Reports of Cases

OPINION OF ADVOCATE GENERAL
KOKOTT
delivered on 17 September 2020[1]

Case C-499/18 P

Bayer CropScience AG and Bayer AG
v

European Commission

(Appeal – Regulation (EC) No 1107/2009 – Plant protection products – Implementing Regulation (EU) No 485/2013 – Active substances clothianidin and imidacloprid – Conditions for approval – Unacceptable environmental effects – Review of approval – Scope of the examination – Precautionary principle – Burden of proof – Prohibition of use outside greenhouses – Prohibition of the sale of seeds treated with those active substances)

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1 Original language: German.

I. Introduction

1. The present case concerns the validity of an implementing regulation [2] by which the European Commission amended the approvals for two plant protection active substances. In essence, under that regulation use of those active substances is permitted only to a very limited extent. The Plant Protection Regulation [3] permits the Commission to withdraw or amend an approval. However, Bayer CropScience AG and Bayer AG ('Bayer') are taking the opportunity in the present case fundamentally to call into question the application of that power.

2. The main objection raised by Bayer is that the Commission reviewed and amended the approvals even though, in the view of Bayer, there was insufficient new scientific knowledge compared with the initial approval procedure. Bayer also calls for a more in-depth scientific assessment of the risks posed by the active substances, based, in particular, on specific guidance. Lastly, Bayer objects to the prohibitions of the use of the active substances for foliar treatment or in a non-professional context in particular.

2 Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances (OJ 2013 L 139, p. 12).

3 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ 2009 L 309, p. 1).

3. The Court has an opportunity in this case comprehensively to address the review procedure and the power to amend an approval of plant protection active substances, and in particular to clarify the significance of the precautionary principle in this connection. Furthermore, new questions are raised concerning the extent of the interest in bringing proceedings as the contested implementing regulation has now been repealed.

II. Legal framework

4. The first rules on the authorisation of plant protection products and the active substances used were laid down in the Plant Protection Directive from 1991,[4] which formed the basis for the approval of the contested active substances. The directive was, however, replaced by the Plant Protection Regulation in 2009.

5. The approval criteria for active substances of plant protection products are set out in particular in Article 4(1) to (3) of the Plant Protection Regulation:

'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.

…

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 Authority 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 the Authority to assess such effects are available; or on groundwater;

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

4 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1).

(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 the Authority to assess such effects are available:

(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation;

(ii) its impact on non-target species, including on the ongoing behaviour of those species;

(iii) its impact on biodiversity and the ecosystem.'

6. Under Article 7 of the Plant Protection Regulation, the producer of the active substance must submit with its application for approval various documents demonstrating that the active substance fulfils the approval criteria provided for in Article 4.

7. Article 12(2) of the Plant Protection Regulation provides that the European Food Safety Authority (EFSA) must use the guidance documents available in assessing whether an active substance can be expected to meet the approval criteria provided for in Article 4.

8. Point 1.3 of Annex II to the Plant Protection Regulation also concerns the use of guidance:

'During the process of evaluation and decision-making provided for in Articles 4 to 21, Member States and the Authority shall take into consideration any further guidance developed in the framework of the Standing Committee on the Food Chain and Animal Health for the purposes of refining, where relevant, the risk assessments.'

9. Point 3.8.3 of Annex II to the Plant Protection Regulation contains specific stipulations regarding the protection of bees:

'An active substance, safener or synergist shall be approved only if it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist:

– will result in a negligible exposure of honeybees, or

– has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.'

10. Article 21 of the Plant Protection Regulation regulates the review of approval:

'1. The Commission may review the approval of an active substance at any time. It shall take into account the request of a Member State to review, in the light of new scientific and technical knowledge and monitoring data, the approval of an active substance, including where, after the review of the authorisations pursuant to Article 44(1), there are indications that the achievement of the objectives established in accordance with Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC is compromised.

Where, in the light of new scientific and technical knowledge it considers that there are indications that the substance no longer satisfies the approval criteria provided for in Article 4, or further information required in accordance with Article 6(f) has not been provided, it shall inform the Member States, the Authority and the producer of the active substance, setting a period for the producer to submit its comments.

2. The Commission may ask the Member States and the Authority for an opinion, or for scientific or technical assistance. The Member States may provide their comments to the Commission within three months from the date of the request. The Authority shall provide its opinion or the results of its work to the Commission within three months of the date of the request.

3. Where the Commission concludes that the approval criteria provided for in Article 4 are no longer satisfied, or the further information required in accordance with Article 6(f) has not been provided, a Regulation to withdraw or amend the approval shall be adopted in accordance with the regulatory procedure referred to in Article 79(3).

Article 13(4) and Article 20(2) shall apply.'

11. Recital 16 of the Plant Protection Regulation states in this regard:

'The possibility of amending or withdrawing the approval of an active substance in cases where the criteria for approval are no longer satisfied … should be provided for under certain conditions.'

12. Under Article 53(1) of the Plant Protection Regulation, 'in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means'.

13. Article 69 of the Plant Protection Regulation governs emergency measures:

'Where it is clear that an approved active substance … is likely to constitute a serious risk to human or animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, measures to restrict or prohibit the use and/or sale of that substance or product shall be taken immediately …'

III. Background and appeal

14. By Directive 2006/41/EC[5] and Directive 2008/116/EC[6] the Commission included the active substances clothianidin and imidacloprid, which are part of the neonicotinoid family, in Annex I to the Plant Protection Directive, thereby authorising them. The approval was limited until 31 July 2016 (clothianidin) and 31 July 2019 (imidacloprid).

15. Within the European Union, imidacloprid and clothianidin are produced and marketed by the Bayer group.

5 Commission Directive of 7 July 2006 amending Council Directive 91/414 to include clothianidin and pethoxamid as active substances (OJ 2016 L 187, p. 24).

6 Commission Directive of 15 December 2008 amending Council Directive 91/414 to include aclonifen, imidacloprid and metazachlor as active substances (OJ 2008 L 337, p. 86).

A. The EPPO Guidance

16. The scheme for the assessment of risks posed by plant protection products to bees had initially been drawn up by the European and Mediterranean Plant Protection Organisation (EPPO). The scheme was presented in a document entitled 'Environmental risk assessment scheme for plant protection products' (reference PP 3/10; 'the EPPO Guidance').

17. On 18 March 2011, the Commission asked EFSA to review the EPPO Guidance in relation to the assessment of chronic risks to bees, exposure (of bees) to low doses, exposure through guttation and the cumulative risk assessment.

18. On 23 May 2012, in response to the Commission's request of 18 March 2011, EFSA published an opinion on the science underpinning the assessment of risks posed by plant protection products to bees.[7] This document identified a number of areas in which future risk assessments as regards bees should be improved. The opinion drew attention, inter alia, to several weaknesses in the EPPO Guidance, leading to uncertainties about the real exposure of honeybees, and raised issues of relevance to bee health which had not previously been addressed by the EPPO Guidance.

19. EFSA subsequently developed its own guidance, which had not yet been formally adopted, according to the judgment under appeal[8] and Bayer's submissions in the appeal proceedings, and is not therefore binding.

20. On the other hand, in 2018 the EPPO Working Party on Plant Protection Products concluded that it no longer had the necessary expertise to oversee maintenance of the EPPO Guidance, which it therefore withdrew.[9]

B. The contested implementing regulation

21. In 2008 and 2009 a series of incidents involving the misuse of plant protection products containing the active substances covered resulted in losses of honeybee colonies. The Member States affected reacted by taking various restrictive measures.

22. In response to those incidents, the Commission adopted Directive 2010/21/EU,[10] which introduced additional provisions, including appropriate risk mitigation measures as regards the protection of non-target organisms, in particular honeybees.

23. Restrictive measures applying to the use of plant protection products containing the active substances covered continued to be applied in various Member States at national level. After discussions with the Member States' experts within the framework of the Standing Committee on the Food Chain and Animal Health, the Commission decided, on 22 March 2012, to request an opinion from EFSA. It also relied on the final report of October 2011 of the Apenet monitoring and research programme in Italy, which raised concerns about the use of seeds treated with plant protection products containing the active substances covered.

7 EFSA Panel on Plant Protection Products and their Residues (PPR), Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus spp.* and solitary bees), *EFSA Journal* 2012, 10(5) 2668 (doi:10.2903/j.efsa.2012.2668).

8 Paragraphs 241 to 243.

9 EPPO, Annual Report and Council Recommendations 2018, *EPPO Bulletin*, (2019) 49, p. 509 (602).

10 Commission Directive of 12 March 2010 amending Annex I to Council Directive 91/414 as regards the specific provisions relating to clothianidin, thiamethoxam, fipronil and imidacloprid (OJ 2010 L 65, p. 27).

24. On 30 March 2012, a study on the sub-lethal effects of the active substance imidacloprid on bees was published in *Science* magazine ('the Whitehorn study'). The authors concluded that ordinary levels of use of that active substance could have a considerable effect on the stability and survival of colonies of honeybees and bumble bees.

25. On 3 April 2012, the Commission asked EFSA, under Article 21 of the Plant Protection Regulation, to assess the new study and to verify, by 30 April 2012 (and, after extension, no later than 31 May 2012), whether the doses that served as the basis for the experiments reported in the Whitehorn study were comparable to the actual doses to which bees were exposed in the European Union, on the basis of the supported uses at EU level and the authorisations granted by Member States ('the first mandate'). The Commission also asked whether the results of the study could be applied to other neonicotinoids used for the treatment of seeds, notably to clothianidin.

26. On 25 April 2012, the Commission asked EFSA to update, by 31 December 2012, the risk assessments for, inter alia, the active substances covered. The request concerned in particular the acute and chronic effects on colony development and survival, taking into account effects on bee larvae and bee behaviour and the effects of sub-lethal doses on bee survival and behaviour ('the second mandate').

27. On 1 June 2012, in response to the first mandate, EFSA produced a 'Statement on the findings in recent studies investigating sub-lethal effects in bees of some neonicotinoids in consideration of the uses currently authorised in Europe'. In that statement, EFSA evaluated the Whitehorn study and a study regarding clothianidin, published in January 2012 ('the Schneider study').

28. On 25 July 2012, as a result of concerns expressed by EFSA that it might not be able to fulfil the second mandate by the deadline set, the Commission, taking account of the statement of 1 June 2012 while maintaining the deadline of 31 December 2012, narrowed the second mandate so as to prioritise, aside from the active substances covered, only one other neonicotinoid, thiamethoxam, but not two other neonicotinoids, and to focus on their use for seed treatment and in the form of granules.

