Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fifth Chamber)

17 March 2021 *

(Plant-protection products – Active substance flupyrsulfuron-methyl – Non-renewal of inclusion in the Annex to Implementing Regulation (EU) No 540/2011 – Assessment procedure – Proposed classification of an active substance – Precautionary principle – Rights of defence – Legal certainty – Manifest error of assessment – Proportionality – Principle of non-discrimination – Principle of sound administration – Legitimate expectations)

In Case T-719/17,

FMC Corporation, established in Philadelphia, Pennsylvania (United States), represented by D. Waelbroeck, I. Antypas and A. Accarain, lawyers,

applicant,

v

European Commission, represented by X. Lewis, G. Koleva and I. Naglis, acting as Agents,

defendant,

APPLICATION under Article 263 TFEU for the annulment of Commission Implementing Regulation (EU) 2017/1496 of 23 August 2017 concerning the non-renewal of approval of the active substance DPX KE 459 (flupyrsulfuron-methyl), in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ 2017 L 218, p. 7).

THE GENERAL COURT (Fifth Chamber),

composed of D. Spielmann, President, O. Spineanu-Matei and R. Mastroianni (Rapporteur), Judges,

Registrar: J. Palacio González, Principal Administrator,

having regard to the written part of the procedure and further to the hearing on 30 June 2020,

gives the following

* Language of the case: English.

Judgment

I. Background to the dispute

1 The active substance DPX KE 459 (flupyrsulfuron-methyl) ('FPS') is used as a selective broad-spectrum herbicide, registered for use on various cereal crops.

2 FPS was included in Annex I to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1) by Commission Directive 2001/49/EC of 28 June 2001 amending Annex I to Directive 91/414 to include DPX KE 459 (flupyrsulfuron-methyl) as an active substance (OJ 2001 L 176, p. 61).

3 The active substances listed in Annex I to Directive 91/414 are deemed to be approved under 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) and are 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). Approval of FPS, as resulting from its inclusion in that annex, expired on 30 June 2018.

4 On 25 March 2011, DuPont de Nemours (Deutschland) GmbH, the German subsidiary of the DuPont de Nemours group ('DuPont'), applied, in accordance with Article 14 of Regulation No 1107/2009, for the renewal of approval for FPS. That renewal application was made pursuant to Article 4 of Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414 and establishing the list of those substances (OJ 2010 L 322, p. 10), within the period prescribed by that article.

5 The French Republic and the Kingdom of Denmark were designated as Rapporteur Member State ('RMS') and co-Rapporteur Member State respectively to carry out the renewal risk assessment for FPS on behalf of the European Union, in the context of the procedure for renewing the approval for FPS.

6 In September 2013, the RMS completed its review of the renewal dossier submitted by DuPont in March 2011, complemented by a supplementary dossier in May 2012, and issued a draft renewal assessment report for FPS ('the renewal assessment report'). The RMS noted that the renewal file was complete. It recommended renewing the approval of FPS.

7 On 27 September 2013, a copy of the renewal assessment report was sent to DuPont and to the European Food Safety Authority (EFSA). On 2 October 2013, EFSA initiated the peer review process by sending the renewal assessment report to DuPont and to the Member States for consultation. DuPont and the Member States were requested to provide comments on that report within a period of two months.

8 On 3 December 2013, within the period prescribed, DuPont submitted its comments on the renewal assessment report to EFSA.

9 After considering the comments received on the renewal assessment report, the European Commission decided to mandate EFSA to conduct an expert consultation in the areas of mammalian toxicology, environmental fate and behaviour, and ecotoxicology.

10 At the peer review meeting held on 16 May 2014, EFSA and Member States' experts reviewed the available mammalian toxicity studies on FPS. On the basis of ambiguous hepatic effects observed in a long-term mouse study, the majority of the peer review experts decided to propose, as regards the hazards of FPS, that it be classified as a category 2 carcinogen.

11 Subsequently, when finalising its scientific conclusion on the risk assessment of FPS ('the EFSA conclusion'), EFSA proposed to classify FPS also as a category 2 reproductive toxicant (R2). That proposal was based on ambiguous results in a rat developmental study (delayed hyoid bone ossification).

