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

17 May 2018 (*)

(Plant protection products — Active substances clothianidin, thiamethoxam and imidacloprid — 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 substances in question — Article 49(2) of Regulation No 1107/2009 — Precautionary principle — Proportionality — Right to be heard — Non-contractual liability)

In Cases T−429/13 and T−451/13,

Bayer CropScience AG, established in Monheim am Rhein (Germany), represented by K. Nordlander, lawyer, and P. Harrison, Solicitor,

applicant in Case T−429/13,

Syngenta Crop Protection AG, established in Basel (Switzerland), and the other applicants whose names appear in the annex, (1) represented initially by D. Waelbroek, I. Antypas, lawyers, and D. Slater, Solicitor, and subsequently by D. Waelbroek and I. Antypas,

applicants in Case T−451/13,

supported by

Association générale des producteurs de maïs et autres céréales cultivées de la sous-famille des panicoïdées (AGPM), established in Montardon (France), represented by L. Verdier and B. Trouvé, lawyers,

by

The National Farmers' Union (NFU), established in Stoneleigh (United Kingdom), represented by H. Mercer QC, and N. Winter, Solicitor,

by

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

by

Rapool-Ring GmbH Qualitätsraps deutscher Züchter, established in Isernhagen (Germany), represented initially by C. Stallberg and U. Reese, and subsequently by U. Reese and J. Szemjonneck, lawyers,

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,

and by

Agricultural Industries Confederation Ltd, established in Peterborough (United Kingdom), 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 in Cases T−429/13 and T−451/13,

v

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

defendant in Cases T−429/13 and T−451/13,

supported by

Kingdom of Sweden, represented by A. Falk, C. Meyer-Seitz, U. Persson, E. Karlsson, L. Swedenborg and C. Hagerman, acting as Agents,

by

Union nationale de l'apiculture française (UNAF), established in Paris (France), represented, in Case T−429/13, by B. Fau and J.-F. Funke, lawyers, and, in Case T−451/13, by B. Fau,

by

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

and

Österreichischer Erwerbsimkerbund, established in Großebersdorf (Austria),

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

by

Pesticide Action Network Europe (PAN Europe), established in Brussels,

Bee Life European Beekeeping Coordination (Bee Life), established in Louvain-la-Neuve (Belgium),

and

Buglife — The Invertebrate Conservation Trust, established in Peterborough,

represented by B. Kloostra, lawyer,

and by

Stichting Greenpeace Council, established in Amsterdam (Netherlands), represented by B. Kloostra,

interveners in Cases T−429/13 and T−451/13,

APPLICATION (i) pursuant to Article 263 TFEU for annulment of Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances (OJ 2013 L 139, p. 12), and (ii) in Case T−451/13, pursuant to Article 268 TFEU for compensation for the damage which the applicants claim to have suffered,

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: S. Spyropoulos, Administrator,

having regard to the written part of the procedure and further to the hearings on 15 and 16 February 2017,

gives the following

Judgment

I. Legal Framework

A. Directive 91/414/EEC

1 Before 14 June 2011, the placing of plant protection products on the market was governed by 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).

2 Article 4(1) of Directive 91/414 provided that a plant protection product could not be authorised by a Member State unless, inter alia, its active substances were listed in Annex I to the directive.

3 Article 5(1) of Directive 91/414 stated, in particular:

'1. In the light of current scientific and technical knowledge, an active substance shall be included in Annex I for an initial period not exceeding 10 years, if it may be expected that plant protection products containing the active substance will fulfil the following conditions:

(a) their residues, consequent on application consistent with good plant protection practice, do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, and the said residues, in so far as they are of toxicological or environmental significance, can be measured by methods in general use;

(b) their use, consequent on application consistent with good plant protection practice, does not have any harmful effects on human or animal health or any unacceptable influence on the environment as provided for in Article 4(1)(b)(iv) and (v).

2. For inclusion of an active substance in Annex I, the following shall be taken into particular account:

(a) where relevant, an acceptable daily intake (ADI) for man;

(b) an acceptable operator exposure level if necessary;

(c) where relevant, an estimate of its fate and distribution in the environment as well as its impact on non-target species.

...'

B. Regulation (EC) No 1107/2009

4 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) entered into force on 14 June 2011. It was adopted on the basis of Article 37(2) EC (now, after amendment, Article 43(1) TFEU) concerning the common agricultural policy, Article 95 EC (now Article 114 TFEU) concerning the approximation of laws which have as their object the internal market, in relation, notably, to the environment, and Article 152(4)(b) EC (now, after amendment, Article 168(4)(b) TFEU) concerning public health.

5 Under Article 28(1) of Regulation No 1107/2009, a plant protection product is not to be placed on the market or used unless it has been authorised in the Member State concerned in accordance with that regulation.

6 In accordance with Article 29(1)(a) of Regulation No 1107/2009, authorisation of a plant protection product by a Member State presupposes, inter alia, that its active substances have been approved at EU level.

7 Article 4 of Regulation No 1107/2009, entitled 'Approval criteria for active substances', sets out, in particular, the following criteria:

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

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

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

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

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

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

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

(a) it shall be sufficiently effective;

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

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

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

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

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

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

(iii) its impact on biodiversity and the ecosystem.

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

5. For approval of an active substance, paragraphs 1, 2 and 3 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

...'

8 The uniform principles for evaluation mentioned in Article 4(4) of Regulation No 1107/2009 were defined in Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation No 1107/2009 as regards uniform principles for evaluation and authorisation of plant protection products (OJ 2011 L 155, p. 127), in accordance with Article 29(6) of Regulation No 1107/2009, without substantially modifying the version of those principles set out in Annex VI to Directive 91/414.

9 Article 21 of Regulation No 1107/2009, entitled 'Review of approval', is worded as follows:

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

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

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

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

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

10 Annex II to Regulation No 1107/2009, entitled 'Procedure and criteria for the approval of active substances, safeners and synergists pursuant to Chapter II', contains, in point 3 'Criteria for the approval of an active substance', point 3.8 'Ecotoxicology', a point 3.8.3 which is worded as follows:

'An active substance, safener or synergist shall be approved only if it is established following an appropriate risk assessment on the basis of [EU] or internationally agreed test guidelines, that the use under

the proposed conditions of use of plant protection products containing this active substance, safener or synergist:

– will result in a negligible exposure of honeybees, or

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

11 Article 49 of Regulation No 1107/2009, entitled 'Placing on the market of treated seeds', provides in particular:

'1. Member States shall not prohibit placing on the market and use of seeds treated with plant protection products authorised for that use in at least one Member State.

2. Where there are substantial concerns that treated seeds as referred to in paragraph 1 are likely to constitute a serious risk to human or animal health or to the environment and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, measures to restrict or prohibit the use and/or sale of such treated seeds shall be taken immediately in accordance with the regulatory procedure referred to in Article 79(3). Before taking such measures the Commission shall examine the evidence and may request an opinion from [EFSA]. The Commission may set a time limit within which such an opinion shall be provided.

...'

12 Under Article 78(3) of Regulation No 1107/2009, after the repeal of Directive 91/414 and its replacement by Regulation No 1107/2009, the active substances included in Annex I to Directive 91/414 are to be deemed to have been approved under Regulation No 1107/2009 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).

II. Background to the dispute

13 The active substances clothianidin, thiamethoxam and imidacloprid ('the substances covered'), which are part of the neonicotinoid family, were included in Annex I to Directive 91/414 by Commission Directive 2006/41/EC of 7 July 2006 amending Directive 91/414 to include clothianidin and pethoxamid as active substances (OJ 2006 L 187, p. 24), Commission Directive 2007/6/EC of 14 February 2007 amending Directive 91/414 to include metrafenone, Bacillus subtilis, spinosad and thiamethoxam as active substances (OJ 2007 L 43, p. 13) and Commission Directive 2008/116/EC of 15 December 2008 amending Directive 91/414 to include aclonifen, imidacloprid and metazachlor as active substances (OJ 2008 L 337, p. 86), respectively.

14 Within the European Union, imidacloprid and clothianidin are produced and marketed by the Bayer group and thiamethoxam is produced and marketed by the Syngenta group.

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

16 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.

17 On 18 March 2011, the Commission asked 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').

18 Restrictive measures applying to the use of the products concerned continued to be applied in various Member States at national level. 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 the substances covered, 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.

19 On 30 March 2012, two studies on the sub-lethal effects on bees of substances in the neonicotinoid family were published in *Science* magazine. The first of those studies concerned products containing the active substance thiamethoxam ('the Henry study'), the second, products containing the active substance imidacloprid ('the Whitehorn study'). The authors of these studies concluded that ordinary levels of those two active substances could have a considerable effect on the stability and survival of colonies of honeybees and bumble-bees.

20 On 3 April 2012, the Commission asked EFSA, under Article 21 of Regulation No 1107/2009, to assess the new studies and to verify, by 30 April 2012 (and, after extension, no later than 31 May 2012), whether the doses that served as the basis for the experiments reported in the Henry and Whitehorn studies ('the March 2012 studies') were comparable to the actual doses to which bees were exposed in the European Union, on the basis of the supported uses at EU level and the authorisations granted by Member States ('the first mandate'). The Commission also asked whether the results of the studies could be applied to other neonicotinoids used for the treatment of seeds, notably to clothianidin.

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

22 On 23 May 2012, in response to the Commission's request of 18 March 2011 (see paragraph 17 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.

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

24 It found, in particular, that the concentrations of the substances tested in those studies were higher than those normally found in nectar of the crops for which data were available. EFSA inferred from this that, hourly, the doses used were probably higher than those ingested by honeybees in the field (with the exception of some scenarios for clothianidin), but that, for clothianidin and thiamethoxam, they could be lower than the daily intake. At the same time, EFSA noted that, in the absence of certain additional data, estimates of intake had to be viewed with caution. Overall, EFSA concluded that further research needed to be carried out with different exposure levels or in other situations.

25 On 25 July 2012, as a result of concerns expressed by EFSA that it might not be able to fulfil the second mandate by the deadline set, the Commission — taking account of EFSA's Statement while maintaining the deadline of 31 December 2012 — narrowed the second mandate so as to prioritise the review of only the substances covered, to the exclusion of two other neonicotinoids, and to focus on their use for seed treatment and in the form of granules.

26 On 16 January 2013, EFSA published its conclusions as regards the risk assessment for bees for the substances covered ('EFSA's Conclusions'), in which it identified:

– a high acute risk for honeybees from exposure via dust drift as a result of the sowing of maize and cereal seeds (clothianidin, imidacloprid, thiamethoxam), oilseed rape (clothianidin, imidacloprid and, except for uses at the lower rate authorised in the European Union, thiamethoxam) as well as cotton (imidacloprid, thiamethoxam),

– a high acute risk for bees from exposure to residues in nectar and pollen for the uses in oilseed rape (clothianidin, imidacloprid) as well as cotton and sunflowers (imidacloprid), and

– a high acute risk from exposure to guttation for uses in maize (thiamethoxam).

27 In addition, EFSA's Conclusions identified numerous areas of uncertainty, owing to the lack of scientific data. These related, in particular, to the exposure of honeybees to dust, to ingestion of contaminated nectar and pollen and to guttation, the acute and long-term risk to honeybee colony survival and development, the risk to other pollinating insects, the risk posed by residues in honey dew and by residues in succeeding rotational crops.

28 In the light of the risks identified by EFSA, the Commission submitted a draft implementing regulation and an opinion to the Standing Committee at its meeting on 14 and 15 March 2013. Since no opinion was delivered either by the Standing Committee or the appeal committee, lacking a qualified majority, the Commission adopted, on 24 May 2013, Implementing Regulation (EU) No 485/2013 amending Implementing Regulation No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances (OJ 2013 L 139, p. 12) ('the contested measure').

29 Article 1 of the contested measure in particular introduced, for the three substances covered, the following restrictions:

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

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

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

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

30 Furthermore, Article 2 of the contested measure prohibited the use and placing on the market of seeds of crops listed in Annex II which have been treated with plant protection products containing the substances covered, with the exception of seeds used in greenhouses. That covered, inter alia, the seeds of summer cereals, rapeseed, soya, sunflowers and maize.

31 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 the substances covered, by 30 September 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 30 November 2013 at the latest.

32 The contested measure was published in the *Official Journal of the European Union* on 25 May 2013 and entered into force the following day, in accordance with Article 5 thereof, except for Article 2 which was to apply as of 1 December 2013.

III. Procedure and forms of order sought

A. Procedure

33 Syngenta Crop Protection AG and the other applicants in Case T−451/13 whose names are set out in the annex (together 'Syngenta') brought the action in Case T−451/13 by application lodged at the General Court Registry on 14 August 2013.

34 Bayer CropScience AG ('Bayer') brought the action in Case T−429/13 by application lodged at the General Court Registry on 19 August 2013.

35 By orders of the President of the First Chamber of the General Court of 21 October 2014, *Bayer CropScience* v *Commission* (T−429/13, not published), and by order of 21 October 2014, *Bayer CropScience* v *Commission* (T−429/13, EU:T:2014:920), the Association générale des producteurs de maïs et autres céréales cultivées de la sous-famille des panicoïdées (AGPM), the National Farmers' Union (NFU), the Association européenne pour la protection des cultures (European Crop Protection Association) (ECPA), Rapool-Ring GmbH Qualitätsraps deutscher Züchter ('Rapool-Ring'), the European Seed Association (ESA) and the Agricultural Industries Confederation Ltd ('AIC') were granted leave to intervene in support of the form of order sought by Syngenta, and the Kingdom of Sweden, the Union nationale de l'apiculture française (UNAF), Deutscher Berufs- und Erwerbsimkerbund eV ('DBEB'), Österreichischer Erwerbsimkerbund ('ÖEB'), Stichting Greenpeace Council ('Greenpeace'), Pesticide Action Network Europe (PAN Europe), Bee Life — European Beekeeping Coordination (Bee Life) and Buglife — The Invertebrate Conservation Trust ('Buglife') were granted leave to intervene in support of the form of order sought by the Commission in Case T−451/13.

36 By orders of the President of the First Chamber of the General Court of 20 October 2014, *Syngenta Crop Protection and Others* v *Commission* (T−451/13, not published), and by order of 20 October 2014, *Syngenta Crop Protection and Others* v *Commission* (T−451/13, not published, EU:T:2014:951), the AGPM, the NFU, the ECPA, Rapool-Ring, the ESA and the AIC were granted leave to intervene in support of the form of order sought by Bayer, and the Kingdom of Sweden, UNAF, the DBEB, the ÖEB, PAN Europe, Bee Life, Buglife and Greenpeace were granted leave to intervene in support of the form of order sought by the Commission in Case T−429/13.

37 By orders of 27 March 2015, *Bayer CropScience* v *Commission* (T−429/13, not published, EU:T:2015:199), of 1 April 2015, *Syngenta Crop Protection and Others* v *Commission* (T−451/13, not published, EU:T:2015:204), and of 27 July 2015, *Bayer CropScience* v *Commission* (T−429/13, EU:T:2015:578), 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.

38 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.

39 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.

40 The parties presented oral argument and replied to the questions put by the Court at the hearings on 15 February 2017 in Case T−429/13, and on 16 February 2017 in Case T−451/13.

B. Forms of order sought

1. Case T−429/13

41 Bayer, supported by the AGPM, the NFU, the ECPA, Rapool-Ring, the ESA and the AIC, claims that the Court should:

– annul the contested measure in its entirety or, in the alternative, in so far as it concerns the active substances imidacloprid and clothianidin;

– order the Commission to pay the costs.

42 The Commission, supported by UNAF, the DBEB and the ÖEB, contends that the Court should:

– dismiss the action;

– order the applicant to pay the costs.

43 The Kingdom of Sweden, PAN Europe, Bee Life, Buglife and Greenpeace contend that the Court should dismiss the action.

2. Case T−451/13

44 Syngenta, supported by the ECPA and Rapool-Ring, claims, after rectification at the stage of the reply, that the Court should:

– annul the contested measure in its entirety or, in the alternative, in so far as it imposes restrictions on thiamethoxam, seeds treated with thiamethoxam and products containing thiamethoxam;

– order the European Union, represented by the Commission, to pay compensation for the damage it suffered as a result of the Commission's breach of its legal obligations, and set the amount of compensation provisionally at EUR 367.9 million plus ongoing losses from July 2013 or at an amount to be determined by the Court, which amounts should be increased by interest from the date of delivery of the judgment until actual payment;

– order that interest at the rate set by the European Central Bank (ECB) for main refinancing operations plus two percentage points, or any other appropriate rate to be determined by the Court, be paid on the amount payable as from the date of delivery of the judgment until actual payment;

– order the Commission to pay the costs.

45 The NFU, the ESA and the AIC claim that the Court should:

– annul the contested measure in its entirety or, in the alternative, in so far as it imposes restrictions on thiamethoxam, seeds treated with thiamethoxam and products containing thiamethoxam;

– order the Commission to pay the costs.

46 The AGPM claims that the Court should:

– annul the contested measure;

– order the Commission to pay the costs.

47 The Commission, supported by UNAF, the DBEB and the ÖEB, contends that the Court should:

– dismiss the actions;

– order the applicants to pay the costs.

48 The Kingdom of Sweden, PAN Europe, Bee Life, Buglife and Greenpeace contend that the Court should dismiss the actions.

IV. Law

49 After hearing the views of the parties on the point, the Court finds that it is appropriate that these cases be joined for the purposes of the judgment, in accordance with Article 68(1) of the Rules of Procedure.

A. Admissibility of the applications for annulment

50 In both cases, the Commission has doubts as to the applicants' standing to bring proceedings in relation to active substances of which they are not the notifiers. Furthermore, the Commission observes that the restrictions on use laid down in Article 1 of the contested measure entail implementing measures and that the applicants cannot therefore rely on the final limb of the fourth paragraph of Article 263 TFEU in that regard.

51 Bayer submits that the contested measure is a regulatory act that does not entail implementing measures, which is why Bayer is entitled to challenge it irrespective of any individual concern. It further submits that, as the applicant for approval of imidacloprid and as the holder of exclusive rights in relation to clothianidin, it is individually concerned by the contested measure.

52 Syngenta submits that it raised arguments challenging the legality of the contested measure in its entirety and that it does not appear that the parts of the contested measure relating to thiamethoxam (in respect of which it is the notifier) could be separated from the others and so capable of discrete annulment.

53 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.

54 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 three active substances and, in a general and abstract manner, anyone intending to produce, market or use those substances or seeds, listed in Annex II to the contested measure, treated with plant protection products containing those substances, 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.

55 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.

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

1. Direct concern to the applicants

57 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).

58 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

59 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 substances covered, without any discretion, to amend or withdraw them by 30 November 2013 at the latest, in accordance with Article 4 of the contested measure.

60 Consequently, Article 1 of the contested measure directly affects the legal situation of Bayer and of Syngenta, in so far as they produce and market the substances covered, as well as plant protection products containing them. 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

61 Article 2 of the contested measure prohibits the sale and use of seeds of crops listed in Annex II to that measure which have been treated with plant protection products containing the substances covered (with the exception of seeds used in greenhouses). This prohibition is to apply from 1 December 2013, as stated in Article 5 of the contested measure. Article 2 of the contested measure is directly applicable.

62 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 which have been treated with the substances covered, and farmers who wish to use those seeds.

63 At the hearing on 16 February 2017 Syngenta stated, in reply to a question from the Court, and without being contradicted by the Commission, that the trade in seeds treated with plant protection products containing thiamethoxam accounted for a significant portion of the Syngenta group's business. Accordingly, in so far as Article 2 of the contested measure concerns thiamethoxam, that provision directly affects the legal situation of Syngenta.

64 By contrast, Bayer indicated at the hearing on 15 February 2017 that it did not itself market seeds treated with plant protection products containing the active substances imidacloprid and clothianidin, which it does market. Admittedly the prohibition against using and marketing treated seeds has appreciable effects on Bayer'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 Bayer itself. Therefore, those effects must be characterised as being indirect — since they are relayed via independent decisions of Bayer's customers — and economic, rather than direct and legal. Taken in isolation, that prohibition does not affect Bayer's right to market plant protection products containing the active substances imidacloprid and clothianidin.

65 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).

66 Consequently, Article 2 of the contested measure does not directly affect the legal situation of Bayer.

67 In conclusion, Articles 1, 3 and 4 of the contested measure are of direct concern to Bayer, in so far as they relate to the active substances imidacloprid and clothianidin, and to Syngenta, in so far as they relate to the active substance thiamethoxam, whereas Article 2 is of direct concern only to Syngenta in so far as it relates to the active substance thiamethoxam. Bayer is not, therefore, entitled to seek annulment of Article 2 of the contested measure.

2. Individual concern to the applicants

68 In so far as Bayer and Syngenta are, in part, directly concerned by the contested measure, it is necessary, next, to examine whether they are individually concerned by it.

69 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).

(a) The substances notified by the applicants

70 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 covered.

71 In the present case, it is common ground that Bayer and Syngenta Crop Protection AG are the notifiers, respectively, of imidacloprid and of thiamethoxam, that they submitted the dossiers and participated in the assessment of those two substances and that they still have exclusive rights in respect of those substances. They are, therefore, individually concerned by the contested measure with regard, respectively, to imidacloprid and thiamethoxam, which the Commission has, moreover, expressly acknowledged.

72 Bayer is therefore entitled to challenge Articles 1, 3 and 4 of the contested measure in so far as they relate to imidacloprid, and Syngenta Crop Protection AG is entitled to challenge Articles 1, 2, 3 and 4 of the contested measure in so far as they relate to thiamethoxam.

(b) The substances in respect of which the applicants are not the notifiers

73 The Commission disputes that the applicants are individually concerned by the contested measure with respect to the active substances of which they are not the notifiers. This concerns, on the one hand, the standing of Bayer to bring proceedings with regard to the active substance clothianidin, and, on the other

hand, Bayer and Syngenta Crop Protection AG with regard to the substances of which the other applicant is the notifier.

(1) Individual concern to Bayer, as regards clothianidin

74 The Commission contends that it is Sumitomo Chemicals SA and not Bayer that is the notifier of clothianidin, and that the contested measure is not, therefore, of individual concern to Bayer so far as that substance is concerned.

75 In the light of certain circumstances peculiar to Bayer, which are not disputed by the Commission, and which relate to Bayer's role in the development of clothianidin and in the preparation of the regulatory dossier for approval of that substance, certain intellectual property rights in relation to clothianidin held by Bayer and its participation in the review procedure before EFSA on equal terms with the notifier, it must be concluded that Bayer is in a situation that is in fact comparable to that of the notifier. Consequently, for the same reasons as those set out in paragraph 70 above, Bayer must be regarded as being individually concerned by the contested measure with respect to clothianidin.

76 Accordingly, Bayer has standing to bring proceedings in the present action also in so far as it is challenging Articles 1, 3 and 4 of the contested measure, to the extent that they relate to clothianidin.

(2) Individual concern to the applicants in the case of the substances in respect of which the other applicant is the notifier

77 The applicants submit that their arguments are largely procedural in nature and apply equally to the three substances covered, and that it does not appear that the contested measure could be separated into different parts that apply to one of the substances but not to the others.

78 It is sufficient to observe in that regard that the applicants' standing to bring proceedings is limited to those parts of the contested measure that are of direct and individual concern to them. As indicated above, the contested measure is of individual concern to the applicants only in so far as they are the notifiers of the substances covered or in so far as they can show that special circumstances apply, such as those identified in Bayer's case with respect to clothianidin. By contrast, the contested measure is not of individual concern to Bayer in so far as it relates to thiamethoxam, nor is it of individual concern to Syngenta in so far as it relates to imidacloprid and clothianidin.

79 It must be added that, contrary to the view taken by the applicants, it is possible to separate the contested measure into different parts relating to the different active substances and, if necessary, to annul it with respect to one of the substances but not with respect to the others, in a situation where either the contested measure is challenged only by one party which does not have standing to bring proceedings in respect of all the substances, or the successful plea in favour of annulment relates to only one of the substances.

3. Characterisation of the contested measure as a regulatory act that does not entail implementing measures

80 Bayer submits that the contested measure constitutes a regulatory act that does not entail implementing measures within the meaning of the fourth paragraph of Article 263 TFEU, and that it is therefore entitled to challenge the measure, even in relation to substances in respect of which it is not the notifier, without being required to show that it is individually concerned.

81 In response to a written question from the Court, the Commission maintains that Article 1 of the contested measure, whether read in isolation or in conjunction with Articles 3 and 4 of that measure, entails implementing measures, while Article 2 does not.

(a) Characterisation as a regulatory act

82 According to the case-law, the concept of 'regulatory act' must be understood as covering acts of general application other than legislative acts (judgment of 3 October 2013, *Inuit Tapiriit Kanatami and Others* v *Parliament and Council*, C−583/11 P, EU:C:2013:625, paragraph 60).