29. On 16 January 2013, EFSA published its conclusions as regards the risk assessment for bees for the active substances covered ('EFSA's Conclusions'), in which it found that various uses posed high acute risks for bees. In addition, EFSA's Conclusions found numerous areas of uncertainty owing to the lack of scientific data.

30. By letter of 16 January 2013, the Commission invited Bayer to submit observations on EFSA's Conclusions, which Bayer did by letter of 25 January 2013. In addition, by letter of 22 February 2013, the Commission invited Bayer to submit observations on the draft contested measure. Bayer submitted its observations by letter of 1 March 2013. Furthermore, associations representing the plant protection industry, including, therefore, Bayer, participated in various meetings with the Commission's services in January and February 2013 to obtain the views of stakeholders (industry, environmental non-governmental organisations) on EFSA's Conclusions and the measures envisaged by the Commission.

31. On 24 May 2013, the Commission adopted the contested implementing regulation. It introduced in particular, for the substances concerned, the following restrictions on approval:

– prohibition of any non-professional use, indoors or outdoors;

– prohibition of uses for seed treatment or soil treatment on the following cereals when these are to be sown from January to June: barley, millet, oats, rice, rye, sorghum, triticale, wheat;

– prohibition of foliar treatments for the following cereals: barley, millet, oats, rice, rye, sorghum, triticale, wheat;

– prohibition of uses as seed treatment, soil treatment or foliar application for around 100 crops, including rapeseed, soya, sunflowers and maize, with the exception of uses in greenhouses and of foliar treatment after flowering;

– prohibition of the use and placing on the market of seeds of certain crops which have been treated with plant protection products containing the active substances covered, with the exception of seeds used in greenhouses. That covered, inter alia, the seeds of summer cereals, rapeseed, soya, sunflowers and maize.

32. After the judgment under appeal was delivered, the Commission revised the approvals for clothianidin [11] and imidacloprid [12] and imposed even more stringent restrictions. Bayer has not challenged those measures. As far as can be seen, the approval for clothianidin has now even expired. [13]

IV. Judicial procedure

33. Bayer Cropscience AG brought the action in Case T-429/13 against the contested implementing regulation. The President of the First Chamber of the General Court granted the Association générale des producteurs de maïs et autres céréales cultivées de la sous-famille des panicoïdées (AGPM), the National Farmers' Union (NFU), the European Crop Protection Association (ECPA), Rapool-Ring GmbH Qualitätsraps deutscher Züchter ('Rapool-Ring'), the European Seed Association (ESA) and Agricultural Industries Confederation Ltd ('AIC') leave to intervene in support of the form of order sought by Bayer.

34. The President of the First Chamber of the General Court also granted the Kingdom of Sweden, the Union nationale de l'apiculture française (UNAF), Deutscher Berufs- und Erwerbsimkerbund eV (DBEB), Österreichischer Erwerbsimkerbund (ÖEB), Stichting Greenpeace Council ('Greenpeace'), Pesticide Action Network Europe (PAN Europe), Bee Life – European Beekeeping Coordination ('Bee Life') and Buglife – The Invertebrate Conservation Trust ('Buglife') leave to intervene in support of the form of order sought by the Commission.

35. By the judgment under appeal of 17 May 2018, *Bayer CropScience and Others* v *Commission* (T-429/13 and T-451/13, EU:T:2018:280), the General Court dismissed the action.

36. Bayer, or Bayer CropScience AG and Bayer AG to be precise, lodged the present appeal against the judgment under appeal on 27 July 2018 and claim that the Court should:

– set aside the judgment of the General Court in Case T-429/13;

– grant the application and annul the contested implementing regulation in so far as it concerns the appellants;

– order the Commission to pay the appellants' costs and its own costs, both at first instance and on appeal.

37. NFU and AIC seek the same form of order. ECPA supports the form of order sought by Bayer, but does not put forward any arguments of its own.

11 Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin (OJ 2018 L 132, p. 35).

12 Commission Implementing Regulation (EU) 2018/783 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance imidacloprid (OJ 2018 L 132, p. 31).

13 https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=DE&selectedID= 1154.

38. The Commission contends that the Court should:

– dismiss the appeal and

– order Bayer to pay the costs.

39. UNAF, DBEB/ÖEB, Greenpeace/PAN Europe/Bee Life/Buglife and Sweden support the form of order sought by the Commission.

40. In addition, the President of the Court of Justice granted Stichting De Bijenstichting ('The Bee Foundation') leave to intervene in support of the form of order sought by the Commission in the appeal proceedings.

41. The parties submitted written observations. Bayer, NFU, AIC, the Commission, DBEB/ÖEB and Greenpeace/PAN Europe/Bee Life/Buglife took part in the hearing on 3 June 2020.

V. Legal assessment

42. The appeal challenges the judicial assessment of various stages in the application of Article 21 of the Plant Protection Regulation which led to the contested implementing regulation.

A. Preliminary remark

43. Under Article 21 of the Plant Protection Regulation, the Commission may review the approval of an active substance at any time (first sentence of the first subparagraph of paragraph 1) and amend or withdraw the approval on that basis where it concludes that the approval criteria provided for in Article 4 are no longer satisfied (paragraph 3).

44. As is also shown by recital 8 of the Plant Protection Regulation, Article 4 essentially sets out two conditions for the approval of an active substance. First, its use for plant protection products may not have any harmful effect on human health, including that of vulnerable groups, or animal health or on groundwater (paragraph 2(a) and paragraph 3(b)). Second, there may not be any unacceptable effects on the environment (paragraph 2(b) and paragraph 3(e)).

45. If the approval does not satisfy those requirements it is unlawful. Where an unlawful decision is revoked, a balance must be struck between the requirement for legal certainty and the requirement for legality.[14] The EU legislature may, however, anticipate that balance by laying down specific powers.[15] It did so in Article 21(3) of the Plant Protection Regulation to the effect that an approval is amended or withdrawn if it is incompatible with criteria laid down in Article 4, thus giving priority to legality. This does not raise problems in the light of the principle of legal certainty as the revocation of an unlawful decision as regards the future is always possible.[16]

14 Judgments of 22 March 1961, *S.N.U.P.A.T.* v *High Authority* (42/59 and 49/59, EU:C:1961:5, p. 87); of 4 October 2012, *Byankov* (C-249/11, EU:C:2012:608, paragraph 77); and of 20 December 2017, *Incyte* (C-492/16, EU:C:2017:995, paragraph 48).

15 Opinion of Advocate General Campos Sánchez-Bordona in *Repower* v *EUIPO* (C-281/18 P, EU:C:2019:426, points 34 and 35).

16 Judgment of 9 March 1978, *Herpels* v *Commission* (54/77, EU:C:1978:45, paragraph 38).

46. A particular feature of this case is that it only concerns environmental effects. Harmful environmental effects do not necessarily preclude an approval, but only if they are 'unacceptable'. This is clarified in point 3.8.3 of Annex II to the Plant Protection Regulation with regard to honeybees to the effect that their exposure must be 'negligible' and no 'unacceptable' acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour, may occur.

47. The assessment of the legality of the approval thus depends on a complex assessment. It cannot be limited to weighing effects or exposure in respect of the object of protection, namely honeybees. Consideration must also be given to the interest in the use of the active substance, since it cannot be ruled out that that interest outweighs its adverse effects with the result that the effects are 'acceptable'. This is consistent with recital 8 of the Plant Protection Regulation, which states that the purpose of the regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. With specific regard to the amendment or withdrawal of an approval, the further question arises of the extent to which regard must be had to the rights of the approval holder. [17]

48. The Commission concluded, according to recitals 6, 7, 10, 11 and 14 of the contested regulation and based on assessments by EFSA, that the use of the active substances covered posed certain high acute risks for bees and that other unacceptable risks could not be excluded. The restrictions imposed were therefore necessary.

49. The balancing by the Commission on which this conclusion was based is of key importance for the decision under Article 21(3) of the Plant Protection Regulation. However, the appeal does not contest it directly, but primarily objects that the Commission took the decision on the basis of insufficient information and alleges procedural defects.

50. This procedural strategy is consistent with the scheme of legal protection before the European Union Courts. First, the Commission enjoys wide discretion with regard to the complex scientific and economic assessment under Article 21(3) of the Plant Protection Regulation, so that the European Union Courts may review the assessment substantively only as to whether there has been a manifest error of appraisal. [18] Second, even this limited review requires an appraisal of the facts by the General Court which, save where the facts and evidence are distorted, does not constitute a point of law which is subject, as such, to review by the Court of Justice on appeal. [19]

51. On the other hand, even in the case of complex decisions the Courts of the European Union must examine whether the relevant procedural rules have been complied with, whether the facts admitted by the Commission have been accurately stated and whether there has been a misuse of powers. [20] In particular, in examining whether the institution competent in the matter has committed a manifest error of appraisal, the Courts of the European Union must verify whether that institution has examined, carefully and impartially, all the relevant facts of the individual case, facts which support the conclusions reached. [21]

17 See below, points 137 to 138.

18 See to that effect, with regard to the Plant Protection Directive, judgments of 18 July 2007, *Industrias Químicas del Vallés* v *Commission* (C-326/05 P, EU:C:2007:443, paragraphs 75 and 76), and of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C-77/09, EU:C:2010:803, paragraphs 55 and 56).

19 Orders of 15 April 2010, *Makhteshim-Agan Holding and Others* v *Commission* (C-517/08 P, not published, EU:C:2010:190, paragraph 62), and of 7 May 2013, *Dow AgroSciences and Others* v *Commission* (C-584/11 P, not published, EU:C:2013:281, paragraph 73).

20 See to that effect, with regard to the Plant Protection Directive, judgments of 18 July 2007, *Industrias Químicas del Vallés* v *Commission* (C-326/05 P, EU:C:2007:443, paragraph 76), and of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C-77/09, EU:C:2010:803, paragraph 56).

21 See to that effect, with regard to the Plant Protection Directive, judgments of 18 July 2007, *Industrias Químicas del Vallés* v *Commission* (C-326/05 P, EU:C:2007:443, paragraph 77), and of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C-77/09, EU:C:2010:803, paragraph 57).

52. The appeal therefore concerns the initiation of the review (see under C), the risk assessment by EFSA (see under D), the Commission's assessment whether the approval criteria have been satisfied (see under E) and the impact assessment for the rules (see under F).