12 While recognising that hazard classification is formally decided by the European Chemicals Agency (ECHA) under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1'), EFSA went on to identify two 'critical areas of concern' on the basis of its own classification proposal for FPS:

– In the first place, EFSA concluded that FPS fulfilled the interim endocrine disrupting criteria laid down in Regulation No 1107/2009 on the basis that it was proposed that FPS should be classified as a category 2 carcinogen and as a reproductive toxicant category 2. Nevertheless, EFSA also acknowledged that no endocrine disrupting effects had been observed in vivo and that 'therefore flupyrsulfuron-methyl [was] unlikely to be an endocrine disruptor in mammals according to the current state-of-play'.

– In the second place, EFSA concluded that 'consequent to the classification of the parent compound', the three main soil metabolites of FPS (IN-JV460, IN-KC576 and IN-KY374) that were expected to exceed the concentration limit of 0.1 μg/L in groundwater had to be regarded as toxicologically relevant in accordance with the presumption set out in the Commission guidance document of 25 February 2003 on the assessment of the relevance of groundwater metabolites in the context of Directive 91/414 (Sanco/221/2000 – rev.10 – final) ('Commission guidance document on groundwater metabolites').

13 EFSA invited the Member States to comment on the proposed classification of FPS as toxic for reproduction category 2 and on the two 'critical areas of concern' identified on that basis.

14 In their comments, a number of Member States expressed concerns regarding EFSA's proposal to classify FPS as toxic for reproduction category 2 as well as the consequences ensuing from the EFSA classification proposal.

15 EFSA issued its scientific conclusion on FPS on 6 November 2014. EFSA maintained its classification proposal and concluded that FPS was not expected to meet the approval criteria of Article 4 of Regulation No 1107/2009. In support of that conclusion, EFSA identified four 'critical areas of concern':

– in the first place, it could not be concluded that the batches used in the toxicity studies were representative of the proposed technical specifications;

– in the second place, FPS was considered to meet the interim endocrine disrupting criteria since there was a proposal to classify it as a category 2 carcinogen and as a reproductive toxicant category 2;

– In the third place, the potential for groundwater exposure above the concentration limit of 0.1 μg/L to the three main soil metabolites of FPS (IN-JV460, IN-KC576 and IN-KY374) was deemed unacceptable as those three metabolites were presumed toxicologically relevant on the basis of the EFSA classification proposal for FPS;

– In the fourth place, a risk was identified for aquatic plants.

16 In addition, EFSA identified a 'data gap' as no groundwater exposure assessment was available for two other FPS metabolites (IN-JE127 and IN-KF311).

17 On 2 December 2014, DuPont sent a letter to the Commission setting out its comments on the EFSA conclusion and, in particular, opposing EFSA's classification proposal for FPS. In addition, DuPont expressed surprise that, despite expressly ruling out endocrine activity, EFSA nonetheless went on to identify FPS as a potential endocrine disruptor on the basis of the interim endocrine disrupting criteria under Regulation No 1107/2009.

18 On the basis of the EFSA conclusion, the Commission issued a draft review report on FPS on 18 March 2015, in which it proposed to withdraw the approval of FPS. The Commission proposal was based on three key concerns, namely:

– the interim endocrine disrupting criteria, which were considered to be fulfilled on the basis of the EFSA classification proposal for FPS as a category 2 carcinogen and as a reproductive toxicant category 2;

– the available information that was not sufficient to assess the risk of groundwater exposure to the relevant metabolites;

– a risk to aquatic organisms.

19 On the same day, the Commission informed DuPont that internal discussions were still ongoing within the Commission regarding the EFSA classification proposal and, therefore, regarding the interim endocrine disrupting criteria.

20 On 8 April 2015, DuPont sent a letter to the Commission in which it set out its comments on the draft review report for FPS and stated, inter alia, that a Commission proposal to renew the approval of FPS would have been scientifically justified and legally justified.

21 By email of 29 May 2015, the Commission invited DuPont, based on the finding that FPS met the interim endocrine disrupting criteria, to submit considerations for possible approval by derogation according to the provisions of under Article 4(7) and point 3.6.5 of Annex II to Regulation No 1107/2009. DuPont submitted the two derogation dossiers on 26 June and 13 July 2015.

22 On 24 June 2015, the Commission invited DuPont to a meeting to discuss the renewal review of FPS. During that meeting, and also in a follow-up letter dated 2 July 2015, DuPont, inter alia, urged the Commission to mandate the ECHA, as the competent authority for classification matters, to review the hazard classification for FPS, as well as to postpone its decision pending a final classification decision by the ECHA.