83 First, as stated in paragraph 54 above, the contested measure is a measure of general application.

84 Second, Article 1 of the contested measure has as its legal basis Article 21(3) of Regulation No 1107/2009, which empowers the Commission to adopt, in accordance with the procedure referred to in Article 79(3) of that regulation, a regulation to withdraw or amend approval of the substances covered. Article 79(3) of Regulation No 1107/2009, in turn, refers in particular to Article 5 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23).

85 Since Decision 1999/468 was repealed and replaced, with effect from 1 March 2011, by Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ 2011 L 55, p. 13), the reference in Article 79(3) of Regulation No 1107/2009 must now be understood, in accordance with Article 13(1)(c) of Regulation No 182/2011, as referring to Article 5 of the latter regulation which, in accordance with Article 2(2) thereof, applies, in particular, to implementing acts of general application and to other implementing acts relating to the environment, security and safety or protection of the health or safety of humans, animals or plants.

86 It follows that Article 1 of the contested measure was adopted by the Commission in the exercise of its implementing powers under the review procedure, and that, consequently, it does not constitute a legislative act within the meaning of the case-law stemming from the judgment of 3 October 2013, *Inuit Tapiriit Kanatami and Others* v *Parliament and Council* (C−583/11 P, EU:C:2013:625). It should, moreover, be noted that Bayer does not claim that there were any procedural irregularities in that respect.

87 Consequently, Article 1 of the contested measure, which has general application and is not legislative in nature, is a regulatory act within the meaning of the fourth paragraph of Article 263 TFEU.

(b) Absence of implementing measures

88 As the Court has already held, the question whether a regulatory act entails implementing measures should be assessed by reference to the position of the person pleading the right to bring proceedings under the final limb of the fourth paragraph of Article 263 TFEU. It is therefore irrelevant whether the act in question entails implementing measures with regard to other persons (judgment of 19 December 2013, *Telefónica* v *Commission*, C−274/12 P, EU:C:2013:852, paragraph 30).

89 In the present case, as stated in paragraph 59 above, the amendment of the Annex to Implementing Regulation No 540/2011 provided for by Article 1 of the contested measure requires the Member States that have granted authorisations for plant protection products containing the substances covered to amend or withdraw them by 30 November 2013 at the latest, in accordance with Article 4 of the contested measure. Article 1 of the contested measure thus entails implementing measures.

90 That conclusion is not called into question by the mechanical nature of the measures taken at national level. That question is irrelevant in ascertaining whether a regulatory act entails implementing measures within the meaning of the final limb of the fourth paragraph of Article 263 TFEU (see, to that effect, judgment of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C−456/13 P, EU:C:2015:284, paragraphs 41 and 42).

91 It follows that Article 1 of the contested measure, whether read in isolation or in conjunction with Articles 3 and 4 (see paragraph 60 above), does not constitute an act of general application that does not entail implementing measures within the meaning of the final limb of the fourth paragraph of Article 263 TFEU.

92 The admissibility of the present actions, to the extent that they concern Articles 1, 3 and 4 of the contested measure with regard to the substances in respect of which Bayer and Syngenta Crop Protection AG are not the notifiers, cannot, therefore, be founded on that provision.

4. Admissibility of the action in Case T−451/13, in so far as it was brought by the applicants other than Syngenta Crop Protection AG

93 In case T−451/13, the Commission has doubts as to whether the applicants other than Syngenta Crop Protection AG, which are not the notifiers of the active substance thiamethoxam 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.

94 Syngenta has not commented on those arguments.

95 It should be observed in that regard that, as has been noted in paragraph 72 above, Syngenta Crop Protection AG has standing to bring proceedings with respect to the application for annulment of Articles 1 to 4 of the contested measure, in so far as they relate to the active substance thiamethoxam.

96 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).

97 Furthermore, it is not apparent from the file that, from the point of view of the applicants other than Syngenta Crop Protection AG, the admissibility of their application would extend beyond that of the application brought by Syngenta Crop Protection AG.

98 Consequently, in Case T−451/13, there is no need to consider whether the applicants other than Syngenta Crop Protection AG are entitled to bring proceedings.

5. Summary with regard to admissibility

99 In conclusion, the action in Case T−429/13 is admissible to the extent that Bayer seeks annulment of Articles 1, 3 and 4 of the contested measure with respect to the active substances imidacloprid and clothianidin. As to the remainder, the action is inadmissible.

100 The action in Case T−451/13 is admissible to the extent that Syngenta seeks annulment of Articles 1 to 4 of the contested measure with respect to the active substance thiamethoxam. As to the remainder, the action is inadmissible.

B. The applications for annulment of Articles 1, 3 and 4 of the contested measure

1. Preliminary observations

101 In both cases, the applicants raise 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 right to property and of the freedom to conduct a business.

102 In addition, in Case T−451/13, Syngenta alleges, as a preliminary point, a ‘[lack of] scientific basis for the contested [measure]’. In the context of that complaint, it argues that there are a number of fundamental

problems with the scientific basis for the contested measure. In its opinion, these flaws amount to manifest errors and result in the infringement of numerous provisions of EU law, set out in the other pleas it raises.

103 It must be noted in that regard that this complaint by Syngenta is of a cross-cutting nature, in that it could be relevant to some of the other pleas in law on which it relies and, in particular, to those alleging infringement of provisions of Regulation No 1107/2009 and to those alleging breach of the precautionary principle and of the principle of proportionality. This complaint does no more, therefore, than set out separately and as a preliminary point certain arguments advanced by Syngenta in relation to the scientific basis of the contested measure and which are relevant to a number of the pleas invoked.

104 In those circumstances, this complaint will not be dealt with separately and as a preliminary point below, but will be taken into account in the context of the other pleas raised by Syngenta to which it relates.

2. General considerations

105 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.

106 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).

107 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.

108 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

109 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).

110 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).

111 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

112 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

113 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).

114 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.'

115 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).

116 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).

117 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).

118 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).

119 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).

120 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).

121 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, to that effect, 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

122 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).

123 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).

124 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

125 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).

126 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

127 As explained in paragraphs 12 and 13 above, the substances covered by the contested measure were approved under the rules laid down by Directive 91/414, in accordance with the conditions that applied at the time, and are now listed in Part A of the Annex to Implementing Regulation No 540/2011.

128 Since the review of their 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

129 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.

130 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.

131 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).

132 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

133 It is apparent, when Article 5 of Directive 91/414 (see paragraph 3 above) is compared with Article 4 of Regulation No 1107/2009 (see paragraph 7 above), 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.

134 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 (see paragraph 8 above).

135 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 (see paragraph 10 above), 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'.

136 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 the substances covered, 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

137 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 132 above).

138 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.

139 Furthermore, Article 4(1) of Regulation No 1107/2009, which sets out the conditions for approval of active substances (see paragraph 7 above), 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.

140 However, as the applicants submitted at the hearings, 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).

141 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.

142 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).

(c) Scope of judicial review

143 If the Commission is to be able to pursue effectively the objectives assigned to it by Regulation No 1107/2009 (see paragraphs 105 to 107 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.

144 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).

145 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, not set aside on that point by the judgment of 22 April 2008, *Commission* v *Salzgitter*, C−408/04 P, EU:C:2008:236). 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).

146 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).

147 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

148 The applicants submit, in essence, that the Commission was not entitled to review the approval of the substances covered, since the requirements set out in that respect in Article 21(1) of Regulation No 1107/2009 were not met.

149 The Commission contests the applicants' arguments.

150 Article 21 of Regulation No 1107/2009 (cited in paragraph 9 above) is structured as follows.

151 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.

152 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.

153 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

154 The applicants have not specifically expressed a view on the threshold for the application of Article 21(1) of Regulation No 1107/2009, since, in their arguments, they do not maintain a strict distinction between the respective conditions for applying paragraph 1 and paragraph 3 of that article. Syngenta nevertheless concedes that Article 21(1) allows the Commission to investigate new information that may be of concern. However, Bayer and Syngenta dispute that the March 2012 studies constitute such information. They contend, 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.

155 The ECPA, intervening in support of the applicants, 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.

156 The Commission contests those arguments.

157 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.

158 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.

159 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.

160 That is consistent with the structure of Article 21, outlined in paragraphs 150 to 153 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.

161 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 105 to 107 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.

162 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.

163 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.

164 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

165 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 the substances covered, in the first place, it is necessary to determine when that decision was taken.

166 It should be noted that, in the second mandate (see paragraph 21 above), the Commission instructed EFSA, on 25 April 2012, to update the risk assessment of neonicotinoids 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 (or reassessing) 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 25 April 2012 must therefore be accepted as being the date on which, at the latest, the Commission decided to carry out the review.

167 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 25 April 2012 merely represented the temporal limit of a decision-making process that extended over a certain period of time.

168 Consequently, the 'new scientific and technical knowledge' within the meaning of Article 21(1) of Regulation No 1107/2009 had to pre-date 25 April 2012 in order to be capable of justifying the initiation of the review procedure.

169 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 the substances covered. Recital 4 of that measure states in general terms that, 'in spring 2012, new scientific information on the sub-lethal effects of neonicotinoids on bees was published'. That general description may include, in addition to the March 2012 studies (see paragraph 19 above), the Schneider study, published on 11 January 2012 (see paragraph 23 above), and the EFSA Opinion (see paragraph 22 above). Although the final version of that opinion — on which the Commission also relies in its defence statements, with regard to new scientific information — was not published until 23 May 2012, an initial version had been sent to the Commission on 29 February 2012, as is evident from an email from EFSA to the Commission.

170 Nevertheless, it appears that the new knowledge which the Commission was able to acquire on reading the EFSA Opinion (or, more specifically, the preliminary version of it; see paragraph 169 above) in fact played no more than a minor part in its decision to review the approval of the substances covered. Thus, for example, the discussion paper dated 28 January 2013 for the Standing Committee's meeting on 31 January and 1 February 2013, in which the Commission set out the inferences it considered should be drawn from EFSA's Conclusions published on 16 January 2013, mentioned only the Henry, Whitehorn and Schneider studies as 'new scientific evidence' that had led the Commission to carry out a review, and not the EFSA Opinion.

171 Accordingly, the Court considers it appropriate to confine itself to the March 2012 studies and the Schneider study for the purpose of determining whether the new scientific and technical knowledge available on 25 April 2012 warranted initiation of the review.

(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

172 The March 2012 studies were published in the science journal *Science* on 30 March 2012. The Schneider study was published in January 2012 in the online science journal *PLoS ONE*. In accordance with the guidance set out in paragraph 164 above, it is appropriate therefore to note at the outset that those three studies were new, in the sense that they had not previously been taken into account by EFSA or the Commission for the purposes of assessing the risks posed by the substances covered.

173 According to the summary provided in EFSA's Statement (see paragraph 23 above), the Henry study concerned research conducted in France on the plant protection product Cruiser, marketed by Syngenta, which contains the active substance thiamethoxam. Specifically, that study highlighted research indicating that exposure to non-lethal but field-realistic doses of thiamethoxam caused high mortalities in honeybees due to homing failure at levels that increased the risk that a colony could collapse. A new technology, radiofrequency identification (RFID), was used in the Henry study to follow individual bees as they entered and exited the hive.

174 The Whitehorn study concerned research conducted in the United Kingdom on bumble-bees and the plant protection product Gaucho, marketed by Bayer, containing the active substance imidacloprid. This study concluded that the growth rate and the production of new queens were significantly reduced in colonies of bumble-bees exposed to various sub-lethal doses of imidacloprid.

175 The Schneider study identified effects on the behaviour of bees exposed to sub-lethal doses of imidacloprid and of clothianidin. In particular, a reduction in foraging activity and in the duration of foraging flights was observed. Like the Henry study, the Schneider study used RFID technology to monitor bee movement.

176 The applicants have a certain number of criticisms of the Henry, Whitehorn and Schneider studies, which are capable, in their view, of calling into question the new scientific and technical knowledge the Commission claims to draw from them.

(1) The newness of the results of the March 2012 studies

177 In the first place, Bayer submits that neither the Henry study nor the Whitehorn study nor yet the Schneider study contained new scientific information of relevance for honeybee risk management. It claims that the novelty of the Henry study consists primarily in the use of RFID technology to monitor the movements of individual bees.

178 In that regard, the Commission contends that, even if the March 2012 studies merely confirmed, for example through the use of new methodologies, the results of previous studies, that would constitute a new state of knowledge.

179 However, to describe such confirmatory results as new scientific knowledge presupposes at the very least that the new methodologies are more reliable than those used previously. In such a situation, it would be the increase in the degree of certainty of the previous knowledge that would have to be described as new scientific knowledge. In the context of a risk management decision in accordance with the precautionary principle, such information must be considered relevant, contrary to Bayer's assertions.

180 That is the situation in the present case. Bayer itself relies on a study it commissioned, which was finalised on 24 May 2013 ('the Tier3 study'), into whether the results of the Henry and Schneider studies represented a departure from previous knowledge in this area. According to Bayer, the Tier3 study concluded that 'the use of the RFID technique to measure the activity of honeybees under field situations [was] a new observation technique and [allowed] a more precise measurement of effects on individual worker/forager bees'. Accordingly, the parties are agreed in their view that, even if the Henry study did no more than confirm previous scientific knowledge, it did in any event increase the degree of certainty of that knowledge.

181 Furthermore, as regards Bayer's argument that the lack of novelty of the Henry and Schneider studies was confirmed by the Tier3 study, it should be noted that, contrary to the principle identified in paragraph 163 above, that study does not examine the novelty of the results of the March 2012 studies in relation to the level of knowledge that existed at the time of the previous evaluation of the substances in question, but principally in relation to knowledge emerging from later studies. Thus, it appears that, of the 35 studies taken into account by the Tier3 study, 21 were published or finalised after the respective dates of completion of the risk assessment for the substances in question.

182 Furthermore, the Tier3 study adopts a purely quantitative approach, consisting in a comparison of the levels of exposure to the substances in question in respect of which an influence on bee behaviour was identified in the various studies. However, in order to assess whether the results of the Henry and Schneider studies diverged from the results of the earlier studies, it was necessary also to make a qualitative comparison concerning the nature and seriousness of the effects on behaviour identified. That was particularly so as sub-lethal effects may take very different forms (reduced foraging, effects on homing, changes in reproduction rates, etc.).

183 Last, as the Commission correctly observes, the Whitehorn study was not among the studies compared by the Tier3 study, and therefore it is not possible in any event to draw any conclusion from the latter study regarding the newness of the knowledge provided by the Whitehorn study in relation to imidacloprid, as compared with previous knowledge available concerning that active substance.

184 Consequently, the Tier3 study does not establish that the March 2012 studies and the Schneider study failed to produce new scientific and technical knowledge within the meaning of Article 21(1) of Regulation No 1107/2009.

(2) The doses of the substances covered that were used in the March 2012 studies

185 In the second place, Syngenta maintains that the March 2012 studies involved artificially high doses of neonicotinoids.

186 In that regard, first, it should be noted that the Commission was aware, in the context of its decision to review the approval of the substances covered, of the importance of the issue of doses. That is why, in connection with the first mandate, it also asked EFSA to verify whether the doses that served as the basis for the experiments reported in the March 2012 studies were comparable to the actual doses to which bees were exposed in the European Union, given the supported uses at EU level and the authorisations granted by Member States (see paragraph 20 above).

187 Second, the fact that the doses administered in those studies (and also in the Schneider study) could exceed field exposure levels does not mean, however, that the results of the studies are of no relevance to the assessment of the approval criteria under Article 4 of Regulation No 1107/2009. Thus, EFSA found, in its statement, that, given that the exposure levels applied in the March 2012 studies and in the Schneider study largely exceeded actual exposure levels, additional studies were necessary before definite conclusions could be drawn on the effects on bee behaviour that are likely actually to occur.

188 In those circumstances, the fact that the new scientific and technical knowledge relied on by the Commission was based on experiments conducted with doses that partly exceeded field exposure levels does not mean that they cannot be characterised as studies raising concerns as to whether the conditions of approval in Article 4 of Regulation No 1107/2009 were still satisfied.

(3) The doubt allegedly cast on the March 2012 studies by third parties

189 In the third place, the applicants submit that the irrelevance of the March 2012 studies was confirmed by EFSA's Statement, by certain Member States and by the agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Agency for Food, Environmental and Occupational Health and Safety, France) (ANSES).

190 In that regard, first, it should be noted that, contrary to the applicants' claims, EFSA's Statement does not reject the March 2012 studies as 'fundamentally flawed' or as containing no scientifically relevant information. The extracts from that statement quoted by the applicants merely show that the conclusion, already referred to above, that, given that the exposure levels applied in the March 2012 studies and in the Schneider study largely exceeded field exposure levels, additional studies were necessary before definite conclusions could be drawn.

191 Second, the comments of various Member States, invoked by Syngenta, are not, as a matter of principle, capable of calling into question the fact that the results of the March 2012 studies and of the Schneider study constitute 'new scientific knowledge'. The merits of the Commission's assessments pursuant to Article 21(1) of Regulation No 1107/2009 are not contingent on whether they are shared by (all) the Member States. Furthermore, some of those comments do not substantiate the conclusions suggested by Syngenta.

192 Thus, in the case of the letter from the Netherlands Ministry of Economic Affairs, Agriculture and Innovation, it should be noted that, according to the account given in the application in Case T−451/13, 'the Netherlands considered that regulatory action based only on these Studies was not justified'. However, that opinion of the Netherlands authorities is not a comment on the novelty of the results of the studies referred to and, moreover, it refers to the decision of the French authorities of 29 June 2012 to withdraw the authorisation for a thiamethoxam-based plant protection product. In the present case, the Commission did not adopt the contested measure solely on the basis of the March 2012 studies and the Schneider study, but following a risk assessment by EFSA.

193 The same observation applies with respect to the view expressed by a Member State during the Standing Committee's meeting on 12 and 13 July 2012 that the withdrawal by France of authorisation for a product containing thiamethoxam was disproportionate.

194 The opinion of ANSES of 31 May 2012, relied on by Syngenta, concerns the question whether the dose administered in the Henry study corresponds to situations that are representative of field exposure of bees and whether that study is likely to call into question the conclusions of the previous risk assessments carried out in respect of the active substance thiamethoxam. It should be noted in that regard, first of all, that the finding reported by Syngenta, that the results of the Henry study 'are not considered as calling into question the conclusions of the risk assessment conducted according to the current regulatory criteria in the context of the Marketing Authorisation application for Cruiser OSR. However, they do emphasise the limitations of the models used in this context in terms of sensitivity', may reveal the need for a (re)assessment of the risks associated with the substances covered (in this instance, thiamethoxam) and thus tends to support the Commission's position rather than that of the applicants.

195 In addition, it must be observed that, in its 'recommendations' at the end of the opinion in question, ANSES suggested, in particular, 'instigating a review at the European level of neonicotinoid active substances (thiamethoxam, clothianidin, ...) based on new scientific data from recent studies, as was proposed by EFSA'. It thus appears that ANSES' opinion, albeit reserved as to the implications of the results of the Henry study, was proposing to draw the same inferences from it as those proposed by EFSA, namely to carry out a review of the active substances concerned.

196 As regards, last, the research carried out by the Government of the United Kingdom, an assessment report was drawn up in March 2013 by the United Kingdom Department for Environment, Food and Rural Affairs comparing the March 2012 studies, and another study which found an effect on bumble-bee behaviour following exposure to sub-lethal doses of imidacloprid, to studies that did not find such effects. The report states that that difference might be explained by the fact that the first group of studies, which were laboratory studies, had used higher doses of the substances covered than those encountered by pollinators in the field. The fact that the exposure levels applied in the March 2012 studies largely exceeded field exposure levels had already been established in EFSA's Statement, which had nevertheless concluded that further research was necessary (see paragraph 190 above). The assessment report relied on by Syngenta does not therefore cast doubt on the facts as taken into account by EFSA and by the Commission; it simply draws different conclusions from them. In the light of the broad discretion which the Commission must be recognised as enjoying in connection with risk management decisions under Regulation No 1107/2009 (see paragraph 143 above), that fact cannot constitute evidence that the March 2012 studies are of no relevance.

(4) Interim conclusion

197 In conclusion, the Court considers that the Commission was right in finding that, as compared with previous knowledge, the results of the March 2012 studies and of the Schneider study raised concerns as to whether the conditions of approval in Article 4 of Regulation No 1107/2009 were still satisfied, and that, in so finding, the Commission did not make an error of law or a manifest error of assessment.

198 The findings in the three studies, summarised in paragraphs 173 to 175 above, constituted in themselves a result that was of concern with regard to the question 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.

(5) The role of monitoring data

199 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.

200 The applicants submit, 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. In their view, monitoring data do have a particular value and relevance, given that they are collected in field conditions for the application of plant protection products containing the substances covered, and not in artificially created conditions. They state that, following various monitoring programmes in a number of EU countries, there is a large quantity of high-quality monitoring data available and that the data as a whole show that, in field conditions for the application of plant protection products containing the substances covered, there is no risk for bees at colony level.

(i) The concept of monitoring data

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

202 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 substances covered — 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. In addition, 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.

203 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

204 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.

205 At the hearings, the applicants took issue with that assertion.

206 Bayer stated, in that regard, that monitoring studies enabled a correlation to be established between different factors — in this instance, between bee exposure to crops treated with pesticides containing the substances covered, on the one hand, and a possible increase in bee mortality or a weakening of colonies or their collapse, on the other. In its view, although it cannot be inferred merely from a correlation between those two facts that there is a causal link, it can be inferred from the lack of any correlation that there is no causal link. It argues that, given that there are no monitoring data in the present case to indicate a correlation between the application of pesticides containing the substances covered and increased bee mortality or colony collapse, it may be concluded that those pesticides do not present a risk.

207 Syngenta maintained that the collection of monitoring data was an integral part of the process of monitoring the approval of active substances, to which the legislation referred repeatedly. Given that monitoring studies are the most realistic field studies imaginable, Syngenta is of the view that the monitoring data they generate cannot be ignored.

208 In that regard, first of all, the Court must reject Syngenta's attempt to treat monitoring studies in the same way as field studies or tier 3 studies. As has been stated in paragraphs 202 and 203 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.

209 Thus, it must be observed that, contrary to Bayer's suggestion, 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.

210 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.

211 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 the substances covered 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. It is in that sense that the references to monitoring data in certain provisions of Regulation No 1107/2009, rightly noted by Syngenta, must be understood.

212 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

213 It is apparent from the first subparagraph of Article 21(1) of Regulation No 1107/2009 (see paragraph 9 above) 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.

214 Contrary to Bayer's claims, 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.

215 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 160 above).

216 It follows from this that, if the monitoring data relied on by the applicants consistently failed to show increased bee mortality or colony collapse coinciding with the use of plant protection products containing the substances covered, the data would indeed be capable of casting doubt on the concerns raised by the Henry, Whitehorn and Schneider studies, summarised in paragraphs 197 and 198 above. The data were not, however, capable of demonstrating that those concerns were unfounded.

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

218 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

219 The applicants raise several sets of complaints relating to the application by the Commission and by EFSA of Article 21(3) of Regulation No 1107/2009, namely (i) a lack of consistency between the grounds for initiating the review procedure and those underpinning the contested measure; (ii) 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 the substances covered; and (iii) manifest errors in the application of the precautionary principle or misapplication of that principle.

(a) Complaint alleging a lack of consistency between the grounds for initiating the review procedure and the grounds for the contested measure

220 Bayer claims, at the reply stage, that the Commission used the allegedly novel nature of the March 2012 studies as a pretext for initiating a reassessment of the substances covered, in accordance with Article 21(1) of Regulation No 1107/2009. It was only on reading the defence in Case T−429/13 that it had learned that the contested measure related to the high acute risks of lethal effects identified by EFSA and that, therefore, the sub-lethal effects and the science that was purportedly new, which were the subject matter of the March 2012 studies, were irrelevant for the Commission.

221 The Commission did not specifically respond to that complaint.

222 It must be noted that the present complaint presupposes that there is an obligation of consistency or, at the very least, of equivalence between the grounds justifying initiation of the review procedure under Article 21(1) of Regulation No 1107/2009, on the one hand, and the grounds underpinning an amendment of the approval pursuant to Article 21(3) of Regulation No 1107/2009, on the other. However, no such obligation exists, for the following reasons.

223 As has been stated in paragraph 160 above, the review procedure is 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 in Article 4 of Regulation No 1107/2009, to verify whether that is indeed the case. Article 21 of Regulation No 1107/2009 does not contain any restriction as to the grounds on which it may be found that the approval criteria are no longer met, and, in particular, it does not indicate that the review should relate only to the 'new scientific and technical knowledge' on which the initiation of that review was based.

224 Furthermore, such a restriction would be contrary to the principle of good administration and to the protective purpose of Regulation No 1107/2009 (see paragraphs 105 to 107 above). Assuming that it transpires during the review that an approval criterion is not satisfied, in the light of scientific and technical information that differs from that which led to the review being initiated, the approval could not then be amended in that respect, even where there was a significant risk. However, that information would itself certainly constitute 'new scientific and technical knowledge' within the meaning of Article 21(1) of Regulation No 1107/2009, warranting the initiation of a further review procedure, one that is separate from the first. Clearly, proceeding in this way, which the text certainly does not call for, would be unnecessarily formalistic and would undermine the principle of good administration and the protective purpose of Regulation No 1107/2009.