53. First, however, consideration must be given to the admissibility of the appeal and in particular Bayer's interest in bringing proceedings, as the contested implementing regulation has now been replaced by other rules (see under B).

54. In addition, two remarks should be made regarding the various legal reference points to which a number of parties refer in support of their views. These are the Communication from the Commission of 2 February 2000 on the precautionary principle [22] and various judgments of the General Court. Both sources can certainly provide important arguments, but disregarding them does not necessarily constitute an error in law. Errors in law are the result of an infringement of EU law. Neither the Communications of the Commission nor – especially not on appeal – the case-law of the General Court are conclusive as far as substance is concerned, but only the relevant rules of law, if necessary as interpreted by the Court of Justice.

55. As regards the abovementioned Communication in particular, it is true that the General Court has construed it as being a limitation on the Commission's discretion. [23] However, in its case-law concerning the precautionary principle, the Court of Justice refers exclusively to the principle as such, as laid down in Article 191(2) TFEU. [24]

B. Admissibility and purpose of the appeal

56. The Court, when hearing an appeal under Article 56 of its Statute, is required to rule, if necessary of its own motion, on the admissibility of the action for annulment to which the appeal relates. [25]

57. There are doubts in the present case as to the interest in bringing proceedings because the purpose of the action no longer applies. That interest must, in the light of the purpose of the action, exist at the stage of bringing the action, failing which the action will be inadmissible. That purpose of the action must continue to exist, like the interest in bringing proceedings, until the final decision, failing which there will be no need to adjudicate; this presupposes that the action must be liable, if successful, to procure an advantage to the party bringing it. [26]

58. Until the judgment under appeal, an interest in bringing proceedings undoubtedly existed because the contested implementing regulation significantly restricted the use of plant protection products based on the active substances clothianidin and imidacloprid produced by Bayer. Those restrictions would no longer have applied if the action had been successful.

59. Nevertheless, the Commission revised the approvals for clothianidin and imidacloprid immediately following the judgment under appeal and imposed even more stringent restrictions. [27] The existence of those revised rules would not be affected by the present case and has not been contested separately by Bayer.

22 COM(2000) 1 final.

23 Judgment of 11 September 2002, *Pfizer Animal Health* v *Council* (T-13/99, EU:T:2002:209, paragraph 119).

24 See, by way of illustration, judgments of 1 April 2008, *Parliament and Denmark* v *Commission* (C-14/06 and C-295/06, EU:C:2008:176, paragraph 75); of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C-77/09, EU:C:2010:803, paragraphs 71 to 73); of 21 July 2011, *Etimine* (C-15/10, EU:C:2011:504, paragraph 129); and of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraphs 41 to 43).

25 Judgment of 29 November 2007, *Stadtwerke Schwäbisch Hall and Others* v *Commission* (C-176/06 P, not published, EU:C:2007:730, paragraph 18), and of 29 July 2019, *Bayerische Motoren Werke and Freistaat Sachsen* v *Commission* (C-654/17 P, EU:C:2019:634, paragraph 44).

26 Judgments of 7 June 2007, *Wunenburger* v *Commission* (C-362/05 P, EU:C:2007:322, paragraph 42), and of 23 December 2015, *Parliament* v *Council* (C-595/14, EU:C:2015:847, paragraph 17); and order of 17 December 2019, *Rogesa* v *Commission* (C-568/18 P, not published, EU:C:2019:1092, paragraph 25).

27 See above, point 32.

60. However, the repeal of the contested act, effected after the bringing of the action, does not in itself mean that the Courts of the European Union must declare that there is no need to adjudicate for lack of purpose or for lack of interest in bringing proceedings at the date of the delivery of the judgment. [28] In particular, an applicant may retain an interest in seeking annulment of a decision in order thereby to avoid the risk that the unlawfulness alleged in respect of the contested act will be repeated. [29] The question whether an applicant retains his or her interest in bringing proceedings must be assessed in the light of the specific circumstances, taking account, in particular, of the consequences of the alleged unlawfulness and of the nature of the damage claimed to have been sustained. [30]

61. A first argument militating against a continuing interest in bringing proceedings is that Bayer no longer challenges the restrictions on the use of clothianidin and imidacloprid. It has neither contested the new, more stringent rules nor objected to the expiry of the approval for clothianidin. [31] If the present appeal or even the action were successful, this would not therefore permit the further marketing of those active substances by Bayer.

62. In the light of the considerations below and given the scientific complexity of the Commission's review decision, it also seems unlikely that any breaches of the law by the Commission are sufficiently serious to give grounds for a claim for damages. [32] Furthermore, according to the Commission, any such claim is now time-barred.

63. However, as is well known, Bayer produces and markets many other approved plant protection active substances. Consequently, that undertaking has a particular interest in the clarification of the overall legal conditions for the review and amendment of approvals granted under Article 21 of the Plant Protection Regulation so that the Commission or EFSA does not repeat any errors in applying that provision to other active substances. Contrary to the view taken by the Commission, the present appeal does not concern points specific to the individual case, but questions of interpretation that are of general significance.

64. Bayer's interest in bringing proceedings therefore continues to exist in principle. In connection with the consequences of any errors in law, I will, however, re-examine in detail the extent to which that interest in bringing proceedings justifies further action. [33]

65. Nevertheless, the purpose of the appeal cannot go further than the action in Case T-429/13 which Bayer brought before the General Court. [34] That action concerned the active substances clothianidin and imidacloprid produced and marketed by it, while the neonicotinoid thiamethoxam, the use of which was also restricted by the contested implementing regulation, was the subject of the action brought by Syngenta Crop Protection AG in Case T-451/13. Syngenta has not lodged an appeal. Accordingly, the form of order sought by Bayer is confined to the annulment of the contested implementing regulation in so far as Bayer is affected by the restrictions on the use of clothianidin and imidacloprid.

28 Judgments of 28 May 2013, *Abdulrahim* v *Council and Commission* (C-239/12 P, EU:C:2013:331, paragraph 62), and of 23 December 2015, *Parliament* v *Council* (C-595/14, EU:C:2015:847, paragraph 16).

29 Judgments of 6 March 1979, *Simmenthal* v *Commission* (92/78, EU:C:1979:53, paragraph 32); of 24 June 1986, *AKZO Chemie and AKZO Chemie UK* v *Commission* (53/85, EU:C:1986:256, paragraph 21); of 7 June 2007, *Wunenburger* v *Commission* (C-362/05 P, EU:C:2007:322, paragraph 50); of 28 May 2013, *Abdulrahim* v *Council and Commission* (C-239/12 P, EU:C:2013:331, paragraph 63); and of 4 September 2018, *ClientEarth* v *Commission* (C-57/16 P, EU:C:2018:660, paragraph 48).

30 Judgments of 28 May 2013, *Abdulrahim* v *Council and Commission* (C-239/12 P, EU:C:2013:331, paragraph 65); of 23 December 2015, *Parliament* v *Council* (C-595/14, EU:C:2015:847, paragraph 18); and of 30 April 2020, *Izba Gospodarcza Producentów i Operatorów Urządzeń Rozrywkowych* v *Commission* (C-560/18 P, EU:C:2020:330, paragraph 41).

31 Unlike in the judgment of 27 June 2013, *Xeda International and Pace International* v *Commission* (C-149/12 P, not published, EU:C:2013:433, paragraph 34).

32 With regard to the need for a serious breach, see judgment of 10 September 2019, *HTTS* v *Council* (C-123/18 P, EU:C:2019:694, paragraphs 32 and 33 and 42 and 43).

33 See below, points 94 and 168.

34 See, to that effect, judgment of 14 September 1999, *Commission v AssiDomän Kraft Products and Others* (C-310/97 P, EU:C:1999:407, paragraphs 52 to 55).

66. UNAF considers the appeal to be inadmissible in its entirety as it seeks a new assessment of the facts. That submission must be rejected, however, as it does not address in detail the arguments put forward by Bayer. In addition, the remarks below show that this claim is not accurate.

67. Lastly, consideration must be given to the fact that, although the appeal has been brought on behalf of Bayer CropScience AG and Bayer AG, only the former company was a party to the proceedings before the General Court. In the covering letter enclosed with the appeal, it is explained that the business involving the active substances imidacloprid and clothianidin was transferred from Bayer CropScience AG to Bayer AG in January 2017.

68. Under Article 56 of the Statute of the Court of Justice of the European Union, an appeal may be brought only by parties and interveners in the proceedings before the General Court and by Member States and the institutions of the Union. In the case of a universal succession, the Court of Justice has previously ruled that a legal successor may continue judicial proceedings initiated by the legal predecessor.[35] The General Court, on the other hand, has held that a partial succession does not make the legal successor the addressee of a decision addressed to the legal predecessor. The legal successor also cannot therefore join an action initiated by the legal predecessor against such a decision.[36] Furthermore, Articles 174 to 176 of the Rules of Procedure of the General Court contain special provisions for the situation where a legal successor joins proceedings in the field of intellectual property. Although the present case does not involve the addressee of a decision, the action brought by Bayer CropScience AG was admissible only because the contested implementing regulation was of direct and individual concern to it as the applicant.

69. However, because the purpose of the proceedings now no longer applies, there is no reason to examine whether Bayer AG can join the proceedings as the partial legal successor to Bayer CropScience AG. The interest in bringing proceedings is largely detached from the two contested active substances and is based, in essence, on the other plant protection activities. It is sufficient in this regard to allow Bayer CropScience AG to continue to bring proceedings.

70. In so far as the appeal was brought on behalf of Bayer AG, on the other hand, it is inadmissible.

C. First ground of appeal – initiation of the review

71. By the first ground of appeal, Bayer alleges that the General Court erred in law in finding that an increased degree of certainty of previous scientific knowledge can be regarded as *new* scientific knowledge, such that the Commission was permitted to review the approval in question pursuant to Article 21(1) of the Plant Protection Regulation.

72. Under the first sentence of the first subparagraph of Article 21(1) of the Plant Protection Regulation, the Commission may review the approval of an active substance at any time. The second sentence provides that the Commission is to take into account the request of a Member State to review, in the light of new scientific and technical knowledge and monitoring data, the approval of an active substance. Where, in the light of new scientific and technical knowledge, the Commission considers that there are indications that the substance no longer satisfies the approval criteria provided for in Article 4, under the second subparagraph of Article 21(1) it is to inform the Member States, the Authority and the producer of the active substance, setting a period for the producer to submit its comments.