23 By letter of 9 October 2015, DuPont informed the RMS of its intention to carry out further studies relating to the toxicity of FPS in order to support its position that neither the category 2 carcinogen nor the reproductive toxicant category 2 classification was technically warranted.

24 In January 2016, the Commission mandated EFSA to review the two derogation dossiers submitted by DuPont on 26 June and 13 July 2015. EFSA subsequently requested further information from DuPont to complete the negligible exposure dossier, which DuPont submitted on 31 May 2016. EFSA then set up a working group to develop a methodology for evaluating the agricultural indispensability of herbicide substances. After the publication of the agreed methodology in July 2016, EFSA asked DuPont to revise the derogation dossier under Article 4(7) of Regulation No 1107/2009 (relating to agricultural indispensability) in line with that methodology. DuPont submitted the revised derogation dossier on 19 September 2016.

25 On 3 October 2016, EFSA delivered a revised version of its conclusion ('the revised EFSA conclusion'). In its revised conclusion, EFSA maintained its position in relation to the four 'critical areas of concern' previously identified, but identified an additional 'data gap' in relation to the genotoxic profile of two FPS metabolites (IN-JE127 and IN-KF311). It concluded, in particular, that 'the consumer risk assessment for IN-JE127 [could not] be finalised due to insufficient information on the hazardous potential and reliable consumer exposure estimates for this metabolite (for which a genotoxic potential [could not] be ruled out)'.

26 By letter of 5 October 2016, the Commission invited DuPont to comment on the revised EFSA conclusion. On 18 October 2016, DuPont sent a letter to the Commission in which it challenged the additional genotoxicity 'data gap' identified by EFSA and asked the Commission for permission to submit additional studies addressing that 'data gap' by the end of November 2016.

27 Following publication of the revised EFSA conclusion, the Commission issued a revised version of its draft review report on 22 December 2016, in which it maintained its proposal to withdraw the approval of FPS. However, the Commission no longer made reference to the interim endocrine disrupting criteria as being a concern.

28 On 13 January 2017, DuPont sent a letter to the Commission setting out its comments on the revised draft review report.

29 On 9 February 2017, DuPont wrote to the EU Member States' regulatory authorities, outlining its concerns in relation to the Commission's proposal not to renew the approval of FPS.

30 On 31 March 2017, E.I. du Pont de Nemours and Company, the parent company of DuPont, and FMC Corporation, a company governed by United States law, entered into a divestment agreement relating to the transfer of the activities of DuPont in relation to certain herbicides, including FPS ('the divestment agreement'). The divestment agreement was concluded in order to comply with Commission Decision C(2017) 1946 final of 27 March 2017 declaring the merger between The Dow Chemical Company and E.I. du Pont de Nemours and Company to be compatible with the internal market and the functioning of the EEA Agreement (Case COMP/M.7932 – Dow/DuPont).

31 The divestment agreement provided that FMC would acquire all the rights, titles and interests of DuPont in relation to all assets and properties related to the FPS business, including in particular all marketing authorisations. The divestment agreement was concluded subject to the condition precedent that all requisite approvals for the transfer from the competent competition authorities would be secured. The closing of the transaction was expected to take place on 1 November 2017.

32 On 4 April 2017, the Commission notified the draft regulation on the non-renewal of the approval FPS to the other members of the World Trade Organisation (WTO) as required by the provisions of the WTO Agreement on Technical Barriers to Trade (TBT) of 15 April 1994. By letter of 25 May 2017, the United States authorities commented, on behalf of DuPont, on the proposed decision, outlining the absence of robust scientific grounds for the non-renewal and the availability of data showing the absence of concerns for human health, groundwater and the environment.

33 The Commission answered those comments on 14 July 2017. In its letter, the Commission indicated that it had 'carefully considered all comments received during the decision-making process' but that 'taking into account the limitations on when and how additional data can be submitted', it could not renew the approval of FPS.

II. The contested regulation

34 On 23 August 2017, the Commission adopted Implementing Regulation (EU) 2017/1496 concerning the non-renewal of approval of the active substance DPX KE 459 (flupyrsulfuron-methyl), in accordance with Regulation No 1107/2009, and amending Implementing Regulation No 540/2011 (OJ 2017 L 218, p. 7; 'the contested regulation'). Under the contested regulation, approval for FPS was not renewed.

