the precautionary principle.

89. It is true that, according to recital 8 of Regulation 2018/605, the new criteria for the determination of endocrine disrupting properties should apply as soon as possible, but at the same time *they should take into account the time necessary for Member States and EFSA to prepare for applying those criteria*. However, such a consideration cannot oblige the competent authority of a Member State to assess the application for authorisation of a plant protection product according to old and obsolete criteria which no longer reflect the current state of scientific and technical knowledge.

90. The requirement to apply the most recent scientific and technical knowledge – which, as I pointed out in point 83 of the present Opinion, follows from Article 29(1)(e) in conjunction with Article 4(3) of Regulation No 1107/2009, read in the light of Article 1(4) thereof – obliges the competent authority to be proactive in seeking to protect human and animal health and the environment better. Hence, the content of the new criteria for assessing endocrine disruption should be taken into consideration as part of the latest scientific and technical knowledge when taking a decision on an application for authorisation.

91. Furthermore, given the requirement to use the latest scientific and technical knowledge, relying on the new criteria regarding effects of endocrine disrupting properties on human and animal health would better serve both the objective of Regulation No 1107/2009 and the precautionary principle.

92. The Commission's argument is not convincing [44] in so far as it runs counter to Article 1(4) and recital 8 of Regulation No 1107/2009. Those provisions make clear that that regulation is (i) underpinned by the precautionary principle and (ii) does not prevent Member States from applying that principle when there is scientific uncertainty as to the risks to human or animal health or the environment posed by plant protection products to be authorised in their

[42] 'Scientific criteria for the determination of endocrine disrupting properties of active substances … should be developed taking into account the objectives of Regulation … No 1107/2009, which are to ensure a high level of protection of both human and animal health and the environment, in particular ensuring that substances or products placed on the market have no harmful effect on human or animal health or unacceptable effects on the environment'.

[43] 'The criteria for the determination of endocrine disrupting properties reflect the current state of scientific and technical knowledge and allow identifying active substances having [such] properties more accurately. The new criteria should therefore apply as soon as possible, while taking into account the time necessary for Member States and [EFSA] to prepare for applying those criteria'.

[44] See also the legal literature criticising the Commission's stance in previous cases, in so far as it relied on a narrow evidence-based approach, disregarding the widespread public perception that the uncertain risks posed, for instance, by glyphosate are socially unacceptable, and ignoring the argument that the existing risk management measures are insufficient to achieve the intended EU level of public health and environmental protection (Leonelli, G.C., 'The glyphosate saga and the fading democratic legitimacy of European Union risk regulation', *Maastricht Journal of European and Comparative Law*, 2018, Vol. 25, No 5, pp. 582 to 606).

territory.[45] That requires Member States to take account of any pertinent and reliable current scientific and technical knowledge regardless of the source or document from which it comes in order safeguard compliance with Article 29(1)(e) of that regulation.

93. In relation to the question whether it is incumbent on the competent authority to stay the assessment and decision-making process relating to applications for authorisation pending the findings of the Commission on the effects of Regulation 2018/605 on any proceedings pending under Regulation No 1107/2009, it is true that in accordance with recital 8 of Regulation 2018/605, the Commission will examine the implications of this regulation on any ongoing procedure for the approval of active substances at EU level. However, it does not follow from this recital that the Commission would examine the implications of this regulation on any pending application for authorisation of plant protection products in the Member States. Furthermore, there is no provision in Regulation No 1107/2009 which prescribes the exact nature of the obligations of the competent authority of the Member State with respect to the assessment of applications for authorisation such as those in the main proceedings pending the Commission's conclusions on the consequences of Regulation 2018/605 on any ongoing proceedings under Regulation No 1107/2009. As the Netherlands Government noted, it would not be up to the Commission but rather the EU legislature to introduce amendments in relation to the obligations incumbent on Member States in the context of assessing applications for authorisation under Chapter III of Regulation No 1107/2009.

94. In other words, neither Regulation No 1107/2009 nor Regulation 2018/605 deprive a Member State, in the context of assessing whether plant protection products are to be placed on their market, of their competence to adopt appropriate measures in order to comply with all the requirements under Article 29(1) of Regulation No 1107/2009, so as to protect its society from any potential harmful effects of such products, as identified on the basis of current scientific and technical knowledge.

IV. Conclusion

95. I propose that the Court of Justice answer the first questions referred for a preliminary ruling in these joined cases by the College van Beroep voor het bedrijfsleven (Administrative Court of Appeal for Trade and Industry) as follows:

Article 29(1)(e), read in conjunction with Article 4(1), second subparagraph, and (3) 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, and point 3.6.5 of Annex II to that regulation,

must be interpreted as meaning that where the competent authority of a Member State, responsible for assessing an application for the authorisation in that Member State of a plant protection product, has pertinent and reliable information that is based on current (that is to say the most recent) scientific or technical knowledge, regardless of the source of such information, that indicates that an active substance contained in the product in question could disrupt the endocrine system, that authority must take into account the risk of harmful effects that that product is likely to have, assess that risk and take an appropriate decision on that application having regard to all the requirements set out in Article 29(1) of that regulation.

[45] See the case-law in footnote 28 of the present Opinion.