35 Judgments of 20 October 1983, *Gutmann* v *Commission* (92/82, EU:C:1983:286, paragraph 2), and of 23 April 1986, *Les Verts* v *Parliament* (294/83, EU:C:1986:166, paragraphs 15 to 18).

36 Judgments of 8 July 2004, *JFE Engineering* v *Commission* (T-67/00, T-68/00, T-71/00 and T-78/00, EU:T:2004:221, paragraphs 47 to 50), and of 14 December 2006, *Raiffeisen Zentralbank Österreich and Others* v *Commission* (T-259/02 to T-264/02 and T-271/02, EU:T:2006:396, paragraphs 72 to 74).

73. The General Court holds in paragraphs 160 to 162 of the judgment under appeal that the concept of new scientific and technical knowledge indicates the threshold for the application of Article 21(1) of the Plant Protection Regulation. The threshold is not reached if the new knowledge concerns mere repetition of what was previously known, new suppositions without a well-founded basis or political considerations detached from science. Ultimately, the new scientific and technical knowledge must therefore be genuinely relevant to the assessment as to whether the conditions of approval under Article 4 of the Plant Protection Regulation are still met. In paragraph 179 of the judgment under appeal, the General Court gives a clarification to the effect that results which confirm existing knowledge could be recognised as new scientific knowledge if they are based on new methodologies which are more reliable than those used previously.

74. Bayer contends that according to the principle of legal certainty the review of an approval granted for a limited period is justified only if the state of scientific and technical knowledge changes. The legislature made this clear by supplementing the Commission's proposal and including the criterion of 'new' knowledge. The confirmation of existing knowledge cannot be classified as 'new' knowledge. Otherwise there is no basis for a review and the purpose of the approval procedure, with a comprehensive examination of the active substance, would be undermined. AIC also alleges a breach of the principle of legal certainty.

75. The General Court's findings are in fact vitiated by an error in law, but not along the lines argued by Bayer. The first sentence of the first subparagraph of Article 21(1) of the Plant Protection Regulation permits the Commission to review the approval *at any time*, without specifying further conditions.

76. In so far as the legislature requires new knowledge in Article 21(1) of the Plant Protection Regulation, it relates to obligations for specific cases, first in connection with a Member State's request to review and second in the case that such knowledge provides indications that the substance no longer satisfies the approval criteria. In the case of a request, new knowledge results in the discretion enjoyed by the Commission in respect of the review being limited. It is then *obliged* to initiate the review in the light of that knowledge. If there are the abovementioned indications in the latter case, the Commission must inform the Member States, the Authority and the producer of the active substance, giving them the opportunity to submit comments.

77. This does not mean, however, that the Commission is permitted to initiate a review only in the event of new knowledge. Accordingly, the Court of Justice recently found that new scientific and technical knowledge is just one possible reason for a review ('notamment', 'including'),[37] allowing scope for other reasons.

78. Another reason for a review may be, for example, that the legislature has subsequently decided to reinforce certain protection requirements. The Commission thus explains that the protection of bees has greater importance under the Plant Protection Regulation than under the previously applicable Plant Protection Directive, on the basis of which it had approved the contested active substances. Furthermore, DBEB/ÖEB rightly point out that the EFSA Opinion on the deficiencies in the EPPO Guidance also gave a reason to review the approvals granted on the basis of that guidance. Another possible reason would be the detection of errors in the initial approval procedure.

79. On the basis of this interpretation of Article 21(1) of the Plant Protection Regulation, it is possible to react rapidly and flexibly to all conceivable misgivings about an approval. The Commission is thus able to strive for a high level of protection of human health, as is required by Article 35 of the Charter of Fundamental Rights of the European Union ('the Charter') and Article 9, Article 114(3) and

37 Judgment of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraph 99).

Article 168(1) TFEU,[38] and at the same time to aim at a high level of protection and improvement of the quality of the environment in accordance with Article 3(3) TEU, Article 114(3) TFEU and Article 37 of the Charter. Furthermore, according to Article 1(3) and recital 8 of the Plant Protection Regulation, these are also explicit purposes of the regulation.

80. Recital 16, on which Bayer relies, does not alter this interpretation at all. While that recital does mention 'certain conditions', they must be satisfied in order to amend or withdraw an approval, not to initiate a review. It is only at this stage of the procedure that the principles of legal certainty and protection of legitimate expectations invoked by Bayer are applicable. Under Article 21(3) of the Plant Protection Regulation, the Commission may amend or withdraw an approval only if the approval criteria provided for in Article 4 are no longer satisfied or certain information required has not been provided. In the light of the principle of legal certainty in particular, this provision does not permit an approval to be withdrawn merely because, within the margin of discretion available to it in this regard, the Commission took a different decision on the basis of an unchanged factual situation.[39]

81. It must therefore be stated that the interpretation of Article 21(1) of the Plant Protection Regulation in the judgment under appeal, in particular in paragraph 162, is vitiated by an error in law because it is not a prerequisite for the initiation of a review that there should be new scientific knowledge. That error in law does not, however, cause that judgment to be set aside, as it does not call into question the outcome of the examination by the General Court. It is sufficient in this respect to clarify the grounds.[40] The first ground of appeal should therefore be rejected.

D. Second ground of appeal – Applicable guidance for the risk assessment under Article 21(2) of the Plant Protection Regulation

82. By the second ground of appeal, Bayer objects that the General Court erred in law by finding that EFSA does not have to base its risk assessment on the guidance applicable at the time of the review. This is a legitimate objection in principle but, in relation to the specific case at issue, it is no longer covered by the interest in bringing proceedings and cannot therefore lead to the judgment under appeal being set aside.

83. With regard to the validity of this complaint, it should be stated that under Article 21(3) of the Plant Protection Regulation the Commission is to adopt a regulation to withdraw or amend the approval where it concludes that the approval criteria provided for in Article 4 are no longer satisfied. In order to prepare that decision, the Commission may, pursuant to the first sentence of Article 21(2) of the Plant Protection Regulation, ask EFSA for an opinion, or for scientific or technical assistance.

84. Article 12(2) of the Plant Protection Regulation provides that EFSA must use the guidance documents available in assessing whether an active substance can be expected to meet the approval criteria provided for in Article 4. In addition, under point 3.8.3 of Annex II, an active substance is to be subject to an appropriate risk assessment on the basis of Community or internationally agreed test guidelines.

85. As the General Court stated in paragraph 249 of the judgment under appeal, during the review there was not yet any relevant EU guidance document, only the preparatory EFSA Opinion.[41] The internationally recognised EPPO Guidance did exist, however, and, in the view of Bayer, should have been applied by EFSA. The General Court erred in law in failing to require the application of that guidance.

38 See judgment of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraph 42 and the case-law cited).

39 See below, point 140.

40 See judgment of 23 January 2019, *Deza* v *ECHA* (C-419/17 P, EU:C:2019:52, paragraph 87).

41 See above, point 18.

86. In paragraphs 266 and 271 of the judgment under appeal, the General Court rejected this submission, in essence, on the ground that it was not the guidance of the time of the approval but the most up-to-date guidance which should be used.

87. In response to this argument, Bayer rightly asserts, however, that it does not address its submissions before the General Court, as the appellant had referred to the *updated* guidance. [42]

88. The duty of the General Court under Article 36 of the Statute of the Court of Justice of the European Union and the first paragraph of Article 53 thereof to state the reasons for its judgments does not require that court to provide an account that follows exhaustively and one by one all the arguments put forward by the parties to the dispute. Therefore, so long as the statement of reasons clearly and unequivocally discloses the General Court's thinking, the reasoning may be implicit, on condition that it enables the persons concerned to ascertain the reasons why the measures in question were taken and the Court of Justice to have sufficient evidence to exercise its power of review. [43]

89. In the present case, however, the General Court did not address Bayer's submissions either expressly or implicitly, but distorted their substance. This constitutes a deficient statement of reasons at least and also, moreover, an infringement of the right to effective judicial protection guaranteed in Article 47 of the Charter.

90. Irrespective of whether the references to guidance documents and guidelines in Article 12(2) and point 3.8.3 of Annex II to the Plant Protection Regulation are valid as such in respect of the application of Article 21, this error in law was relevant to the decision in the judgment under appeal.

91. The examination whether the approval criteria provided for in Article 4 of the Plant Protection Regulation are satisfied requires a complex scientific assessment in which the Commission must examine, carefully and impartially, all the relevant facts of the individual case. [44] This includes the relevant guidance in any event, as is only confirmed by Article 12(2) and point 3.8.3 of Annex II.

92. This does not mean that the Commission and EFSA are required to follow that guidance to the letter, as a review does not have to repeat the entire approval procedure. [45] In so far as the guidance is of importance to the matters covered by the review, however, it must be taken into consideration.

93. Because the General Court did not examine whether sufficient consideration was given to the EPPO Guidance, it has not been established whether the contested decision is based on an adequate examination of the relevant information. The judgment under appeal is thus vitiated by an error in law.

94. In order to remedy this error in law, however, the Court of Justice would have to refer the case back to the General Court to conduct the examination which was not carried out. A role could be played in this regard by the assessment of the EPPO Guidance in the EFSA Opinion and the Commission's submission that it is clear from the EPPO Guidance itself that it is not suitable for assessing certain questions. It would also be necessary to consider the argument put forward by Sweden that EFSA did in fact comply with the EPPO Guidance in so far as it was relevant.

42 Paragraphs 109 and 116 of the application before the General Court.

43 Judgments of 8 February 2007, *Groupe Danone* v *Commission* (C-3/06 P, EU:C:2007:88, paragraph 46), and of 10 July 2019, *VG* v *Commission* (C-19/18 P, EU:C:2019:578, paragraph 31).

44 See to that effect, with regard to the Plant Protection Directive, judgments of 18 July 2007, *Industrias Químicas del Vallés* v *Commission* (C-326/05 P, EU:C:2007:443, paragraphs 75 and 77), and of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C-77/09, EU:C:2010:803, paragraphs 55 and 57).

45 See also the comments below regarding the third, fourth and fifth grounds of appeal.

95. Bayer's interest in bringing proceedings does not justify those legal consequences, however. It is true that it covers the fundamental question of the extent to which guidance must be taken into account in a review, as this question may arise in connection with other reviews. However, there is no legitimate interest in further investigating the significance of the EPPO Guidance because EPPO has now withdrawn it.[46] At the same time, there is now more recent EFSA guidance which, while not yet formally applicable,[47] at least contains scientifically relevant considerations.