35 Recitals 8 to 14 of the contested regulation state as follows:

'(8) On 30 September 2016 the [EFSA] communicated to the Commission its conclusion on whether [FPS could] be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. Based on the studies assessed, the [EFSA] concluded that the parent substance [had] certain intrinsic toxicological properties, in particular as regards to carcinogenicity and reproductive toxicity. In the view of the [EFSA] this information even justifies the classification as a category 2 carcinogen and as a reproductive toxicant category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council. The [EFSA] concluded that considering the representative uses assessed, there [was] a high potential to result in groundwater exposure above the parametric drinking water limit of 0.1 μg/L by several metabolites of [FPS] in situations represented by all pertinent groundwater scenarios.

(9) Regardless of the classification proposed by the [EFSA], given the intrinsic toxicological properties of the parent substance shown in the studies, in particular in relation to carcinogenicity and reproductive toxicity, the presence of the metabolites in groundwater is of particular concern since it has not been demonstrated that these metabolites do not share the same intrinsic properties. Therefore it cannot currently be established that the presence of the metabolites in groundwater will not result in unacceptable effects on groundwater and in harmful effects on human health.

(10) Furthermore, the [EFSA] concluded that the groundwater exposure assessment could not be finalised based on the available information for metabolite IN-JE127, the genotoxic potential of which cannot be excluded.

(11) Given the uncertainty about the presence of that metabolite in groundwater, unacceptable effects on groundwater and harmful effects on human health cannot currently be excluded.

(12) Moreover, the [EFSA] concluded that there is a high risk to aquatic organisms, in particular for algae and aquatic plants, from exposure to [FPS].

(13) Based on these risks identified in recitals 9, 11 and 12, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of [FPS] in accordance with Article 20(1)(b) of that Regulation.

(14) Given the risks detailed in recitals 9, 11 and 12, the derogation provided for in Article 4(7) of Regulation (EC) No 1107/2009 does not apply. The application of that derogation is also excluded on the grounds that it has not been established that any of the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are not satisfied.'

36 The contested regulation also states, in recital 19, that 'this regulation does not prejudice the submission of a further application for [FPS] in accordance with Article 7 of Regulation (EC) No 1107/2009.'

III. Procedure and forms of order sought

37 By application lodged at the Court Registry on 23 October 2017, DuPont de Nemours (Deutschland) and 11 other DuPont companies (together, 'the DuPont applicants'), and FMC, brought an action for annulment of the contested regulation.

38 By a separate document lodged at the Court Registry on the same day, FMC lodged an application for interim relief, seeking suspension of the operation of the contested regulation and the adoption of appropriate interim measures.

39 On 19 February 2018, the Commission lodged its defence.

40 By document lodged at the Court Registry on 14 March 2018, FMC sought to be substituted for the DuPont applicants as applicant in the present case.

41 By documents lodged at the Court Registry on 6 April and 1 June 2018 respectively, the DuPont applicants and the Commission stated, in essence, that they had no objection to the substitution of FMC for the DuPont applicants.

42 The reply was lodged at the Court Registry on 12 April 2018 and the rejoinder on 4 July 2018.

43 By order of 22 June 2018 in *FMC* v *Commission* (T-719/17 R, EU:T:2018:408), the President of the General Court dismissed the application for interim relief and reserved the costs.

44 By order of 30 November 2018 in *FMC* v *Commission* (T-719/17, not published, EU:T:2018:893), the Court allowed FMC to be substituted for the DuPont applicants as applicant in the present case and reserved the costs. The written part of the procedure was closed on that same date.

45 Following a change in the composition of the Chambers of the General Court, pursuant to Article 27(5) of the Rules of Procedure of the General Court, the case was allocated to the Fifth Chamber, to which a new Judge-Rapporteur was assigned.

46 On a proposal from the Judge-Rapporteur, the General Court (Fifth Chamber), by way of measures of organisation of procedure under Article 89 of the Rules of Procedure, put written questions to the parties to which the latter replied within the prescribed period.

47 On a proposal from the Judge-Rapporteur, the Court decided to open the oral part of the procedure.

48 The parties presented oral argument and replied to the questions put by the Court at the hearing on 30 June 2020.

49 The applicant claims that the Court should:

– Annul the contested regulation;

– order the Commission to pay the costs.

50 The Commission contends that the Court should:

– dismiss the action;

– order the applicant to pay the costs.