225 In those circumstances, the complaint as to a lack of consistency between the grounds for initiation of the review procedure and the grounds for the contested measure must be rejected, and it is not necessary to consider whether that complaint, first put forward in the reply, is out of time, or to verify whether there really is in this instance a lack of consistency between the respective grounds referred to above.

(b) Complaints concerning the application of assessment methodologies and criteria that differ from those applicable at the time of the request for approval

226 The applicants raise a number of complaints concerning the assessment methodologies and criteria applied by EFSA in the review of the risks relating to the substances covered. In particular, they are critical of the fact that the evaluation methodologies were not the same as those used at the time of the initial approval of those substances.

227 They maintain that it was impossible for them, given the timetable imposed by the Commission and the lack of any properly finalised guidance document, to gather the material required by the new criteria and methodologies applied in the review, since that would, inter alia, have required new field studies to be carried out. In their view, it was consequently inevitable that there would be certain gaps in the data and that, in those circumstances, they did not have any real chance of preventing the adoption of the contested measure, irrespective of the actual level of risk entailed by the substances covered.

228 The applicants submit, in particular, that Article 12(2) of Regulation No 1107/2009 and point 3.8.3 of Annex II thereto, as well as the principle of protection of legitimate expectations, required EFSA and the Commission to base the risk assessments on a guidance document — adopted either at EU or international level — available at the time of the request for approval of an active substance. As is apparent from point 1.3 of Annex II, further guidance was to be developed in the framework of the Standing Committee in order to be taken into account. As regards the procedure and criteria to be applied, the applicants maintain that there is no difference between initial approvals, renewals and reviews.

229 Bayer argues that the only document satisfying those criteria at the time of EFSA's risk assessment was the EPPO Guidance (see paragraph 17 above). The applicants maintain that, on the Commission's

instructions, EFSA relied in its risk assessment on its own opinion of May 2012 (see paragraph 22 above), which was merely preparatory to the drawing up of a proper guidance document, and, to a lesser extent, on its draft guidance on the assessment of risks posed by plant protection products to bees, which was only finalised on 4 July 2013 and thus after the adoption of the contested measure. That would have completely altered the result of EFSA's assessment and the Commission's findings on the management of the risk.

230 In Syngenta's opinion, if the view were to be taken that, in the context of Article 21 of the Regulation No 1107/2009, the methodologies could be altered and applied to active substances after their approval, three conditions would have to be satisfied: new scientific knowledge would have to be available; the new methodology would have to be finalised; and notifiers would have to be given the opportunity to generate the scientific data necessary to meet the requirements of the new methodology. In its opinion, none of those conditions was satisfied in the present case.

231 The Commission disputes the applicants' arguments.

(1) The question as to which documents were used as the basis of EFSA's risk assessment

232 As a preliminary point, it is necessary to clarify certain concepts, in particular concerning the designation of certain documents that may be taken into account by EFSA in assessing the risks of an active substance.

(i) The EFSA Opinion

233 It should be recalled that the EFSA Opinion related to a review of the EPPO Guidance, which until then had constituted the reference scheme for the assessment of risks posed by plant protection products to bees, in relation to the assessment of chronic risks, exposure to low doses, exposure through guttation and the cumulative risk assessment (see paragraph 17 above). Under the heading 'Abstract' of the EFSA Opinion, the objective pursued and the work undertaken by EFSA to that end are presented as follows:

'The [EFSA Panel on Plant Protection Products and their Residues] was asked to deliver a scientific opinion on the science behind the development of a risk assessment of plant protection products on bees (*Apis mellifera*, *Bombusspp*. and solitary bees). Specific protection goals options were suggested based on the ecosystem services approach. The different routes of exposure were analysed in detail for different categories of bees. The existing test guidelines were evaluated and suggestions for improvement and further research needs were listed. A simple prioritisation tool to assess cumulative effects of single pesticides using mortality data is suggested. Effects from repeated and simultaneous exposure and synergism are discussed. Proposals for separate risk assessment schemes, one for honeybees and one for bumble-bees and solitary bees, were developed.'

234 It is also apparent from the EFSA Opinion, under the heading 'Summary', that its authors carried out this work on the basis of very comprehensive use of the studies available, the list of references running to 23 pages. However, the authors did not conduct their own scientific tests. Therefore, while the EFSA Opinion does not contain new scientific knowledge, it is, in principle, capable of being used as a reference for determining the state of scientific knowledge at the time when it was finalised, at least with respect to published studies.

235 Thus, the EFSA Opinion is a 'high-level' document on the assessment of risks posed by plant protection products to bees, which recommends protection goals with respect to categories, magnitude and duration of tolerable effects, at different levels of the ecosystem, for individual bees and for colonies, producing suggestions as to the factors to be taken into account when assessing the risks. In addition, the EFSA Opinion analyses in detail the various routes of exposure for different categories of bees, evaluates existing test guidelines and makes suggestions for their improvement and for further research.

236 The parties agree that, as a high-level document, the EFSA Opinion is preparatory in nature in two respects.

237 First, as regards protection goals, the EFSA Opinion merely puts forward proposals, while the final setting of those goals is then a matter for the Commission as risk manager. The EFSA Opinion itself states in that regard, in Chapter 8, entitled 'Recommendations and Conclusions':

'For the development of robust and efficient environmental risk assessment procedures it is crucial to know what to protect, where to protect it and over what time period …

The final decision on protection goals needs to be taken by risk managers. There is a trade-off between plant protection and the protection of bees. The effects on pollinators need to be weighed against increase in crop yields due to better protection of crops against pests. The overall level of protection also includes the exposure assessment goals. Decisions need to be taken on how conservative the exposure estimate should be and what percentage of exposure situations should be covered in the risk assessment.'

238 Second, with regard to the methodology to be applied, the EFSA Opinion identifies certain weaknesses in the test guidance documents used to date, both as regards laboratory studies and field studies, and notes the lack of guidance in relation to the studies on the effects on bumble-bees and solitary bees. Consequently, it advocates developing the existing guidelines with a view to including the current state of scientific knowledge on certain points, or developing new guidelines. In particular, it is stated that:

'It is recommended to add the current state of scientific knowledge on a number of issues to the existing guidelines ...

… further work is required to develop guidelines, including the minimum field size, number of colonies or nesting females per treatment, methodology for dead bee assessments and foraging assessments and agreement of appropriate approaches for determining colony development [for bumble-bees] …

Separate risk assessment schemes are proposed, one for honeybees and one for bumble-bees and solitary bees ...

There is a need to improve the testing protocols concerning bumble-bees and solitary bees, in particular to better address the chronic risk and the identification and measurement of sub-lethal effects ...'

239 It follows that the EFSA Opinion provides a scientific basis that may be used to develop guidance documents and test guidelines, but does not itself constitute such a document.

240 That does not, however, mean that EFSA could not rely on its own opinion in the context of the risk assessment. As a document that analyses in detail the different routes of exposure for different categories of bees and evaluates the existing test guidelines, the EFSA Opinion could serve to highlight the areas in which there were gaps in the assessments made to date that could hide risks that had not yet been assessed and which had not been taken into account in the previous risk management decisions relating to the substances covered.

(ii) The guidance documents

241 It is apparent, in essence, from the parties' replies to the Court's written questions that a guidance document contains the protection goals, as set by the risk manager, and the substantive assessment criteria (assessment schemes and actual numerical values the attainment of which leads to non-approval, etc.) necessary for the evaluation of those protection goals.

242 At the Commission's request, EFSA drew up a draft guidance document on the basis of its opinion. A preliminary version of this 'EFSA Guidance on the risk assessment of plant protection products on bees and solitary bees' was published for public consultation on 20 September 2012. The amended document was published on 4 July 2013 (the '2013 Guidance').

243 However, in order for that guidance to be formally applicable, the draft 2013 Guidance first had to be approved by the Member States within the Standing Committee. It is evident from the parties' statements that the draft 2013 Guidance was the subject of a first meeting with the Member States in December 2013 and that, on that occasion, its entry into force was envisaged for 1 January 2015. However, owing to persistent disagreements between the Commission and certain Member States on key points in the draft, it had still not been formally approved by the date of the hearings in the present cases, on 15 and 16 February 2017.

244 The Commission indicated, moreover, that in view of that provisional status, it was not, for the time being, relying on that document in order to take risk management decisions.

(iii) The claim that EFSA relied on the draft guidance document

245 Bayer did not substantiate its claim that EFSA relied on the draft 2013 Guidance in the context of the risk assessment. However, Syngenta drew attention to footnotes 14 to 17 in EFSA's Conclusions on thiamethoxam, which refer to the draft 2013 Guidance.

246 According to the Commission, those references were not made in order 'to refer to the methodology but rather to the input data without which the risk assessment would not have been carried out'. Specifically, footnotes 14 and 15 referred to some of the protection goals contained in the draft 2013 Guidance. Moreover, footnotes 16 and 17 referred to data relating to residues in nectar and pollen, data which had already been included in the EFSA Opinion and in EFSA's Statement, and which had then been reproduced in the draft 2013 Guidance.

247 In the first place, it should be noted that the second mandate, by which the Commission asked EFSA to update the risk assessments of the substances covered (see paragraph 21 above), expressly mentions certain material which EFSA was required to take into account in that regard. That material includes the EFSA Opinion but not the draft 2013 Guidance.

248 In the second place, it is apparent from Syngenta's own assertions, which are substantiated by the material in the file, that not only had the Commission not asked EFSA to use the draft 2013 Guidance, but there was in fact a consensus between those two entities that the draft could not be taken into account in the reassessment of the substances covered. In an email dated 29 October 2012 sent to Syngenta by the former Head of EFSA's Pesticides Unit, the latter confirmed that 'the Commission knew the [2013] guidance would not be ready in time in order to consider it for [EFSA's Conclusions], which need[ed] to be finalised by the end of [2012]', and that that was why it had requested EFSA to consider the EFSA Opinion.

249 That statement is corroborated by other evidence, notably the evidence given by the same head of unit on 6 February 2013 as a witness before a United Kingdom parliamentary committee and on which the applicants rely, in which he stated, in particular, as follows:

'We have been asked [by the Commission] to use a scientific opinion that is only preparatory to a guidance document ... When we were performing our evaluation, we did not have the guidance document. We had the scientific opinion, which is not a guidance document. In the guidance document, you need to lay down the criteria. The criteria so far have not been laid down ... and [they] have to be laid down in dialogue with the risk managers because, "What is safe?" is not just a scientific question ... This has not been done, and from there the fact that on many occasions we have written in our conclusion, "No criteria. We can't for sure finalise the risk assessment. There is a high level of uncertainty".'

250 It may be inferred from those explanations that EFSA did not in fact use the draft 2013 Guidance, since it contained, according to the applicants' own statements, proposals for assessment criteria. Accordingly, if EFSA had used that draft, the issue of the absence of criteria would not have arisen.

251 Likewise, the summary report of the Standing Committee's meeting on 12 and 13 July 2012 indicates that the draft 2013 Guidance was prepared by EFSA in parallel with the risk assessment of the substances

covered and that that work cannot therefore be taken into account in the re-evaluation process.

252 In the third place, as regards footnotes 14 to 17 of EFSA's Conclusions on thiamethoxam, relied on by Syngenta, it is necessary to distinguish between the application, in the strict sense, of the draft 2013 Guidance, in that EFSA would have considered itself bound by the proposals it contained even though they had not been validated by the Standing Committee, on the one hand, and the mere mention of that document for informative or illustrative purposes, for example, where reference is made to pre-existing data merely reproduced or compiled in the draft 2013 Guidance, on the other. While the first was not permissible at the time of the risk assessment carried out by EFSA, given that the 2013 Guidance had not been properly finalised, the second cannot be considered an irregularity.

253 Since the footnotes relied on by Syngenta are merely a reference to the draft 2013 Guidance, the question as to which of the alternatives set out in paragraph 252 above applies to the references made depends on the wording of the sentences in which those footnotes appear. It should further be noted that EFSA's Conclusions on thiamethoxam include the reference '16' twice, on pages 21 and 22, but that there is only one footnote 16, on page 21 of those conclusions.

254 First, the sentence containing the reference to footnote 15 shows that the experts wanted to express certain data in the format envisaged by the draft 2013 Guidance in order to facilitate comparisons once the 2013 Guidance was finalised. That cannot be described as the 'application' of the draft 2013 Guidance.

255 Second, the sentence containing the reference to footnote 17 refers to data 'reported' in Appendix I to the draft 2013 Guidance. As is apparent on reading the preceding sentences, those data come from various studies and were merely compiled in Appendix I to the draft 2013 Guidance. Consequently, the reference to that appendix cannot be described as an 'application' of the draft 2013 Guidance.

256 Third, the sentence preceding that containing the second reference to footnote 16 shows that the database mentioned there had already featured in earlier EFSA publications (namely the EFSA Opinion and EFSA's Statement) and was amended and improved for the draft 2013 Guidance. In so far as what is at issue is the mere taking into account of pre-existing data, it must be held that this is not an 'application' of the draft 2013 Guidance, in the sense of the application of new methodologies not approved by the Member States.

257 Fourth, the sentences containing the reference to footnote 14 and the first reference to footnote 16 mention that the deposition values 'were considered within the draft EFSA guidance document'. In reply to a written question from the Court, the Commission indicated that that wording, used twice by EFSA, meant that the deposition values used by EFSA, which were taken from another document drawn up by the Directorate-General (DG) for Health and Food Safety, had also been taken into account in the draft 2013 Guidance — and not that the values taken from the draft 2013 Guidance had been used in the risk assessment. In the light of this information, which may be added to the more general matters set out in paragraphs 248 to 251 above, it must be concluded that the wording in question does not constitute an application of the draft 2013 Guidance, in the strict sense of the word.

258 It follows from this that, in its assessment of the risks posed by the substances covered, EFSA relied, inter alia, on its opinion. However, it did not apply the draft 2013 Guidance as a guidance document.

(2) The complaint alleging infringement of Article 12(2) of Regulation No 1107/2009

259 Article 12(1) and (2) of Regulation No 1107/2009, entitled 'Conclusion by [EFSA]', is worded as follows:

'1. [EFSA] shall circulate the draft assessment report received from the rapporteur Member State to the applicant and the other Member States at the latest 30 days after its receipt. It shall ask the applicant to circulate an update of the dossier where applicable to the Member States, the Commission and [EFSA].

[EFSA] shall make the draft assessment report available to the public, after giving the applicant two weeks to request, pursuant to Article 63, that certain parts of the draft assessment report be kept confidential.

[EFSA] shall allow a period of 60 days for the submission of written comments.

2. [EFSA], where appropriate shall organise a consultation of experts, including experts from the rapporteur Member State.

Within 120 days of the end of the period provided for the submission of written comments, [EFSA] shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents available at the time of application on whether the active substance can be expected to meet the approval criteria provided for in Article 4 and shall communicate it to the applicant, the Member States and the Commission and shall make it available to the public. In the event of a consultation as provided for in this paragraph, the 120-day period shall be extended by 30 days.

Where appropriate, [EFSA] shall address in its conclusion the risk mitigation options identified in the draft assessment report.'

260 The applicants submit, in essence, that Article 12(2) of Regulation No 1107/2009 required that, in the present case, the risk assessment of the active substances be carried out using the guidance documents available at the time of the request for approval of the substance in question, that is to say, the EPPO Guidance.

261 It is necessary to determine, in that regard, whether Article 12 of Regulation No 1107/2009 is applicable in the context of the review procedure, which the Commission disputes.

262 First of all, it must be noted that Article 12 is part of subsection 2, 'Approval procedure', in the 'Active substances' section of Chapter II of Regulation No 1107/2009. Article 21, however, is part of subsection 3 'Renewal and review'.

263 Consequently, a systematic assessment would militate against the application of provisions of subsection 2 in the context of subsection 3, unless expressly referred to therein. One example of such a reference appears in the second subparagraph of Article 21(3) (see paragraph 9 above), which expressly provides, inter alia, that Article 13(4) (which falls under subsection 2) is to apply. That reference would be superfluous if the provisions of subsection 2 were applicable in any event in the context of reviews.

264 That interpretation is confirmed by the structure of Article 12 of Regulation No 1107/2009. The second subparagraph of Article 12(2) of Regulation No 1107/2009 provides that EFSA is to adopt its conclusion within 120 days 'of the end of the period provided for the submission of written comments'. The starting point for that time limit is by reference to the third subparagraph of Article 12(1), which provides that EFSA 'shall allow a period of 60 days for the submission of written comments' after the draft assessment report (drawn up by the rapporteur Member State) has been made available to the public, in accordance with the second subparagraph.

265 In the context of the review procedure under Article 21, there is no provision for a draft assessment report to be drawn up or, moreover, to be made available to the public. The second subparagraph of Article 12(2), the object of which is, inter alia, to set a time limit for the presentation of EFSA's conclusion, is not therefore applicable to the review, not least since the starting point for the time limit cannot be determined. By contrast, Article 21(2) of Regulation No 1107/2009 prescribes a different time limit for submission of the results of EFSA's risk assessment in the context of the review, namely 'within three months of the date of the request' by the Commission.

266 Last, it must be added that, in the light of the protection goals of Regulation No 1107/2009 (see paragraphs 105 to 107 above), it would be difficult to accept that the methods for assessing the risks posed by an approved substance must remain fixed as at the date of the request for approval, in the context of a review which may take place, as in the present case, more than 10 years after that date.

267 It must be held, therefore, that Article 12(2) of Regulation No 1107/2009 cannot properly be relied upon in order to challenge the application, in the review of the substances covered, of methodologies and criteria that differ from those applied when those substances were approved, and, in particular, the non-application of the EPPO Guidance.

268 Consequently, the complaint alleging infringement of that provision must be rejected.

(3) The complaint alleging infringement of point 3.8.3 of Annex II to Regulation No 1107/2009

269 The applicants submit that it follows from point 3.8.3 of Annex II (see paragraph 10 above), read in conjunction with Article 12(2) of Regulation No 1107/2009, that the Commission and EFSA cannot rely on a non-finalised methodology in order to determine whether a substance continues to meet the criteria of Article 4 of that regulation, but that the risk assessment must be performed using guidance documents applicable at the date of the submission of the dossier or data. Bayer states that, at the time of EFSA's risk assessment of the substances covered, the EPPO Guidance was the only document fulfilling the requirement contained in the expression 'on the basis of [EU] or internationally agreed test guidelines' in point 3.8.3 of Annex II.

270 The Commission disputes those arguments.

271 As regards, in the first place, the argument relating to Article 12(2) of Regulation No 1107/2009, it has been stated above that that provision does not support the applicants' claims that the risk assessment should be based on guidance documents available at the time of the request for approval of an active substance.

272 As regards, in the second place, point 3.8.3 of Annex II to Regulation No 1107/2009, the complaint that that provision has been infringed concerns, in essence, the question whether that provision precluded EFSA, when assessing the risks posed by the substances covered, from applying assessment criteria and methodologies that differed from those applicable when the substances covered were originally approved and, in particular, from departing from documents prepared in that respect in the context of the EPPO.

273 In that regard, it is necessary to take into account the fact that the regulatory framework has evolved since the original approval of the substances covered, particularly through the adoption of Regulation No 1107/2009 and associated implementing regulations, which now provide that special attention must be paid to the risks that active substances and notably pesticides pose to bees, as explained in paragraphs 133 to 136 above.

274 In particular, as the Commission correctly contends, the inclusion of the new point 3.8.3 in Annex II to Regulation No 1107/2009 constitutes a change in the requirements for approval of active substances as regards the risk that pesticides pose to bees.

275 Moreover, as explained in paragraph 136 above, that change in the regulatory framework is supposed to be applied to any risk assessment performed since the entry into force of Regulation No 1107/2009, whether it is an initial approval or a review.

276 In those circumstances, it must be held that not only did point 3.8.3 of Annex II to Regulation No 1107/2009 not preclude the application, by EFSA, of criteria and methodologies differing from those applied when the substances covered were initially approved, but, on the contrary, and in accordance with the EU legislature's intentions, the application of amended criteria was required by Regulation No 1107/2009. That concerned in particular the EFSA Opinion, as a document summarising the state of scientific knowledge in that field at the time of the risk assessment of the substances covered.

277 Accordingly, the complaint alleging infringement of point 3.8.3 of Annex II to Regulation No 1107/2009 must be rejected and, furthermore, there is no need to comment on whether the words 'test guidelines',

used in the introductory part of that provision, are a reference to guidance documents, as the applicants maintain, or to a document on test methods, as the Commission contends.

(4) The complaint concerning the protection of legitimate expectations

278 It has consistently been held that any individual whom an institution of the European Union has led to entertain legitimate expectations by giving him precise assurances may rely on the principle of the protection of legitimate expectations (judgment of 11 March 1987, *Van den Bergh en Jurgens and Van Dijk Food Products (Lopik)* v *EEC*, 265/85, EU:C:1987:121, paragraph 44; see also judgment of 8 September 2010, *Deltafina* v *Commission*, T−29/05, EU:T:2010:355, paragraph 427 and the case-law cited).

279 Bayer claims in that regard that, in the circumstances of the case, the absence of written assurances by the Commission regarding the use of the EPPO Guidance cannot be sufficient to deny Bayer its legitimate expectation to that effect. It submits that, given that the prior version of that guidance had been used as the basis for the risk assessment and risk management procedures regarding the substances covered, and given that that guidance had been updated in 2010 with the involvement of its representatives and those of the various Member State authorities, and given that certain Member States had applied it only recently, it had every reason to believe, in the absence of any indication by the Commission to the contrary, that the revised and updated 2010 version of that guidance would be used as the basis for future risk assessments of the substances covered. Furthermore, all stakeholders, including EFSA, considered that Regulation No 1107/2009 required the EPPO Guidance to be used.

280 It must be noted in that regard, as the Commission correctly contends and as is apparent from Bayer's own assertions, that the applicants do not refer to any assurances given by the Commission to the effect that the risk assessment conducted under Article 21(3) of Regulation No 1107/2009 would be performed on the basis of guidance documents available at the dates of the requests for approval of the substances covered — which could be more than 10 years before the review — and, in particular, on the basis of the EPPO Guidance. The applicants' alleged beliefs, based on other circumstances, do not fulfil the requirements set out by the case-law cited in paragraph 278 above.

281 In so far as Bayer relies on the evidence given by the former Head of EFSA's Pesticides Unit as a witness before a United Kingdom parliamentary committee (see paragraph 249 above), with regard to EFSA's alleged belief that the EPPO Guidance would be applied, it must be noted that that evidence does not in any way substantiate that allegation. While it is apparent from that evidence that the Commission asked EFSA to use the EFSA Opinion and that that was not a 'guidance document with a risk assessment methodology', it certainly does not appear that EFSA disagreed with that request or that, had it not been made, EFSA would have considered itself bound to rely on the EPPO Guidance.

282 Furthermore, inasmuch as Bayer relies on point 3.8.3 of Annex II to Regulation No 1107/2009 as the basis for a legitimate expectation, it follows from the considerations set out in paragraphs 274 to 276 above that that provision cannot serve as the basis for such an expectation.

283 Consequently, the application, in the context of the review of the substances covered, of methodologies and criteria that differ from those applied when the substances were approved did not breach the principle of protection of legitimate expectations.

284 Accordingly, the complaint alleging breach of that principle must be rejected.

(5) The complaint concerning legal certainty

285 It has consistently been held that the principle of legal certainty requires that rules of law be clear and precise and predictable in their effect, so that interested parties can ascertain their position in situations and legal relationships governed by EU law (see judgment of 8 December 2011, *France Télécom* v *Commission*, C−81/10 P, EU:C:2011:811, paragraph 100 and the case-law cited; judgment of 31 January 2013, *LVK*, C−643/11, EU:C:2013:55, paragraph 51).

286 That requirement of legal certainty must be observed all the more strictly in the case, as here, of rules liable to entail financial consequences, in order that those concerned may know precisely the extent of the obligations which those rules impose on them (judgment of 15 December 1987, *Ireland* v *Commission*, 325/85, EU:C:1987:546, paragraph 18).

287 Syngenta submits, in that regard, that it is essential that the 'rules of the game' are laid down in advance, that is to say, substance reviews are carried out only on the basis of established and agreed guidelines known to notifiers at the time of the request for approval. It further submits that, if the reverse were true, any approval could be withdrawn at any time simply as a result of the production of new draft guidelines, which would necessarily render 'incomplete' the existing dossier relating to an active substance. There would thus be no legal certainty at all.

288 In the first place, it should be noted in that regard that notifiers do not have a general right, arising from the principle of legal certainty, to expect the risk assessment and risk management criteria in respect of an active substance to remain fixed, in the event of a review, as at the date of the request for approval.

