ОБЩ СЪД НА ЕВРОПЕЙСКИЯ СЪЮЗ
TRIBUNAL GENERAL DE LA UNIÓN EUROPEA
TRIBUNÁL EVROPSKÉ UNIE
DEN EUROPÆISKE UNIONS RET
GERICHT DER EUROPÄISCHEN UNION
EUROOPA LIIDU ÜLDKOHUS
ΓΕΝΙΚΟ ΔΙΚΑΣΤΗΡΙΟ ΤΗΣ ΕΥΡΩΠΑΪΚΗΣ ΕΝΩΣΗΣ
GENERAL COURT OF THE EUROPEAN UNION
TRIBUNAL DE L'UNION EUROPÉENNE
CÚIRT GHINEARÁLTA AN AONTAIS EORPAIGH
OPĆI SUD EUROPSKE UNIJE
TRIBUNALE DELL'UNIONE EUROPEA
EIROPAS SAVIENĪBAS VISPĀRĒJĀ TIESA
EUROPOS SĄJUNGOS BENDRASIS TEISMAS
AZ EURÓPAI UNIÓ TÖRVÉNYSZÉKE
IL-QORTI ĠENERALI TAL-UNJONI EWROPEA
GERECHT VAN DE EUROPESE UNIE
SĄD UNII EUROPEJSKIEJ
TRIBUNAL GERAL DA UNIÃO EUROPEIA
TRIBUNALUL UNIUNII EUROPENE
VŠEOBECNÝ SÚD EURÓPSKEJ ÚNIE
SPLOŠNO SODIŠČE EVROPSKE UNIJE
EUROOPAN UNIONIN YLEINEN TUOMIOISTUIN
EUROPEISKA UNIONENS TRIBUNAL

JUDGMENT OF THE GENERAL COURT (First Chamber, Extended Composition)

17 May 2018 *

(Plant protection products — Active substance fipronil — Review of approval — Article 21 of Regulation (EC) No 1107/2009 — Prohibition of the use and sale of seeds treated with plant protection products containing the active substance in question — Article 49(2) of Regulation No 1107/2009 — Precautionary principle — Impact assessment)

In Case T-584/13,

BASF Agro BV, established in Arnhem (Netherlands), and the other applicants whose names appear in the annex, [1] represented by J.-P. Montfort and M. Peristeraki, lawyers,

applicants,

supported by

Association européenne pour la protection des cultures (ECPA), established in Brussels (Belgium), represented by I. de Seze and É. Mullier, lawyers, and D. Abrahams, Barrister,

and by

European Seed Association (ESA), established in Brussels, represented initially by P. de Jong, P. Vlaemminck and B. Van Vooren, and subsequently by P. de Jong, K. Claeyé and E. Bertolotto, lawyers,

interveners,

v

* Language of the case: English.

[1] The list of applicants is annexed only to the version notified to the parties.

European Commission, represented by P. Ondrůšek and G. von Rintelen, acting as Agents,

defendant,

supported by

Deutscher Berufs- und Erwerbsimkerbund eV, established in Soltau (Germany),

Österreichischer Erwerbsimkerbund, established in Großebersdorf (Austria),

and

Österreichischer Imkerbund (ÖIB), established in Vienna (Austria)

represented by A. Willand and B. Tschida, lawyers,

interveners,

APPLICATION pursuant to Article 263 TFEU for annulment of Commission Implementing Regulation (EU) No 781/2013 of 14 August 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substance fipronil, and prohibiting the use and sale of seeds treated with plant protection products containing this active substance (OJ 2013 L 219, p. 22),

THE GENERAL COURT (First Chamber, Extended Composition),

composed of H. Kanninen, President, I. Pelikánová (Rapporteur), E. Buttigieg, S. Gervasoni and L. Calvo-Sotelo Ibáñez-Martín, Judges,

Registrar: P. Cullen, Administrator,

having regard to the written part of the procedure and further to the hearing on 17 February 2017,

gives the following

Judgment

I. Background to the dispute

1 The active substance fipronil, which is part of the phenylpyrazole family, was included in Annex I to 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) by Commission Directive 2007/52/EC of 16 August 2007 amending Directive 91/414

to include ethoprophos, pirimiphos-methyl and fipronil as active substances (OJ 2007 L 214, p. 3).

2 Within the European Union, fipronil is produced and marketed by the BASF group.

3 Following the replacement of Directive 91/414 by 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 (OJ 2009 L 309, p. 1), the active substances included in Annex I to Directive 91/414 were deemed to be approved under Regulation No 1107/2009, pursuant to Article 78(3) thereof, and are now listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation No 1107/2009 as regards the list of approved active substances (OJ 2011 L 153, p. 1).

4 In 2008 and 2009, a number of incidents involving the misuse of plant protection products containing active substances belonging to the neonicotinoid family resulted in losses of honeybee colonies. The Member States affected reacted by taking various restrictive measures.

5 In 2010, in response to those incidents, the European Commission adopted Directive 2010/21/EU of 12 March 2010 amending Annex I to Directive 91/414 as regards the specific provisions relating to clothianidin, thiamethoxam, fipronil and imidacloprid (OJ 2010 L 65, p. 27). This measure strengthened the terms of approval of the substances in question as regards the protection of non-target organisms, in particular honeybees.

6 On 18 March 2011, the Commission asked the European Food Safety Authority (EFSA) to review the existing scheme for the assessment of risks posed by plant protection products to bees, drawn up by the European and Mediterranean Plant Protection Organisation (EPPO), in relation to the assessment of chronic risks to bees, exposure to low doses, exposure through guttation and the cumulative risk assessment. The scheme was presented in a document entitled 'Environmental risk assessment scheme for plant protection products' (reference PP 3/10; 'the EPPO Guidance').

7 On the basis of 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, inter alia, fipronil, and after discussions with the Member States' experts within the framework of the Standing Committee on the Food Chain and Animal Health ('the Standing Committee'), the Commission decided, on 22 March 2012, in accordance with Article 49(2) of Regulation No 1107/2009, to request an opinion from EFSA on the subject.

8 On 23 May 2012, in response to the Commission's request of 18 March 2011 (see paragraph 6 above), EFSA published a scientific opinion on the science underpinning the assessment of risks posed by plant protection products to bees

('the EFSA Opinion'). 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.

9 In June 2012, in response to the Commission's request of 22 March 2012 (see paragraph 7 above), EFSA produced a statement on the assessment of the scientific information from the Italian Apenet research project on the effects on bees of maize seeds coated with certain neonicotinoids and fipronil. In that statement, EFSA noted that, due to certain deficiencies and certain weaknesses in the Apenet project, it had not been possible for it to draw a definitive conclusion, but that a number of potential concerns had nevertheless been identified in the context of the project, suggesting that a change might be required in the assessment of some neonicotinoids and fipronil as regards their effects on bees.

10 On 6 August 2012, the Commission asked EFSA to conduct, by 31 March 2013, a thorough risk assessment of fipronil as regards its impact on bee health, pursuant to Article 21 of Regulation No 1107/2009.

11 On 27 May 2013, EFSA published its conclusions on the peer review of the assessment of risks posed to bees by the active substance fipronil, used as a pesticide ('EFSA's Conclusions'). It identified, in particular, a high acute risk to honeybees from exposure to dust drift during the sowing of maize. It was unable to rule out the existence of a similarly high risk in respect of other field crops.

12 EFSA's Conclusions also highlighted several issues which it had not been possible to finalise on the basis of the data available and which related, inter alia, to the exposure of honeybees via dust, from consumption of contaminated nectar and pollen, and from exposure via guttation.

13 In the light of the issues noted by EFSA, the Commission submitted a draft implementing regulation and an opinion to the Standing Committee at its meeting on 15 and 16 July 2013. Since the draft was supported by a qualified majority of Member States, on 14 August 2013 the Commission adopted Implementing Regulation (EU) No 781/2013 amending Implementing Regulation No 540/2011, as regards the conditions of approval of the active substance fipronil, and prohibiting the use and sale of seeds treated with plant protection products containing this active substance (OJ 2013 L 219, p. 22; 'the contested measure').

14 Article 1 of the contested measure restricted the use of plant protection products containing fipronil to crops in greenhouses and to seeds of leek, onions, shallots and the group of *Brassica* vegetables intended to be sown in fields and harvested before flowering.

15 In addition, by Article 2, the contested measure prohibited the use and placing on the market of seeds treated with plant protection products containing fipronil, with the exception of seeds intended to be sown in greenhouses and seeds of leek,

onions, shallots and the group of *Brassica* vegetables intended to be sown in fields and harvested before flowering.

16 Under Article 3 of the contested measure, the Member States were required, in accordance with Regulation No 1107/2009, to amend or withdraw existing authorisations for plant protection products containing fipronil by 31 December 2013. Article 4 of the contested measure provided that any period of grace granted by Member States was required to be as short as possible and to expire on 28 February 2014 at the latest.