IV. Law

51 The applicant puts forward six pleas in law in support of its action for annulment.

52 The first plea, which is divided into three parts, alleges that the Commission infringed Regulation No 1141/2010, Regulation No 1272/2008 and the rules on animal experimentation contained in Regulation No 1107/2009 and Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ 2010 L 276, p. 33).

53 The second plea alleges that the Commission relied wrongly on new and unestablished guidance in breach of the principle of legal certainty and the rights of the defence of the applicant for renewal.

54 The third plea alleges that there was a failure to conduct a complete risk assessment in breach of several provisions of EU law and the rights of the defence of the applicant for renewal.

55 The fourth plea alleges infringement of the principle of proportionality.

56 The fifth plea alleges infringement of the principle of non-discrimination.

57 The sixth plea in law alleges infringement of the principles of sound administration and of the protection of legitimate expectations.

A. Preliminary observations

58 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.

59 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. That protection takes precedence over economic considerations, with the result that it may justify adverse economic consequences, even those which are substantial, for certain traders (see, by analogy, 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).

60 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.

61 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 were based on 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).

1. The precautionary principle

(a) Definition

62 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, paragraph 184).

63 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 6 September 2013, *Sepro Europe* v *Commission*, T-483/11, not published, EU:T:2013:407, paragraph 44 and the case-law cited; see also, by analogy, judgment 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).

64 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 (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 136).

(b) Risk assessment

65 Assessment of the risks to public health, safety and the environment consists, for the institution required to cope with 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).

(1) The scientific assessment

66 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).

67 In its communication COM(2000) 1 final of 2 February 2000 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.’

68 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).

69 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 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).

70 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).

71 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).

72 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 (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 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, paragraphs 31 and 32).

73 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).

74 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 process capable of having an adverse effect on human health or any other interest safeguarded by the legal order (judgment of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 144; see also, by analogy, judgments of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 147, and of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 147).

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

75 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 judgement, 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).

76 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, by analogy, 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).

77 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, by analogy, judgment of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 153).

(c) Risk management

78 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).

79 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).

2. Renewal of an active substance included in Part A of the Annex to Implementing Regulation No 540/2011

80 As explained in paragraph 2 above, the substance covered by the contested regulation was approved under the regime provided for in Directive 91/414, in accordance with the conditions applicable at the time.

81 Since the renewal of its approval by the Commission was requested under 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.

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

82 Article 5(1) of Directive 91/414 provided that, in order for a substance to be included in Annex I thereto, it could be expected that, in the light of the current scientific and technical knowledge, the use of plant protection products containing that active substance and residues of those products, 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.

83 It has been held that it followed from Article 5(1) of Directive 91/414, interpreted in the light of 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.

84 Last, it has been held that, under the rules laid down by Directive 91/414, it is the notifier who must 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).

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

85 It follows from a comparison of Article 5 of Directive 91/414 with Article 4 of Regulation No 1107/2009 that, in the context of 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 (judgment of 17 May 2018, *BASF Agro and Others* v *Commission*, T-584/13, EU:T:2018:279, paragraph 82). The considerations set out in paragraph 84 above with regard to human health are applicable, by analogy, with regard to 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.

86 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 (judgment of 17 May 2018, *BASF Agro and Others* v *Commission*, T-584/13, EU:T:2018:279, paragraph 83).

87 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 that regulation are to be applied at the time of renewal or review of their approval. It follows that, in the present case, the renewal of the approval of the substance 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

88 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 84 above).

89 In particular, recital 8 of Regulation No 1107/2009 states that the latter '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.

90 Furthermore, Article 4(1) of Regulation No 1107/2009, which sets out the conditions for approval of active substances, requires that it may be expected that the plant protection products containing an active substance meet the requirements provided for in paragraphs 2 and 3 of that article, which, in turn, require that those products and their residues meet the requirements laid down. 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.

4. Scope of judicial review

91 If the Commission is to be able to pursue effectively the objectives assigned to it by Regulation No 1107/2009 (see paragraphs 58 to 60 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.

92 The exercise of that discretion is not, however, removed 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).

93 As regards the assessment by the Courts of the European Union as to whether there has been a manifest error of assessment, it must be stated that, in order to establish that the Commission made a manifest error in assessing complex facts such as to justify the annulment of the contested measure, the evidence adduced by the applicant must be sufficient to make the factual assessments used in that measure implausible (see, to that effect, judgments of 12 December 1996, *AIUFFASS and AKT* v *Commission*, T-380/94, EU:T:1996:195, paragraph 59, and of 1 July 2004, *Salzgitter* v *Commission*, T-308/00, EU:T:2004:199, paragraph 138). Without prejudice to that examination of plausibility, it is not for the 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).