289 It should be borne in mind that Article 114(3) TFEU, on which Regulation No 1107/2009 is notably based, provides that, in its proposals concerning, in particular, environmental protection, made on the basis of the approximation of legislation having as its 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. Furthermore, it has been held that that 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). It follows from those principles, which constitute the basis of the general protection goal of Regulation No 1107/2009 (see paragraphs 105 to 107 above), that, unless otherwise specified, the decisions which the Commission is required to take in the context of that regulation must always take account of the latest scientific and technical knowledge.

290 Article 21 of Regulation No 1107/2009, on which the contested measure is based, merely articulates those points of principle when it provides, in essence, that the existence of new scientific knowledge may justify the withdrawal or amendment of an existing approval.

291 In the second place, however, that principle of taking into account new scientific knowledge may be accompanied by transitional provisions and, in particular, transitional periods, where the protection goal pursued, in particular, by Regulation No 1107/2009 is not affected.

292 That is, for example, the case as regards Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation No 1107/2009 (OJ 2013 L 93, p. 1), and Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation No 1107/2009 (OJ 2013 L 93, p. 85), cited by Syngenta. Recital 5 of those regulations indicates that 'a reasonable period should be allowed to elapse before the modified data requirements become applicable in order to permit applicants to prepare themselves to meet those requirements', and Article 5(2) of each regulation provides, in consequence, for application to be deferred by eight months in relation to the date of the regulations' entry into force. Likewise, recital 6 of those regulations states that 'in order to permit Member States and the interested parties to prepare themselves to meet the new requirements, it is appropriate to lay down transitional measures concerning data submitted' for applications for the approval of active substances. Last, both regulations provide in Section 8 of Part A of the Annex thereto that, 'pending the validation and adoption of new studies and of a new risk assessment scheme, existing protocols shall be used to address the acute and chronic risk to bees, including those on colony survival and development, and the identification and measurement of relevant sub-lethal effects in the risk assessment'.

293 First, it should be noted that Regulations No 283/2013 and No 284/2013 are not applicable to the facts of the present case. As is apparent from Article 3 of each regulation, and as the Commission correctly submits, the transitional provisions included therein apply only to procedures concerning approval, renewal or amendment of approval requirements, governed by Articles 7 to 20 of Regulation No 1107/2009, and not the review procedure governed by Article 21 of that regulation. Consequently, those regulations can, in this instance, serve only to illustrate the fact, noted in paragraph 291 above, that there may be exceptions to the principle of taking into account, in decisions based on Regulation No 1107/2009, the latest scientific knowledge.

294 Second, it must be emphasised that the fact that the deferred application of those two regulations does not cover the review procedure is not a matter of chance but is attributable to the balance struck between the principle of legal certainty and the protection goal of Regulation No 1107/2009. The procedures concerning approval, renewal and amendment of the approval requirements are initiated at the request of the producer of the substance in question, in accordance with Article 7(1) and Article 15(1) of Regulation No 1107/2009. In order to be able to compile the files to be submitted with a request, it is clearly necessary for the applicant to be aware, sufficiently in advance, of the data to be collected for the purposes of the procedure, and the protection goals of Regulation No 1107/2009 (see paragraphs 105 to 107 above) do not preclude it. By contrast, in accordance with Article 21(1) of Regulation No 1107/2009 (cited in paragraph 8 above), the review procedure is commenced by the Commission on its own initiative, and may be commenced at any time where, in the light of new scientific and technical knowledge, the Commission considers that there are indications that the substance in question no longer satisfies the approval criteria. Since it is precisely the new scientific and technical knowledge that is the reason for the initiation of the review procedure, in so far as it would suggest that the substance in question may no longer satisfy the approval criteria, it would be illogical and contrary both in general terms to the protection goal of Regulation No 1107/2009 and specifically to the practical effect of Article 21 of that regulation not to take that new knowledge into account in the context of the review and, in particular, in the risk assessment.

295 Third, with regard to the practical consequences of recitals 5 and 6 of Regulations No 283/2013 and No 284/2013 and the application of Article 3, it should be noted that those expressions of the principle of legal certainty do imply that a file relating to an active substance cannot be rejected as being incomplete for failure to comply with the new requirements if the 'applicant' did not have the time to comply with them. However, that does not mean, given the protection goals of Regulation No 1107/2009 (see paragraphs 105 to 107 above), that EFSA and the Commission would be precluded from drawing the appropriate inferences, at the risk assessment and risk management level, from the absence of certain data which did not previously have to be provided but which, in the light of new scientific and technical knowledge, proves to be important for the purposes of the examination. If that were otherwise, EFSA and the Commission would be required to approve active substances in respect of which it has not been established, contrary to the requirements of point 3.8.3 of Annex II to Regulation No 1107/2009, that their use will result in negligible exposure of honeybees or has no unacceptable acute or chronic effects on colony survival and development. Compliance with the requirements concerning the data to be provided under procedures concerning approval, renewal and amendment of approval requirements is therefore within the scope of the admissibility of the request rather than the substantive conditions of the approval. That interpretation is confirmed by Article 9 of Regulation No 1107/2009, which provides that, after receiving the application for approval or for amendment of the approval requirements, the rapporteur Member State is to check whether the dossiers submitted with the application contain all the elements provided for (including the data required under Regulations No 283/2013 and No 284/2013) and that, if they do not, and if the missing elements have not been submitted within three months, the application is inadmissible.

296 In the third place, for reasons similar to those set out in paragraphs 293 and 294 above, the Court must reject Syngenta's arguments relating to Article 13 of Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation No 1107/2009 (OJ 2012 L 252, p. 26) and the judgment of 3 September 2009, *Cheminova and Others* v *Commission* (T−326/07,

EU:T:2009:299, paragraphs 137 and 236). First, Implementing Regulation No 844/2012 concerns the renewal procedure and, second, the judgment of 3 September 2009, *Cheminova and Others* v *Commission* (T−326/07, EU:T:2009:299) concerned a request for an active substance to be included in the Annex to Directive 91/414, a procedure similar to the approval procedure under Regulation No 1107/2009.

297 In conclusion, having regard in particular to the considerations set out in paragraph 289 above, it was sufficiently foreseeable, for the producers of the active substances approved under Regulation No 1107/2009, that the approvals of those substances might be reviewed in the light of scientific and technical knowledge appearing after the initial application for approval had been submitted.

298 Consequently, the application, in the context of the review of the substances covered, of methodologies and criteria that differ from those applied when the substances were approved did not breach legal certainty.

299 Accordingly, the complaint alleging breach of that principle must be rejected.

(6) The complaint that the risk assessment was based on the EFSA Opinion and not on a guidance document

300 The applicants submit, first, that the EFSA risk assessments were conducted, in large part, on the basis of the EFSA Opinion. In their submission, since that opinion did not — unlike in the case of a guidance document — set out a proper structure for conducting risk assessments, EFSA's Conclusions do not constitute as thorough a scientific assessment as possible of the relevant risks. EFSA's reliance on its opinion as the principal basis for its risk assessments vitiated the entire assessment and led to the facile and unscientific conclusion that a number of risks could not be excluded and that data gaps existed.

301 The Commission contests the applicants' arguments.

(i) Preliminary remarks

302 First of all, it should be recalled that the EFSA Opinion is a 'high-level' document, in that it summarises the state of scientific knowledge in relation to the assessment of the risks that plant protection products pose to bees, in order to produce proposals as to the protection goals to be achieved in this area and the factors to be taken into account when assessing the risks. By contrast, a guidance document contains protection goals as set by the risk manager, and, with a view to achieving those goals, guidelines on the degree of caution to be applied in interpreting the data (see paragraphs 235 and 241 above).

303 In addition, the applicants submit that, in the absence of an existing guidance document, taking into account the current state of scientific knowledge, as set out in the EFSA Opinion, they were not in a position to know which tests they should have carried out in order to generate the data that was identified as missing from EFSA's Conclusions (see paragraph 227 above). Those facts have not been disputed by the Commission.

304 The EFSA Opinion was published on 23 May 2012 (see paragraph 22 above). Subsequently, on the basis of that opinion, EFSA prepared a draft guidance document, a first draft of which was published for public consultation on 20 September 2012 and which had not been finally adopted when the hearings in the present cases were held (see paragraphs 242 and 243 above). In parallel, the second mandate, concerning a risk assessment of the substances covered, was conferred on EFSA as early as 25 April 2012 (see paragraph 21 above). As the applicants correctly submit, the timetable imposed by the Commission therefore made it impossible for EFSA to conduct a risk assessment on the basis of a guidance document that took into account the state of scientific knowledge documented in its opinion and that was duly adopted.

305 Last, it should be recalled that the EFSA Opinion was drawn up, on the one hand, in response to incidents and information that cast doubt on the comprehensiveness and adequacy of assessments of the risks the

substances covered posed to bees, in accordance with the practice at that time (see paragraph 17 above), and, on the other hand, in the context of an amendment of the approval requirements for active substances as regards the risk posed to bees by pesticides (see paragraph 274 above).

(ii) The consequences of choosing to proceed with a risk assessment without a guidance document being available

306 In the first place, given that the EFSA Opinion gives an account of the state of scientific knowledge that existed when the opinion was adopted (see paragraph 234 above), which is not disputed by the applicants, and that the Commission was obliged, in the present case, to take into account the latest scientific and technical knowledge (see paragraph 289 above), no criticism can be attached to the fact that EFSA relied on its opinion when assessing the risks.

307 In the second place, it seems probable, or even obvious, that extending the deadline for EFSA's risk assessment in order to wait for a test guidance document to be finalised and to enable the applicants to take that guidance document into account would have ensured that an even more advanced state of scientific knowledge than that represented by the EFSA Opinion could be taken into account. Since science in general is always likely to evolve, and the science of the effects of pesticides on bees has evolved particularly over a number of years, any extension of the deadline for the risk assessment would necessarily ensure that even more recent data and studies can be taken into account. From that aspect, the fact that the risk assessment was concluded on 31 December 2012 therefore implies that the scientific evaluation of the risks was less comprehensive than it would have been had that deadline been extended to a later date.

308 Furthermore, the risk assessment was essentially conducted on the basis of laboratory tests (tier 1), since semi-field testing (tier 2) and field testing (tier 3) presupposed the existence of a guidance document and modified test methodologies, which were not yet available on 31 December 2012. As the Commission acknowledged at the hearings, that necessarily led EFSA to conclude that the existence of certain risks could not be ruled out, when those risks might well have been dismissed at a later stage, in the light of the results of future tier 2 and tier 3 tests. In other words, it is possible that the fact that the risk assessment was concluded on 31 December 2012 means that certain risks could not be ruled out when they did not in fact exist. That situation could have been avoided by extending the deadline.

309 However, such an extension would necessarily have delayed the Commission's becoming aware, however imprecisely, as risk manager, of the level of risk posed by the substances covered and, as a result, the taking of a decision on the need to amend the approval requirements for those substances and on the usefulness of doing so. The Commission therefore had conflicting goals: on the one hand, the promptness of the risk assessment and, on the other, its comprehensiveness and accuracy.

310 The question that arises in the present case is not therefore whether, in the abstract and with no time constraints, a more comprehensive and accurate scientific evaluation would have been possible. It follows from the above that the answer to that question will probably be in the affirmative. It is, however, necessary to examine initially whether the deadline for the risk assessment was lawfully selected by the Commission (see paragraph 311 et seq. below) and, if it was, whether that assessment was conducted taking into account the state of scientific knowledge available on the chosen date (see paragraph 354 et seq. below).

(iii) The choice of deadline for the risk assessment

311 With regard to the choice of deadline for the risk assessment, it should be borne in mind, as a preliminary point, that the Courts of the European Union have recognised that, in order to be able to pursue effectively the objectives assigned to it by Regulation No 1107/2009, the Commission enjoys a broad discretion, particularly in relation to risk management decisions which it is required to adopt pursuant to that regulation; that review by the Courts is limited in that respect; and that, in order to establish that the Commission has made a manifest error of assessment that would justify the annulment of the measure

whose annulment is sought, the applicant must adduce sufficient evidence to make the Commission's assessments of the facts implausible (see the case-law cited in paragraphs 143 to 145 above).

312 In the present case, the Commission chose to have the assessment of the risks posed by the substances covered updated to 31 December 2012. It contended, in that respect, that a longer period could have put at risk the achievement of the objectives of the contested measure.

313 In the first place, it should be noted that Article 21(2) of Regulation No 1107/2009 provides that, in the context of a review, EFSA is to provide its opinion or the results of its work to the Commission within three months of the date of the request (see paragraph 9 above). It must therefore be held that the date of 31 December 2012 — eight months after the original version of the second mandate, dated 25 April 2012 (see paragraph 21 above), and five months after that mandate was narrowed, on 25 July 2012 (see paragraph 25 above) — gave EFSA more time than legally prescribed (see also, in that regard, paragraph 351 below).

314 In the second place, it should be noted that the Commission was fully entitled to take the view that the precautionary principle precluded the setting of a deadline for EFSA that would enable later scientific knowledge to be taken into account and, in particular, both EFSA and the applicants to take into account the guidance document that was in the process of being drawn up and the higher tier testing that could have been carried out once the document had been properly finalised.

315 First, in that regard, it is necessary to determine, at least approximately, how much time would have been required. It must be pointed out that the period in question must include not only the time needed in order properly to finalise the guidance document and, if necessary, to draw up and agree new testing methodologies, but also the time needed for the design and implementation of higher tier testing to generate the missing data.

316 On the one hand, regarding the time that would have been required in order for a guidance document to be properly finalised and approved, it is apparent from the facts set out in paragraphs 242 and 243 above that the 2013 Guidance was finalised in 2013 and submitted to the Member States for approval, with a view to its entering into force on 1 January 2015, and that that entry into force subsequently had to be postponed several times. Even on the assumption that the drawing up of that guidance could perhaps have been speeded up if necessary, and that the subsequent postponements were not foreseeable at the date of the second mandate, on 25 April 2012, the Commission thus had to proceed, on that date, on the assumption that the 2013 Guidance was not going to be formally applicable for two years.

317 On the other hand, as regards the time needed in order for the applicants to be able to conduct the new testing required in accordance with the 2013 Guidance, the Commission submits that generating the data necessary to fill those gaps would have taken 'at least 1-2 years, as field studies must be implemented during a growing season and planned beforehand'. In response to a written question from the Court, Bayer confirmed that that estimate was realistic, whereas Syngenta did not express a view in that regard.

318 It follows from this that, if the intention had been to ensure that the applicants and EFSA were in a position properly to take into account a duly finalised and approved guidance document, it would have been necessary to postpone the risk assessment of the substances covered by at least four years (at least two years between the date of the second mandate, 25 April 2012, and the entry into force of the 2013 Guidance, and a further two years for the necessary tests to be conducted), even without taking into account the subsequent postponements of approval of the 2013 Guidance by the Member States, which were not foreseeable at the time of the Commission's decision regarding the deadline for the risk assessment. It is certainly possible to envisage that period being reduced, assuming that the applicants would have been able to plan and initiate certain studies and certain tests on the basis of the draft guidance document without awaiting the final version. Nevertheless, it seems that, at best, the period by which the risk assessment would have been postponed might be estimated as being somewhere between two years and six months, and three years.

319 Second, as regards the circumstances to be taken into account by the Commission, the following should be recalled:

– the Henry, Whitehorn and Schneider studies had produced findings of concern as regards the effects of bee exposure to sub-lethal doses of the substances covered, the reduction in the proportion of foraging honeybees returning to the hive and the development of bumble-bee colonies (paragraphs 173 to 175 above);

– the Commission was fully entitled to conclude that, as compared with previous knowledge, those findings raised concerns as to whether the conditions of approval in Article 4 of Regulation No 1107/2009 were still satisfied (paragraphs 197 and 198 above);

– those concerns therefore justified the initiation of a procedure to review the approvals of the substances covered (paragraph 217 above).

320 It should also be borne in mind that the scientific and political context of that time included the following elements:

– the incidents in the period 2008 to 2009 involving the misuse of plant protection products containing the substances covered which resulted in losses of honeybee colonies (see paragraph 15 above);

– the introduction at national level, between 2008 and 2012, of various inconsistent measures limiting the use of plant protection products containing the substances covered (see paragraphs 15 and 18 above);

– the presentation in 2011 of the results of the Italian Apenet monitoring and research programme, raising concerns about the use of seeds treated with plant protection products containing the substances covered;

– the publication of the Henry, Whitehorn and Schneider studies in early 2012.

321 Furthermore, it is necessary to take into account the important role of bees and other pollinators, both for natural flora and for arable crops. The Commission emphasises, in that regard, without being contradicted by the applicants, that bees are critically important in the environment, sustaining biodiversity by providing essential pollination for a wide range of crops and wild plants. Thus, according to the Food and Agriculture Organisation of the United Nations (FAO), of some 100 crop species which provide 90% of food worldwide, 71 are bee-pollinated. In Europe alone, 84% of the 264 crop species are dependent on pollinators, including bees.

322 This critical importance of bees and other pollinators is, moreover, reflected in the context of Regulation No 1107/2009 in the existence of special provisions laying down specific requirements in relation to bee exposure to active substances. Point 3.8.3 of Annex II to Regulation No 1107/2009 (see paragraph 10 above) requires that the exposure of honeybees to the active substance in question be negligible or that it have no unacceptable acute or chronic effects at colony level (see paragraph 135 above).

323 Last, it is appropriate to recall the case-law cited in paragraph 106 above, which makes clear, in particular, that the goal of a high level of protection of the environment, as referred to in Article 1(3) of Regulation No 1107/2009, on the basis of Article 11 and Article 114(3) TFEU, takes precedence over economic considerations, with the result that it may justify adverse economic consequences, even those which are substantial, for certain traders.

324 In particular, as regards the precautionary principle specifically, it follows from the case-law cited in paragraph 119 above that the adoption, in the absence of scientific certainty, of preventive measures which, once that certainty has been acquired, might prove to be overly conservative cannot be regarded in itself as a breach of the precautionary principle and is, on the contrary, inherent in that principle.

325 In those circumstances, and in view of the broad discretion enjoyed by the Commission in this area (see paragraph 311 above), the Commission did not make a manifest error of assessment in finding that the additional period identified in paragraph 318 above, whether two years and six months or four years, was not in any event compatible with the goal of maintaining a high level of protection of the environment, and that it was for the Commission, pursuant to the precautionary principle, to adopt protective measures without being required to wait for the reality and severity of the risks indicated by the matters referred to in paragraphs 319 and 320 above to be fully demonstrated.

326 Accordingly, the complaint concerning the fact that the risk assessment was based on the EFSA Opinion and not on a guidance document must be rejected.

(7) The conditions allegedly required in order for the assessment methodologies to be modified for the purpose of the review, as compared with the original approval

327 Syngenta submits that, should the Court consider that the methodologies may be modified and applied to active substances after their approval, in the context of a review under Article 21 of Regulation No 1107/2009, three conditions would need to be met: (i) the review itself cannot be triggered by a new methodology alone but should also be based on new scientific knowledge; (ii) the new methodology must have been finalised; and (iii) notifiers must be given the chance to generate the scientific data necessary to respond to the requirements of that finalised methodology. It maintains that none of those conditions is satisfied in the present case.

328 The Commission did not specifically comment on those arguments.

329 On that point, and without there being any need to answer the question as to whether the application of new methodologies in the review of an approved active substance is indeed subject to the three cumulative conditions put forward by Syngenta, it is sufficient, for the purpose of refuting those arguments, to refer back to the considerations already set out above.

330 Thus, first, it has been stated, in paragraph 198 above, that the Commission did have new scientific knowledge justifying the initiation of a review of the approval of the substances covered, pursuant to Article 21 of Regulation No 1107/2009, alongside an awareness, articulated in the EFSA Opinion, of the inadequacy of the methodology previously used.

331 Second, it is stated in paragraphs 325 and 326 above that the fact that the 'new methodology' — in the present case, laid down in the 2013 Guidance — was not finalised did not prevent new scientific and technical knowledge from being taken into account, in the context of the risk assessment, in so far as such knowledge was available at the time of the assessment, and, in particular, that the Commission was fully entitled to consider that the taking of a decision on the inferences to be drawn from the new scientific and technical knowledge could not be deferred until the applicants were able to gather the necessary data in accordance with specifications that had yet to be established.

332 Consequently, the Court must reject Syngenta's arguments in relation to the conditions it claims apply to the use, in connection with a review, of modified methodologies, as compared with those applied in connection with the original approval.

333 In conclusion, the Court must reject all of the complaints relating to the application of criteria and methodologies that differ from those applicable at the time of the approval of the substances covered.

(c) Complaints alleging manifest errors of assessment and misapplication of the precautionary principle

334 The applicants claim, in essence, that there was no evidence to suggest that the substances covered no longer satisfied the approval criteria laid down in Article 4 of Regulation No 1107/2009. In coming to the opposite conclusion, the Commission had made a manifest error of assessment.

335 Furthermore, the applicants submit that, in the present case, the criteria for the proper application of the precautionary principle were not met. In particular, they complain that purely hypothetical risks were taken into account, that there was no adequate scientific assessment or cost/benefit analysis, and that the measures taken were disproportionate.

336 The complaints alleging manifest errors of assessment and those alleging misapplication of the precautionary principle must be examined together. The answer to the question whether, given the Commission's discretion in relation to risk management, certain scientific knowledge and information supported the conclusion that the conditions of approval were no longer satisfied and that the approval of the substances covered had to be amended is, in particular, influenced by the precautionary principle.

337 However, in so far as Syngenta also maintains, in the context of the plea alleging breach of the precautionary principle, that it was given no opportunity to participate in the procedure in an appropriate manner, that complaint is indissociable from the complaint alleging infringement of the rights of the defence and will therefore be dealt with in that context (see paragraph 430 et seq. below).

(1) The question of the extent to which the contested measure is based on the application of the precautionary principle

338 First of all, it should be pointed out that the contested measure is based, inter alia, on the precautionary principle. The fact that that principle is not specifically mentioned in the recitals of the contested measure seems to have led to some uncertainty among the applicants in that respect. In particular, Syngenta seems to assume that the Commission did apply that principle in so far as the contested measure is based on the fact that certain risks could not be ruled out with certainty, while there was no application of that principle in so far as the existence of risks was positively established.

339 As the Commission correctly notes, 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.

340 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 122 to 124 above), or assess how it should be dealt with in a risk management context (see paragraph 125 above).

341 In those circumstances, there is no need to ask, as Syngenta does, whether the contested measure is founded in its entirety, or only in part, on the precautionary principle. By contrast, it will be appropriate, in the analysis below, to take into account any influence which that principle may have on the discretion enjoyed by the Commission.

(2) The complaints relating to EFSA's risk assessment

342 The applicants raise a number of complaints challenging EFSA's risk assessment. In particular, they submit that EFSA's Conclusions are not based on as thorough a scientific assessment as possible or on the best available data and that EFSA took a purely hypothetical approach to the risk.

(i) Complaint alleging that EFSA was placed under great time pressure

343 Syngenta submits that the risk assessment was rushed, which undermined the quality and completeness of the scientific investigation. In particular, it claims that EFSA had repeatedly indicated to the Commission that it would be unrealistic, or impossible, to keep to the deadline imposed for the assessment, which was only five months away.

344 Syngenta also claims that certain circumstances peculiar to the present case were likely to cause problems and that more time was required than would normally have been necessary for EFSA's assessment.

345 Thus, first, Syngenta submits that, in the absence of a guidance document drawn up on the basis of the EFSA Opinion, EFSA did not have any established methodology for assessing the safety of the substances covered for bees, and no defined protection goals.

346 Second, Syngenta states that, normally, EFSA reviews assessments already carried out by rapporteur Member States on the basis of a dossier submitted by the notifier. However, in this instance, since the case concerned a reassessment in the context of a review, on the Commission's own initiative, of the approval of the substances covered, there was neither a dossier prepared by the notifier nor a report from the rapporteur Member State, so that EFSA had to carry out the assessment itself.

347 Third, Syngenta submits that, in accordance with Article 4(5) of Regulation No 1107/2009 (cited in paragraph 7 above), the assessment is normally limited to representative uses, whereas in the present case the second mandate related to all authorised uses of the substances covered.

348 The Commission contests Syngenta's arguments.

349 In this regard, it should be noted first of all that the five-month period alleged by Syngenta covers the period from 25 July 2012 until the end of 2012. However, the second mandate had already been conferred on 25 April 2012 (see paragraph 21 above), while 25 July 2012 is the date on which the second mandate was narrowed by the Commission following an exchange of emails with EFSA and in order to take account of EFSA's concerns about being unable to carry out the work within the allotted time (see paragraph 25 above). Although the final scope of the second mandate was not therefore determined until 25 July 2012, EFSA was in a position to start preparatory work much earlier. In particular, it is evident from the exchange of emails in that respect between EFSA and the Commission that the Member States had been invited to submit the relevant data in their possession by 8 June 2012. It follows from this that EFSA had a period of approximately eight months and thus clearly much more than the five months claimed by Syngenta, even if one takes into account the fact that, after 25 April 2012, clarification of a number of questions concerning the precise scope of the task conferred on EFSA had to be given to EFSA by the Commission.