17 The contested measure was published in the *Official Journal of the European Union* on 15 August 2013 and entered into force the following day, in accordance with Article 5 thereof, except for Article 2 which was to apply from 1 March 2014.

II. Procedure and forms of order sought

18 BASF Agro BV and the other applicants whose names are set out in the annex (together 'BASF') brought the present action by application lodged at the General Court Registry on 4 November 2013.

19 By order of the President of the First Chamber of the General Court of 9 October 2014, *BASF Agro and Others* v *Commission* (T-584/13, not published), and by order of 9 October 2014, *BASF Agro and Others* v *Commission* (T-584/13, not published, EU:T:2014:907), the European Seed Association (ESA) and the Association européenne pour la protection des cultures (European Crop Protection Association) (ECPA) were granted leave to intervene in support of the form of order sought by the applicants, and Deutscher Berufs- und Erwerbsimkerbund eV ('DBEB'), Österreichischer Erwerbsimkerbund ('ÖEB') and Österreichischer Imkerbund (ÖIB) were granted leave to intervene in support of the form of order sought by the Commission.

20 By orders of 27 March 2015, *BASF Agro and Others* v *Commission* (T-584/13, not published, EU:T:2015:203), and of 27 July 2015, *BASF Agro and Others* v *Commission* (T-584/13, EU:T:2015:580), the President of the First Chamber of the General Court ruled on the objections raised by some of the interveners to the requests for confidentiality submitted by the applicants.

21 On a proposal from the First Chamber, the Court decided, pursuant to Article 28 of its Rules of Procedure, to refer the case to the First Chamber sitting in extended composition.

22 Acting on a proposal from the Judge-Rapporteur, the Court (First Chamber, Extended Composition) decided to open the oral part of the procedure and, by way of measures of organisation of procedure provided for in Article 89 of the Rules of Procedure, put written questions to the parties, to which they replied within the prescribed period.

23 The parties presented oral argument and replied to the questions put by the Court at the hearing on 17 February 2017.

24 BASF, supported by the ECPA, claims that the Court should:

– annul the contested measure in its entirety or, in the alternative, in so far as it withdraws authorisation for the use and sale of sunflower seeds treated with fipronil;

– order the Commission to pay the costs.

25 The ESA claims that the Court should:

– annul the contested measure;

– order the Commission to pay the costs.

26 The Commission, supported by the DBEB, the ÖEB and the ÖIB, contends that the Court should:

– dismiss the action as unfounded;

– order BASF to pay the costs.

III. Law

A. Admissibility

27 The Commission submits that, unlike the first applicant, BASF Agro BV, the other applicants do not have the status of notifiers of the active substance fipronil and do not appear, therefore, to be individually concerned by the contested measure. Consequently, they cannot rely on the final limb of the fourth paragraph of Article 263 TFEU to challenge that measure, which, moreover, entails implementing measures.

28 BASF notes that the first applicant's standing to bring proceedings is not contested and argues that, since all the other applicants hold national authorisations for seed treatment products containing fipronil, they are directly and individually concerned by the contested measure. Furthermore, the contested measure is a regulatory act which concerns the applicants directly and does not entail implementing measures.

29 Under the fourth paragraph of Article 263 TFEU, any natural or legal person may, under the conditions laid down in the first and second paragraphs of that article, institute proceedings against an act addressed to that person or which is of direct and individual concern to them, and against a regulatory act which is of direct concern to them and does not entail implementing measures.

30 It must be noted, first of all, that the contested measure is a measure of general application in that it applies to objectively determined situations and entails legal effects for categories of persons envisaged in a general and abstract manner. Articles 1 to 4 of the contested measure concern the active substance fipronil and, in a general and abstract manner, anyone intending to produce, market or use that substance or seeds treated with plant protection products containing that substance, and anyone holding authorisations for those plant protection products. Consequently, having regard to those provisions and without prejudice to the existence of additional characteristics peculiar to them, all those persons are affected by the contested measure in the same way and are in the same situation.

31 Since the contested measure was not addressed to the applicants, it is necessary therefore to consider whether, as the applicants claim, that measure is of direct and individual concern to them or whether it is a regulatory act which is of direct concern to them and which does not entail implementing measures.

32 Given that both alternatives presuppose that the applicants are directly concerned, that condition should be examined first.

1. Direct concern to the applicants

33 With regard to the condition of direct concern to the applicants, it should be noted that that condition requires that the measure at issue directly affect the legal situation of the individual and that it leave no discretion to the addressees of the measure who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from the contested rules without the application of other intermediate rules (judgments of 5 May 1998, *Dreyfus* v *Commission*, C-386/96 P, EU:C:1998:193, paragraph 43; of 10 September 2009, *Commission* v *Ente per le Ville vesuviane* and *Ente per le Ville vesuviane* v *Commission*, C-445/07 P and C-455/07 P, EU:C:2009:529, paragraph 45; and order of 9 July 2013, *Regione Puglia* v *Commission*, C-586/11 P, not published, EU:C:2013:459, paragraph 31).

34 In the present case, Articles 1, 3 and 4 of the contested measure must be distinguished from Article 2 thereof.

(a) Articles 1, 3 and 4 of the contested measure

35 Article 1 of the contested measure amends the list of active substances approved for use in plant protection products that is set out in the Annex to Implementing Regulation No 540/2011. That amendment requires the Member States that have granted authorisations for plant protection products containing the active substance fipronil, without any discretion, to amend or withdraw them by 28 February 2014 at the latest, in accordance with Article 4 of the contested measure.

36 Consequently, Article 1 of the contested measure directly affects the legal situation of BASF, which produces and markets fipronil and plant protection products containing fipronil. The same applies to Articles 3 and 4 of the contested measure, which are purely ancillary to Article 1, in that they specify the arrangements for its implementation by the Member States.

(b) Article 2 of the contested measure

37 Article 2 of the contested measure prohibits the sale and use of seeds of crops which have been treated with plant protection products containing fipronil (with the exception of seeds used in greenhouses and seeds of leek, onions, shallots, and the group of *Brassica* vegetables intended to be sown in fields and harvested before flowering). This prohibition is to apply from 1 March 2014, as stated in Article 5 of the contested measure. Article 2 of the contested measure does not require implementing measures on the part of the Member States and thus applies directly.

38 It should, however, be noted in that regard that the persons concerned by the prohibition laid down in Article 2 of the contested measure are producers and traders of seeds that have been treated with fipronil, and farmers who wish to use those seeds.

39 BASF indicated at the hearing on 17 February 2017 that it did not itself market seeds treated with plant protection products containing fipronil. Admittedly the prohibition against using and marketing seeds treated with that substance has appreciable effects on BASF's economic situation, in that it will in fact no longer be possible for it to sell the products whose application to the seeds will result in the trade and the use of those seeds being prohibited. However, those effects are merely the economic consequence of a prohibition which, as a matter of law, affects only seed producers and farmers and not BASF itself. Therefore, those effects must be characterised as being indirect — since they are relayed via independent decisions of BASF's customers — and economic, rather than direct and legal. Taken in isolation, that prohibition does not affect BASF's right to market plant protection products containing fipronil.

40 It should be noted in that regard that the mere fact that an act may have economic repercussions on an applicant's activities is not sufficient to establish that that applicant is directly concerned by that act (orders of 18 February 1998, *Comité d'entreprise de la Société française de production and Others* v *Commission*, T-189/97, EU:T:1998:38, paragraph 48, and of 1 June 2015, *Polyelectrolyte Producers Group and SNF* v *Commission*, T-573/14, not published, EU:T:2015:365, paragraph 32; see also, to that effect, judgment of 27 June 2000, *Salamander and Others* v *Parliament and Council*, T-172/98 and T-175/98 to T-177/98, EU:T:2000:168, paragraph 62).

41 Consequently, Article 2 of the contested measure does not directly affect the legal situation of BASF.

42 In conclusion, only Articles 1, 3 and 4 of the contested measure are of direct concern to BASF. BASF is not, therefore, entitled to seek annulment of Article 2 of the contested measure.

2. Individual concern to the applicants

43 In so far as BASF is, in part, directly concerned by the contested measure, it is necessary, next, to examine whether BASF is individually concerned by it.

44 In that regard, it should be recalled that persons other than those to whom an act is addressed may claim to be individually concerned within the meaning of the fourth paragraph of Article 263 TFEU only if that act affects them, by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons, and thereby distinguishes them individually just as in the case of the person addressed (judgment of 15 July 1963, *Plaumann* v *Commission*, 25/62, EU:C:1963:17, p. 107, and order of 26 November 2009, *Região autónoma dos Açores* v *Council*, C-444/08 P, not published, EU:C:2009:733, paragraph 36).