94 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).

95 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).

96 It is in the light of those fundamental considerations that the merits of the present action must be examined.

B. The first plea, alleging infringement of Regulation No 1141/2010, Regulation No 1272/2008 and the rules on animal experimentation contained in Regulation No 1107/2009 and Directive 2010/63.

97 This plea is divided into three parts. The first part alleges infringement of Regulation No 1141/2010 and the Commission guidance document of 12 December 2014 on the renewal of the approval of active substances to be assessed under Regulation (EU) No 844/2012 (Regulation on the renewal of so-called 'AIR-3' substances, SANCO/2012/11251 rev. 4) ('the guidance document on the renewal of AIR-3 substances'), the second alleges infringement of Regulations No 1107/2009 and No 1272/2008 and of the Commission guidance document on the assessment of the relevance of groundwater metabolites and the third alleges infringement of the rules on animal experimentation contained in Regulation No 1107/2009 and Directive 2010/63.

1. Infringement of Regulation No 1141/2010 and of the guidance document on the renewal of AIR-3 substances

98 In this part of the plea, the applicant submits that, in the absence of any change in the state of scientific knowledge, EFSA was not entitled to re-assess the previously accepted toxicity data set for FPS.

99 According to the applicant, pursuant to Article 10(1)(c) of Regulation No 1141/2010, EFSA and the Member States must limit their assessment to the new data and information submitted in the supplementary dossier, as is expressly stated in the guidance document on the renewal of AIR-3 substances: 'only new data should be assessed hence the previously submitted and accepted data should not be re-opened, unless such is necessary in the light of current scientific and technical knowledge which may require a re-assessment of old data'.

100 In the absence of any change in the state of scientific knowledge or in applicable data requirements since the initial approval of FPS, the applicant was not required to, and did not, submit any new toxicity data when it applied for the renewal of the approval of FPS in 2011. Accordingly, there were no circumstances that could have justified EFSA reviewing previously accepted toxicology studies and proposing, against the opinion of the peer review experts and the RMS, classification as a category 2 carcinogen and as a reproductive toxicant category 2.

101 The applicant considers that the renewal dossier therefore remained based on the exact same toxicity data set that was evaluated by the European Chemicals Bureau ('ECB') in 1998 and accepted by the European Commission as demonstrating the safety of FPS, leading to the initial approval of the substance in 2001. It is unclear to the applicant what the Commission refers to when it claims in its defence that the re-evaluation of the hazard profile of FPS was necessary to ensure that the 'new criteria' were met. The relevant criteria for the hazard classification of substances laid down by Regulation No 1107/2009 have remained the same since the first approval of FPS.

102 EFSA's re-assessment of the hazard profile of FPS was therefore, according to the applicant, an infringement of Regulations No 1107/2009 and No 1141/2010.

103 The Commission disputes the applicant's arguments.

104 In the present case, with regard to the evaluation of the dossier to be carried out in the context of the examination of an application for renewal of the approval of an active substance, it should be recalled, first of all that, according to recital 15 of Regulation No 1107/2009, the 'experience gained from the actual use of plant protection products containing the substances concerned and any developments in science and technology should be taken into account when any decision regarding the renewal of an approval is taken'.

105 In addition, recital 8 of Regulation No 1141/2010 states that: 'the dossiers submitted for renewal should include new data relevant to the active substance and new risk assessments to reflect any changes in data requirements and any changes in scientific or technical knowledge since the active substance was first included in Annex I to Directive 91/414/EEC, as reflected in guidance documents published by the Commission and in relevant opinions from the Scientific Committee on Plants or the European Food Safety Authority'.

106 Furthermore, point 2.1 of the guidance document of 28 October 2010 on the renewal of active substances included in Annex I to Directive 91/414 to be assessed under Regulation No 1141/2010 (SANCO/10387/2010 rev.8) states, in essence, that applicants are to identify, inter alia, in their applications, the new data they intend to submit from that first stage, since any new data submitted must be justified in terms of amendments to data requirements, developments in scientific and technical knowledge, development of guidance documents and the need to amend or extend inclusion restrictions or changes in the range of representative uses.