350 Next, it is true that the particular circumstances highlighted by Syngenta (see paragraphs 345 to 347 above) were liable to make EFSA's task more difficult and to increase the time needed to assess the risks.

351 Nevertheless, it appears that EFSA's deadline in the present case was not excessively short. Thus, first, the Commission contends, without being contradicted by the applicants, that EFSA generally took between seven months and one year to finalise the peer review and the conclusions for one active substance. The period allowed in the present case was therefore not unusual. Second, the fact that the assessment in this case covered only the risks to bees and not all risks is a further aspect that reduces the complexity of the assessment and the time required, as compared with a full assessment. Consequently, the deadline for the second mandate — between five and eight months, depending on the starting date used (see paragraph 349 above) — took the particular circumstances of the case sufficiently into account. Third, as stated in paragraph 313 above, the legal time limit provided for in Article 21(2) of Regulation No 1107/2009 was only three months from the date on which the matter was referred to EFSA. While it is true that that legal time limit would clearly have been too short in the present case, it must in any event be noted that Regulation No 1107/2009 also therefore did not require EFSA to be given more time than the eight months set by the Commission.

352 Last, it must be pointed out that the presentation, on 15 November 2012, of the former Head of EFSA's Pesticides Unit to an association of producers of plant protection products, to which Syngenta refers, would tend to confirm the Commission's view rather than that of the applicants. As the Commission correctly contends, although that presentation, made during the final phase of the risk assessment of the substances covered, identified certain problems encountered by EFSA (namely the fact that there was no

report by a rapporteur Member State and that Member States had submitted data in different formats, languages and to different time scales), it did not indicate that EFSA or the head of unit responsible took the view that the deadline imposed was impossible to achieve or would affect the quality of the results.

353 Consequently, the complaint relating to the great time pressure under which EFSA was allegedly placed must be rejected.

(ii) Complaints alleging EFSA's failure to take into account important relevant scientific data

354 The applicants submit that EFSA failed to take account, in the context of the risk assessment, of important relevant scientific data, such as specific relevant peer-reviewed literature, certain studies, monitoring data and risk mitigation measures.

– *The alleged failure to examine in detail relevant peer-reviewed scientific literature*

355 In the first place, Bayer submits that, owing to the short deadline imposed by the Commission, EFSA decided to forgo entirely the customary detailed review of relevant peer-reviewed scientific literature.

356 In that regard, as the Commission correctly contends, in so far as Bayer is thereby referring to the review by EFSA of scientific peer-reviewed literature which must, in accordance with Article 8(5) of Regulation No 1107/2009, be added to the dossier submitted by notifiers, suffice it to note that the contested measure was adopted under the review procedure referred to in Article 21 of Regulation No 1107/2009, which is launched by the Commission on its own initiative, and not on the basis of a dossier submitted by a notifier.

357 Consequently, in the present case, there was no 'dossier', within the meaning of Article 8 of Regulation No 1107/2009, submitted by a notifier containing that scientific literature which could have been reviewed by EFSA.

358 However, that does not mean that the relevant scientific literature does not have to be taken into consideration in the context of a review under Article 21 of Regulation No 1107/2009. As has been established in paragraph 289 above, it follows from Article 114(3) TFEU and the case-law relating thereto that, unless otherwise specified, the decisions which the Commission is required to take in the context of that regulation must always take account of the latest scientific and technical knowledge.

– *The alleged failure to take into account certain existing studies*

359 The applicants claim that EFSA failed to take into account all the relevant scientific studies available and, in particular, the tier 2 and 3 studies (semi-field studies and field studies). They identify certain studies which they claim were not — or were not correctly — taken into account.

360 Bayer submits, in that respect, in an annex to the reply in Case T−429/13, a list of semi-field and field studies in relation to imidacloprid and clothianidin which it maintains were not properly considered and which were thus ignored in the risk assessment process. It also mentioned, at the application stage, two articles allegedly not taken into account by EFSA, published in 2012 by Blacquière et al and by Cresswell et al, respectively.

361 Syngenta submits a list of studies in relation to thiamethoxam which it claims it made available to EFSA but which EFSA did not consider. It specifically mentions the Genersch (2010) study and the Fent (2012) study.

362 The Commission contests the applicants' arguments. It submitted, in both cases, tables drawn up on the basis of those submitted by the applicants, indicating, for each of the studies identified by the applicants, either that they were considered (with an indication, where appropriate, of the reference in EFSA's Conclusions or in other documents), or the reasons why they were rejected by EFSA. For the most part, those reasons relate to the fact that the study in question concerned a use not evaluated by EFSA or that its

design had shortcomings affecting its usefulness or its conclusiveness for the purpose of the risk assessment.

363 First of all, the Court must reject at the outset the complaint that EFSA generally ignored the higher tier studies. EFSA's Conclusions on the substances covered each contain points that specifically deal with risk assessment by reference to higher tier studies (points 2.4.1, 2.2.5, 2.3.2 and 3.1.4 of EFSA's Conclusions on imidacloprid; points 2.1.4, 2.2.5, 2.3.2 and 3.2.2 of EFSA's Conclusions on clothianidin; points 2.1.4, 2.2.5 and 2.3.2 of EFSA's Conclusions on thiamethoxam). In those points, EFSA summarises what it has been able to learn from the studies it considered, and those matters in respect of which the studies were unable to provide sufficient clarification. The complaint alleging a failure to take into account higher tier studies can therefore only relate to certain specific studies.

364 Next, in the first place, as regards the studies identified by Bayer, it should be noted that, apart from a general allegation that EFSA had failed to take all studies into account, Bayer confined itself at the application stage to identifying two 2012 publications (the article by Blacquière et al and an article published by Cresswell et al). The Commission challenged the argument relating to those two articles in several respects at the stage of the defence. In particular, it asserted that the study that gave rise to the article by Blacquière et al was a 'secondary' study in the form of a systematic review, which was not based on its own experiments but compiled and summarised the results of earlier studies, and that the article by Cresswell et al was merely commenting on the Henry study relating to thiamethoxam, and thus on a substance not marketed by Bayer. In addition, according to the Commission, the authors of the two articles, which concerned sub-lethal effects, did not conclude that the substances were safe for bees but discussed the fallacies of the testing methods and recommended further testing and other improvements. Last, the Commission states that, contrary to Bayer's assertions, EFSA had considered both articles. In the light of those points, not disputed by Bayer at the stage of the reply, the argument relating to those two studies must be rejected.

365 At the stage of the reply, Bayer submitted a further list of studies allegedly not considered by EFSA. That list must, however, be rejected as being out of time. On the one hand, on the assumption that this is a new plea in law, as against that alleging a failure to consider the 2012 studies, the first subparagraph of Article 48(2) of the Rules of Procedure of the General Court of 2 May 1991 precludes its being taken into account. On the other hand, if it is the same plea in law, it must be rejected pursuant to Article 48(1) of the Rules of Procedure of 2 May 1991, as a piece of evidence for the late production of which no reasons have been given.

366 In the second place, as regards the studies identified by Syngenta, Syngenta does attempt, in the reply in Case T−451/13, by using the expression 'for some reason', to create the impression that the Commission did not give any reasons in that regard, but that is incorrect given the explanations provided by the Commission in the table set out in Annex B.17 to the defence in the same case, which are sufficient to explain and justify the failure to consider (in part) certain studies.

367 In particular, in the case of the Fent (2012) study, the fact that that study, according to Syngenta's own assertions, was completed only after EFSA's Conclusions, accounts sufficiently for the fact that it could not be considered in those conclusions. It should, moreover, be observed that the Commission did not merely '[state] that it was not available to EFSA', contrary to what is claimed by Syngenta, but explained in detail, referring notably to the criticisms expressed by Germany, the shortcomings and limits of that study.

368 Likewise, in the case of the Genersch (2010) study, the Commission states both in the defence and in the rejoinder in Case T−451/13 that that study did not concern thiamethoxam and could not therefore provide reliable information on the absence of risks posed by products containing that substance. Syngenta did not respond to that argument. In those circumstances, it must be held that it has not demonstrated that the failure to consider the Genersch (2010) study — a failure for which, moreover, the Commission acknowledges that EFSA should have expressly given reasons — could have had an impact on EFSA's Conclusions on thiamethoxam.

369 Last, the Commission commented on a third study, the Muehlen et al (1999) study, which EFSA had considered 'irrelevant' owing to the fact that certain essential information about the circumstances of the tests was not provided by the authors. In the light of these statements by the Commission, the age of the study concerned and the fact that it had not been peer-reviewed when the dossier was examined in connection with the initial inclusion of thiamethoxam in the list of active substances (which may have been due to the shortcomings noted by the Commission), it must be concluded that EFSA's failure to consider the Muehlen et al (1999) study cannot be assumed to have had any impact on EFSA's Conclusions on thiamethoxam.

370 Accordingly, the complaint alleging that EFSA failed to take certain scientific studies into account must be rejected.

– *The alleged failure to take into account monitoring data and risk mitigation measures*

371 The applicants submit that, contrary to the requirements of Article 21 of Regulation No 1107/2009, EFSA did not take into account the monitoring data and risk mitigation measures available, although they constituted relevant data and information.

372 The Commission contends that the relevance of the monitoring data was indeed examined by the experts, in order to determine, in accordance with Article 21(3) of Regulation No 1107/2009, whether the approval criteria referred to in Article 4 thereof continued to be satisfied. It also disputes the claim that the existing monitoring data conclusively prove that there are no unacceptable risks to bees.

373 In the first place, it is necessary to distinguish, within the present complaint, between two allegations: the first, that the monitoring data and risk mitigation measures were ignored by EFSA, the second, that those data or those measures, although examined by EFSA, were not correctly taken into account.

374 As regards the first allegation, it is apparent from the dossier that, contrary to the applicants' assertions, EFSA did not ignore the available monitoring data or risk mitigation measures. EFSA's Conclusions on each of the substances covered contain a section devoted specifically to a summary of the monitoring data received by EFSA (point 5 of the Conclusions on imidacloprid; point 4 of the Conclusions on clothianidin; point 3 of the Conclusions on thiamethoxam), which includes reports of incidents that took place and that were linked to the use of the substances covered, and, where relevant, the results observed following the introduction of any mitigation measures taken, provided these had been communicated to EFSA. As regards the latter measures, specifically, EFSA took note, in particular, of the fact that, in Austria, the introduction of measures such as the use of deflectors during sowing had significantly improved the situation.

375 It should be pointed out in that regard that the monitoring data are recorded and the risk mitigation measures taken at national level and are thus available to the competent authorities of the Member States. Those authorities were invited by EFSA, by email of 15 October 2012, to provide it with all the data they had available in that respect, so that these could be discussed by EFSA's and the Member States' experts in November 2012. However, it is evident from the introductory sentence of those sections of EFSA's Conclusions dealing with monitoring data that the only Member States to have submitted such data were France, Italy, Austria and Slovenia. In those circumstances, EFSA cannot be criticised for failing to take into account data and measures which, despite the invitation referred to above, were not disclosed by Member States, nor can such failure be regarded as vitiating the contested measure. That renders ineffective, inter alia, Bayer's reference to the risk mitigation measures allegedly implemented in Hungary.

376 It should also be noted, in that context, that the mitigation measures mentioned by the applicants concern above all the use of deflectors during sowing, for the purpose of reducing dust exposure. Therefore, that mitigation measure is unlikely to reduce the risks posed by other routes of exposure, such as exposure to residues in nectar and pollen and exposure via guttation, identified in EFSA's Conclusions.

377 The first allegation must therefore be rejected.

378 As regards the second allegation, Syngenta submits that EFSA's Conclusions on thiamethoxam summarise in less than two pages several thousand pages of monitoring data, which are then dismissed in their entirety, on the basis of brief remarks.

379 In each of its three sets of conclusions on the substances covered, EFSA ended the section on monitoring data with a paragraph headed 'Overall conclusion on the monitoring data', worded as follows:

'During the Pesticides Peer Review Experts' Meeting [(meeting of the EFSA Panel on Plant Protection Products and their Residues (PPR), held from 5 to 9 November 2012)], the experts discussed the use of monitoring data for risk assessment. It was considered that it can be difficult to use monitoring data directly in risk assessment due to the fact that there are many influential parameters in the monitoring data that cannot be fully understood (pesticide exposure, climatic conditions, presence of disease, farming practices, etc.). Furthermore, it is difficult to link exposure and observed effects in monitoring data (i.e. causality). It was also noted that monitoring data may not provide a complete picture as, in some cases, not all parameters are investigated (e.g. use of veterinary medicines). It was also noted that the monitoring data are only relevant to the specific Member State (and to the [good agricultural practices] approved in that Member State) and not to all authorised uses, environmental and agronomic conditions in the [European Union]. Overall, it was considered that monitoring data are of limited use for risk assessment but may be useful to provide feedback for risk managers to consider prevention measures.'

380 It should be noted that those remarks correctly take into account the characteristics and limitations of the monitoring data, already noted in paragraphs 208 to 212 above, which affect their usefulness for risk assessment purposes. Since these are characteristics shared by all monitoring data, they could be described in overall terms, and EFSA cannot be criticised for the brevity of the review. These characteristics explain why the monitoring data, although taken into account by EFSA, cannot have a decisive influence on the outcome of the risk assessment and, in particular, cannot establish with sufficient certainty the safety of the substances covered.

381 It follows that the Court must reject the second allegation, that EFSA did not take monitoring data and risk mitigation measures into account correctly.

382 Accordingly, the complaint alleging EFSA's failure to take monitoring data and risk mitigation measures into account must be rejected.

(iii) Complaint alleging a purely hypothetical approach to risk

383 The applicants recall the case-law cited in paragraph 116 above, according to which a preventive measure cannot properly be based on a purely hypothetical approach to the risk that is founded on mere conjecture which has not been scientifically verified, and maintain that EFSA's Conclusions did not identify any risk in the majority of cases, that the monitoring data all pointed to there being no risk and that some high risks identified are purely hypothetical.

384 The Commission disputes the applicants' arguments.

– *As to whether EFSA's Conclusions identified the risks*

385 First, as to whether EFSA's Conclusions identified the risks, it should be recalled that EFSA identified, in particular:

– a high acute risk for honeybees from exposure via dust drift as a result of the treatment of maize, oilseed rape and cereal seeds (clothianidin, imidacloprid, thiamethoxam) and of cotton seeds (imidacloprid, thiamethoxam);

– a high acute risk for bees from exposure to residues in nectar and pollen for uses in oilseed rape (clothianidin, imidacloprid) as well as cotton and sunflowers (imidacloprid);

– a high acute risk from exposure to guttation for uses in maize (thiamethoxam).

386 Second, EFSA's Conclusions identified a number of uncertainties as regards, inter alia, certain crops, certain forms of exposure, acute and long-term risks to colony survival and development as well as risks to other pollinating insects. EFSA thus considered that the available data were not such as to enable any conclusions to be drawn as to the existence or absence of a risk.

387 Consequently, it must be held that EFSA's Conclusions identified, for each of the substances covered, several relevant risks relating to a number of authorised uses. In those circumstances, the question whether, as Syngenta claims, those risks did not concern 'the large majority of cases' is of no relevance.

388 By contrast, owing to the insufficiency of the available scientific knowledge, EFSA refrained, in its conclusions on the substances covered, from adopting findings as to the existence or absence of risks, whether acute or long term, for bee colony survival, despite the fact that those risks were explicitly part of the subject matter of the Commission's second mandate (see paragraph 21 above). Thus, in the section of the conclusions dealing with data gaps identified during the assessment, EFSA lists numerous areas in which further research is necessary if conclusions are to be drawn, in particular, on the acute and long-term effects on colony survival.

389 Syngenta argues, on that basis, that the conclusions are 'inconclusive' or 'non-conclusions'. However, it must be held that the fact that the risk assessment could not result in firm conclusions about some of the risks explored does not in any way affect its legality or its usefulness, for the purposes of the adoption of the contested measure.

– *As to whether the risks identified by EFSA are hypothetical*

390 In the first place, in so far as the applicants base their argument generally on the alleged lack of scientific basis and allegedly erroneous content of EFSA's Conclusions, it is apparent from the examination of the complaints raised in that regard, in paragraphs 342 to 382 above, that the risk assessment of the substances covered, of which EFSA's Conclusions are the result, was conducted in accordance with scientific rules. Since the applicants have not established that the assessment was defective, the risks established in EFSA's Conclusions must be deemed to be scientifically sound and cannot be considered, in general terms, to be hypothetical.

391 In particular, Syngenta's claim that the few risks identified are purely hypothetical because the approach taken to tier 1 assessments was overly conservative is unfounded.

392 Reference is made in that regard to paragraphs 306 to 325 above, where it is explained that, while the Commission's decision to proceed with a risk assessment of the substances covered without waiting for a test guidance document to be finalised certainly implied that some of the risks identified, or that could not be ruled out, might subsequently prove not to exist (see paragraph 308 above), that choice was nevertheless justified in the present case, particularly under the precautionary principle (see paragraph 325 above).

393 It must therefore be concluded that, while EFSA's Conclusions may contain potential 'false alarms', that aspect cannot be deemed to be the result, generally, of an overly conservative approach by EFSA in relation to tier 1 assessments, but is the consequence of the Commission's decision to proceed with a risk assessment at a time when carrying out a tier 2 or 3 assessment was largely impossible — first, because of the absence of a finalised guidance document, and, second, because of the need to react as quickly as possible, when confronted with new scientific knowledge indicating that the approval requirements could no longer be satisfied. Since consideration of the Commission's choice has not revealed any unlawfulness, even given its consequences, the argument as to an overly conservative approach to the tier 1 assessment must be rejected.

394 Last, as regards the claim that the monitoring data and higher tier studies showed that there was no risk, it has been explained in paragraph 380 above why that conclusion cannot be drawn from those data.

395 In the second place, Bayer submits that even open issues that were perceived as minor made EFSA invalidate comprehensive data sets or not take them into account in its conclusions, and that, even in areas in which there was no suggestion of risk whatsoever, EFSA 'still' concluded that there were data gaps as a result of the fact that no established testing and assessment procedures had been laid out.

396 In rejecting that argument, it is sufficient to note, as the Commission does, that Bayer fails to give any details in that regard, and it is therefore not possible for the Court to verify whether its claims are well founded.

397 In the third place, Syngenta raises a number of detailed objections in respect of the risks noted in EFSA's Conclusions.

398 First, Syngenta claims that EFSA used unreasonably high sowing rates for oilseed rape and sunflowers when calculating exposure from dust drift. It maintains that realistic maximum rates would be 4 kg/ha for oilseed rape and 5.5 kg/ha for sunflowers. According to Syngenta, those errors had a direct impact on the outcome of the risk assessment concerning thiamethoxam.

399 The Commission contests Syngenta's arguments.

400 It should be noted, first of all, that it is evident from the table in Appendix A to EFSA's Conclusions on thiamethoxam that the sowing rates used vary significantly as between the Member States and are between 4 and 8 kg/ha for oilseed rape and between 6 and 7 kg/ha for sunflower.

401 Next, Syngenta did not dispute the Commission's assertions that the sowing rates used by EFSA were those which had been communicated to it by the Member States in order to take into account the 'good agricultural practices' defined in each Member State and the conditions for approval of different plant protection products in different Member States. The rates in question must be stated by producers in a request for approval of plant protection products at national level.

402 In those circumstances, it is not relevant whether the sowing rates actually used in practice might be lower than those used by EFSA. The authorisations for plant protection products granted by the Member States are based on sowing rates corresponding to the 'good agricultural practices' specific to each Member State, and it cannot therefore be ruled out that those rates may actually be achieved in practice. Accordingly, EFSA was required to examine the risk posed by thiamethoxam by applying the maximum sowing rate authorised, in order to take account of all authorised uses in the European Union.

403 Consequently, the argument as to the use of unrealistic sowing rates must be rejected.

404 Second, Syngenta maintains that EFSA used too high a deposition value for exposure from dust drift from sowing of oilseed rape. Whereas EFSA set a rate of 2.7%, a lower rate was later set in the 2013 Guidance.

405 The Commission contests that argument.

406 As is evident from paragraph 161 of the application in Case T−451/13, Syngenta puts forward that argument by way of example to illustrate its proposition that, in the context of a tier 1 assessment, 'a slight change in one single assumed value can completely change the results of risk assessment [and] a change in several variables magnifies that effect exponentially'. First, that proposition merely describes the inevitable consequences of the fact that the risk assessment is the result of complex appraisals in which numerous variables are taken into account, some of which are based on estimates or represent approximate values. It cannot, however, be used to challenge the validity of the assessment as such, provided that sufficient account is taken of the uncertainties caused by the interdependence of several uncertain factors. Second, EFSA expressly noted the need to take account of those circumstances in its conclusions on thiamethoxam, stating that 'it [was] important to note that these values [were] taken from a draft guidance document and [could] therefore [be] subject to change at a later date; therefore, care [had to] be taken with the interpretation of the following risk assessments'.

407 Consequently, the argument concerning the use of too high a deposition rate must be rejected as ineffective.

408 Third, Syngenta maintains that the identification of a high risk, in relation to exposure via guttation for maize, is based on unrealistic assumptions. It states that the assessment was based on concentration levels of thiamethoxam in guttation fluid up to 6 weeks after emergence (when the plant comes out of the ground), although the concentration level then drops off and it is not until 10 to 13 weeks after emergence that the plant flowers, which is when it becomes attractive to bees. In addition, Syngenta emphasises that it is not certain that bees use guttation fluid from maize, since guttation occurs only in humid conditions, that is where there are other sources of water available to bees, and, moreover, maize is wind pollinated and is not therefore a 'bee-attractive crop', even when flowering. It mentions that that uncertainty is referred to repeatedly by EFSA itself.

409 The Commission contests those arguments.

410 It should be noted in that regard that point 2.3 of EFSA's Conclusions on thiamethoxam, concerning the assessment of the risk posed by guttation, is subdivided into three points, covering the first-tier risk assessment (point 2.3.1), the assessment using higher tier studies (point 2.3.2) and the conclusion on the risk posed by guttation (point 2.3.3). Syngenta's arguments relate exclusively to point 2.3.1 and thus the first-tier assessment.

411 As is expressly stated in that paragraph, the assessment, at that level, is of the risk potentially posed by the consumption of guttation fluid by bees, although it is not yet known whether, and to what extent, bees actually consume guttation fluid. Furthermore, EFSA notes that the information available regarding water consumption by forager bees is insufficient. Consequently, it is simply stated, at the end of point 2.3.1, that 'it is clear that the concentrations found in the guttation fluid in maize seedlings could potentially pose a concern to bees if there is exposure to guttation fluid'.

412 Syngenta omits to mention that EFSA goes on to explain, in point 2.3.2, that it is apparent from four field studies (tier 3) in relation to guttation that were available and were considered by EFSA, first, that a peak of bee mortality occurred at the time of emergence of the maize plants and, second, that it could reasonably be assumed that that mortality was due to exposure to thiamethoxam (or to its metabolite clothianidin) via the guttation fluid. EFSA concluded from this that 'overall, mortality results from three of the studies indicate[d] that there [was] an acute risk to bees from guttation fluid at the time of emergence'.

413 Admittedly EFSA states repeatedly that, owing to the small number of studies in relation to guttation available, uncertainties remain and that those conclusions should be confirmed by further research. Nevertheless, it must be held that, clearly, the various matters noted by Syngenta, set out in paragraph 408 above, did not prevent bees from being exposed to guttation fluid as soon as the plants emerged and thus at a time when the concentration of thiamethoxam in the guttation fluid was at its highest. The existence of an acute risk to bees from exposure via guttation from maize was therefore identified, by EFSA, on the basis of field studies and therefore in respect of realistic conditions of use of plant protection products containing the active substance thiamethoxam.

414 In those circumstances, the Court must reject Syngenta's arguments concerning the allegedly unrealistic assumptions on the basis of which EFSA found that there was a high risk linked to guttation from maize.

415 Accordingly, the complaint alleging a purely hypothetical approach to risk must be rejected, as, therefore, must the complaints relating to the risk assessment carried out by EFSA in their entirety.

(3) The complaints relating to the Commission's risk management

416 It is appropriate at this point to examine the complaints concerning the way in which the Commission took account of EFSA's Conclusions and decided on the measures taken in the contested measure, in the context

of its task of risk management. The applicants submit that the measures taken are ineffective, disproportionate or even arbitrary.

(i) Complaint concerning the precipitate nature of the procedure and the Commission's public comments

417 The applicants submit that the 'break-neck speed' with which the Commission proceeded following receipt of EFSA's Conclusions clearly shows that it failed to give proper consideration to other, less restrictive options. They say that the Commission failed to take account either of the possibility of adopting less strict measures or of possible risk mitigation measures.