45 The Courts of the European Union have, on a number of occasions, held that a notifier of an active substance, having submitted the dossier and participated in the assessment procedure, is individually concerned as much by a measure authorising the active substance subject to conditions as by a measure refusing authorisation (see, to that effect, judgments of 3 September 2009, *Cheminova and Others* v *Commission*, T-326/07, EU:T:2009:299, paragraph 66; of 7 October 2009, *Vischim* v *Commission*, T-420/05, EU:T:2009:391, paragraph 72; and of 6 September 2013, *Sepro Europe* v *Commission*, T-483/11, not published, EU:T:2013:407, paragraph 30). The same analysis must be considered to apply in principle where the measure in question withdraws or restricts the approval of the active substance referred to.

46 In the present case, it is common ground that BASF Agro BV is the legal successor of the notifier of fipronil, which submitted the dossier and participated in the assessment of that active substance, and that BASF Agro BV still has exclusive rights in respect of that substance. It is, therefore, individually concerned by the contested measure, which the Commission has, moreover, expressly acknowledged. It is therefore entitled to challenge Articles 1, 3 and 4 of the contested measure.

3. Admissibility of the action in so far as it was brought by the applicants other than BASF Agro BV

47 The Commission has doubts as to whether the applicants other than BASF Agro BV, which do not have the status of notifier of the active substance fipronil and which, at most, are holders of national authorisations to place plant protection products on the market, are individually concerned by the contested measure. Given that the restrictions on use laid down in Article 1 of the contested measure

entail implementing measures, they cannot, on any view, rely on the final limb of the fourth paragraph of Article 263 TFEU.

48 It should be observed in that regard that, as has been noted in paragraph 46 above, BASF Agro BV has standing to bring proceedings with respect to the application for annulment of Articles 1, 3 and 4 of the contested measure.

49 In those circumstances, since one and the same application is involved, there is no need to consider whether the other applicants are entitled to bring proceedings (see, to that effect, judgments of 24 March 1993, *CIRFS and Others* v *Commission*, C-313/90, EU:C:1993:111, paragraph 31; of 6 July 1995, *AITEC and Others* v *Commission*, T-447/93 to T-449/93, EU:T:1995:130, paragraph 82; and of 8 July 2003, *Verband der freien Rohrwerke and Others* v *Commission*, T-374/00, EU:T:2003:188, paragraph 57).

50 Furthermore, it is not apparent from the file that, from the point of view of the applicants other than BASF Agro BV, the admissibility of their application would extend beyond that of the application brought by BASF Agro BV.

51 Consequently, there is no need to consider whether the applicants other than BASF Agro BV are entitled to bring proceedings.

4. Summary with regard to admissibility

52 In conclusion, the action is admissible to the extent that BASF seeks annulment of Articles 1, 3 and 4 of the contested measure. As to the remainder, the action is inadmissible.

B. Substance

53 In the present case, the applicant raises complaints alleging infringement of Article 4, Article 12(2), Articles 21 and 49 and point 3.8.3 of Annex II to Regulation No 1107/2009, breach of the principles of legal certainty, protection of legitimate expectations and respect for the rights of the defence, breach of the precautionary principle and of the principles of proportionality and of good administration, and infringement of the obligation to state reasons.

1. General considerations

54 According to Article 1(3) of Regulation No 1107/2009, the purpose of the regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.

55 In requiring that a high level of protection of the environment be maintained, Regulation No 1107/2009 is applying Article 11 and Article 114(3)

TFEU. Article 11 TFEU provides that environmental protection requirements must be integrated into the definition and implementation of the European Union's policies and activities, in particular with a view to promoting sustainable development. Giving concrete expression to that obligation, Article 114(3) TFEU provides that, in its proposals concerning, inter alia, environmental protection, made on the basis of the approximation of laws which have as their object the establishment and functioning of the internal market, the Commission will take as a base a high level of protection, taking account in particular of any new development based on scientific facts, and that, within their respective powers, the European Parliament and the Council of the European Union will also seek to achieve this objective. The protection of the environment takes precedence over economic considerations, with the result that it may justify adverse economic consequences, even those which are substantial, for certain traders (see, to that effect, judgments of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 143; of 6 September 2013, *Sepro Europe* v *Commission*, T-483/11, not published, EU:T:2013:407, paragraph 85; and of 12 December 2014, *Xeda International* v *Commission*, T-269/11, not published, EU:T:2014:1069, paragraph 138).

56 Moreover, recital 8 of Regulation No 1107/2009 states that the precautionary principle should be applied and that the regulation seeks to ensure that industry demonstrate that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.

57 In that regard, it should be noted that the prior authorisation and approval procedures put in place by Regulation No 1107/2009 (and, previously, by Directive 91/414) for plant protection products and their active substances emanate from the general principle of EU law that is the precautionary principle (see, to that effect, judgment of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 133).

(a) The precautionary principle

(1) Definition

58 The precautionary principle is a general principle of EU law requiring the authorities in question, in the particular context of the exercise of the powers conferred on them by the relevant rules, to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests (see judgments of 21 October 2003, *Solvay Pharmaceuticals* v *Council*, T-392/02, EU:T:2003:277, paragraph 121 and the case-law cited, and of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 134 and the case-law cited; see also, to that effect, judgment of 26 November 2002, *Artegodan and Others* 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 183 and 184).

59 Where there is scientific uncertainty as to the existence or extent of risks to human health or to the environment, the precautionary principle allows the institutions to take protective measures without having to wait until the reality and seriousness of those risks become fully apparent or until the adverse health effects materialise (see judgments of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 135 and the case-law cited, and of 6 September 2013, *Sepro Europe* v *Commission*, T-483/11, not published, EU:T:2013:407, paragraph 44 and the case-law cited).

60 Within the process leading to the adoption by an institution of appropriate measures to prevent specific potential risks to public health, safety and the environment by reason of the precautionary principle, three successive stages can be identified: first, identification of the potentially adverse effects arising from a phenomenon; second, assessment of the risks to public health, safety and the environment which are related to that phenomenon; and, third, when the potential risks identified exceed the threshold of what is acceptable for society, risk management by the adoption of appropriate protective measures. Although the first of those stages does not require further explanation, the two subsequent stages call for clarification.

(2) Risk assessment

61 Assessment of the risks to public health, safety and the environment consists, for the institution required to consider potentially adverse effects arising from a phenomenon, in scientifically assessing those risks and in determining whether they exceed the level of risk deemed acceptable for society. Thus, in order for the institutions to be able to carry out a risk assessment, it is important for them, first, to have a scientific assessment of the risks and, second, to determine what level of risk is deemed unacceptable for society (see judgment of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 137 and the case-law cited).

(i) The scientific assessment

62 A scientific risk assessment is a scientific process consisting, in so far as possible, in the identification and characterisation of a hazard, the assessment of exposure to that hazard and the characterisation of the risk (see judgment of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 138 and the case-law cited).

63 In its communication COM(2000) 1 final of 2 February 2000 on the precautionary principle ('the Communication on the precautionary principle'), the Commission defined those four components of a scientific risk assessment as follows (see Annex III to that communication):

'Hazard identification means identifying the biological, chemical or physical agents that may have adverse effects …

Hazard characterisation consists of determining, in quantitative and/or qualitative terms, the nature and severity of the adverse effects associated with the causal agents or activity ...

Appraisal of exposure consists of quantitatively or qualitatively evaluating the probability of exposure to the agent under study …

Risk characterisation corresponds to the qualitative and/or quantitative estimation, taking account of inherent uncertainties, of the probability, of the frequency and severity of the known or potential adverse environmental or health effects liable to occur. It is established on the basis of the three preceding and closely depends on the uncertainties, variations, working hypotheses and conjectures made at each stage of the process. When the available data are inadequate or non-conclusive, a prudent and cautious approach to environmental protection, health or safety could be to opt for the worst-case hypothesis. When such hypotheses are accumulated, this will lead to an exaggeration of the real risk but gives a certain assurance that it will not be underestimated.'

64 As a scientific process, the scientific risk assessment must be entrusted by the institution to scientific experts (judgments of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 157; of 11 September 2002, *Alpharma* v *Council*, T-70/99, EU:T:2002:210, paragraph 170; and of 9 September 2011, *France* v *Commission*, T-257/07, EU:T:2011:444, paragraph 73).

65 The scientific risk assessment is not required to provide the institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality. A situation in which the precautionary principle is applied by definition coincides with a situation in which there is scientific uncertainty. Furthermore, the adoption of a preventive measure, or, conversely, its withdrawal or relaxation, cannot be made subject to proof of the lack of any risk, in so far as such proof is generally impossible to give in scientific terms since zero risk does not exist in practice (judgment of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 140; see also, to that effect, judgment of 21 October 2003, *Solvay Pharmaceuticals* v *Council*, T-392/02, EU:T:2003:277, paragraph 130). However, a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified (judgments of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraphs 142 and 143, and of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 140; see also, to that effect, judgment of 11 July 2007, *Sweden* v *Commission*, T-229/04, EU:T:2007:217, paragraph 161).