107 In those circumstances, it should be noted that, while it is true that, in the context of the assessment of an examination of an application for renewal, particular attention must be paid to new data relevant to the active substance and new risk assessments, it is in no way apparent from the abovementioned texts, contrary to what the applicant claims, that the applicant is not required to submit a complete dossier or that the RMS and EFSA are not required to assess all the available data to determine whether or not the approval criteria are met. As noted by the Commission, a detailed scientific assessment must take into account all available information, including the data submitted at the time of the application for approval.

108 It should be pointed out, as the Commission observes, that since the approval criteria laid down in Regulation No 1107/2009 must be taken into account, a full assessment of the safety of the substance must be carried out. That assessment may also involve examining information that had already been assessed in the first assessment, in order to assess it in the light of the most recent scientific knowledge. The scientific assessment should take into account the weight of the available evidence. That principle would not be respected if only new studies were taken into account.

109 As regards Article 10 of Regulation No 1141/2010, concerning the content of the supplementary dossier, it should be noted, as observed by the Commission, that that article does not limit EFSA's assessment to the new studies included in that dossier. That provision deals only with the content of

that supplementary dossier, not with the scope of the assessment, and its purpose is to update the application by including the dossiers submitted for the first inclusion of the active substance, as provided for in Article 9(1) of that regulation, according to which additional dossiers are to be attached to the dossiers submitted at the time of the first inclusion, together with their subsequent updates.

110 As regards, lastly, the guidance document on the renewal of AIR-3 substances, according to which 'only new data should be assessed hence the previously submitted and accepted data should not [in principle] be re-opened', suffice it to note that that document is inapplicable in the present case because it refers to AIR-3 substances, which do not include FPS.

111 In the light of the foregoing, this part of the first plea in law must be rejected.

2. Infringement of Regulations No 1107/2009 and No 1272/2008 and the Commission guidance document on groundwater metabolites

112 The applicant submits that the contested regulation infringes Regulation No 1107/2009 and Regulation No 1272/2008 in so far as it endorses the EFSA conclusion that three FPS metabolites (IN-JV460, IN-KC576 and IN-KY374) must be presumed toxicologically relevant for groundwater exposure in the absence of a formal classification of FPS under Regulation No 1272/2008, but merely on the basis of EFSA's own proposal to classify FPS as a suspected carcinogen and reproductive toxicant (category 2 carcinogen and reproductive toxicant category 2) (see paragraph 12 above).

113 The applicant claims that the hazard classification process of chemical substances, including plant protection product substances, is a process entirely distinct from the substance approval and renewal process and is governed by a different set of EU rules, namely Regulation No 1272/2008.

114 The applicant adds that Regulation No 1107/2009 and Regulation No 1272/2008 provide that the relevance of groundwater metabolites can be assumed only where the parent substance has already been classified for human health hazards by the ECHA under Regulation No 1272/2008 or, at least, where the ECHA's Committee for Risk Assessment has delivered an opinion in the context of Regulation No 1272/2008 proposing a classification for human health hazards for the parent substance. The ECHA has been accorded the exclusive competence under Regulation No 1272/2008 to apply the hazard classification criteria contained in that regulation and to decide on the hazard classification of substances contained in plant protection products. A mere EFSA classification proposal is insufficient. According to the applicant, EFSA lacks both the technical expertise and the legal competence to apply the classification criteria under Regulation No 1272/2008, as it recognised itself in its conclusion on FPS.

115 The applicant argues that, in the absence of a formal classification of FPS under Regulation No 1272/2008, EFSA was not entitled to rely on its own classification to presume the toxicological relevance of three FPS groundwater metabolites. It takes the view that it is clear that EFSA and the Commission presumed that relevance on the basis of the EFSA classification proposal itself and its underlying assessment of the intrinsic properties of FPS.

116 The applicant adds that that interpretation is confirmed by the Commission guidance document on groundwater metabolites, which states that 'the toxicity classification of the parent active substance as determined according to [the current Regulation No 1272/2008] is used for pragmatic reasons as a starting point to focus the screening activity'.

117 The applicant also draws attention to the fact that EFSA's undue reliance on its own classification proposal to presume the relevance of FPS groundwater metabolites was rightly opposed by several Member States during the peer review process.