418 The Commission denies that the contested measure was adopted in a rushed manner. In particular, it claims that it considered the risk mitigation measures and their various forms and aspects.

419 It should be noted, first of all, that the procedure between the publication of EFSA's Conclusions and the adoption of the contested measure was as follows:

– 20 December 2012: communication of a preliminary version of EFSA's Conclusions to the Commission and the applicants;

– 16 January 2013: publication of EFSA's Conclusions; invitation to the applicants to submit their observations within 10 days;

– 25 January 2013: observations of the applicants on EFSA's Conclusions;

– 28 January 2013: distribution to the Member States of the discussion paper for the Standing Committee's meeting on 31 January and 1 February 2013;

– 31 January and 1 February 2013: meeting of the Standing Committee;

– 22 February 2013: communication to the applicants of the draft contested measure, with an invitation to submit observations within eight days;

– 1 March 2013: observations of the applicants on the draft contested measure;

– 14 and 15 March 2013: discussion of the draft contested measure within the Standing Committee (no qualified majority);

– 29 April 2013: meeting of the appeal committee (no qualified majority);

– 24 May 2013: adoption of the contested measure.

420 As regards, first, the time that elapsed between publication of EFSA's Conclusions and the proposal to impose the restrictions included in the contested measure, the Commission states that it received the preliminary version of EFSA's Conclusions on 20 December 2012 and that it first submitted a proposal of the draft contested measure to the Standing Committee in mid-March 2013, about three months later.

421 Even if, formally, that is correct, it should nevertheless be noted that the measures included in the contested measure had already, in essence, been proposed in the discussion paper of 28 January 2013, for discussion at the Standing Committee's meeting on 31 January and 1 February 2013. That paper contained, inter alia, the following passage: 'Given the data gaps and the risks identified by EFSA, DG SANCO believes that it is now urgently necessary to take regulatory actions. We have identified a number of actions: 1. … restrict the use of plant protection products containing these substances only to crops non attractive to bees … and to winter cereals … 5. Restrict the use to professional users …' In fact, as the applicants correctly claim, the Commission therefore announced its intention to restrict the use of the substances covered, notably for all bee-attractive crops, as early as 28 January 2013, and thus just five weeks or so after receiving the preliminary version of the conclusions.

422 Nevertheless, it appears that that was sufficient time for the Commission's services to be able to form an initial opinion on the inferences they considered it appropriate to draw from EFSA's Conclusions, and to do so, in particular, without disregarding the possibility of adopting less restrictive measures. It should be pointed out in that regard that the uses which the Commission proposed to restrict in the discussion paper of 28 January 2013 corresponded largely with those in respect of which EFSA had either identified an acute risk or had been unable to rule out a risk because the necessary data were unavailable. It is also necessary to take into account the fact that, in the present case, EFSA had positively identified certain risks and that the Commission was thus fully entitled to consider that there should be no undue delay in adopting appropriate measures — unlike the situation that obtains when the initial approval of a substance is being prepared, where, by definition, a delay in the procedure is not likely to cause harm to the environment.

423 Second, it must be noted that the period of three days, including a weekend, between receipt by the Commission on Friday 25 January 2013 of the applicants' observations on EFSA's Conclusions, and the dispatch to the Member States of the discussion paper on Monday 28 January 2013 for the Standing Committee's meeting on 31 January and 1 February 2013, also does not support the conclusion that the procedure was rushed. While that period may seem too short for the applicants' observations to have been taken into account in the discussion paper, it should be noted that that paper does not mention the applicants having been consulted prior to its being drawn up, nor does the Commission claim that that was the case, and, moreover, the Commission was not obliged to carry out such a consultation in order to draw up a discussion paper for the Standing Committee. The discussion between the Commission and the Member States regarding the action to be taken in response to EFSA's Conclusions was independent of the applicants' observations in that respect and there was no order of priority to be observed as between the two. Therefore, the Commission was entitled to consult the Member States and to seek the applicants' observations at the same time, and it was sufficient for those to be taken into account for the purposes of drawing up the draft contested measure, which was issued on 22 February 2013.

424 Third, the various statements by the Commission dated 28 January 2013, reported by Syngenta, do not, contrary to what Syngenta claims, show that the Commission's opinion on the measures to be taken had already been definitively formed by that date in such a way as to rule out or prevent any further reflection on the possibility of adopting less restrictive measures.

425 First of all, with regard to the statements of a director in DG 'Health and Food Safety' before the European Parliament's Environment, Public Health and Food Safety Committee, these are reported as follows in an electronic press article of 25 January 2013:

'Many will have been pleased to hear [X], a director in DG SANCO, declare that "we have to act straight away". Although he also admitted that in practice the Commission was still "evaluating" and "reflecting" upon the evidence, while waiting for more recommendations from the EFSA.'

426 It follows from these comments, assuming they were quoted accurately, that the Commission considered that the findings in EFSA's Conclusions necessitated immediate action, but that the process of reflection had not yet come to an end. It must be held that such a stance appears measured, in that, on the one hand, it was justified by the seriousness of the risks and of the uncertainties identified by EFSA and, on the other, it duly took account of the fact that the nature and scope of the measures to be taken had yet to be determined.

427 The same applies with regard to the Council's press release on the Council's 'Agriculture and Fisheries' meeting on 28 January 2013, and the speech made in that meeting by the Commissioner responsible, according to the text produced by Syngenta, in the following terms:

'In its conclusions, EFSA has identified a number of concerns and [has] confirmed serious risks linked with the use of the three neonicotinoids used on several important crops grown across the [European Union]. These concerns call for swift and decisive action! The time is now ripe to act to ensure an equally high level of protection of bees across the [European Union]. The Commission will propose a set of ambitious but proportionate legislative measures to be presented for first discussion at the meeting of the

[Standing Committee] that will take place on Thursday of this week. There is one particular point I want to be clear: Our proposal will call for EU harmonised and legally binding measures, inspired by the precautionary principle, but also by the principle of proportionality! In fact, a number of safe uses of these substances as regards bees have been identified by EFSA. A total ban would not therefore be justified.'

428 While pointing to the need to react to the concerns identified by EFSA, the Commissioner repeatedly emphasised that the proposed measures would have to respect the principle of proportionality; he even stated expressly that a total ban did not seem justified, and also mentioned that this was a proposal 'for first discussion'. Such comments cannot be interpreted as exhibiting a Commission stance that was fixed and unlikely to be altered subsequently as regards the precise content of the measures to be taken.

429 The applicants have not, therefore, demonstrated that the Commission had formed a definitive view of the measures to be adopted, at an early stage in the procedure, which would have prevented it from contemplating the possibility of adopting less restrictive measures than those covered by the contested measure.

(ii) Complaint alleging infringement of the right to be heard and of the rights of the defence

430 The applicants claim that the Commission did not afford them the opportunity to provide the data necessary to fill the alleged gaps noted by EFSA in its review of the substances covered. In view of the fact that the requirements stemming from the EFSA Opinion, applied in the context of that review, were strengthened by comparison with those that applied previously, that amounts to an infringement of the right to be heard (according to Bayer), and of the rights of the defence (according to Syngenta).

431 Syngenta further submits, in general terms, that it was not given the opportunity to be involved in the procedure in an appropriate manner.

432 The Commission disputes the applicants' arguments.

433 It should be noted in that regard that, in accordance with the second subparagraph of Article 21(1) of Regulation No 1107/2009, where, in the light of new scientific and technical knowledge, the Commission considers that there are indications that an active substance no longer satisfies the approval criteria, it is to inform, inter alia, the producer of that substance, setting a period for that producer to submit its comments.

434 As Bayer correctly argues, that right to be heard cannot be reduced to just a formal requirement, without any genuine effect on the outcome of the procedure.

435 In the present case, in the first place, it must be noted that the applicants were able to formulate their comments in sufficient time. It is apparent from the documents in the file that the Commission obtained their comments both on EFSA's Conclusions and on the draft contested measure. Thus, by letters of 16 January 2013, the Commission invited the applicants to provide their comments on EFSA's Conclusions, which they did by letters of 25 January 2013. Likewise, the Commission invited the applicants to submit their comments on the draft contested measure by letters of 22 February 2013. The applicants submitted their comments by letters of 1 March 2013. Furthermore, associations representing the plant protection industry, including, therefore, the applicants, participated in various meetings with the Commission's services in January and February 2013 to obtain the views of stakeholders (industry, environmental non-governmental organisations (NGOs)) on EFSA's Conclusions and the measures envisaged by the Commission.

436 It follows from this that the applicants were invited to make comments and that they did make them, both in writing and, through the organisations representing them, at a meeting with the Commission's services. In those circumstances, the Commission was fully entitled to regard itself as being sufficiently apprised of the applicants' point of view and, in particular, it was not obliged to act on Bayer's requests to meet Commission staff responsible for reviewing the substances covered.

437 Moreover, in so far as Bayer submits, in that context, at the stage of the reply, that the period of nine days which it had to submit its comments on EFSA's Conclusions was 'plainly inadequate', that complaint appears unfounded.

438 First of all, it should be noted that, admittedly, EFSA's Conclusions were published on 16 January 2013 and the applicants were invited to provide their comments on these nine days later, by 25 January 2013. However, as the Commission correctly submits, the applicants had had a preliminary version of EFSA's Conclusions, in essence identical to the final version, since 20 December 2012 for the purpose of identifying confidential data. Consequently, they were in a position, from that point, to prepare themselves to state their views on the substance of EFSA's Conclusions. Although that additional period of 26 days included the end-of-year holidays, it must be held that the total period of 35 days was sufficient to enable Bayer properly to state its views on EFSA's Conclusions.

439 Accordingly, the complaint, raised by Bayer, that the period for submission of its comments on EFSA's Conclusions was inadequate must be rejected as unfounded.

440 In the second place, the Court must consider whether the principle, set out in paragraph 434 above, that the right to be heard must be capable of having an effect on the substance of the decision, means, in this instance, that the applicants must have an opportunity to fill the gaps revealed by EFSA's Conclusions by submitting further scientific data and studies.

441 In that regard, first, it is necessary to take into account the broad discretion enjoyed by the Commission in the implementation of Regulation No 1107/2009 (see paragraph 143 above).

442 Second, it must be recalled that it was held, in paragraph 325 above, that, in the light of the circumstances of the case, the precautionary principle warranted the approval of the substances covered being amended without the need to wait for data to fill the gaps identified in EFSA's Conclusions to become available.

443 In particular, it should be borne in mind that the Commission and Bayer both agree that generating the data necessary to fill those gaps would take at least one or two years from the time when a guidance document is available, while Syngenta did not comment on that period (see paragraph 317 above). In those circumstances, giving the applicants that time would have resulted in the entry into force of the measures covered by the contested measure being delayed unduly. It follows that the Commission was fully entitled to conclude, in balancing the interests at stake, that the public interest in immediate implementation of the amendment of the approval overrode the applicants' interest in having the time necessary to generate the missing data.

444 For the same reason, the Commission was not obliged to require EFSA to examine a further study, comprising 1 000 pages and produced by Bayer on 25 January 2013, at the same time as its comments on EFSA's Conclusions and thus at a late stage in the procedure. On the contrary, it was entitled to confine itself to having that study examined by its own staff, for the purposes of assessing its impact on the risk management that was its responsibility.

445 Third, the Commission took account of the fact that the scientific and technical knowledge concerning the gaps identified in EFSA's Conclusions were liable to change, notably following field studies conducted by the applicants and independent scientists, by stating at the outset, in recital 16 of the contested measure, that 'within two years from the date of entry into force of the present Regulation the Commission will initiate without undue delay a review of the new scientific information which it has received'.

446 It follows that the applicants were not entitled to have the Commission delay amendment of the approval of the substances covered in order to give them the opportunity to generate the data necessary to fill the gaps identified in EFSA's Conclusions.

447 In the fourth place, the applicants' arguments concerning the case-law of the Court are not such as to invalidate that conclusion.

448 First, the applicants invoke paragraphs 186 and 187 of the judgment of 21 October 2003, *Solvay Pharmaceuticals* v *Council* (T−392/02, EU:T:2003:277), in which the Court ruled, in essence, that, apart from urgent cases, the Commission cannot withdraw the authorisation of a product without allowing its holder to provide the information which the Commission considers appropriate in order to fill those gaps, and that that holder must be closely associated with the procedure for the re-evaluation of that substance and may invoke the right to be informed of the main gaps in its dossier which stand in the way of the authorisation being maintained.

449 Second, the applicants invoke paragraph 140 of the judgment of 7 October 2009, *Vischim* v *Commission* (T−420/05, EU:T:2009:391), in which the Court, referring to the judgment of 21 October 2003, *Solvay Pharmaceuticals* v *Council* (T−392/02, EU:T:2003:277), found as follows:

'… in the context of a procedure involving a reassessment of an existing product on the market on the basis of a dossier submitted by the manufacturer concerned, the latter must be closely associated with the assessment and may invoke the right to be informed of the main gaps in its dossier which stand in the way of authorisation of its product, compliance with such procedural safeguards being subject to judicial review. In the light of the principles of legal certainty and of sound administration, except in urgent cases the Commission cannot refuse authorisation for an existing product on the market without having allowed the person concerned to provide the information appropriate for filling those gaps ...'

450 It should be noted in that regard that the legal and factual circumstances that gave rise to those judgments were substantially different from those of the present case.

451 Thus, first, from a legal perspective, both in the case giving rise to the judgment of 21 October 2003, *Solvay Pharmaceuticals* v *Council* (T−392/02, EU:T:2003:277), and in the case giving rise to the judgment of 7 October 2009, *Vischim* v *Commission* (T−420/05, EU:T:2009:391), the administrative procedures in question had been initiated by the producers of the substances concerned and involved the submission by them of comprehensive dossiers on the adverse effects of those substances. The fact that those circumstances constituted a condition of the application of the principle invoked by the applicants is particularly evident at the beginning of paragraph 140 of the judgment of 7 October 2009, *Vischim* v *Commission* (T−420/05, EU:T:2009:391). Moreover, paragraph 141 of the same judgment further underlines that conditionality, stating that 'these considerations apply in the context of the procedure at issue, which was initiated by the notification submitted by the applicant and the detailed rules for which provide that the notifier is associated with the assessment of his dossier'.

452 By contrast, in the present case, the review of the conditions of approval of an active substance, in accordance with Article 21 of Regulation No 1107/2009, is a procedure launched by the Commission on its own initiative, without the applicants being required to submit a dossier. For that reason alone, the applicants' argument concerning the judgments of 21 October 2003, *Solvay Pharmaceuticals* v *Council* (T−392/02, EU:T:2003:277), and of 7 October 2009, *Vischim* v *Commission* (T−420/05, EU:T:2009:391), cannot succeed.

453 Second, the present case is also distinguishable on the facts from the cases giving rise to the judgments of 21 October 2003, *Solvay Pharmaceuticals* v *Council* (T−392/02, EU:T:2003:277), and of 7 October 2009, *Vischim* v *Commission* (T−420/05, EU:T:2009:391), in so far as, as is apparent from the examination of the complaints related to risk management above, the Commission was entitled to conclude, without thereby acting unlawfully, that the approval criteria provided for in Article 4 of Regulation No 1107/2009 were no longer satisfied, following the review of the approval of the substances covered in the light of the risks identified in EFSA's Conclusions, and in so far as, as stated in paragraphs 314 to 325 above, the precautionary principle did not justify amendment of the approval of those substances being delayed pending the generation of data enabling the gaps identified, moreover, by EFSA, to be filled.

454 As the Commission correctly maintains, those circumstances, which did not apply in the case giving rise to the judgment of 21 October 2003, *Solvay Pharmaceuticals* v *Council* (T−392/02, EU:T:2003:277), or in

that giving rise to the judgment of 7 October 2009, *Vischim* v *Commission* (T−420/05, EU:T:2009:391), preclude the right to be heard from being interpreted in this instance as a right to submit detailed studies, in that that would amount to granting the applicants a right to delay unduly the adoption of a decision to withdraw or amend the approval under Article 21 of Regulation No 1107/2009.

455 It follows that the argument relating to the judgments of 21 October 2003, *Solvay Pharmaceuticals* v *Council* (T−392/02, EU:T:2003:277), and of 7 October 2009, *Vischim* v *Commission* (T−420/05, EU:T:2009:391), must be rejected.

(iii) Complaint alleging the lack of any impact assessment

456 The applicants submit that the Commission failed to conduct an impact assessment of the measures adopted in the contested measure, despite this being provided for in the Communication on the precautionary principle (paragraph 114 above), which prevented the Commission from appreciating the seriously damaging effects that the contested measure could have in economic and environmental terms, as made apparent in a study commissioned by them, the Humboldt study.

457 The Commission contests the applicants' arguments.

458 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.'

459 First, 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.

460 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.

461 Second, it should be noted that the Commission has clearly drawn a comparison between the most likely positive or negative consequences of the action proposed and those of inaction in terms of the overall cost to the European Union, thereby satisfying the requirements of point 6.3.4 of the Communication on the precautionary principle. That is evident from the note dated 21 January 2013 for the attention of the Commissioner responsible at that time. The note sought to inform the Commissioner of the discussion under way on EFSA's Conclusions and to request his approval for the measures proposed by the Commission's services. In Annex V to the note, headed 'Background information on EP, Industry, NGOs', various circumstances were set out which had been considered in connection with the proposal. In particular, with regard to the fact that neonicotinoids are largely used in agriculture, Annex V mentioned the main results of the Humboldt study, produced to the Commission by the applicants, including the conclusions of that study as to the effects of a ban on neonicotinoids on the economy, the employment market and the environmental record of the European Union. Reference was also made to the fact that the Commission did not have a complete overview of the alternative plant protection products, since these were authorised at national level. Last, the note indicated that the Parliament was going to discuss the matter three days later, on 24 January 2013, on the basis of a study it had commissioned on the risks posed by the substances covered and which recommended a total ban of neonicotinoids (rather than just a restriction on use) and the fact that environmental NGOs were also calling for a total ban. It follows from all these points that the Commission was aware of the challenges, both economic and environmental, linked to the use of the substances covered.

462 Third, in that context, the Court must reject certain claims made by Syngenta.

463 First of all, the impact on agriculture and on the environment of the measures covered by the contested measure seems less significant than Syngenta claims. It must be pointed out that, under Article 53(1) of Regulation No 1107/2009, Member States may authorise, for a period not exceeding 120 days, plant protection products containing active substances, including for uses which are not approved at EU level, where there are no other alternatives. As the Commission observes, that provision ensures that Member States can avoid significant negative impacts on agriculture and covers situations where there is no other alternative to fight a particular pest, and several Member States have made use of that option to issue such authorisations, as Syngenta itself acknowledges.

464 Likewise, the Commission also recalls that, although Germany, France, Italy and Slovenia suspended certain uses of the substances covered for several years, no negative effects on productivity or on the environment were reported by those Member States.

465 Syngenta submits, in that regard, that it would be more accurate to say that the Commission has not conducted any investigation in that respect and that 'if one does not look one will not find', in reasserting that the Commission had failed to conduct adequate due diligence in analysing the effects of the contested measure. However, the Commission did not assert that there had been no adverse impact in absolute terms on productivity or on the environment, but simply that the Member States concerned had not reported such

effects. During the period between publication of EFSA's Conclusions and the adoption of the contested measure, the Commission was in regular contact with the representatives of the Member States, in order to discuss the inferences to be drawn from the risks and data gaps identified by EFSA. In particular, on 28 January 2013, a discussion paper was distributed to the Member States which was subsequently discussed by the Standing Committee at its meeting on 31 January and 1 February 2013; on 14 and 15 March 2013, the draft contested measure was discussed within the Standing Committee and, on 29 April 2013, the appeal committee also discussed that draft. In those circumstances, it must be held that if, on none of those occasions, the Member States which restricted the use of the substances covered at national level reported adverse consequences for productivity or the environment, the Commission was entitled to rely on that silence and assume that there were no such consequences or, in any event, that they were insignificant, and that it was not required to carry out its own investigation in that regard.

466 The impact assessment to be conducted by the Commission could therefore take into account, on the one hand, the fact that it was possible, if necessary, to grant exemptions at national level and, on the other, the fact that, in certain Member States, agriculture had in the past been able to function satisfactorily without recourse to plant protection products containing the substances covered.

467 Next, Syngenta argues on the basis of the note of 21 January 2013 that it is in fact as a result of political pressure that the Commission decided to take the steps covered by the contested measure. It is sufficient to observe in that regard that the note merely refers to the 'very high political sensitivity' of the issue, together with the risks identified by EFSA, as grounds for taking action at a regulatory level. It should be observed that the politically sensitive nature of an issue is an aspect which the Commission, as a political body, can and must take into account in determining its priorities and in its decisions. As the Commission correctly notes, that does not mean, however, that the contested measure is the result of inappropriate political pressure.

468 Last, Syngenta asserts that the note of 21 January 2013 shows that the Commission did not have details of substances that could replace the substances covered. The Commission's response is that it does have a detailed overview of all insecticide substances approved at EU level, as it is the Commission that approves them, and that the passage of the note in question related to formulated products authorised by the Member States.

469 The relevant sentence of the note of 21 January 2013 reads as follows: 'A complete overview of the alternatives available is not available, as the formulated products are authorised at national level.' In view of the two-stage system introduced by Regulation No 1107/2009, in which the Commission is competent to approve the active substances at EU level, while the Member States are competent to authorise plant protection products containing the approved active substances (see paragraph 6 above), and given that the sentence in question explicitly mentioned the 'formulated products', Syngenta's assertion regarding the active substances must be rejected.

470 As regards the formulated products, in view of the many plant protection products authorised in the various Member States for various uses (by way of example, the list of Bayer's plant protection products containing only the active substances imidacloprid and clothianidin annexed to the application in Case T-429/13 comprises 11 pages), and the possibility of obtaining exemptions at national level (see paragraph 463 above), it was impossible for the Commission to determine, in respect of the entire European Union, to what extent, for which uses and for which crops farmers had alternatives to the products containing the substances covered.

471 Accordingly, the complaint relating to the lack of any impact assessment of the steps taken in the contested measure must be rejected.

(iv) Complaint concerning the selective nature and inconsistency of the contested measure

472 Syngenta submits that the Communication on the precautionary principle requires a consistent approach, which is entirely absent in this case. It recalls that the Commission confirmed that the risk assessment of

the active substances was required to be conducted in the light of the latest scientific knowledge, as set out, in particular, in the EFSA Opinion. Ever since the second mandate had been issued to EFSA, a number of active substances, including chlorantraniliprole, had been approved by the Commission without reference to the scientific opinion or the draft guidance document. This then was an ad hoc and selective application of the rules.

473 The Commission contests those arguments.

474 Point 6.3.3 of the Communication on the precautionary principle, entitled 'Consistency', is worded as follows:

'Measures should be consistent with the measures already adopted in similar circumstances or using similar approaches. Risk evaluations include a series of factors to be taken into account to ensure that they are as thorough as possible. The goal here is to identify and characterise the hazards, notably by establishing a relationship between the dose and the effect and assessing the exposure of the target population or the environment. If the absence of certain scientific data makes it impossible to characterise the risk, taking into account the uncertainties inherent to the evaluation, the measures taken under the precautionary principle should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available.

Measures should be consistent with the measures already adopted in similar circumstances or using similar approaches.'

475 It should be noted, in the first place, that point 6.3.3 of the Communication on the precautionary principle is worded in very general, even vague terms. In particular, the principle of consistency seems to overlap to a large extent with that of non-discrimination, which is covered in point 6.3.2 of the same communication. The Commission contends, moreover, in its response to Syngenta's arguments, that it 'treats similar issues in a similar manner' and emphasises the aspects that differentiate the substances covered from the substance mentioned by Syngenta.

476 In the second place, the EFSA Opinion is not part of the regulatory framework amended following the entry into force of Regulation No 1107/2009, but stems from the realisation by EFSA and the Commission that the assessments and tests used until then to evaluate the risks of plant protection products for bees had certain shortcomings (see paragraph 233 et seq. above). Furthermore, the subject matter of that opinion is not confined to neonicotinoid substances but concerns all plant protection products, which militates in favour of its general application to all active substances.

477 There are, moreover, similarities between the substances covered and the active substance chlorantraniliprole. Thus, both the substances covered and chlorantraniliprole are insecticides and are therefore capable of having adverse, even lethal, effects on bees, even if the way in which they work and their risk profile are different, as the Commission emphasises.

478 In the third place, however, it should be noted that, in the present case, the administrative procedure concerned a review of the approval of the substances covered, whereas, in the case of chlorantraniliprole, the procedure in question was an approval procedure. As explained in paragraph 294 above, the approval procedure is initiated at the request of the producer of the substance in question on the basis of a dossier submitted by him, while the review procedure is commenced by the Commission, on its own initiative, on the basis of new scientific and technical knowledge indicating that the substance in question no longer satisfies the approval criteria.