66 Indeed, the scientific risk assessment should be based on the best scientific data available and should be undertaken in an independent, objective and transparent manner (see judgment of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 141 and the case-law cited).

67 In addition, it must be noted that it may prove impossible to carry out a full scientific risk assessment because of the inadequate nature of the available scientific data. However, that does not prevent the competent public authority from taking preventive measures in accordance with the precautionary principle. It is important, in such a situation, that scientific experts carry out a scientific risk assessment notwithstanding the existing scientific uncertainty, so that the competent public authority has available to it sufficiently reliable and cogent information to allow it to understand the ramifications of the scientific question raised and decide upon a policy in full knowledge of the facts (judgment of 9 September 2011, *France* v *Commission*, T-257/07, EU:T:2011:444, paragraph 77; see also, to that effect, judgments of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraphs 160 to 163, and of 11 September 2002, *Alpharma* v *Council*, T-70/99, EU:T:2002:210, paragraphs 173 to 176).

68 Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures, provided they are non-discriminatory and objective (judgment of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 142 and the case-law cited, and judgment of the EFTA Court of 5 April 2001, *EFTA Surveillance Authority* v *Norway*, E–3/00, EFTA Court Report 2000-2001, p. 73, paragraph 31).

69 It follows that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been ‘fully’ demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken (see judgment of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 143 and the case-law cited).

70 In such a situation, ‘risk’ thus constitutes the degree of probability that the acceptance of certain measures or practices will adversely affect the interests safeguarded by the legal order. ‘Hazard’ (‘danger’) is commonly used in a broader sense and describes any product or procedure capable of having an adverse effect on human health or any other interest safeguarded by the legal order (judgment of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 144; see also, by analogy, judgments of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209,

paragraph 147, and of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 147).

(ii) The determination of the level of risk deemed unacceptable

71 The responsibility for determining the level of risk which is deemed unacceptable for society lies, provided that the applicable rules are observed, with the institutions responsible for the political choice of determining an appropriate level of protection for society. It is for those institutions to determine the critical probability threshold for adverse effects on public health, safety and the environment and for the degree of those potential effects which, in their judgment, is no longer acceptable for society and above which it is necessary, in the interests of protecting public health, safety and the environment, to take preventive measures in spite of the existing scientific uncertainty (judgment of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 145; see also, to that effect, judgments of 11 July 2000, *Toolex*, C-473/98, EU:C:2000:379, paragraph 45, and of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraphs 150 and 151).

72 In determining the level of risk deemed unacceptable for society, the institutions are bound by their obligation to ensure a high level of protection of public health, safety and the environment. That high level of protection does not necessarily have to be the highest that is technically possible, in order to be compatible with Article 114(3) TFEU (judgment of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 146; see also, to that effect, judgment of 14 July 1998, *Safety Hi-Tech*, C-284/95, EU:C:1998:352, paragraph 49). Moreover, those institutions may not take a purely hypothetical approach to risk and may not base their decisions on a 'zero risk' (judgments of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 152, and of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 146).

73 The level of risk deemed unacceptable for society will depend on the assessment made by the competent public authority of the particular circumstances of each individual case. In that regard, the authority may take account, inter alia, of the severity of the impact on public health, safety and the environment were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects as well as of the more or less concrete perception of the risk based on available scientific knowledge (judgment 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 147; see also, to that effect, judgment of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 153).

(3) Risk management

74 Risk management corresponds to the body of actions taken by an institution faced with a risk in order to reduce it to a level deemed acceptable for society having regard to its obligation, in accordance with the precautionary principle, to ensure a high level of protection of public health, safety and the environment (judgment 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 148).

75 Those actions include the adoption of provisional measures, which must be proportionate, non-discriminatory, transparent, and consistent with similar measures already taken (judgment 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 149; see also, to that effect, judgment of 1 April 2004, *Bellio F.lli*, C-286/02, EU:C:2004:212, paragraph 59).

(b) Review of an active substance included in Part A of the Annex to Implementing Regulation No 540/2011

76 As explained in paragraphs 1 and 3 above, fipronil was approved under the rules laid down by Directive 91/414, in accordance with the conditions that applied at the time, and is now listed in Part A of the Annex to Implementing Regulation No 540/2011.

77 Since the review of its approval by the Commission was carried out pursuant to Regulation No 1107/2009, it should be noted in that regard that the specific requirements for the approval of active substances changed when that regulation was adopted.

(1) The original conditions for inclusion under Directive 91/414

78 Article 5(1) of Directive 91/414 provided that, in order for a substance to be included in Annex I thereto, it had to be the case that it could be expected that, in the light of then current scientific and technical knowledge, the use of, and residues from, plant protection products containing that active substance, consequent on application consistent with good plant protection practice, would not have any harmful effects on human or animal health or any unacceptable influence on the environment.

79 It has been held that it followed from Article 5(1) of Directive 91/414, interpreted in conjunction with the precautionary principle, that, in the domain of human health, the existence of solid evidence which, while not resolving scientific uncertainty, could reasonably raise doubts as to the safety of a substance, justified, in principle, the refusal to include that substance in Annex I thereto (judgment of 11 July 2007, *Sweden* v *Commission*, T-229/04, EU:T:2007:217, paragraph 161). Those considerations apply, by analogy, in respect of the other interests protected by Article 4 of Regulation No 1107/2009 (identical to those protected by

Article 5(1) of Directive 91/414), namely, in particular, animal health and the environment.

80 However, it is also apparent from the case-law that the effect of Article 5(4) of Directive 91/414, which provides that inclusion of an active substance in Annex I to that directive may be subject to restrictions on use, is to permit inclusion of substances which do not fulfil the requirements of Article 5(1) of the directive subject to certain restrictions which exclude problematic uses of the substance involved. Since Article 5(4) of Directive 91/414 is to be regarded as a limitation on Article 5(1) of that directive, it must be interpreted in the light of the precautionary principle. Consequently, before including a substance in that annex, it must be established beyond a reasonable doubt that the restrictions on the use of the substance involved make it possible to ensure that use of that substance will be in accordance with the requirements laid down in Article 5(1) of the directive (judgment of 11 July 2007, *Sweden* v *Commission*, T-229/04, EU:T:2007:217, paragraphs 169 and 170).

81 Last, it has been held that, under the rules laid down by Directive 91/414, it is the notifier who has to demonstrate that, on the basis of the information submitted for one or more preparations for a limited range of representative uses, the conditions for approval are met (judgment of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 154).

(2) Amendment of the approval criteria by Regulation No 1107/2009

82 It is apparent, when Article 5 of Directive 91/414 is compared with Article 4 of Regulation No 1107/2009, that, in the replacement of Directive 91/414 by Regulation No 1107/2009, the general approval criteria and conditions were reformulated in greater detail, although that did not necessarily lead to any substantive strengthening of those criteria and conditions.

83 In addition, the uniform principles for evaluation and authorisation of plant protection products, defining in particular the thresholds for hazard quotients for oral and contact exposure, did not change substantially when Regulation No 1107/2009 entered into force.

84 However, Regulation No 1107/2009 introduced specific new requirements for the approval of active substances, including, in particular, point 3.8.3 of Annex II to that regulation, which contains special requirements in relation to the exposure of honeybees and acute or chronic effects on colony survival and development. It follows from a comparison of that criterion with the earlier legislation and, in particular, Article 5(1) of Directive 91/414, that the requirements relating to the absence of unacceptable effects on bees were substantially strengthened when Regulation No 1107/2009 entered into force, in so far as it is now expressly required that exposure of honeybees to the active substance in question be only ‘negligible’ or that its use not have ‘unacceptable acute or chronic effects on

colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour'.

85 Recital 10 of Regulation No 1107/2009 states that, for active substances already approved prior to entry into force of the regulation, criteria harmonised by Regulation No 1107/2009 are to be applied at the time of renewal or review of their approval. It follows that, in the present case, the review of the approval of fipronil, approved under Directive 91/414, must proceed according to the criteria and conditions set out by Regulation No 1107/2009.

(3) The burden of proof

86 Last, it is evident from the wording and the organisation of the relevant provisions of Regulation No 1107/2009 that the burden of proving that the conditions for approval under Article 4 of Regulation No 1107/2009 are met lies, in principle, with the notifier, as was expressly provided for in Directive 91/414 (see paragraph 81 above).

87 In particular, recital 8 of Regulation No 1107/2009 states that the regulation 'should ensure that industry demonstrates that substances or products produced or placed on the market do not have … any unacceptable effects on the environment'. Similarly, according to recital 10, substances should be included in plant protection products 'only ... where it has been demonstrated', in particular, that they are not expected to have any unacceptable effects on the environment.