96. The Court should therefore only rule that the finding that it had not been necessary, in connection with the adoption of the contested implementing regulation, to take account of the EPPO Guidance is vitiated by an error in law, but should not set aside the judgment under appeal on this point.

E. Third, fourth and fifth grounds of appeal – approval criteria

97. The third, fourth and fifth grounds of appeal concern the application of Article 21(3) of the Plant Protection Regulation by the General Court and specifically the precautionary principle. Under Article 21(3), the approval is to be amended or withdrawn where the Commission concludes in particular that the approval criteria provided for in Article 4 are no longer satisfied. As has already been explained, it is key in the present case whether unacceptable environmental effects are linked to the use of the active substances.

1. Review of the risks posed by the active substances

98. By the first part of the third ground of appeal and by the fifth ground of appeal, Bayer objects that the General Court found, in paragraphs 309 and 310 of the judgment under appeal, that the Commission was permitted to decide on the basis of a provisional risk assessment by EFSA, rather than waiting for a more comprehensive and accurate scientific evaluation of the level of risk posed by the active substances covered.

99. Bayer relies in this respect on point 3.8.3 of Annex II to the Plant Protection Regulation, according to which the risk assessment must be appropriate, and on the case-law of the General Court. Bayer suggests that the General Court accepted an incomplete and rash risk assessment. There is, however, no justification for this position, which is not consistent with the reasoning of the General Court.

100. As is shown by paragraphs 306 to 308 of the judgment under appeal, EFSA's risk assessment was based on the available scientific knowledge. The General Court made the contested findings only in order to demonstrate why EFSA and the Commission did not have to wait until there was EU guidance on risk assessment which included a framework for field tests.

101. As regards the duration of the risk assessment, Sweden and the environmental and beekeeping associations that are parties in this case rightly maintain that EFSA had a period of eight months to deliver its Opinion, while Article 21(2) of the Plant Protection Regulation provides for a period of only three months. There is therefore no question of a rash decision.

102. This approach is justified by the precautionary principle, which was applicable in the present case.

103. Article 191(2) TFEU provides that the policy on the environment is to be based, inter alia, on the precautionary principle, whereas the Plant Protection Regulation was not based on the Union's environmental competence. Nevertheless, the precautionary principle is also applicable in the context of other EU competences, in particular for the protection of public health under Article 168 TFEU

46 See above, point 20.

47 See above, point 19.

and where the EU institutions adopt, under the common agricultural policy or the policy on the internal market, measures for the protection of human health.[48] In that regard, it is clear from recital 8 and Article 1(4) of the Plant Protection Regulation that the provisions of that regulation are based on the precautionary principle.[49]

104. Accordingly, Article 21 of the Plant Protection Regulation and the appropriateness of a risk assessment under point 3.8.3 of Annex II must also be assessed in the light of this principle. On the other hand, the criticism raised by AIC that the General Court permitted the application of the precautionary principle in isolation is unfounded.

105. A correct application of the precautionary principle presupposes, first, identification of the potentially negative consequences for health of the use of the contested active substances and, secondly, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research.[50] The same considerations apply to environmental risks.[51]

106. It also follows from the precautionary principle, however, that where there is uncertainty as to the existence or extent of risks, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent.[52] Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk, the precautionary principle thus justifies the adoption of restrictive measures. That is the case where the results of studies conducted are inconclusive, but the likelihood of real harm persists should the risk materialise.[53] Therefore, protective measures may be taken in the light of the precautionary principle even if it proves impossible to carry out as full a scientific risk assessment as possible in the particular circumstances of a given case because of the inadequate nature of the available scientific data.[54]

107. The General Court mentions several times, in paragraphs 116, 118, 120 and 122 of the judgment under appeal for example, that the precautionary principle would permit *preventive* measures. In doing so, it confuses the precautionary principle terminologically with the principle that preventive action should be taken, which is also referred to in Article 191(2) TFEU. Although the General Court may rely on opinions expressed in legal literature,[55] it makes more sense, rather, to apply the principle that preventive action should be taken, which has been discussed less extensively in case-law, to the duty to prevent environmental damage which according to existing knowledge would certainly occur,[56] whilst

48 Judgment of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraph 41 and the case-law cited).

49 Judgment of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraph 44 and the case-law cited).

50 Judgments of 23 September 2003, *Commission* v *Denmark* (C-192/01, EU:C:2003:492, paragraph 51); of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C-77/09, EU:C:2010:803, paragraph 75); and of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraph 46 and the case-law cited and paragraph 94).

51 Judgment of 28 March 2019, *Verlezza and Others* (C-487/17 to C-489/17, EU:C:2019:270, paragraph 57). See also judgments of 29 July 2019, *Inter-Environnement Wallonie and Bond Beter Leefmilieu Vlaanderen* (C-411/17, EU:C:2019:622, paragraph 134); of 10 October 2019, *Luonnonsuojeluyhdistys Tapiola* (C-674/17, EU:C:2019:851, paragraph 66); and of 24 October 2019, *Prato Nevoso Termo Energy* (C-212/18, EU:C:2019:898, paragraph 58).

52 Judgments of 5 May 1998, *National Farmers' Union and Others* (C-157/96, EU:C:1998:191, paragraphs 63 and 64); of 9 September 2003, *Monsanto Agricoltura Italia and Others* (C-236/01, EU:C:2003:431, paragraph 111); and of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraph 43).

53 Judgments of 23 September 2003, *Commission* v *Denmark* (C-192/01, EU:C:2003:492, paragraph 52); of 28 January 2010, *Commission* v *France* (C-333/08, EU:C:2010:44, paragraph 93); of 29 April 2010, *Solgar and Others* (C-446/08, EU:C:2010:233, paragraph 70); and of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraph 43).

54 Judgment of 9 September 2003, *Monsanto Agricoltura Italia and Others* (C-236/01, EU:C:2003:431, paragraph 112).

55 Krämer, L., in: von der Groeben/Schwarze (ed.), *Kommentar zum Vertrag über die Europäische Union und zur Gründung der Europäischen Gemeinschaft*, 7th edition, Nomos, Baden-Baden, 2015, Article 191 TFEU, paragraph 40, Scherer, J. and Heselhaus, S., Umweltrecht, paragraph 36, in: Dauses (ed.), *Handbuch des EU-Wirtschaftsrechts*, C.H. Beck, Munich, EL 49, November 2019.

56 See judgments of 5 October 1999, *Lirussi and Bizzaro* (C-175/98 and C-177/98, EU:C:1999:486, paragraph 51); of 22 June 2000, *Fornasar and Others* (C-318/98, EU:C:2000:337, paragraph 37); and of 26 April 2005, *Commission* v *Ireland* (C-494/01, EU:C:2005:250, paragraph 165).

the precautionary principle permits protective measures in the event of uncertainty over the effects.[57] This lack of terminological precision on the part of the General Court has no effect on the continued validity of the judgment under appeal, however, as, from a substantive point of view, it does not refer to genuine preventive action throughout, but to precautionary measures.

108. It is crucial in relation to these objections to the judgment under appeal that the precautionary principle requires that the best *available* scientific knowledge is taken into account. Therefore, EFSA and the Commission are not required to delay the risk assessment until other studies or new EU guidance is available .[58] For the General Court there were also no grounds for criticism in this regard.

109. Furthermore, the contested implementing regulation was not intended to impose protective measures permanently on the basis of provisional findings. Rather, the Commission was anticipating progress in risk assessment, as recital 16 of the implementing regulation expressly provided that the Commission would immediately seek a review of new scientific knowledge obtained by it within two years. Accordingly, it was stated in Part B of the entry for the active substance in question that the undertakings concerned should submit further information on certain risks by 31 December 2014.[59]

110. The first part of the third ground of appeal and the fifth ground of appeal are therefore unfounded.

2. Emergency measures on the basis of Article 21(3) of the Plant Protection Regulation

111. By the second part of the third ground of appeal, Bayer expands on the complaint of a rash decision and takes the view that if a decision was particularly urgent, the Commission was not permitted to rely on Article 21 of the Plant Protection Regulation, but should instead have relied on Article 69 of that regulation.

112. This submission was not part of the subject matter of the action before the General Court, however, and is therefore inadmissible under the second sentence of Article 170(1) of the Rules of Procedure.

113. That is because, on an appeal, the jurisdiction of the Court of Justice is confined to review of the findings of law at first instance. To allow a party to put forward for the first time before the Court of Justice a plea for or against the measure contested before the General Court which it has not raised before the General Court – or as in this case it raised only belatedly in the reply – would be to authorise it to bring before the Court of Justice, whose jurisdiction on appeal is limited, a case of wider ambit than that which came before the General Court.[60]

114. Nevertheless, this submission is also unsuccessful in substance, as there is no evident basis for an obligation for the Commission to utilise the procedure laid down in Article 69 or 70 of the Plant Protection Regulation if the requirements for the application of Article 21 are satisfied.[61]

57 See Calliess, C. in: Calliess/Ruffert (ed.), *EUV/AEUV*, 5th edition 2016, Article 191 TFEU, paragraphs 32 and 33; Kahl, W. in: Streinz (ed.), *EUV/AEUV*, 3rd edition 2018, Article 114 TFEU, paragraphs 81 and 82; and Nettesheim, M. in Grabitz/Hilf/Nettesheim (ed.), *Das Recht der Europäischen Union*, 44th supplement, May 2011, Article 191, paragraph 89.

58 See also judgment of 21 July 2011, *Etimine* (C-15/10, EU:C:2011:504, paragraphs 128 and 129).

59 There was a similar situation with the rules at issue in the judgment of 8 July 2010, *Afton Chemical* (C-343/09, EU:C:2010:419, paragraphs 60 and 64).

60 Judgments of 1 June 1994, *Commission* v *Brazzelli Lualdi and Others* (C-136/92 P, EU:C:1994:211, paragraph 59); of 28 June 2005, *Dansk Rørindustri and Others* v *Commission* (C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P, EU:C:2005:408, paragraph 165); and of 16 November 2017, *Ludwig-Bölkow-Systemtechnik* v *Commission* (C-250/16 P, EU:C:2017:871, paragraph 29).

61 See my Opinion in *Union des industries de la protection des plantes* (C-514/19, EU:C:2020:422, points 91 and 92).

3. No invitation to submit new information

115. The third part of the third ground of appeal concerns the fact that Bayer was not given an opportunity to submit updated information to the Commission in order to dispel doubts as to whether the requirements laid down in Article 4 of the Plant Protection Regulation were still satisfied.