479 First, that explains why an applicant for approval must be aware, sufficiently in advance, of the data to be collected in order to compile the dossier and, moreover, that the request will in principle be examined in the light of the substantive conditions for approval as applicable at the time when the dossier was submitted, subject only to the reservation set out in paragraph 295 above.

480 That is why, when Regulation No 1107/2009 replaced Directive 91/414, transitional provisions were laid down governing the treatment of requests submitted under Directive 91/414 on which a decision had not yet been taken when Regulation No 1107/2009 entered into force. Thus, under Article 80(1)(a) of Regulation No 1107/2009, Directive 91/414 is to apply, with respect to the procedure and the conditions for approval, to active substances for which the Commission has established, in accordance with Article 6(3) of that directive and before the entry into force of Regulation No 1107/2009 on 14 June 2011, that the dossier was complete.

481 That was precisely what happened in the case of the active substance chlorantraniliprole, the approval of which was invoked by Syngenta. Although the implementing regulation approving chlorantraniliprole was adopted on 25 November 2013, and thus almost two and a half years after Directive 91/414 was repealed by Regulation No 1107/2009 on 14 June 2011, that approval was given in accordance with the substantive conditions laid down by Directive 91/414, under the transitional provision referred to in paragraph 480 above. The Commission had found, on 2 August 2007, that the dossier relating to the inclusion of chlorantraniliprole was complete.

482 Consequently, the amendment of the regulatory framework as a result of the adoption of Regulation No 1107/2009 (see paragraph 133 et seq., in particular paragraphs 135 and 136 above) did not, in principle, apply to the approval of chlorantraniliprole.

483 Second, it should be borne in mind that, in the present case, the amendment of the regulatory context and the new scientific knowledge that triggered the review of the substances covered occurred at the same time. Since neither circumstance obtained in the case of chlorantraniliprole, the situations are thus different in two respects.

484 In the fourth place, even on the assumption that there is indeed an inconsistency between the way in which the Commission applied the precautionary principle in the present case and in the case of the approval of chlorantraniliprole, it must be noted that Syngenta has nevertheless failed to prove the existence of a Commission practice, after the date of the contested measure, of failing to take into account the EFSA Opinion in the context of the approval of active substances. Although Syngenta claimed that ‘a number’ of active substances were approved without the EFSA Opinion being taken into account, it identified only one, chlorantraniliprole, which, given the matters identified in paragraphs 481 to 483 above, has not been established as being comparable to the substances covered.

485 Accordingly, the complaint concerning the selective nature and inconsistency of the contested measure must be rejected.

(v) Complaint that the three substances covered were treated ‘equally’

486 Syngenta submits that, although EFSA’s assessment resulted in three separate sets of scientific conclusions and three different risk profiles for the substances covered, the contested measure treats all three substances in the same way by imposing a virtual blanket ban.

487 The Commission contests Syngenta’s arguments. It argues, in particular, that the three substances covered are very similar in that they have the same mode of action on insects, comparable toxicity to honeybees and a very similar risk profile.

488 It should be noted first of all that, in the present complaint, Syngenta confined itself to criticising in general terms the uniform treatment of the three substances covered, without specifically identifying the particular restrictions allegedly imposed in relation to thiamethoxam (its own product) despite being justified only in relation to one of the other substances. In those circumstances, it is not for the Court, in the context of the present complaint, to ascertain whether the contested measure contains such restrictions, and it may confine itself to a general assessment to determine whether the Commission was entitled to include in a single implementing regulation the measures taken in relation to all three substances.

489 On that basis, it is apparent from a comparison of the paragraphs relating to 'Concerns' in EFSA's Conclusions on the substances covered that the concerns respectively identified by EFSA are largely identical as regards all three substances.

490 Thus, in the case of the paragraph headed 'Issues that could not be finalised', it is noted, in respect of each of the three substances in virtually identical terms, that 'several issues that could not be finalised were identified in relation to the exposure of honeybees via dust, from consumption of contaminated nectar and pollen, and from exposure via guttation fluid', and that, 'in addition, the risk to pollinators other than honeybees, the risk from residues in insect honey dew, and the risk from exposure to residues in succeeding crops could not be finalised'.

491 Similarly, in the case of the paragraph headed 'Critical areas of concern', first, the existence of an acute risk to honeybees was identified in respect of each of the three substances from exposure via dust drift during sowing of certain crops (cereals, maize, cotton and oilseed rape for imidacloprid, cereals, maize and oilseed rape for clothianidin, and cereals, cotton and oilseed rape for thiamethoxam). Second, a high acute risk was identified for exposure via residues in nectar and pollen for imidacloprid (cotton, oilseed rape and sunflowers) and for clothianidin (oilseed rape), and also for exposure via guttation fluid for thiamethoxam (maize).

492 It follows from this that the risk profiles presented by the three substances covered are largely similar as regards issues that are not finalised and as regards the risk linked to exposure via dust drift during sowing. By contrast, although imidacloprid and clothianidin present risks at the level of exposure via contaminated nectar and pollen for certain crops, thiamethoxam poses a risk at the level of exposure via guttation for maize.

493 In those circumstances, there was nothing to preclude the Commission from including in a single implementing regulation the measures taken with respect to all three substances covered. In particular, it was possible for the Commission, even in a single regulation, to take sufficient account of the respective specificities of the risk profile of the substances covered and, in particular, of restrictions that were specifically warranted by the prevention of risks linked to exposure to nectar and pollen for imidacloprid and clothianidin, and to guttation, for thiamethoxam.

494 Consequently, the complaint that the three substances covered were treated 'equally' must be rejected as unfounded.

(vi) Complaint concerning the account taken of the risk to individual bees rather than to colonies

495 The applicants submit that there are only data showing a risk to individual bees but no data showing a risk to colonies, even though it is the latter that is critical.

496 It should, first of all, be recalled in that regard that point 3.8.3 of Annex II to Regulation No 1107/2009 provides, as a specific condition for approval of an active substance, inter alia, that the use of plant protection products containing that active substance 'has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour'. It follows that the approval of an active substance is not precluded only if the survival of bee colonies is jeopardised but even where there are unacceptable effects on colony development.

497 It should also be pointed out that it is for the Commission, as risk manager, to define what should be considered to be unacceptable effects within the meaning of point 3.8.3 of Annex II to Regulation No 1107/2009.

498 In reply to a written question from the Court, the parties acknowledged, in essence, that there was a correlation between the risk to individual bees and the risk to colonies, in the sense that a large number of individual bee losses could transform itself into a risk to the colony concerned. However, the parties disagree as to the extent of that correlation. While the Commission, in reliance on the EFSA Opinion,

states that losses exceeding 3.5% of the population can no longer be described as 'negligible', Bayer mentions the rate of 7% proposed by the draft 2013 Guidance as the limit of a 'relevant' effect, while emphasising that that limit is disputed by some Member States. For its part, Syngenta refers to a study carried out by its employees, which finds that the reduction in colony size should be over 20% 'to produce any effects at colony level'.

499 It is therefore common ground that there is a correlation between the risk to individual bees and the risk to the colony. By contrast, there is at this stage scientific uncertainty as to the individual bee mortality rate threshold above which 'unacceptable acute or chronic effects' on colony survival and development are likely to arise. That uncertainty is due in particular to the difficulties of measuring under field conditions the extent of individual losses and their impact on the colony.

500 In those circumstances, it must be concluded that the Commission was fully entitled to find that, in the light of the hazard quotient values identified in respect of the substances covered in EFSA's Conclusions, a risk to the colonies could not be ruled out, and that it was therefore for the Commission, on the basis of the precautionary principle, to adopt protective measures without having to wait for the conditions under which, and the mortality rate threshold above which, the loss of individual bees was likely to endanger colony survival or development to be established.

501 This is without prejudice to the assessment of the potential consequences, at colony level, of any effects on bee behaviour of exposure to sub-lethal doses of the substances covered. As is apparent from EFSA's Conclusions on the substances covered, there is also uncertainty, due to a lack of scientific data, regarding the existence and any implications of such consequences.

(vii) Complaint alleging breach of the principle of proportionality

502 The applicants claim that the contested measure breaches the principle of proportionality. Since that principle concerns the appropriateness of the measures adopted in terms of the objectives pursued, this plea should be dealt with in the context of the complaints raised with regard to the Commission's risk management.

503 The applicants claim that the contested measure goes beyond what is necessary to ensure the safe use of the substances covered and for the achievement of any legitimate objectives relating to bee health. In their view, this relates, in particular, to the ban on the use of thiamethoxam on 'bee-attractive crops', the ban on the use of foliar sprays and the prohibition of non-professional uses outdoors and indoors.

504 The Commission contests the applicants' arguments.

505 According to settled case-law, the principle of proportionality, which is one of the general principles of EU law, requires that measures adopted by EU institutions should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question, and where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (judgments of 18 November 1987, *Maizena and Others*, 137/85, EU:C:1987:493, paragraph 15, and of 11 September 2002, *Pfizer Animal Health* v *Council*, T−13/99, EU:T:2002:209, paragraph 411).

506 Nonetheless, in agricultural matters, judicial review of compliance with the principle of proportionality is special in so far as the Court of Justice and the General Court recognise that the EU legislature has a discretionary power which corresponds to the political responsibilities given to it by Articles 40 to 43 TFEU in that field. Consequently, the legality of such a measure can be affected only if the measure is manifestly inappropriate in terms of the objective which the competent institution is seeking to pursue (judgments of 5 May 1998, *National Farmers' Union and Others*, C−157/96, EU:C:1998:191, paragraph 61, and of 3 September 2009, *Cheminova and Others* v *Commission*, T−326/07, EU:T:2009:299, paragraph 195).

507 In this case, the contested measure is based on Regulation No 1107/2009, the legal basis of which is, in particular, Article 37 EC (now, after amendment, Article 43 TFEU) and Article 95 EC (now Article 114 TFEU). In those circumstances, it is necessary to consider whether the measures introduced by the contested measure are manifestly inappropriate for the purpose of attaining the objective pursued and forming part of the objectives envisaged by that regulation, namely protection of the environment and, in particular, the protection of bees.

508 As a preliminary point, it should be borne in mind that the restrictions introduced in respect of the substances covered by the contested measure are as follows:

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

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

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

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

– *Harmful potential of the contested measure in relation to bees*

509 The applicants submit that, in general terms, the contested measure may not only fail to protect bee health but, on the contrary, may help to put bees at risk. They claim that the Commission failed to appreciate the seriously damaging effects that the contested measure could have on the environment and, in particular, on honeybees, as set out in a study commissioned by them (the Humboldt study). These effects are due to the fact that farmers unable to use plant protection products containing the substances covered, in particular for seed treatment, would be obliged to resort to older, less targeted products requiring higher doses and often applied as foliar sprays. Syngenta states that the effects of those products on bees have not been subject to a risk assessment based on the methodologies and criteria applied to the substances covered, and that therefore their specific risk for bees is unknown.

510 The Commission responds that there are no scientific data showing that restrictions on the use of neonicotinoids have adverse effects on the environment.

511 In that regard, it should be noted that the Humboldt study is above all an economic study on the losses that may result, for EU agriculture and for the economy in general, from the ban on neonicotinoids, in different scenarios. While certain environmental effects are also examined, these are limited to the deterioration of the European Union's carbon balance on account of the 'virtual' import of arable land, which might take place because of lower productivity in the European Union. However, the study does not include any examination or any conclusion in relation to the effects on the environment and, in particular, on bees or other pollinators, that could arise if neonicotinoid plant protection products were replaced by other products. The applicants have therefore failed to detail or to demonstrate the truth of their claims regarding the possible consequences for the environment of the substances covered being replaced by other pesticides.

512 It is true that the Commission could and had reasonably to assume that, following the adoption of the contested measure, farmers would to a certain extent use other pesticides requiring higher doses or applied as foliar sprays.

513 However, it is also necessary to take into account in that regard the exceptions that may be authorised by the Member States, pursuant to Article 53(1) of Regulation No 1107/2009 (see paragraph 463 above), which are likely to limit the use of replacement products.

514 Last, the Commission contends, without being contradicted by the applicants, that the Member States which suspended certain uses of neonicotinoids for several years (notably Germany, France, Italy and Slovenia) never reported any adverse effects on the environment. As explained in paragraph 465 above, the Commission was entitled to rely on that silence and assume that there were no such effects or, in any event, that they were insignificant, and it was not incumbent on the Commission to carry out any investigation in that regard.

515 Consequently, the potential adverse effects for bees and other pollinators resulting from the replacement of the substances covered by other active substances does not mean that the contested measure must be characterised as 'manifestly inappropriate for the purpose of attaining the objective pursued'.

– *The ban on the use of thiamethoxam on 'bee-attractive crops'*

516 Syngenta maintains that the general ban on the use of thiamethoxam on 'bee-attractive crops' went beyond what was necessary for the protection of bee health, given that EFSA found no risk in relation to exposure to residues of thiamethoxam in pollen and nectar, and that the question of bee attractiveness is irrelevant to any risk created by dust drift or guttation.

517 The Commission disputes those arguments.

518 First, it should be noted that the parties are agreed that a crop must be considered bee attractive on the basis of the presence and quality of pollen and nectar. The Commission contends however that, to a lesser extent, guttation fluid, as a source of water, may also attract bees, particularly when there are few other sources of water available.

519 Second, the contested measure does not expressly identify the uses of thiamethoxam that are specifically prohibited in relation to 'bee-attractive crops'. In response to a written question from the Court, the Commission confirmed that the uses in question were those set out in the fourth sentence of Part A of the Annex to Implementing Regulation No 540/2011, as amended by the contested measure.

520 Third, as is evident from paragraphs 490 and 491 above, EFSA's Conclusions on thiamethoxam did not reveal a risk linked to exposure via pollen or nectar. The imposition of restrictions on the use of plant protection products containing the active substance thiamethoxam, covering all bee-attractive crops equally, was not, therefore, justified by the risks positively identified by EFSA. However, EFSA found a certain number of data gaps which prevented it from reaching a firm conclusion as to whether or not there was a risk from exposure to nectar and pollen and to guttation, for most crops.

521 In that respect, in response to a written question from the Court, the Commission indicated that, since EFSA had established a high risk from guttation in maize — the only crop for which data were available —, it was necessary to take into account the fact that guttation was also taking place in other crops.

522 At the hearing, Syngenta argued that bees visited fields only during periods of flowering, that guttation was particularly marked after nightfall and before sunrise, and that the risk of exposure via guttation was therefore entirely 'made up'.

523 In that regard, the beekeeping expert commenting under the supervision of the representatives of the DBEB confirmed that, early in the morning, bees, having no access to water during the night, would leave first of all to forage for water, looking above all for small sources of water that is not too cold, which they would collect to take back to the hive, that this foraging for water would take place in all crops, whether flowering or not, and that the concentration of the substances covered in the guttation fluid would be at its highest when the plants were young.

524 Since that statement may explain certain findings made by EFSA, summarised in paragraphs 411 and 412 above, it must be held that the Commission was fully entitled to consider that account had to be taken of the potential attraction of guttation fluid to bees, in the determination of 'bee-attractive crops'.

Consequently, it was fully entitled to consider that, applying the precautionary principle, it was necessary to prohibit the use of thiamethoxam on crops subject to guttation, even where there was no scientific certainty as to the actual extent of consumption of guttation fluid by bees.

525 It follows that Syngenta was unable to demonstrate that the ban on thiamethoxam on all 'bee-attractive crops', as listed in the fourth sentence of Part A of the Annex to Implementing Regulation No 540/2011, as amended by the contested measure, was manifestly inappropriate for the purpose of attaining the objectives of that measure, within the meaning of paragraph 507 above.

– *The ban on the use of the substances covered on winter rapeseed*

526 Rapool-Ring emphasises the lack of proportionality of the contested measure in particular with regard to the use of the substances covered on winter rapeseed. Since winter rapeseed, like winter cereals, is sown during a period of the year — at the beginning of autumn — when bees have already considerably reduced their activity, any contaminated dust drift that may occur at that time of year could not have any negative effects on individual bees or on bee colonies. Unlike in the case of winter cereals, however, the contested measure does not provide for an exception for winter rapeseed.

527 The Commission contends, first, that, contrary to Rapool-Ring's claim, the winter rapeseed sowing period is not the same as that of winter cereals but starts, depending on the area, as early as mid-August. Second, it notes that, unlike winter cereals, winter rapeseed, which is not harvested until July, is a crop that attracts bees, with the result that they may find themselves exposed to pollen and nectar that may be contaminated.

528 Even if it is the case that, as Rapool-Ring claimed at the hearing, the sowing period of winter rapeseed starts at the end of August and not in mid-August, it must be held that the facts set out by the Commission distinguish winter rapeseed sufficiently from winter cereals for the two to be treated differently, having regard to the objectives pursued by the contested measure.

529 Accordingly, the complaint concerning the ban on the use of the substances covered on winter rapeseed must be rejected, and there is no need to rule on its admissibility in so far as that complaint is raised only by an intervener.

– *The ban on foliar applications*

530 The applicants submit that even though, at the time when the contested measure was adopted, EFSA had not assessed foliar uses of the substances covered, the measure nonetheless restricts such use. They claim that the simplistic assertion by the Commission in recital 7 of the contested measure that, in essence, the risk from foliar applications is similar to the risk identified for seed treatment applications and soil treatment, due to the systemic translocation of the substances covered through the plant, has no scientific basis and overlooks the various risk mitigation measures that have long been applied.

531 The Commission contests the applicants' arguments.

532 It should be noted in the first place that recitals 7 and 11 of the contested measure include the following passages:

'(7) … In particular, pending the evaluation of [EFSA] on foliar uses it considered that the risk for bees from foliar applications is similar to the risk identified by [EFSA] for seed treatment applications and soil treatment, due to the systemic translocation of the active substances clothianidin, thiamethoxam and imidacloprid through the plant.'

'(11) … Foliar treatments with plant protection products containing clothianidin, thiamethoxam or imidacloprid should be prohibited for crops attractive to bees and for cereals with the exception of uses in greenhouses and uses after flowering. Crops which are harvested before flowering are not considered attractive to bees.'

533 In the second place, it should be pointed out that the second mandate issued to EFSA by the Commission, as revised on 25 July 2012 (see paragraphs 21 and 25 above), was expressly limited to the 'authorised uses of these substances for seed treatment and granules'. Consequently, the risk assessment carried out by EFSA did not relate to other authorised uses and EFSA's Conclusions on the three substances covered did not contain any indication of the risk associated with foliar applications.

534 In the third place, it should be borne in mind that the measures adopted in the contested measure are based on the application of the precautionary principle, in that there was solid evidence that some of the uses of the substances covered which had been approved until then could entail unacceptable risks to bees, even though there was not yet any scientific certainty in that respect. In that situation, the Commission was entitled to adopt preventive measures also in respect of uses that had not yet been specifically assessed by EFSA, if and in so far as it could reasonably assume that these posed similar risks to those posed by uses that had been assessed.

535 In the fourth place, it is apparent from recital 7 of the contested measure that it was due to the systemic translocation of the substances covered through the plant that the Commission considered the risk from foliar applications to be similar to the risk identified for the uses examined by EFSA.

536 As regards such translocation following foliar spray applications, two means of translocation within the plant must be distinguished: on the one hand, basipetal, that is from the upper extremities of the plant towards the base of the plant following absorption through the leaves, and, on the other, acropetal, that is to say, from the roots towards the rest of the plant, following absorption through the roots.

537 As regards, first of all, basipetal translocation, the Commission indicates that it relied on two studies from 2009 (Skerl study) and 2012 (Blacquière study).

538 However, as Bayer submits, the Blacquière study, which the parties are agreed was a 'secondary' study (see paragraph 364 above), merely referred to the Skerl study. It must therefore be concluded that, in fact, the Commission relied on just one study in asserting that systemic translocation towards pollen could have occurred following the foliar application of a neonicotinoid.

539 Moreover, the Skerl study related to thiacloprid and not one of the substances covered. Although thiacloprid is also a neonicotinoid and may therefore have similar characteristics to the substances covered, the fact remains that it is one of a group of 'cyano-substituted' neonicotinoids, whereas the substances covered are nitroguanidine-substituted neonicotinoids. As the Commission indicates, cyano-substituted neonicotinoids are characterised by lower acute toxicity profiles for bees than nitroguanidine-substituted neonicotinoids, which, according to the Commission, justified their exclusion from the second mandate issued to EFSA, as revised on 25 July 2012 (see paragraph 25 above).

540 Furthermore, Bayer itself produced to the Court, at the stage of the reply, a secondary study in the form of an unpublished systematic review carried out in 2008 by two of its employees, in order to demonstrate that foliar applications of plant protection products containing imidacloprid did not create a risk to bees.

541 That study did not find that there was no translocation at all, or no likelihood of translocation, towards pollen or nectar after foliar applications, but only that there were no residues that could pose a risk to bees. Further, according to the description in Section 2, 'Objective', of that study, it concerned, in particular, 'available information concerning the systemicity and translocation of imidacloprid in plants to demonstrate that imidacloprid residues in nectar or pollen will be negligible following foliar sprays made to crops or ornamental plants according to label directions'. The purpose of that study was not neutral therefore, but geared at the outset to demonstrating the safety of imidacloprid. Last, that study, which is unpublished, has not been peer-reviewed.

542 Given the shortcomings of the scientific studies invoked by both sides — the study submitted by Bayer being limited, moreover, to imidacloprid —, it cannot be concluded that the Commission was reasonably

entitled to assume that foliar applications posed similar risks to those of the assessed uses in the light of any risk that might be caused by basipetal translocation, or that the applicants had established the contrary.

543 Second, as regards acropetal translocation, the Commission contended that foliar applications resulted in deposits of the product concerned on the soil, from where its active substances could be absorbed by the roots and dispersed throughout the plant.

544 It must be held that those aspects were such that the Commission could reasonably assume that foliar applications posed similar risks to those of the uses assessed by EFSA in its conclusions.

545 It is true that the applicants claimed at the hearing that the substances covered, contained in the part of the product deposited on the soil, would rapidly degrade and that they therefore posed no risk. However, first, that was disputed by Greenpeace, which stated that the rate of degradation depended on soil conditions, and, moreover, it was not apparent what the rate of degradation was below which soil reabsorption could be considered no longer to pose a risk to bees in the light of acropetal translocation. Second, Bayer did not provide any details of the speed at which imidacloprid and clothianidin degrade. In the case of thiamethoxam, Syngenta indicated a half-life of 30 days, which, it submitted, is below the value limit of 120 days at which a substance may be categorised as ‘persistent’. However, according to Greenpeace, the half-life of thiamethoxam can, depending on soil conditions, be hundreds of days. Furthermore, it is necessary to take into account the fact that thiamethoxam degrades into clothianidin and that that first degree of degradation does not therefore permit the inference that reabsorption by the plant no longer poses a risk with regard to acropetal translocation.

546 The applicants have not therefore demonstrated that the ban on foliar uses was manifestly inappropriate for the purpose of attaining the objectives of the contested measure, within the meaning of paragraph 507 above.

547 Consequently, the complaint relating to that ban must be rejected.

– *The prohibition of non-professional uses*

548 The applicants submit that the restriction of non-professional uses exceeds what is appropriate in order to achieve the objectives of the contested measure. As regards outdoor uses, honeybees forming honeybee colonies forage over very wide areas, and therefore the foraging typically extends to a large number of gardens in urban or semi-urban areas, together with nearby woods, parks and playing fields. The existence of a risk to bees at colony level therefore presupposes that almost all gardeners use plant protection products containing the substances covered, failing which exposure levels would not reach levels having any relevance to bee health at colony level. Bayer adds that no significant case of bee intoxication in the European Union that was caused by amateur use of imidacloprid or clothianidin has ever been identified and that, in so far as the Commission is concerned that amateur users might not comply with risk mitigation measures, as set out in the instructions for use, there is no evidence, even anecdotal, to substantiate those concerns.

549 As regards non-professional uses indoors, these have even less of an impact on bee health than uses in private gardens. Given that honeybees live and forage outdoors, it is, they argue, absurd to prohibit indoor use for reasons relating to bee health, particularly as, in relation to professional uses, applications in greenhouses were not restricted.

550 The Commission disputes those arguments.

551 In that regard, first, it should be borne in mind that the responsibility for determining the level of risk deemed unacceptable for society lies with the institutions responsible for the political choice of determining an appropriate level of protection for that society (see the case-law cited in paragraph 122 above).

552 Second, it must be noted, as the Commission did, that, according to the EU legislature's understanding of risk management, as expressed, for example, in recital 19 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1), 'scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and ... other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls'. Accordingly, the Commission is entitled to take into account matters such as the fact that certain groups of users might be more likely than others not to follow the instructions given on the use of plant protection products, and the impossibility of controlling the way in which they apply those products.