88 Furthermore, Article 4(1) of Regulation No 1107/2009, which sets out the conditions for approval of active substances, requires that it may be 'expected' that the plant protection products containing an active substance meet the requirements provided for in paragraphs 2 and 3 of that article, which, in turn, require that those products and their residues meet the requirements that are then set out. In accordance with the principle that a party who relies on a legal provision must prove that the conditions of application of that provision are met, it follows from the wording above that it is the person seeking approval who must prove that the conditions of such approval are met in order to obtain it, and not the Commission that must prove that the conditions of approval are not met in order to be able to refuse it.

89 However, in the context of a review taking place before the end of the approval period, it is for the Commission to demonstrate that the conditions of approval are no longer met. It is the party that relies on a legal provision — in this instance, Article 21(3) of Regulation No 1107/2009 — that must prove that the conditions of its application are met. It should be pointed out in that regard that acceptance that in cases of scientific uncertainty reasonable doubts as to the safety of an active substance approved at EU level are capable of justifying a precautionary measure cannot be treated as equivalent to a reversal of the burden of proof (see, by analogy, judgment of 26 November 2002, *Artegodan and Others* 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, paragraph 191).

90 Nevertheless, the Commission discharges the burden of proof if it establishes that the conclusion, at the time of the initial approval, that the approval criteria provided for in Article 4 of Regulation No 1107/2009 were satisfied is invalidated by subsequent regulatory or technical developments.

91 Thus, the Commission will discharge to the requisite legal standard its burden of proof, in the light of Article 21(3) of Regulation No 1107/2009, if it is able to demonstrate that, in the light of a legislative change involving a strengthening of the conditions of approval, 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, as regards, for example, certain routes of exposure. The precautionary principle requires the withdrawal or amendment of an approval of an active substance where new data invalidate the earlier conclusion that that substance satisfies the approval criteria provided for in Article 4 of Regulation No 1107/2009. Against that background, the Commission need do no more than provide, in accordance with the general rules of evidence, solid and convincing evidence which, while not resolving the scientific uncertainty, may reasonably raise doubts as to the fact that the active substance in question satisfies the approval criteria (see, to that effect and by analogy, judgment of 26 November 2002, *Artegodan and Others* 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, paragraph 192).

2. Scope of judicial review

92 If the Commission is to be able to pursue effectively the objectives assigned to it by Regulation No 1107/2009 (see paragraphs 54 to 56 above), account being taken of the complex technical assessments which it must undertake, it must be recognised as enjoying a broad discretion (see, to that effect, judgments of 18 July 2007, *Industrias Químicas del Vallés* v *Commission*, C-326/05 P, EU:C:2007:443, paragraphs 74 and 75, and of 6 September 2013, *Sepro Europe* v *Commission*, T-483/11, not published, EU:T:2013:407, paragraph 38). That applies, in particular, to risk management decisions which it must take pursuant to that regulation.

93 The exercise of that discretion is not, however, excluded from judicial review. In that regard, according to settled case-law, in the context of such a review the Courts of the European Union must verify 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 manifest error of assessment or a misuse of powers (judgments of 25 January 1979, *Racke*, 98/78, EU:C:1979:14, paragraph 5; of 22 October 1991, *Nölle*, C-16/90, EU:C:1991:402, paragraph 12; and of 9 September 2008, *Bayer CropScience and Others* v *Commission*, T-75/06, EU:T:2008:317, paragraph 83).

94 As regards the assessment by the Courts of the European Union as to whether there has been a manifest error of assessment, it must be stated that, in order to establish that the Commission made a manifest error in assessing complex facts such as to justify the annulment of the contested measure, the evidence adduced by the applicant must be sufficient to make the factual assessments used in that measure implausible (see, to that effect, judgments of 12 December 1996, *AIUFFASS and AKT* v *Commission*, T-380/94, EU:T:1996:195, paragraph 59, and of 1 July 2004, *Salzgitter* v *Commission*, T-308/00, EU:T:2004:199, paragraph 138). Without prejudice to that examination of plausibility, it is not for the General Court to substitute its assessment of complex facts for that of the institution which adopted the measure (judgment of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 152; see also, to that effect, judgment of 15 October 2009, *Enviro Tech (Europe)*, C-425/08, EU:C:2009:635, paragraph 47).

95 Moreover, it must be recalled that, where an institution has a wide discretion, the review of observance of guarantees conferred by the EU legal order in administrative procedures is of fundamental importance. The Court of Justice has had occasion to specify that those guarantees include, in particular for the competent institution, the obligations to examine carefully and impartially all the relevant elements of the individual case and to give an adequate statement of the reasons for its decision (judgments of 21 November 1991, *Technische Universität München*, C-269/90, EU:C:1991:438, paragraph 14; of 7 May 1992, *Pesquerias de Bermeo and Naviera Laida* v *Commission*, C-258/90 and C-259/90, EU:C:1992:199, paragraph 26; and of 6 November 2008, *Netherlands* v *Commission*, C-405/07 P, EU:C:2008:613, paragraph 56).

96 Thus, it has already been held that a scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures (judgment of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 172).

3. Complaints relating to the application of Article 21(1) of Regulation No 1107/2009

97 BASF submits, in essence, that the Commission was not entitled to review the approval of fipronil, since the requirements set out in that respect in Article 21(1) of Regulation No 1107/2009 were not met.

98 The Commission contests BASF's arguments.

99 Article 21 of Regulation No 1107/2009 is structured as follows.

100 Paragraph 1 provides that the Commission may at any time review the approval of an active substance, either on its own initiative or at the request of a Member

State. In accordance with the second subparagraph of paragraph 1, where the Commission decides to carry out a review, it is to inform the Member States, EFSA and the producer of the substance in question and set a period for the producer to submit its comments.

101 Paragraph 2 provides that, in the context of the review, the Commission may ask the Member States and EFSA for an opinion, or for scientific or technical assistance, and prescribes the time limits with which they must comply.

102 Last, paragraph 3 provides that, where the Commission concludes that the approval criteria are no longer satisfied, it is to propose the adoption of a regulation to withdraw or amend the approval, under the committee procedure, in accordance with Article 79(3) of Regulation No 1107/2009.

(a) The threshold for the application of Article 21(1) of Regulation No 1107/2009

103 BASF has not specifically expressed a view on the threshold for the application of Article 21(1) of Regulation No 1107/2009, since, in its arguments, it does not maintain a strict distinction between the respective conditions for applying paragraph 1 and paragraph 3 of that article. However, it contends, in particular, that there was no new scientific and technical knowledge within the meaning of Article 21(1) of Regulation No 1107/2009 indicating that the substances concerned no longer met the approval criteria.

104 The ECPA, intervening in support of BASF, submits, inter alia, that the requirement for the scientific and technical knowledge in question to be 'new' should not be understood primarily as being temporal, but rather as a qualitative requirement.

105 The Commission contests those arguments.

106 In the first place, it must be noted that it is evident from the actual wording of Article 21 of Regulation No 1107/2009 that the threshold for the application of paragraph 1 thereof is lower than that of paragraph 3.

107 First of all, the first sentence of Article 21(1) provides that the Commission may review the approval of an active substance 'at any time'. Although the implementation of that very general power is subsequently made subject to certain conditions, the legislature's choice of wording indicates that it did not consider that the approval of an active substance must give the notifier special protection against the initiation of a review procedure.

108 In addition, whereas the second subparagraph of Article 21(1) provides for a review, in particular, where the Commission 'considers that there are indications that the substance no longer satisfies the approval criteria provided for in Article 4', paragraph 3 of that article requires the Commission to have 'conclude[d] that the approval criteria provided for in Article 4 are no longer

satisfied', if a regulation to withdraw or amend the approval is to be adopted. The wording of Article 21 itself therefore indicates that the threshold for the application of paragraph 1 is lower than that of paragraph 3.

109 That is consistent with the structure of Article 21, outlined in paragraphs 99 to 102 above. The review procedure is precisely required to enable the Commission, in the event of new scientific knowledge emerging to suggest that the substance in question might no longer satisfy the approval criteria, to verify whether that is indeed the case. It would therefore be entirely illogical to require the same degree of certainty for initiation of the review procedure as for the withdrawal or amendment of the approval.

110 In the second place, as regards the specific definition of the threshold for the application of Article 21(1) of Regulation No 1107/2009, it should be noted that the interests of the notifiers of the substances in question are protected by the fact that an approval can actually be amended or withdrawn only if, at the end of the review procedure, it is concluded that the conditions of Article 4 of Regulation No 1107/2009 are no longer satisfied. Moreover, in order to be able to establish whether that is indeed the case, taking account, in particular, of the objective of protection pursued by Regulation No 1107/2009 (see paragraphs 54 to 56 above), the Commission must be able to initiate a review even if the degree of doubt raised by the new scientific and technical knowledge is only relatively small.