116. Bayer objects to paragraph 142 of the judgment under appeal. In that paragraph, the General Court ruled that the Commission may withdraw the approval of Bayer's active substances because the data generated by studies carried out for the purposes of the initial approval were insufficient to identify all the risks for bees linked to the active substance concerned in the light of the amended approval requirements.

117. Bayer is correct in so far as the Commission is permitted to withdraw or amend the approval for an active substance only after it has given the producer an opportunity to submit comments. With regard to certain cases this is expressly laid down in the second subparagraph of Article 21(1) of the Plant Protection Regulation. It also follows from Article 41(2)(a) of the Charter, under which every person has the right to be heard before any individual measure which would affect him or her adversely is taken.

118. As the General Court explained in paragraph 435 of the judgment under appeal, however, Bayer had several opportunities to make such comments.[62]

119. The right to be heard does not, conversely, oblige the Commission, in the context of a review under Article 21 of the Plant Protection Regulation, to give the producer an opportunity to carry out new studies in order to fill any data gaps.

120. An obligation to that effect does apply in a procedure for the initial approval of the active substance under Article 11(3) and Article 12(3) of the Plant Protection Regulation[63] and possibly also under Articles 15 and 17 in connection with the renewal of approvals. Article 21 of the Plant Protection Regulation does not contain any comparable reference, however.

121. This is also logical, as the active substance cannot be used or cause harm prior to an approval. If, on the other hand, doubts subsequently arise as to compatibility with Article 4 of the Plant Protection Regulation, on the basis of which the Commission initiates a review, then waiting for full information from the producer would extend the period during which the possible risks to human health or the environment persist. The General Court states in paragraph 443 of the judgment under appeal that the Commission and Bayer both agree that generating the data necessary to fill those gaps would take at least one or two years from the time when a guidance document is available.

122. As the General Court states in paragraph 442 of the judgment under appeal, it is thus consistent with the precautionary principle that the Commission is not obliged, in reviewing an approval, to allow the producer to fill all gaps in the data, but is only required to give it an opportunity to submit comments before the approval is amended.[64] Of course, this does not mean that the Commission is not required to relax the requirements for the use of active substances again if the producer is subsequently able to fill gaps in the data, thereby dispelling the anticipated risks.

123. The third part of the third ground of appeal is therefore unfounded.

62 See above, point 30.

63 Judgment of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraph 92).

64 See also judgment of 21 July 2011, *Etimine* (C-15/10, EU:C:2011:504, paragraphs 128 and 129).

4. Legal certainty in respect of new legal requirements

124. The fourth part of the third ground of appeal concerns a contradiction in the General Court's reasoning. On the one hand, in paragraphs 160 to 162 of the judgment under appeal, the General Court holds that new scientific knowledge is required for the initiation of the review procedure under Article 21(1) of the Plant Protection Regulation, whilst, on the other hand, according to paragraph 142 of the judgment under appeal, the withdrawal or amendment of the approval under Article 21(3) may be based on new, more stringent approval criteria. New knowledge is also mentioned in paragraph 142, but would not be indispensable if there were to be new criteria. It would in fact be contradictory to lay down more demanding or entirely different requirements for the initiation of the review procedure than for a final decision.

125. This contradiction confirms the error in law already established in connection with the first ground of appeal.[65] New scientific knowledge is necessarily just one conceivable justification for a review. If there are new approval requirements, such a review must likewise be possible.

126. However, like the abovementioned error in law, this contradiction does not lead to the judgment under appeal being set aside. Rather, it will be rectified if the Court follows my proposal and makes clear in connection with the first ground of appeal that the initiation of the review of an approval does not require new information.

127. Therefore, the fourth part of the third ground of appeal is also unfounded.

5. Increased certainty with regard to risks and new data

128. By the first part of the fourth ground of appeal, Bayer objects that the General Court erred in law by failing to determine a degree of scientific certainty as to the materialisation of the alleged risk appropriate for the application of precautionary measures.

129. Bayer again objects to paragraph 142 of the judgment under appeal, but this time to the finding that it is sufficient if the Commission provides solid and convincing evidence which may reasonably raise doubts as to the fact that the active substance in question satisfies the approval criteria.

130. In the view of Bayer, however, it is clear from case-law that, for measures which impinge on existing approvals, first, there is a need for a higher degree of certainty regarding the materialisation of the alleged risk, which, second, is based on new scientific data.[66]

131. In connection with the review of an approval, Article 21(3) of the Plant Protection Regulation establishes as conditions for a withdrawal or amendment either that the approval criteria provided for in Article 4 are no longer satisfied or that certain information has not been provided. That provision prescribes neither the development of new scientific knowledge[67] nor particular certainty regarding the materialisation of the risk in question.

132. While reference is made to new knowledge several times in Article 21(1) of the Plant Protection Regulation, it concerns only certain cases of the review of an approval.[68] Consequently, this reference to new knowledge does not establish any additional requirements for the amendment or withdrawal of an approval under Article 21(3).

65 See above, point 75 et seq.

66 Bayer mentions the judgment of 13 September 2017, *Fidenato and Others* (C-111/16, EU:C:2017:676, paragraph 52), the Opinion of Advocate General Bobek in *Fidenato and Others* (EU:C:2017:248, points 74 to 77) and the judgment of the General Court of 26 November 2002, *Artegodan* v *Commission* (T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00, EU:T:2002:283, paragraphs 192 and 195).

67 Judgment of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraph 99). See also above, points 76 and 115 et seq.

68 See above, point 76.

133. As regards the approval criteria under Article 4 of the Plant Protection Regulation, the Commission must examine in particular whether the active substances have unacceptable effects on the environment (Article 4(2)(b) and (3)(e)). As the present case concerns the protection of bees, it had to be investigated, pursuant to point 3.8.3 of Annex II to the Plant Protection Regulation, whether the exposure of bees is 'negligible' and whether there are no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.[69]

134. This is the same examination that would have to be carried out for a first approval of the active substance. In principle, increased certainty is not required with regard to the materialisation of risks compared with the first approval procedure.

135. Nevertheless, the degree of certainty can affect the assessment whether certain risks to the environment posed by the active substance are 'acceptable' or 'unacceptable'. Where there is a higher degree of certainty that a risk will materialise, lesser expected harm can outweigh the interest in the use of the active substance than where risks are less certain.

136. I therefore understand Bayer's argument to the effect that legal certainty and legitimate expectations as to the continued validity of the approval represent additional factors in the assessment, which become less significant only if there is increased certainty with regard to the materialisation of risks compared with the first approval. Moreover, such increased certainty would also require new knowledge, as the certainty as to risks obtained in the approval procedure, which is not sufficient for an amendment according to Bayer, was based on knowledge available at the time.

137. This idea seems plausible at first sight, but is ultimately untenable. The threshold for the use of an active substance set by Article 4 of the Plant Protection Regulation cannot depend on whether or not the substance has already been approved. By the references in Article 21(3) to Article 4, the legislature set precisely the *same* threshold as for the initial approval. As is explained by De Bijenstichting and other parties, the legislature thus did not understand the approval of an active substance as constituting a right to cause 'unacceptable' environmental effects, but merely as a finding that the identified environmental effects and risks are acceptable. If that finding subsequently proves to be incorrect, Article 21(3) allows it to be amended or withdrawn. Accordingly, increased certainty with regard to the materialisation of risks compared with an approval is not necessary for the purposes of the application of Article 21(3) of the Plant Protection Regulation.

138. The Court's judgment in *Fidenato*, which is cited by Bayer, does not give rise to more extensive requirements for certainty as to environmental risks. That judgment concerned emergency measures under Article 34 of Regulation (EC) No 1829/2003 in connection with authorised genetically modified feed and food.[70] The Court held that the expressions 'likely' and 'serious risk' used in that article must be understood as referring to a significant risk which clearly jeopardises human health, animal health or the environment.[71] Appropriate measures would have to be taken in the context of the Plant Protection Regulation not on the basis of Article 21, but pursuant to Article 69 thereof, where the same terms are used as in Article 34 of Regulation No 1829/2003.

69 See above, points 44 to 49.

70 Regulation of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ 2003 L 268, p. 1).

71 Judgments of 8 September 2011, *Monsanto and Others* (C-58/10 to C-68/10, EU:C:2011:553, paragraph 76), and of 13 September 2017, *Fidenato and Others* (C-111/16, EU:C:2017:676, paragraph 51).

139. The Court also expressly distinguished those emergency measures from general precautionary measures, for which it is sufficient that, following an assessment of available information, the possibility of harmful effects on health is identified but that scientific uncertainty persists.[72] In that case at least, the Court did not therefore consider significant risks to be absolutely necessary in order to justify non-emergency precautionary measures. Consequently, that judgment also does not provide any basis for inferring such requirements by way of interpretation from Article 21(3) of the Plant Protection Regulation.

140. Bayer is nevertheless correct in stating that, in principle, a decision-making basis which is *unchanged* compared with the specific approval does not permit the Commission to modify its assessment whether certain environmental effects or environmental risks are 'unacceptable'. It is a core function of legal certainty that the administrative authorities do not call into question their assessment of the situation, once made, without sufficient grounds.[73] This applies a fortiori if, as in the case of the approval of active substances, the effects of that assessment are limited in time and the approval holder thus has particular legitimate expectations in the continued validity of the approval during that period of time.

141. As regards the restriction of an approval under Article 21(3) of the Plant Protection Regulation, it follows, in essence, that the Commission must have new evidence which would have been sufficient in the initial approval procedure to limit the approval in this way from the outset.

142. No error in law is evident in the judgment under appeal in so far as the General Court expressly made the contested finding in paragraph 142 regarding solid and convincing evidence which may reasonably raise doubts against the background of a changed, and thus new, decision-making basis.

143. Possible changes in the decision-making basis are not limited to scientific knowledge, but include the changes in the applicable legislation mentioned in paragraph 142 of the judgment under appeal.[74] Compared with the Plant Protection Directive, on the basis of which the initial approvals were granted, the Plant Protection Regulation placed greater emphasis on the protection of honeybees and specified more generally the rules on the limitation of harmful effects.