553 Third, as regards the likelihood of plant protection products containing the substances covered being used inappropriately by non-professional users, neither the Commission nor the applicants have actually proved to what extent such a likelihood does or does not exist. However, Bayer referred to a 2011 survey requested by the Commission on 'consumer understanding of labels and the safe use of chemicals', which showed that some 80% of those responding read the labels on pesticide products 'always' or 'most of the time' and that a further 12% read them 'sometimes'. Of those who read the instructions on the labels, almost 74% followed them 'fully', while 23% followed them 'partially'. Those figures were confirmed by another survey, of which Bayer produced only excerpts.

554 It should be noted, first of all, that the figures stated by Bayer in respect of the first of those surveys do not correspond to those which appear in the copy it produced. In fact, the percentage of those responding who answered that they read the labels on plant protection products 'always' or 'most of the time' was 66% (50% 'always' and 16% 'most of the time') and not the 'some 80%' indicated by Bayer.

555 Next, the excerpt of the second survey produced by Bayer does not show who carried out the survey, how the sample of those surveyed was made up and whether it was representative of the population of the seven countries in which it was carried out. In those circumstances, it can have only very limited evidential value.

556 Last, the first survey, conducted throughout all the Member States on the basis of a representative sample, reveals that 34% of those surveyed read the instructions for use on the labels of plant protection products only 'sometimes' or 'never'. It must be held, in those circumstances, and given, in particular, the high degree of toxicity of the substances covered, that the Commission was fully entitled to conclude that non-professional users were likely, more so than professional users, not to comply with the instructions for use.

557 Therefore, the prohibition of non-professional uses outdoors of the substances covered cannot be categorised as 'manifestly inappropriate for the purpose of achieving the objective pursued' within the meaning of the case-law cited in paragraph 506 above.

558 Fourth, with regard specifically to non-professional uses indoors, it is true that it seems prima facie unlikely that bees will be put at risk, assuming that the instructions for use are followed. However, as has just been explained, misuse, by a failure to comply with the instructions for use, cannot be ruled out, particularly in the case of non-professional users. In that regard, the risk, mentioned by the Commission, of a plant being treated indoors and then being placed outdoors seems to be anecdotal and, in any event, occasional. By contrast, it seems likely, given the effectiveness as insecticides of the substances covered, that some users may be tempted to use the products containing them directly outdoors, even if they are sold for indoor use.

559 Consequently, and given the greater certainty in any event in respect of a use that is entirely prohibited than a use in respect of which it is necessary to rely on the conscience of the user, it must be held that the restriction of those non-professional uses indoors cannot be categorised as 'manifestly inappropriate for the purpose of achieving the objective pursued'.

– *Risk mitigation measures that should allegedly have been considered as less restrictive measures*

560 The applicants submit that the Commission should have made use of the possibility, provided for in Article 6(i) of Regulation No 1107/2009, of approval of the substances covered being made subject to the imposition of risk mitigation measures and to monitoring after use. In particular, the Commission should have ensured enforcement of the requirement imposed on Member States under Directive 2010/21 (see paragraph 16 above) to 'ensure that ... monitoring programmes are initiated to verify the real exposure of honeybees to [the neonicotinoids] in areas extensively used by bees for foraging or by beekeepers, where and as appropriate', it could have made labelling or specific instructions for use mandatory, or indeed the use of deflectors to prevent bee exposure from dust during sowing, and it should have taken into account the action plan which the applicants had jointly proposed to the Commission on 28 March 2013.

561 The Commission contests the applicants' arguments.

562 First, as regards the monitoring programmes required to be initiated under Directive 2010/21, on the one hand, it should be noted, as did the Commission, that the purpose of these is the collection of data about risks, not the prevention of risks, which follows inter alia from the wording used in the Annex to Directive 2010/21, according to which monitoring programmes must be initiated 'to verify the real exposure of honeybees' to the substances covered. These measures are, moreover, renewed by the contested measure.

563 On the other hand, Bayer itself states that 'only relatively few Member State monitoring programmes have been set up to date', citing Germany, France, Italy, Austria and Slovenia, while suggesting that the Commission should have insisted that more monitoring programmes be initiated, in order to be in a better position to assess the real exposure of honeybees to neonicotinoids in the field. These statements show that, in fact, the imposition on the Member States of post-approval monitoring obligations is not necessarily effective and that the usefulness of such a measure depends largely on the degree of diligence shown by the various Member States.

564 Second, as regards the risk mitigation measures that could, according to the applicants, prevent exposure via dust during sowing, the Commission correctly puts forward a series of considerations that call into question the efficacy of those measures. Thus, measures such as labelling and specific instructions for use have the disadvantage that compliance with instructions given is not a certainty and is difficult to verify. As to the filters used to reduce dust emission, the Commission states that, according to the results of the Italian Apenet monitoring and research programme, a part of the finest dust fraction emitted during sowing was not retained by those filters and could give rise to an elevated mortality rate. As regards, last, the deflectors with which sowing machines could be equipped, the Commission cites an evaluation by EFSA which was unable to quantify the effectiveness of the deflectors and which expressly noted that 'based on the available data, significant exposure of bees (or other pollinators), even if a deflector [were] used, [could not] be excluded'. Furthermore, as explained in paragraph 376 above, like the other measures proposed by the applicants, deflectors are measures intended to reduce exposure via dust and have no effect in the case of exposure via nectar, pollen and guttation or exposure resulting from the systemic translocation of the substances covered through plants from treated seeds.

565 In the light of these matters, it must be held that the fact that the Commission deemed the risk mitigation measures that might be taken insufficient did not permit the inference that the contested measure manifestly exceeded what was necessary in order to achieve the objectives pursued.

– *Summary with regard to proportionality*

566 It follows from paragraphs 502 to 565 above that the complaint alleging breach of the principle of proportionality must be rejected.

(viii) Complaint alleging failure to take into account monitoring data

567 The applicants also claim that the Commission failed to take monitoring data into account in a risk management context, despite being expressly invited to do so by EFSA.

568 The Commission contests those arguments.

569 It should, first of all, be noted in that regard that the available monitoring data must be taken into account, in the same way as any other relevant information, in a review of the approval of an active substance, an obligation which the Commission has, moreover, acknowledged (see paragraph 215 above). As to the precise scope of that obligation, a distinction must be drawn between the risk assessment stage and the risk management stage (see paragraph 111 above).

570 Further, it should be borne in mind that the applicants have not established that EFSA failed to take due account of monitoring data in the context of the risk assessment (see paragraph 382 above).

571 Given that the lessons to be learned from the monitoring data in the context of the assessment of risk are incorporated into EFSA's Conclusions, the risks which EFSA had identified, or those whose non-existence EFSA considered could not be established, were therefore those that subsisted or which could not be ruled out in view, inter alia, of the monitoring data available. In the context of the decision on managing those risks which the Commission was required to take under Article 21(3) of Regulation No 1107/2009, it was not therefore for the Commission to call into question the findings made in EFSA's Conclusions, in the light of data that EFSA had already taken into account. It was, however, required to examine whether, in the light of the monitoring data, the risks which had been found to exist or which could not be ruled out could be alleviated by the adoption of mitigation measures.

572 It is in that sense that the alleged 'invitation' by EFSA to the Commission, invoked by the applicants, must be understood. The relevant sentence, which is identical in EFSA's Conclusions on each of the substances covered, is worded as follows:

'Overall, it was considered that monitoring data are of limited use for risk assessment but may be useful to provide feedback for risk managers to consider prevention measures.'

573 Furthermore, it should be noted in that regard that that observation by EFSA does not relate to the Commission alone but to risk managers in general. While the Commission is indeed the risk manager with respect to the approval of active substances under Regulation No 1107/2009, the Member States also have a risk manager role in the authorisation of plant protection products under that regulation. Given that, as the Commission correctly observed, monitoring data are based on conditions specific to Member States or regions, notably in relation to agricultural practices, climatic conditions and the presence of diseases, which cannot be generalised for the entire European Union, monitoring data may even be more useful for risk management purposes at a national level than at EU level.

574 Last, as has already been stated in paragraphs 562 to 565 above, the applicants have not demonstrated that the Commission's assessment — according to which, in the light of the monitoring data, the risks found to exist or which could not be ruled out could not be alleviated by the adoption of risk mitigation measures — was flawed.

575 Consequently, the complaint alleging a failure to take account of monitoring data in the context of the Commission's risk management must be rejected.

(ix) Complaint as to the allegedly arbitrary nature of certain measures

576 Bayer submits that some of the measures taken in the contested measure are arbitrary and cannot, therefore, be rendered legitimate by reference to the precautionary principle. That applies, in its view, to the restrictions on uses via foliar application and on non-professional uses, imposed without any basis whatsoever, scientific or otherwise, in respect of which EFSA's Conclusions did not identify any risk.

577 The Commission disputes those arguments.

578 It should be noted that the arguments put forward by Bayer in support of this complaint are such that it cannot be distinguished, in its essence, from the complaint alleging breach of the principle of proportionality, to the extent that it concerns foliar applications and non-professional uses. Given that it has been found in paragraphs 532 to 547 and 551 to 559 above that those grounds, in so far as they were established, did not constitute a breach of the principle of proportionality, they cannot be characterised as arbitrary either.

579 Accordingly, the present complaint must be rejected.

(4) Conclusion on the complaints alleging manifest errors of assessment and misapplication of the precautionary principle

580 In the light of the foregoing examination, it must be concluded that the Commission has demonstrated, in accordance with the requirements set out in paragraphs 141 and 142 above, that, having regard to the amendment of the regulatory framework resulting from the adoption of Regulation No 1107/2009, and, in particular, having regard to the considerable strengthening of the requirements that there should be no unacceptable effects of the active substances on bees, introduced by point 3.8.3 of Annex II to that regulation (see paragraph 135 above), the risks identified by EFSA warranted the conclusion that the substances covered no longer satisfied the approval criteria provided for in Article 4 of that regulation, in relation to the uses restricted or prohibited by Article 1 of the contested measure.

581 Consideration of the arguments put forward by the applicants has not revealed any errors in the application of Article 21(3) of Regulation No 1107/2009 or, in particular, manifest errors of assessment, nor any misapplication of the precautionary principle or the principle of proportionality.

582 Consequently, those complaints, and all the complaints concerning the application of Article 21(3) of Regulation No 1107/2009, must be rejected.

5. Infringement of the right to property and of the freedom to conduct a business

583 Bayer submits that the adoption and the content of the contested measure constitute a disproportionate and intolerable interference which infringes upon the very substance of its right to property and its freedom to conduct a business, which the Commission was required to take into account in the interpretation and application of Articles 21 and 49 and Article 12(2) of Regulation No 1107/2009, as well as point 3.8.3 of Annex II thereto. It further submits that the Commission's interpretation of Regulation No 1107/2009 infringes the Charter of Fundamental Rights of the European Union in a number of ways.

584 The Commission disputes those arguments.

585 In the first place, it should be recalled in that regard that, as Bayer correctly states, both the freedom to pursue a trade or business and the right to property are, according to settled case-law, general principles of EU law (see judgment of 29 March 2012, *Interseroh Scrap and Metals Trading*, C−1/11, EU:C:2012:194, paragraph 43 and the case-law cited), and are now expressly guaranteed under Articles 16 and 17 of the Charter of Fundamental Rights.

586 However, it is also evident from settled case-law that those principles are not absolute but must be viewed in relation to their social purpose. Consequently, the exercise of the right to property and the right to conduct a business may be restricted, provided that those restrictions in fact correspond to objectives of general interest pursued by the European Union and do not constitute, in relation to the aim pursued, a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed (judgments of 11 July 1989, *Schräder HS Kraftfutter*, 265/87, EU:C:1989:303, paragraph 15; of 3 December 1998, *Generics (UK) and Others*, C−368/96, EU:C:1998:583, paragraph 79; and of 23 October 2003, *Van den Bergh Foods* v *Commission*, T−65/98, EU:T:2003:281, paragraph 170).

587 In particular, as set out in paragraph 106 above, the protection of the environment provided for, in particular, in Article 37 of the Charter of Fundamental Rights, and in Article 11 and Article 114(3) TFEU, 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).

588 In accordance with Article 52(1) of the Charter of Fundamental Rights, any limitation on the exercise of the rights and freedoms recognised by the Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the European Union or the need to protect the rights and freedoms of others.

589 In the second place, in this instance, the contested measure is based on Article 21 of Regulation No 1107/2009 and is therefore provided for by law. Examination of the other pleas raised by the applicants has disclosed no misinterpretation or misapplication of that provision, nor any breach of the principle of proportionality.

590 Bayer based its assertion that the adoption and content of the contested measure constituted an interference which infringed upon the very substance of the right to property and the freedom to conduct a business solely upon the Commission's allegedly erroneous interpretation and application of Regulation No 1107/2009 — in general terms in the application and in more detail at the stage of the reply. Since those claims have all been rejected in the context of the other pleas raised by the applicants, they cannot be accepted on the basis of a breach of Bayer's fundamental rights either.

591 In particular, the Court must reject the argument advanced by Bayer at the stage of the reply that, once approval of the substances covered had been granted, the applicants acquired additional property rights, protected under the Charter of Fundamental Rights, which should mean that a higher standard applies when the Commission is considering withdrawing that approval, which is why, in particular, according to Bayer, Article 21 of Regulation No 1107/2009 should be interpreted narrowly.

592 Assuming that the approval of the substances covered did create new rights with respect to the applicants which are protected by Article 17 of the Charter of Fundamental Rights, that does not mean that Article 21 of Regulation No 1107/2009 must be interpreted narrowly, since it contains sufficient guarantees for anyone who has had an active substance approved. In particular, withdrawal or amendment of an existing approval presupposes that the Commission has concluded, on the basis of new scientific knowledge, that the approval criteria are no longer satisfied. As is apparent from the examination of the application of Article 21(3) of Regulation No 1107/2009 above, and contrary to the applicants' assertion, that is the case here. Furthermore, in accordance with the second subparagraph of Article 21(1) of Regulation No 1107/2009, the Commission is required to seek the comments of the producer of the active substance before taking a decision.

593 It cannot, moreover, be claimed that the contested measure infringes upon the very substance of the freedom to conduct a business or of the right to property. The applicants remain free to carry on their business of producing plant protection products. In particular, the substances covered are still approved for certain uses within the European Union and may also be exported. Similarly, contrary to Bayer's claims, the discretion enjoyed by the Commission under Article 21 of Regulation No 1107/2009 does not amount to a 'freedom [for the Commission] to do what it wants, when it wants, regardless of the science', but is circumscribed by standards the application of which is subject to review by the Courts of the European Union.

594 Consequently, the plea alleging infringement of the right to property and of the freedom to conduct a business must be rejected.

6. Breach of the principle of good administration

595 Syngenta notes five major flaws, which, in its view, have led to a breach of the principle of good administration.

596 In particular, it claims, first, that EFSA's mandate was unreasonable on account of its scope, the time pressure to which it was subject and the lack of any finalised guidelines; second, that the entire procedure was rushed, despite the lack of urgency, which suggests that the Commission was intent from the outset on imposing a sweeping ban on the substances covered; third, that the Commission failed to take account of relevant and important scientific information; fourth, that the risk assessment was conducted on the basis of an incomplete methodology; and fifth, that the Commission failed to comply with its obligation to conduct an impact assessment.

597 The Commission disputes Syngenta's arguments.

598 It is sufficient, in this regard, to note that Syngenta is merely repeating here the arguments already raised, and rejected above, in connection with other pleas, either as having no factual basis or as being unfounded in law. In both cases, the same claims cannot therefore constitute breaches of the principle of good administration.

599 In particular, it has been explained:

– in paragraphs 349 to 353 above, that EFSA's mandate was not unreasonable, in view of the time it had available;

– in paragraphs 420 to 429 above, that the procedure was not so rushed as to indicate that the Commission was intent from the outset on imposing a sweeping ban on the substances covered;

– in paragraphs 354 to 382 and 569 to 575 above, that it could not be claimed that EFSA and the Commission failed to take into account relevant and important scientific information;

– in paragraphs 325 and 326 above, that the risk assessment was not vitiated by the absence of a guidance document; and

– in paragraphs 459 to 471 above, that the Commission had not failed to fulfil an obligation to carry out an impact assessment.

600 In describing the facts, Syngenta also claimed, with regard to the comitology procedure, that the Member States had not had enough time to review the measures proposed in the discussion paper of 28 January 2013 (see paragraph 419 above) and to consider its comments on EFSA's Conclusions on thiamethoxam.

601 It is sufficient to observe in that regard, as did the Commission, that, under Article 3(3) of Regulation No 182/2011, the Commission was not obliged, in the context of the committee procedure, to prepare a discussion paper, but only to present a draft of the implementing act that it proposed to adopt. Where, as in this instance, it goes beyond that obligation by preparing a discussion paper in order to facilitate the work of the committee prior to presentation of a draft implementing act, it cannot be subjected to any criticism in relation to time limits. Furthermore, it is apparent from the summary report of the meeting of the Standing Committee on 31 January and 1 February 2013 that the Member States were invited to send in any additional comments on the discussion paper until 5 February 2013, and thus even after that meeting.

602 Consequently, the complaint alleging breach of the principle of good administration must be rejected.

7. Conclusion on the applications for annulment of Articles 1, 3 and 4 of the contested measure

603 It follows from the foregoing that the applications for annulment of Articles 1, 3 and 4 of the contested measure must be dismissed.

C. The application for annulment of Article 2 of the contested measure, in Case T−451/13

604 It will be recalled that, as stated in paragraphs 61 to 67 and paragraph 99 above, the action in Case T−429/13 is admissible only in so far as it concerns Articles 1, 3 and 4 of the contested measure, and is inadmissible in so far as it is directed against Article 2. Accordingly, in that case, it is not necessary to examine the plea alleging infringement of Article 49 of Regulation No 1107/2009, which is put forward solely in support of the application for annulment of Article 2 of the contested measure.

605 By contrast, in Case T−451/13, Syngenta, which is engaged in the marketing of treated seeds, is entitled to seek annulment of Article 2 of the contested measure. It is therefore appropriate, in this case only, to examine also the plea alleging infringement of Article 49 of Regulation No 1107/2009, put forward in support of that application.

606 Syngenta submits, in that regard, that none of the three conditions for the application of Article 49(2) of Regulation No 1107/2009 is fulfilled in the present case. First, it alleges that the Commission did not consider all the available evidence. Second, there being no sound scientific basis for the ban on the sale and use of treated seeds, there were no 'substantial concerns' within the meaning of that provision. Third, the Commission had not examined whether the risk to bee health could not be contained by means of risk mitigation measures taken at a national level.

607 The Commission contests those arguments.

608 As is apparent from Article 49(2) of Regulation No 1107/2009 (see paragraph 11 above), the application of that provision presupposes that two conditions are satisfied: first, there must be 'substantial concerns' as to the serious risk constituted by the treated seeds, notably to the environment, and, second, it must be the case that that risk cannot be contained satisfactorily by measures taken by the Member States. The requirement that the Commission examine the evidence before taking restrictive or prohibitive measures is only declaratory, since the Commission is in all events bound, if only under the principle of good administration, to examine the available evidence before adopting measures.

609 As regards the first condition, relating to the existence of 'substantial concerns', it must, as the Commission contends, be held that it is automatically fulfilled in the case of seeds treated with plant protection products containing active substances the approval of which no longer covers the application concerned and in respect of which any authorisations at national level have been withdrawn, because the Commission concluded that the conditions for approval under Article 4 of Regulation No 1107/2009 were no longer satisfied. In such a situation, the Commission has already established, in the context of the amendment or withdrawal of the approval of the active substance in question, that there are 'substantial concerns' linked to the use of the seeds concerned.

610 That interpretation does not, moreover, remove the practical effect of the first condition of Article 49(2) of Regulation No 1107/2009, in so far as there may be 'substantial concerns' which are not linked to a prior restriction of the approval of the active substance, in which case the Commission will be required to examine the issue for the purposes of applying that provision.

611 As regards the second condition, relating to the need for action at EU level, the Commission contends that, without Article 2 of the contested measure, existing stocks of seeds lawfully treated before the actual withdrawal or amendment of existing authorisations at national level could have circulated among the Member States and been used in those Member States which had not adopted any national measures, with the effect of undermining both the objectives set out in Article 1 of the contested measure and the harmonisation of the regulatory regime concerning the movement of goods in the single market. That analysis must be endorsed. It should be noted that, if the Commission wished to ensure, uniformly and simultaneously throughout the whole of the European Union, the practical effect of the restriction of the approval of the substances covered, as provided for in Article 1 of the contested measure, namely cessation of the use of the substances covered via the use of treated seeds so as to avoid the risks to bees which it had

identified, the only way to achieve that was to prohibit the placing on the market of treated seeds and their use, as provided for in Article 2 of the contested measure.

612 Last, as to the question whether the Commission did in fact examine the available evidence before adopting Article 2 of the contested measure, it must be pointed out that that has been answered in the affirmative in the examination of the pleas directed against Articles 1, 3 and 4 of the contested measure.

613 Accordingly, the plea alleging infringement of Article 49(2) of Regulation No 1107/2009 must be rejected and, therefore, the application for annulment of Article 2 of the contested measure, in Case T−451/13, must be dismissed.

D. The claim for compensation in Case T−451/13

614 Syngenta submits that the contested measure constitutes a manifest breach of a rule of law intended to confer rights on individuals which is sufficiently explicit, clear and serious to render the European Union liable.

615 It claims that the damage it has suffered comprises loss of gross profit relating to the sale of products containing thiamethoxam; harm to its image and reputation; and extraordinary costs incurred in defending the approval of thiamethoxam during the review procedure. It argues that this damage is the direct, immediate and exclusive result of the Commission's unlawful conduct.

616 The Commission contests Syngenta's arguments.

617 It should be noted, in that regard, that the non-contractual liability of the European Union for unlawful conduct on the part of its institutions, within the meaning of the second paragraph of Article 340 TFEU, depends on the fulfilment of a set of conditions, namely the unlawfulness of the conduct alleged against the institutions, the fact of damage and the existence of a causal link between that conduct and the damage complained of (see judgments of 9 November 2006, *Agraz and Others* v *Commission*, C−243/05 P, EU:C:2006:708, paragraph 26 and the case-law cited, and of 2 March 2010, *Arcelor* v *Parliament and Council*, T−16/04, EU:T:2010:54, paragraph 139 and the case-law cited).

618 Given the cumulative nature of those conditions, the claim must be dismissed in its entirety where one of those conditions is not satisfied (see judgment of 2 March 2010, *Arcelor* v *Parliament and Council*, T−16/04, EU:T:2010:54, paragraph 140 and the case-law cited).

619 In the present case, it is apparent from the Court's examination of the pleas in favour of annulment put forward by Syngenta above that no finding of unlawfulness that would justify annulment, even in part, of the contested measure is to be made, and that, consequently, the first of the above mentioned conditions is thus not fulfilled.

620 It follows that the claim for compensation must be dismissed, without there being any need to consider the second and third conditions.

V. Costs

621 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 applicants have been unsuccessful, they must be ordered to bear their own costs and to pay those incurred by the Commission, in accordance with the form of order sought by the Commission, as well as those incurred by UNAF, the DBEB and the ÖEB, interveners in support of the form of order sought by the Commission, as applied for by them.

622 Under Article 138(1) of the Rules of Procedure, the Member States which have intervened in the proceedings are to bear their own costs. Accordingly, the Kingdom of Sweden, intervener in support of the

form of order sought by the Commission, shall bear its own costs.

623 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 AGPM, the NFU, the ECPA, Rapool-Ring, the ESA and the AIC, interveners in support of the form of order sought by the applicants, shall bear their own costs. Similarly, PAN Europe, Bee Life, Buglife and Greenpeace, which made no application for costs, shall bear their own costs.

On those grounds,

THE GENERAL COURT (First Chamber, Extended Composition)

hereby:

1. Orders that Cases T−429/13 and T−451/13 be joined for the purposes of the judgment closing the proceedings;

2. Dismisses the actions;

3. Orders Bayer CropScience AG, Syngenta Crop Protection AG and the other applicants whose names appear in the annex to bear their own costs, and to pay those incurred by the European Commission, the Union nationale de l'apiculture française (UNAF), Deutscher Berufs- und Erwerbsimkerbund eV and Österreichischer Erwerbsimkerbund;

4. Orders the Kingdom of Sweden to bear its own costs;

5. Orders the Association générale des producteurs de maïs et autres céréales cultivées de la sous-famille des panicoïdées (AGPM), The National Farmers' Union (NFU), the Association européenne pour la protection des cultures (ECPA), Rapool-Ring GmbH Qualitätsraps deutscher Züchter, the European Seed Association (ESA), the Agricultural Industries Confederation Ltd, Pesticide Action Network Europe (PAN Europe), Bee Life European Beekeeping Coordination (Bee Life), Buglife — The Invertebrate Conservation Trust and Stichting Greenpeace Council 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 G. Berardis

Registrar President

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* Language of the case: English.

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