111 Nonetheless, that does not mean that the Commission is entirely free in making its assessment. As the ECPA correctly noted, the concept of 'new scientific and technical knowledge' cannot be understood as only temporal; it also has a qualitative component which applies, moreover, both to the term 'new' and to the term 'scientific'. It follows that the threshold for the application of Article 21(1) of Regulation No 1107/2009 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 Regulation No 1107/2009 are still met.

112 Last, in the third place, the definition of the level of previous scientific and technical knowledge should also be clarified, since the newness of new knowledge can only be assessed in relation to a previous level. It must be concluded in that regard that the previous level of knowledge cannot be that which immediately precedes publication of the new knowledge, but rather that which obtained at the time of the previous risk assessment of the substance concerned. First, that previous assessment represents a stable benchmark since it contains a summary of the knowledge available at the time. Second, if the novelty of the knowledge related to the level of knowledge immediately preceding its publication, it would not be possible to take account of the gradual development of scientific and technical knowledge, each stage of which may not necessarily in itself raise concerns, but which, as a whole, may give rise to concern.

113 In the present case, since the previous risk assessment for fipronil took place on 3 March 2006, as is evident from recital 3 of Directive 2007/52, the level of previous knowledge was thus that which obtained on 3 March 2006.

114 In conclusion, in order for the Commission to be able to carry out a review of the approval of an active substance under Article 21(1) of Regulation No 1107/2009, it is therefore sufficient that there are new studies (that is to say, studies which have not yet been taken into account by EFSA or the Commission in an earlier assessment of the substance concerned) the results of which, as compared with the knowledge available at the time of the earlier assessment, raise concerns as to whether the conditions of approval in Article 4 of Regulation No 1107/2009 are still satisfied, and it is not necessary, at that stage, to verify whether those concerns are well founded, such verification being a matter for the review itself.

(b) The information relied on by the Commission in order to justify initiation of the review procedure

115 In order to identify which information the Commission was entitled or, as the case may be, was required to take into account in its decision to review the approval of fipronil, in the first place, it is necessary to determine when that decision was taken.

116 It should be noted that, on 6 August 2012 (see paragraph 10 above), the Commission mandated EFSA to update the risk assessment of fipronil with regard to bees, in particular as regards (i) the acute and chronic effects on colony development and survival, and (ii) the effects of sub-lethal doses on bee survival and behaviour. Such an 'update' cannot but be interpreted as the first stage of the review of the approval of the substances in question, within the meaning of Article 21 of Regulation No 1107/2009, namely that of identifying and assessing the risks posed by those substances, a task which Regulation No 1107/2009 confers on EFSA (the second stage, risk management, being the Commission's responsibility). The date of 6 August 2012 must therefore be accepted as being the date on which, at the latest, the Commission decided to carry out the review.

117 In reply to a written question from the Court, the Commission essentially confirmed that date, while emphasising that, since Article 21(1) of Regulation No 1107/2009 does not require a formal decision to be adopted in order for a review to be initiated, the date of 6 August 2012 merely represented the temporal limit of a decision-making process that extended over a certain period of time.

118 Consequently, the 'new scientific and technical knowledge' within the meaning of Article 21(1) of Regulation No 1107/2009 had to pre-date 6 August 2012 in order to be capable of justifying the initiation of the review procedure.

119 In the second place, it should be noted that the contested measure does not precisely identify the new scientific and technical knowledge that led the Commission to carry out a review of the approval of fipronil. Recital 4 of that

measure refers, in general terms, to 'new information received from Italy concerning risks to honeybees caused by coated maize seeds treated with plant protection products containing fipronil'. It is, however, apparent from the file that what was at issue was the report on the Apenet project, mentioned in paragraph 7 above, and the statement by EFSA mentioned in paragraph 9 above, containing EFSA's scientific assessment of the Apenet project and its results (see paragraph 9 above). Moreover, the Commission was in possession of the EFSA Opinion (see paragraph 8 above), which called into question the scheme for the assessment of risks posed by plant protection products to bees that had been applied until then.

(c) Whether the Commission had new scientific and technical knowledge, within the meaning of Article 21(1) of Regulation No 1107/2009, at the time of the initiation of the review procedure

(1) The results of the Apenet project

120 The Apenet project was a multidisciplinary monitoring and research project, mainly aimed at evaluating the status of bee health, the dust dispersal during the sowing of maize seeds treated with certain neonicotinoids and fipronil, the lethal effects on bees exposed to that dust and the effects on bees' homing behaviour and orientation. In the context of that project, tests were carried out in which bees were exposed to dust during sowing, with and without the installation of deflectors on sowing machines, and tests were carried out on the effects of contamination with sub-lethal doses of fipronil on bee navigation, and the learning abilities and olfactory memory of bees.

121 Following EFSA's evaluation of the Apenet project at the Commission's request, it concluded in its statement that, due to some deficiencies in the design of the studies, weaknesses in the statistical analysis and the incomplete nature of the reporting of results, it was not possible to draw a definitive conclusion on all the scientific information gathered in the context of that project. Nevertheless, EFSA considered it possible to draw the following conclusions with regard to fipronil:

– forager bees are at risk if they fly through the dust clouds emitted by seeders sowing maize seeds coated with fipronil;

– some potential concerns such as lethal effects on bees exposed to dust and sub-lethal effects were identified, suggesting that a change in the assessment of fipronil as regards its effects on bees might be required.

122 It is true in that respect, as BASF claims, that the acute risk from dust exposure during sowing was not new, since it had already been mentioned in the Annex to Directive 2007/52 adding fipronil to Annex I to Directive 91/414, which provided that, in order to ensure that the release of dust clouds during storage, transport and application could be excluded, the best available techniques had to be applied.

123 However, EFSA also noted potential concerns with regard to sub-lethal effects which, according to EFSA, suggested a change in the assessment of fipronil. That confirmed the general reservations, contained in the EFSA Opinion published on 23 May 2012, regarding the scheme for the assessment of risks posed by plant protection products to bees that had been applied until then.

124 In those circumstances, the Commission was right, and made no error of law, in finding that, as compared with previous knowledge, the results of the Apenet project raised concerns as to whether the conditions of approval in Article 4 of Regulation No 1107/2009 were still satisfied. That applies in particular to the condition laid down in Article 4(3)(e) of that regulation, relating to unacceptable effects on the environment and, specifically, to the impact on non-target species.

(2) The role of monitoring data

125 The parties disagree on the role to be assigned to monitoring data in the context of the decision, under Article 21(1) of Regulation No 1107/2009, to initiate a review of the approval of an active substance, and in the context of the risk assessment and the decision to be taken by the Commission pursuant to Article 21(3) of that regulation.

126 BASF submits, in essence, that the Commission and, where appropriate, EFSA are obliged to take into account available monitoring data in the same way as the 'new scientific and technical knowledge' referred to in Article 21(1) of Regulation No 1107/2009. It states that the monitoring data available show that, in field conditions for the application of plant protection products containing fipronil, there is no risk for bees at colony level.

(i) The concept of monitoring data

127 It must be noted, first of all, that the concept of 'monitoring data' is not defined in Regulation No 1107/2009.

128 It is apparent, however, from the parties' replies to a written question put by the Court that monitoring data are data gathered following the real-life application in the field of plant protection products containing a substance approved pursuant to Regulation No 1107/2009. In some cases, those data are gathered in the context of monitoring programmes — which are conducted over a period of years and which typically do not include a control group that has not been exposed to the active substance in question — in which the non-simulated application of pesticides is observed and studied. Given that these are non-interventional studies, the parameters for bee exposure to pesticides are neither defined nor controlled. Despite certain attempts at achieving standardisation within some monitoring programmes, there is no uniform methodology for monitoring studies that could ensure consistency in the quality of data generated, the quality of which thus depends on observance of scientific principles and good practice. A fortiori, the

quality and consistency of monitoring data gathered outside a monitoring programme are not guaranteed.

129 It is also apparent from the replies of the parties to the written questions put by the Court that monitoring studies must be distinguished from field studies, also described as 'tier 3 studies'. The latter are experimental studies, with clearly defined parameters and a control group of untreated colonies, which are conducted over a period of weeks or months, in which real-life conditions of colony exposure to pesticides are simulated as far as possible.

(ii) The value to be attributed to monitoring data

130 The Commission states that, given the absence of a control population and of clearly identified scientific parameters that distinguish the observed situation from a control population, the monitoring studies do not allow credible conclusions about causality to be drawn. It concludes from this that monitoring studies may reveal the existence of a risk, but, unlike field studies, they cannot be used to establish the absence of a risk.

131 At the hearing, BASF took issue with that assertion. It stated in particular that the relevance of the monitoring data depended on the degree of realism of the conditions in which the monitoring studies had been conducted, and that, for example, studies conducted in Spain, where there were many bees, were particularly relevant. BASF also noted that some monitoring studies included a control group comprising colonies placed next to untreated crops. In its opinion, the monitoring studies cover all situations and routes of exposure, and any weaknesses must be weighed up in the evaluation rather than result in the studies concerned or the data generated by them being dismissed out of hand.