144. In addition, the EFSA Opinion discussed in paragraphs 233 to 240 of the judgment under appeal, which identifies the current state of scientific knowledge and the deficiencies in the EPPO Guidance that was applied in the approval of the active substances, is also new. While the General Court states in paragraph 170 that the EFSA Opinion plays only a minor part in the Commission's decision, EFSA's Conclusions on the two active substances at least also refer to the Opinion.[75]

145. Furthermore, the Commission has cited the new studies from 2012 as the specific reason for the review, presumably referring to the new data mentioned in paragraph 142 of the judgment under appeal. According to paragraph 198 of the judgment under appeal, those studies constituted a result that was of concern with regard to the question whether unacceptable effects on non-target species are excluded.

72 Judgment of 13 September 2017, *Fidenato and Others* (C-111/16, EU:C:2017:676, paragraphs 50, 52 and 53).

73 See, by way of illustration with regard to binding tariff information, judgments of 29 January 1998, *Lopex Export* (C-315/96, EU:C:1998:31, paragraph 28); of 2 December 2010, *Schenker* (C-199/09, EU:C:2010:728, paragraph 16); and of 7 April 2011, *Sony Supply Chain Solutions (Europe)* (C-153/10, EU:C:2011:224, paragraph 24).

74 See judgment of 29 January 1998, *Lopex Export* (C-315/96, EU:C:1998:31, paragraphs 28 and 29).

75 EFSA, Conclusion on the peer review of the pesticide risk assessment for bees for the active substance clothianidin, *EFSA Journal* 2013, 11(1):3066 (doi:10.2903/j.efsa.2013.3066), p. 6, and European Food Safety Authority, Conclusion on the peer review of the pesticide risk assessment for bees for the active substance imidacloprid, *EFSA Journal* 2013, 11(1):3068 (doi:10.2903/j.efsa.2013.3068), p. 6.

146. The objections to the test applied by the General Court in paragraph 142 of the judgment under appeal, which Bayer raises on the ground that there is not increased certainty with regard to environmental effects or any new knowledge, cannot therefore be accepted. Accordingly, the first part of the fourth ground of appeal is unfounded.

6. Reversal of the burden of proof

147. By the third part of the fourth ground of appeal, Bayer complains that the General Court required it to demonstrate certain facts even though the Commission is obliged to prove that the approval requirements are no longer satisfied.

148. Bayer misunderstands the standard of proof in the review procedure, however. It is not for the Commission to provide full proof that the active substance infringes the requirements laid down in Article 4 of the Plant Protection Regulation.

149. Under Article 7(1) of the Plant Protection Regulation, the notifier in the approval procedure must instead demonstrate that the active substance fulfils the criteria laid down by that regulation.[76] This allocation of the burden of proof also applies in the review procedure since, as has been stated, that procedure seeks to achieve the same level of protection as the approval procedure.

150. The starting point is the fact that the approval holder is already required under Article 7 of the Plant Protection Regulation to demonstrate that the active substance satisfies the requirements laid down by Article 4. However, if, as is as stipulated in paragraph 142 of the judgment under appeal, the Commission provides solid and convincing evidence which may reasonably raise doubts as to compliance with those requirements, the initial burden of proof is restored. The approval holder must then provide supplementary proof in order to rebut the Commission's evidence.

151. It must be acknowledged that this burden of proof in plant protection law can be heavy if the Commission identifies data gaps. However, the approval holder should have filled those gaps already in the initial approval procedure before the active substance was first used.

152. The complaint of a reversal of the burden of proof is therefore also unfounded.

7. Hypothetical risks

153. This interim conclusion nevertheless does not prevent Bayer and AIC from rightly claiming, in the second part of the fourth ground of appeal, errors in law in the *specific* application of the burden of proof. These relate to the prohibitions of use for foliar applications and non-professional use as insecticide.

(a) Foliar applications

154. Bayer objects that the General Court permitted the prohibition of foliar applications in paragraph 534 of the judgment under appeal because some of the uses of the substances covered which had been approved until then could entail unacceptable risks to bees, even though that use had not been investigated by EFSA. Bayer and AIC complain in particular that the Commission itself conducted the risk assessment, rather than having it carried out by EFSA. The risk assessment is a task for experts.

76 See also judgments of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C-77/09, EU:C:2010:803, paragraph 58), and of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraph 79).

155. In response to that objection, it should be stated that it lies within the discretion of the Commission to refer the matter to EFSA pursuant to Article 21(2) of the Plant Protection Regulation [77] and that, under that provision, EFSA is required to make its contribution within three months. That provision thus assumes a risk assessment by EFSA which is limited in scale and not absolutely necessary. Therefore, the fact that the Commission did not refer the question of foliar applications to EFSA does not, in itself, call into question the prohibition of foliar applications.

156. Bayer and AIC rely, moreover, on settled case-law regarding the precautionary principle, according to which the risk assessment cannot be based on purely hypothetical considerations. [78] This means mere conjecture which has not been scientifically verified. [79] On the other hand, scientifically based concerns satisfy the requirements under that principle even where there is still some scientific uncertainty. [80]

157. However, Bayer reproduces the General Court's findings selectively, as the Court expressly permitted a prohibition of uses which have not been assessed, in paragraph 534 of the judgment under appeal, only if and in so far as the Commission could reasonably assume that these posed similar risks to those posed by uses that had been assessed.

158. Furthermore, the detailed appraisal of the arguments presented, in paragraphs 537 to 545 of the judgment under appeal, shows that the General Court does not accept mere conjecture which has not been scientifically verified as a 'reasonable assumption'. Rather, in paragraph 542 it rejects some of the arguments put forward by the Commission because they find no support in the cited scientific study.

159. However, in paragraphs 544 and 545 the General Court finds the Commission's remaining arguments to be sufficient to justify the prohibition. They show that foliar applications resulted in deposits of the plant protection product concerned on the soil, from where its active substances could be absorbed by the roots and dispersed throughout the plant. In this way they may ultimately harm bees.

160. Therefore, contrary to the view taken by Bayer, the General Court did not permit a risk assessment based on purely hypothetical considerations in connection with the prohibition of foliar applications.

161. This objection is therefore unfounded.

(b) Prohibition of non-professional uses

162. As far as the prohibition of the non-professional use of active substances as insecticide is concerned, it should be borne in mind, first of all, that the contested implementing regulation does permit certain professional uses, but prohibits non-professional use completely.

77 See also judgments of 13 September 2007, *Land Oberösterreich and Austria* v *Commission* (C-439/05 P and C-454/05 P, EU:C:2007:510, paragraph 32), and of 6 November 2008, *Netherlands* v *Commission* (C-405/07 P, EU:C:2008:613, paragraph 67).

78 Judgments of 9 September 2003, *Monsanto Agricoltura Italia and Others* (C-236/01, EU:C:2003:431, paragraph 106); of 28 January 2010, *Commission* v *France* (C-333/08, EU:C:2010:44, paragraph 91); and of 19 January 2017, *Queisser Pharma* (C-282/15, EU:C:2017:26, paragraph 60).

79 Judgments of 9 September 2003, *Monsanto Agricoltura Italia and Others* (C-236/01, EU:C:2003:431, paragraph 106); of 8 September 2011, *Monsanto and Others* (C-58/10 to C-68/10, EU:C:2011:553, paragraph 77); and of 13 September 2017, *Fidenato and Others* (C-111/16, EU:C:2017:676, paragraph 51).

80 Judgment of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C-77/09, EU:C:2010:803, paragraphs 78 and 79).

163. With regard to this more extensive prohibition, Bayer criticises the fact that in paragraph 558 of the judgment under appeal the General Court finds that misuse, by a failure to comply with the instructions for use, cannot be ruled out, particularly in the case of non-professional users. At the same time, in paragraph 553 it recognised that neither the Commission nor the applicants have proved whether such a likelihood does or does not exist.

164. This objection is justified. In paragraphs 551 and 552 of the judgment under appeal, the General Court accepts the Commission's main argument that it is responsible for determining the acceptable level of risk on the basis of political factors. In so far as the General Court actually takes into account scientific considerations, namely two surveys, in paragraphs 553 to 556, it is exclusively on the initiative of Bayer.

165. At the hearing the Commission argued that the distinction between professional and non-professional uses of plant protection products is common in EU law. It relied, first, on the definition of professional user in Article 3(25) of the Plant Protection Regulation and, second, on the fact that in recital 17 of the Directive establishing a framework for Community action to achieve the sustainable use of pesticides,[81] the legislature stated that inappropriate handling is very likely to occur in the group of non-professional users due to their lack of knowledge.

166. However, this does not alter the fact that the Commission failed to carry out any assessment of the available scientific data, such as the surveys submitted by Bayer, for the specific prohibitions in respect of non-professional users, even though that is necessary for the adoption of precautionary measures.[82]

167. It may be that subsequently, in connection with the assessment whether risks are acceptable, the interests of non-professional users in the use of certain plant protection products are given less significance than those of professional users. Particular risks may also be posed for non-professional users, on account of their lack of professional qualifications or the particular characteristics of private gardens for example. This does not mean, however, that mere conjecture is sufficient in respect of restrictions, without taking into account the available scientific knowledge.

168. On this point, the appeal lodged by Bayer should therefore be upheld. Consequently, the judgment under appeal should be set aside to the extent that the General Court dismissed the action in respect of the prohibition of the non-professional use of clothianidin and imidacloprid as insecticide in so far as the prohibition on non-professional use is more extensive than the prohibition on professional use. Doubts as to the interest in bringing proceedings are not evident in this regard. Rather, the failure to take into account relevant information, which the General Court failed to find, directly affects the contested implementing regulation with the result that the Court of Justice may also annul it in this regard.

F. Sixth ground of appeal – scope of the impact assessment

169. By the sixth ground of appeal, Bayer objects to the appraisal of the Commission's impact assessment in paragraphs 459 to 461 of the judgment under appeal. The General Court found that it was sufficient that the Commission acquainted itself with the effects of the measure (paragraph 460) and that the scope and the format of the assessment lie within the discretion of the Commission (paragraphs 459 and 460). The General Court was thus satisfied with a four-point summary of a study of economic effects submitted inter alia by Bayer, even though the Commission did not have a complete overview of alternative plant protection products (paragraph 461). The obligation to carry out an impact assessment is thus rendered meaningless.

81 Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 (OJ 2009 L 309, p. 71).
82 See above, point 105.

170. Bayer is correct in its view that under the third indent of Article 191(3) TFEU, in preparing its policy on the environment, the Union must take account the potential benefits and costs of action or lack of action.

171. It is also true that the precautionary principle must be applied having regard to the principle of proportionality. That principle requires that measures adopted by EU institutions should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question. Where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued. [83]

172. In this connection, contrary to the view taken by the Commission, it is not sufficient to take into account only the adverse effects of the active substances on the environment, in particular on bees, and the data gaps and risks identified. On the contrary, socioeconomic concerns must also be considered, at least in so far as Article 21(3) of the Plant Protection Regulation allows a margin of discretion within which the Commission can apply the principle of proportionality.

173. Although such a margin is ruled out under Article 4 of the Plant Protection Regulation in respect of harmful effects on human health or groundwater, the relevant effects on the environment prevent the approval of an active substance only if they are 'unacceptable'. With regard to honeybees specifically, 'unacceptable' effects on bee colonies are to be avoided under point 3.8.3 of Annex II. [84]

174. Accordingly, the Commission must assess the advantages and disadvantages of the measure in question, that is, the restriction of the approvals, and any possible alternatives to the measure.

175. A distinction must, however, be drawn between the requirements of the principle of proportionality and its judicial review. This is of limited scope in relation to legislation in particular, but it at least requires that the EU institutions which have adopted the act in question must be able to show before the Court that in adopting the act they actually exercised their discretion. This presupposes the taking into consideration of all the relevant factors and circumstances of the situation the act was intended to regulate. The EU institutions must at the very least be able to produce and set out clearly and unequivocally the basic facts which had to be taken into account as the basis of the contested measures of the act and on which the exercise of their discretion depended. [85] Those duties to provide evidence must apply a fortiori to the exercise of implementing powers by the Commission. [86]

83 Judgments of 8 July 2010, *Afton Chemical* (C-343/09, EU:C:2010:419, paragraphs 45 and 60 to 62), and of 9 June 2016, *Pesce and Others* (C-78/16 and C-79/16, EU:C:2016:428, paragraph 48).

84 See above, points 44 to 49.

85 See judgments of 7 September 2006, *Spain* v *Council* (C-310/04, EU:C:2006:521, paragraphs 122 and 123); of 8 July 2010, *Afton Chemical* (C-343/09, EU:C:2010:419, paragraph 34); and of 13 March 2019, *Poland* v *Parliament and Council* (C-128/17, EU:C:2019:194, paragraph 73).

86 Orders of 22 May 2014, *Bilbaína de Alquitranes and Others* v *ECHA* (C-287/13 P, not published, EU:C:2014:599, paragraph 20), and of 4 September 2014, *Rütgers Germany and Others* v *ECHA* (C-290/13 P, not published, EU:C:2014:2174, paragraph 26).

176. It should also be borne in mind, however, that the Commission's broad discretion, which implies limited judicial review of its exercise,[87] applies not only to the nature and scope of the measures to be taken but also, to some extent, to the finding of the basic facts.[88] In particular, the form in which the source data considered are set out is immaterial. Although a comprehensive formal impact assessment can be very useful,[89] the Commission can also take into consideration any other information source.[90]

177. The General Court correctly gauged the assessment by the Commission of the adverse impacts of the contested rules against these criteria.

178. As regards the economic impacts, in paragraph 461 of the judgment under appeal it rightly inferred from the abovementioned four-point summary that the Commission took into account the study summarised in those points. Furthermore, in paragraphs 464 and 465 of the judgment under appeal, the General Court acknowledged that the Member States which already had experience of the prohibition of neonicotinoids reported no particular negative effects on productivity or on the environment to the Commission.

179. In connection with this ground of appeal, Bayer and above all NFU complain in particular that the importance of alternative plant protection products was not assessed adequately.

180. It is true in this regard that the disadvantages associated with the restrictions depend on the plant protection products that can still be used by farmers. Their cost-effectiveness influences the crop yields of farmers and, moreover, the adverse effects of their increased use on health and the environment must be taken into consideration.

181. As is clear from paragraph 468 of the judgment under appeal, however, the Commission had a comprehensive overview of the active substances approved by it and was therefore also aware of their benefit for agriculture and their effects on health and the environment. This knowledge was also taken into consideration by the Commission, as it was aware that two other neonicotinoids were still available at the time.[91]

182. The Commission was not required, on the other hand, to investigate the extent to which Member States had already approved plant protection products based on other active substances which could replace the products that would cease to be used pursuant to the contested implementing regulation. Although it would have been possible to obtain that information from the Member States, this would have been merely a snapshot. It had to be assumed that further to the new rules the producers would notify plant protection products for the harmful organisms concerned based on still approved active substances.

183. The General Court also rightly states in paragraph 463 of the judgment under appeal that under Article 53 of the Plant Protection Regulation it is possible to avoid disproportionate impacts of the contested restrictions. According to that provision, Member States may temporarily authorise the placing on the market of plant protection products based on non-approved active substances, for

87 See above, point 50.

88 See judgments of 12 July 1979, *Italy* v *Council* (166/78, EU:C:1979:195, paragraph 14); of 25 June 1997, *Italy* v *Commission* (C-285/94, EU:C:1997:313, paragraph 23); of 9 November 2006, *Agraz and Others* v *Commission* (C-243/05 P, EU:C:2006:708, paragraph 73); of 8 July 2010, *Afton Chemical* (C-343/09, EU:C:2010:419, paragraph 33); and of 30 April 2019, *Italy* v *Council (Fishing quotas for Mediterranean swordfish)* (C-611/17, EU:C:2019:332, paragraph 57).

89 See judgments of 8 June 2010, *Vodafone and Others* (C-58/08, EU:C:2010:321, paragraphs 55, 58 and 65), and of 12 May 2011, *Luxembourg* v *Parliament and Council* (C-176/09, EU:C:2011:290, paragraph 65).

90 See judgment of 13 March 2019, *Poland* v *Parliament and Council* (C-128/17, EU:C:2019:194, paragraph 31), illustrated by judgments of 8 July 2010, *Afton Chemical* (C-343/09, EU:C:2010:419, paragraphs 36, 37 and 40), and of 4 May 2016, *Pillbox 38* (C-477/14, EU:C:2016:324, paragraphs 64 to 66).

91 Annex 23 to the appeal, p. 3 (p. 633 of the annexes).

limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means. The Commission was thus permitted to consider that the restrictions imposed by it would not apply absolutely and immutably, but that the Member States would allow derogations in urgent cases.

184. Though NFU argues that the practice of applying that derogation in the United Kingdom is highly restrictive, in this way the principle of proportionality is expressed. If the competent national authorities conclude that the adverse effects preclude an approval by way of derogation in a specific individual case, in other words that the adverse effects of a derogation outweigh the positive effects, the principle of proportionality requires no broader general authorisation.

185. Moreover, because the Member States are responsible within this framework for balancing the conflicting interests, the Commission cannot be expected to anticipate their practice when reviewing an approval.

186. The sixth ground of appeal is therefore unfounded.

VI. The action before the General Court

187. In accordance with the first paragraph of Article 61 of the Statute of the Court of Justice of the European Union, the latter may, where the decision of the General Court has been set aside, either itself give final judgment in the matter, where the state of the proceedings so permits, or refer the case back to the General Court.

188. In the light of the above considerations, the judgment of the General Court should be set aside only to the extent that it dismissed the action in respect of the prohibition of the non-professional use of clothianidin and imidacloprid as insecticide in so far as the prohibition on non-professional use is more extensive than the prohibition on professional use. On this point, the state of the proceedings permits the Court of Justice to give final judgment as it is clear that the Commission did not rely on the available scientific knowledge in this regard. Consequently, the contested implementing regulation should be annulled on this point.

VII. Costs

189. Under Article 184(2) of its Rules of Procedure, where the appeal is unfounded or where the appeal is well founded and the Court of Justice itself gives final judgment in the case, the Court is to make a decision as to the costs.

190. Under Article 138(1) of the Rules of Procedure, which applies *mutatis mutandis* to appeal proceedings pursuant to Article 184(1) of those rules, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Under the first sentence of Article 138(3), however, the parties are to bear their own costs where each party succeeds on some and fails on other heads. The first sentence of Article 134(3) of the Rules of Procedure of the General Court contains the same rule.

191. The Commission and Bayer should therefore bear their own costs in the proceedings before the General Court and before the Court of Justice.

192. This also applies with regard to the inadmissible appeal brought on behalf of Bayer AG as it did not give rise to any additional costs for the other parties compared with the admissible appeal brought by Bayer CropScience AG.

193. Furthermore, under Article 184(4) of the Rules of Procedure, where the appeal has not been brought by an intervener at first instance, he may not be ordered to pay costs in the appeal proceedings unless he participated in the written or oral part of the proceedings before the Court of Justice. Where an intervener at first instance takes part in the proceedings, the Court may decide that he shall bear his own costs. Therefore, in the light of the outcome of the proceedings, I suggest that the interveners at first instance which took part in the present proceedings be ordered to bear their own costs. [92]

194. In addition, the decision as to costs should also be rectified for the interveners at first instance. They too should each bear their own costs in accordance with Article 138(3) of the Rules of Procedure of the General Court.

195. Lastly, with regard to De Bijenstichting, I suggest that the Court apply Article 140(3) of the Rules of Procedure, under which the Court may order it to bear its own costs.

VIII. Conclusion

196. I therefore propose that in the present dispute the Court should:

(1) Declare that the appeal is inadmissible in so far as it was brought on behalf of Bayer AG;

(2) Set aside the judgment of the General Court of 17 May 2018, *Bayer and Others* v *Commission* (T-429/13 and T-451/13, EU:T:2018:280), to the extent that the General Court dismissed the action in respect of the prohibition of the non-professional use of clothianidin and imidacloprid as insecticide in so far as the prohibition on non-professional use is more extensive than the prohibition on professional use;

(3) Declare that the judgment of the General Court of 17 May 2018, *Bayer and Others* v *Commission* (T-429/13 and T-451/13, EU:T:2018:280) is vitiated by an error in law in so far as it is found that it had not been necessary, in connection with the adoption of Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances, to take account of the Environmental risk assessment scheme for plant protection products published by the European and Mediterranean Plant Protection Organisation, as updated in 2010;

(4) Annul Implementing Regulation No 485/2013, in so far as it makes the non-professional use of clothianidin and imidacloprid as insecticide subject to a more extensive prohibition than for professional use;

(5) Order that all the parties in the proceedings before the General Court and before the Court of Justice and the interveners in those proceedings are to bear their own costs.

92 See judgment of 11 September 2014, *MasterCard and Others* v *Commission* (C-382/12 P, EU:C:2014:2201, paragraph 265).