132 It should be noted in that regard that, as has been stated in paragraphs 128 and 129 above, field studies are experimental scientific studies, with clear parameters and a control group, whereas monitoring studies are (non-interventional) observational studies, without defined parameters. Consequently, the quality of the data generated by the two types of study differs, particularly as regards their ability to sustain conclusions concerning the relationship of cause and effect of a phenomenon observed, or concerning a lack of causality, in the absence of a phenomenon observed.

133 Thus, it must be observed that monitoring studies merely enable a coincidence of two observed facts to be established, not a correlation, a term which presupposes the establishment of a link between the two facts. Owing to the absence of defined and controlled parameters in the monitoring studies, it is necessarily the case that such a link cannot be established between two observed facts in such a study. Since a multitude of undefined factors, which cannot be monitored and which are capable of influencing the facts observed, are present in the field (exposure, altitude, meteorological conditions, environment of the hives, adjacent crops,

etc.), two facts observed as being coincident cannot be related to each other with any certainty, in the sense of a correlation.

134 It follows from this that monitoring data, whether collected in the context of a monitoring programme or otherwise, cannot be treated in the same way as data generated by field studies as regards their ability to be used to support scientific findings as to the existence or absence of a cause-and-effect relationship.

135 That does not, however, mean that monitoring data are of no use or relevance. Such data may provide information as to whether or not the application of plant protection products containing fipronil coincides with the phenomena of elevated bee mortality or colony collapse. That information may then serve, for the risk managers concerned, as evidence of the existence or non-existence of risks — albeit that those risks may not be established with any certainty.

136 The Commission was therefore right in submitting that, while monitoring studies may reveal evidence of the existence of a risk, they cannot, unlike field studies, be used to demonstrate the absence of a risk.

(iii) The role of monitoring data in the context of the decision to carry out a review under Article 21(1) of Regulation No 1107/2009

137 It is apparent from the first subparagraph of Article 21(1) of Regulation No 1107/2009 that, although the Commission is required to 'take into account' the request of a Member State to review the approval of an active substance, it is free to assess whether such a review must be undertaken, taking into account new scientific knowledge available. That constitutes, moreover, protection for producers of approved active substances against unfounded, or unlawful, requests for review that might be put forward by Member States.

138 Monitoring data are mentioned in that subparagraph, in the second sentence, solely in order to describe the circumstances in which Member States may request that an approval be reviewed, and not those governing the Commission's decision to initiate a review procedure. The latter circumstances are determined in the second subparagraph of Article 21(1) of Regulation No 1107/2009, which provides only for 'new scientific and technical knowledge' to be taken into account. If it were otherwise, the second subparagraph would be a duplication, in that it would provide for the Commission to take into account new scientific and technical knowledge already referred to in the second sentence of the first subparagraph.

139 It should be recalled in that regard that the purpose of the reassessment of the approval of an active substance is precisely to verify new scientific knowledge thoroughly and to consider whether it supports the conclusion that the substance does not satisfy or no longer satisfies (entirely) the approval criteria set out in Article 4 of Regulation No 1107/2009 (see paragraph 109 above).

140 It follows from this that, if the monitoring data relied on by BASF consistently failed to show increased bee mortality or colony collapse coinciding with the use of plant protection products containing fipronil, the data would indeed be capable of casting doubt on the concerns raised by the results of the Apenet project summarised in paragraph 121 above. The data were not, however, capable of demonstrating that those concerns were unfounded.

141 Furthermore, contrary to BASF's claims, the monitoring data did not consistently indicate that plant protection products containing fipronil were safe for bees. BASF referred to a study on monitoring data which it had drawn to the Commission's attention and which had been favourable to it ('the 2011 Bernal study'), in so far as it did not identify residues of fipronil or of its metabolites in the samples examined.

142 It should be observed first of all in that regard that BASF drew the Commission's attention to that study in its comments of 12 June 2013 on EFSA's Conclusions, and thus after the decision to initiate the review procedure. In addition, it had not claimed that EFSA had failed to take account of the 2011 Bernal study, which, moreover, is referred to several times in EFSA's Conclusions, but that those conclusions did not expressly include one of the conclusions of the study, which was particularly favourable to BASF.

143 Finally, and above all, BASF omits to mention several monitoring studies, mentioned, like the 2011 Bernal study, in the section of EFSA's Conclusions entitled 'Monitoring data', which had detected residues of fipronil or of its metabolites in bee samples. It must therefore be held that the available monitoring data did not make it possible to draw unequivocal conclusions to the effect that there was no risk to bees associated with fipronil. The Court must therefore reject BASF's argument relating to the failure to take account of the 2011 Bernal study in the decision to initiate the review procedure.

144 The Commission was therefore fully entitled to find, in the present case, that it was appropriate to review the approval of fipronil.

145 Consequently, the complaints relating to the application of Article 21(1) of Regulation No 1107/2009 must be rejected.

4. Complaints relating to the application of Article 21(3) of Regulation No 1107/2009

146 BASF raises two sets of complaints relating to the application by the Commission and by EFSA of Article 21(3) of Regulation No 1107/2009, namely, first, the fact that the Commission and EFSA allegedly applied methodologies and criteria that differed from those applicable at the time of the request for approval of fipronil and, second, manifest errors in the application of the precautionary principle or misapplication of that principle.

147 The complaints relating to misapplication of the precautionary principle must be examined first of all.

148 In that regard, BASF submits, first, that there is no scope for application of the precautionary principle in the context of Regulation No 1107/2009, outside the emergency procedures provided for in Articles 69 and 70 of that regulation.

149 Second, BASF maintains that the Commission did not produce evidence to show that fipronil no longer satisfied the criteria laid down in Article 4 of Regulation No 1107/2009, as it was required to do under Article 21(3) of that regulation. In particular, the high acute risk linked to dust, identified by EFSA in relation to maize, did not result in an unacceptable effect on the survival and development of bee colonies. In any event, the Commission had not even submitted solid evidence that could reasonably raise doubts as to the safety of fipronil and justify the contested measure.

150 Furthermore, BASF submits that, in the present case, the Commission did not meet the conditions for the proper application of the precautionary principle.

151 The Commission contests BASF's arguments.

(a) The question whether the contested measure is based on the application of the precautionary principle

152 First of all, it should be noted that the contested measure is based, inter alia, on the precautionary principle, even though that principle is not specifically mentioned in its recitals.

153 It is apparent from recital 8 of Regulation No 1107/2009 and Article 1(4) thereof that all the provisions of that regulation are underpinned by the precautionary principle with a view to ensuring that active substances or products do not adversely affect, inter alia, the environment. It follows from this that any act adopted on the basis of Regulation No 1107/2009 is *ipso jure* founded on the precautionary principle.

154 Furthermore, the application of the precautionary principle is not limited to cases in which it is uncertain that there is a risk; the principle may also be applied where a risk has been proved to exist and where the Commission must assess whether that risk is acceptable or not (see paragraphs 71 to 73 above), or assess how it should be dealt with in a risk management context (see paragraph 74 above).

155 As regards the argument put forward by BASF that the application of the precautionary principle, in the context of Regulation No 1107/2009, is limited to emergency procedures, this is based on the proposition that the precautionary principle is already integrated in the provisions of that regulation and, in particular, in the emergency procedures provided for in Articles 69 and 70, which embody the essential elements of the application of that principle. It follows,

according to BASF, that it is not possible to apply that principle in the context of the other provisions of Regulation No 1107/2009.

156 It is sufficient, for the purpose of rejecting that argument, to recall that, as is apparent from recital 8 of Regulation No 1107/2009 and Article 1(4) thereof, all the provisions of that regulation are underpinned by the precautionary principle with a view to ensuring that active substances or plant protection products do not adversely affect, inter alia, the environment. That basis is not limited to Articles 69 and 70 of Regulation No 1107/2009, relating to emergency procedures. As the Commission correctly notes, that statement is confirmed by settled case-law according to which the precautionary principle must be applied for the assessment of the approval criteria provided for in Article 4 of Regulation No 1107/2009 (see, by analogy, judgments of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 152 and the case-law cited, and of 6 September 2013, *Sepro Europe* v *Commission*, T-483/11, not published, EU:T:2013:407, paragraph 44 and the case-law cited), to which Article 21(3) of that regulation refers.

(b) The question whether the Commission applied the precautionary principle correctly, in a risk management context

157 BASF raises various complaints relating to the way in which the Commission applied the precautionary principle in the context of risk management. In particular, it submits that the Commission failed to carry out an impact assessment, that it (BASF) was not involved in risk management options and that the measures taken are disproportionate.

158 The complaint alleging the lack of any impact assessment should be examined first.

159 BASF submits in that regard that the Commission did not analyse the potential costs and benefits of the restrictions imposed or of a lack of action, even though such an analysis is provided for in point 6.3.4 of the Communication on the precautionary principle.

160 The Commission contests BASF's arguments.

161 Point 6.3.4 of the Communication on the precautionary principle, entitled 'Examination of the benefits and costs of action and lack of action', is worded as follows:

'A comparison must be made between the most likely positive or negative consequences of the envisaged action and those of inaction in terms of the overall cost to the [Union], both in the long and short term. The measures envisaged must produce an overall advantage as regards reducing risks to an acceptable level.

Examination of the pros and cons cannot be reduced to an economic cost-benefit analysis. It is wider in scope and includes non-economic considerations.

However, examination of the pros and cons should include an economic cost-benefit analysis where this is appropriate and possible.

Besides, other analysis methods, such as those concerning the efficacy of possible options and their acceptability to the public may also have to be taken into account. A society may be willing to pay a higher cost to protect an interest, such as the environment or health, to which it attaches priority.

The Commission affirms, in accordance with the case-law of the Court that requirements linked to the protection of public health should undoubtedly be given greater weight [than] economic considerations.

The measures adopted presuppose examination of the benefits and costs of action and lack of action. This examination should include an economic cost/benefit analysis when this is appropriate and feasible. However, other analysis methods, such as those concerning efficacy and the socio-economic impact of the various options, may also be relevant. Besides the decision-maker may, in certain circumstances, by guided by non-economic considerations such as the protection of health.'

162 First of all, in that regard, it should be noted that point 6.3.4 of the Communication on the precautionary principle provides for an examination to be carried out of the benefits and costs of action and lack of action. However, the format and scope of that examination are not specified. In particular, it is not at all apparent that the authority concerned is obliged to initiate a specific assessment procedure culminating, for example, in a formal, written assessment report. In addition, it is apparent from the text that the authority applying the precautionary principle enjoys considerable discretion regarding methods of analysis. Although the communication indicates that the examination 'should' include an economic analysis, the authority concerned must in any event also include non-economic considerations. Furthermore, it is expressly stated that it may be the case that, in certain circumstances, economic considerations must be considered less important than other interests which are given priority; interests such as the environment or health are expressly mentioned by way of example.

163 Moreover, it is not necessary for the economic analysis of the costs and benefits to be made on the basis of a precise calculation of the respective costs of the action proposed or of inaction. Such precise calculations will in most cases be impossible to make, given that, in the context of the application of the precautionary principle, their results depend on different variables which are, by definition, unknown. If all the consequences of inaction and of action were known, it would not be necessary to resort to the precautionary principle; it would be possible to decide on the basis of certainties. In conclusion, the requirements of the Communication on the precautionary principle are satisfied where the authority concerned — in the present case, the Commission — has in fact acquainted itself with the effects, positive and negative, economic and otherwise, to which the proposed action, as well as the failure to act, may lead, and has taken that into

account in its decision. By contrast, it is not necessary for those effects to be estimated precisely, if that is not possible or would require disproportionate effort.

164 In the present case, the Commission asserted, in paragraph 165 of the defence, that BASF 'errs in saying that the Commission did not weigh in the pros and cons of the Contested Measure before adopting it'. However, it did not submit any evidence to show that such an analysis was in fact carried out. On being questioned in that respect at the hearing, the Commission acknowledged that there was no documentary proof. It nevertheless maintained that, given that the decision on fipronil had been taken after the decision on neonicotinoids, the 'political level', that is the College of Commissioners, was aware of the analysis that had been conducted for the purposes of the earlier decision.

165 The Commission also stated at the hearing, with regard only to the economic element of such an analysis (economic cost/benefit analysis), that the Communication on the precautionary principle envisaged such an economic analysis only 'where this [was] appropriate and possible'. It argued that, in the context of Regulation No 1107/2009 however, the legislature had already pre-empted that analysis by prioritising, in accordance with recital 24 of that regulation, the objective of protection, notably of the environment, over that of improving plant production.

166 First, in that regard, it must be pointed out that, in point 6.3.4 of the Communication on the precautionary principle, to which the Commission refers, the proviso regarding the appropriate and possible nature of the analysis does indeed relate only to the purely economic element of the impact assessment, while the analysis as such is required in all circumstances.

167 Second, it must be noted that recital 24 of Regulation No 1107/2009 does not support the Commission's arguments, even in relation solely to the economic element of the impact assessment. According to the clear wording of that recital, it concerns only the granting of authorisations (at national level) of plant protection products, and not the approval of active substances (at EU level) which are contained in those products.

168 Third, it is true that the Court has recognised, on the basis of Article 11 and Article 114(3) TFEU, that, in the context of the application of Regulation No 1107/2009, the protection of the environment takes precedence over economic considerations, with the result that it may justify adverse economic consequences, even those which are substantial, for certain traders (see the case-law cited in paragraph 55 above), a formula that is, moreover, restated by point 6.3.4 of the Communication on the precautionary principle with a reference to the case-law of the Court of Justice.

169 However, the general assertion of such a principle cannot be seen as the pre-emptive exercise of the legislature's discretion, relieving the Commission of the need to analyse the costs and benefits of a specific measure. An impact assessment

concerns a specific risk management measure; such an assessment can therefore be made only by taking into account the specific relevant circumstances applying in that particular case and not generally or in advance, for every case in which a rule applies. Therefore, the Court must reject the argument which the Commission put forward at the hearing, concerning the awareness, by the College of Commissioners, of the impact assessment in relation to the restrictions on the approval of neonicotinoid substances.

170 Fourth, it must be pointed out that the obligation, set out in point 6.3.4 of the Communication on the precautionary principle, to carry out an impact assessment is ultimately no more than a specific expression of the principle of proportionality. Consequently, the Commission's argument would mean that, in the context of the application of Regulation No 1107/2009, it was free not to observe that principle, at least with regard to its economic element. However, to assert, in relation to an area in which the Commission has a broad discretion, that it is entitled to adopt measures without being required to assess their advantages and disadvantages is not compatible with the principle of proportionality. The necessary and indispensable corollary of a discretion being conferred on the administration is an obligation to exercise that discretion and to take all relevant information into account for that purpose. That applies a fortiori in the context of the application of the precautionary principle, where the administration adopts measures restricting the rights of individuals, not on the basis of scientific certainty, but on the basis of uncertainty: if the individual must accept that he may be barred from carrying on an economic activity even though it is not even certain that it entails an unacceptable risk, the administration must at least be required to assess fully, as far as possible, the consequences of its action, as against the possible consequences of its inaction, for the various interests at stake.

171 In conclusion, it must be held that the Commission was obliged, pursuant to the precautionary principle, to carry out an impact assessment of the measures proposed. As is apparent from paragraphs 162 and 163 above, the formal and substantive requirements in that respect were moderate.

172 The Commission has acknowledged that there was no written record of such an assessment. Given that it must be assumed that there would have been a written record of any — even summary — assessment in the administrative file, and given that the Commission asserted that the College of Commissioners was sufficiently informed by the impact assessment conducted in connection with the restriction of the approval of neonicotinoids, it must be concluded from that absence of any written record that no impact assessment of the restrictions imposed by the contested measure was in fact carried out.

173 The complaint alleging that there was no impact assessment and, accordingly, the plea alleging breach of the precautionary principle, must therefore be upheld. Since the contested measure was founded on that principle, Articles 1, 3 and 4 of that measure must be annulled for that reason, and there is no need to examine the other pleas and arguments put forward by BASF.

IV. Costs

174 Under Article 134(1) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has been largely unsuccessful, it must be ordered to bear its own costs and to pay those incurred by BASF, in accordance with the form of order sought by the latter, as well as those incurred by the ECPA and the ESA, interveners in support of the form of order sought by BASF, as applied for by them.

175 Under Article 138(3) of the Rules of Procedure, the Court may order an intervener other than those referred to in paragraphs 1 and 2 of that article to bear its own costs. In the present case, the DBEB, the ÖEB and the ÖIB, interveners in support of the form of order sought by the Commission, shall bear their own costs.

On those grounds,

THE GENERAL COURT (First Chamber, Extended Composition)

hereby:

1. Annuls Articles 1, 3 and 4 of Commission Implementing Regulation (EU) No 781/2013 of 14 August 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substance fipronil, and prohibiting the use and sale of seeds treated with plant protection products containing this active substance;

2. Dismisses the action as to the remainder;

3. Orders the European Commission to bear its own costs and to pay those incurred by BASF Agro BV and the other applicants whose names appear in the annex, as well as those incurred by the Association européenne pour la protection des cultures (ECPA) and the European Seed Association (ESA);

4. Orders Deutscher Berufs- und Erwerbsimkerbund eV, Österreichischer Erwerbsimkerbund and Österreichischer Imkerbund (ÖIB) to bear their own costs.

Kanninen Pelikánová Buttigieg

Gervasoni Calvo-Sotelo Ibáñez-Martín

Delivered in open court in Luxembourg on 17 May 2018.

E. Coulon

Registrar President

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