118 The Commission disputes the applicant's arguments.

119 In that respect, it should first of all be noted, as observed by the applicant, that EFSA is not competent to propose or decide on the hazard classification for plant protection product substances. Under the provisions of Regulation No 1272/2008, EFSA has no role to play either in the context of self-classification, which is open to any manufacturer, importer and downstream user of the substance concerned, or in the context of the harmonised classification, which may be proposed by the abovementioned actors or by the competent authority of a Member State and is subject to an opinion from ECHA. Those considerations are not contested substantively by the Commission.

120 It follows that a proposal by EFSA to classify a substance under the provisions of Regulation No 1272/2008 cannot, on its own, have any legal consequences. Moreover, it is misleading to refer to a 'classification proposal' since EFSA has no competence to propose such a classification.

121 Nevertheless, it must be held that, in application of the precautionary principle, it is for the Commission to take protective measures where scientific uncertainties remain as to the existence or extent of risks to human health or to the environment.

122 It is apparent from the contested regulation that the Commission's concerns were related to 'intrinsic toxicological properties' as regards the carcinogenicity and toxicity to reproduction of the parent substance and were not directly related to the classification considered appropriate by EFSA.

123 Recitals 8 and 9 of the contested regulation make reference to the fact that, based on the studies assessed, the parent substance has intrinsic toxicological properties, in particular as regards carcinogenicity and toxicity.

124 More specifically, the Commission considered that, in view of the effects observed in the studies, it was legitimate to have concerns regarding the three FPS metabolites (IN-JV460, IN-KC576 and IN-KY374) and their presence in groundwater, since it had not been possible to demonstrate that those metabolites did not have the same intrinsic properties as the parent substance.

125 In that respect, it should be noted that Article 3(32) of Regulation No 1107/2009 defines the circumstances in which metabolites are considered 'relevant' for the risk assessment of their parent substance as follows:

'A metabolite is deemed relevant if there is a reason to assume that it has intrinsic properties comparable to the parent substance in terms of its biological target activity, or that it poses a higher or comparable risk to organisms than the parent substance or that it has certain toxicological properties that are considered unacceptable. Such a metabolite is relevant for the overall approval decision or for the definition of risk mitigation measures.'

126 It is certainly true that, according to the Commission guidance document on groundwater metabolites, where the parent substance is classified in a certain way, for example as category 2 carcinogen (C2) or reproductive toxicant category 2 (R2), metabolites are presumed to share the same properties as the parent substance and are considered to be relevant unless the applicant produces convincing evidence showing that the metabolites do not qualify for the same classification as the parent substance.

127 However, according to the guidance document referred to in paragraph 126 above, while relevance is often linked to the formal classification of the parent substance, that is not the only consideration that can determine the relevance of metabolites. Such relevance can also be determined independently of that classification. That guidance document states that 'the toxicity classification of the parent active substance … is used for pragmatic reasons as a starting point to focus the screening activity'.

128 In addition, the Commission guidance document on groundwater metabolites expressly states that 'independent of the classification of the parent active substance, if there is reason to expect that a certain degradation product may be toxic or highly toxic, a targeted testing may be necessary'.

129 In the present case, as stated in recital 9 of the contested regulation, it was the intrinsic properties of the parent substance shown in the studies, in particular in relation to carcinogenicity in mammals and reproductive toxicity, which led the Commission to find that the metabolites were 'relevant'.

130 In those circumstances, in the light of the effects observed in studies on FPS and the specific need to ensure the protection of groundwater as stated explicitly in Regulation No 1107/2009, the Commission, in accordance with the precautionary principle and in its capacity as risk manager, considered, without committing a manifest error of assessment, that the presence of the three FPS metabolites in groundwater was a concern since it had not been demonstrated that those metabolites did not have the same intrinsic properties as those of the parent substance. It thus concluded that it was impossible to establish that the presence of the metabolites in groundwater, some of which exceeded the threshold of 0.1 μg/L in all scenarios, would not result in unacceptable effects on groundwater or in harmful effects on human health.

131 In the light of the foregoing considerations, it must be held that, contrary to the applicant's submission, the Commission has not infringed either Regulation No 1107/2009 or Regulation No 1272/2008 or its guidance document on groundwater metabolites.

132 Consequently, the present part of the first plea in law must be rejected.

3. Infringement of the rules on animal experimentation contained in Regulation No 1107/2009 and Directive 2010/63

133 By this part of its first plea, the applicant claims that the contested regulation infringes the rules on animal experimentation in so far as EFSA and the Commission failed to consider adequate alternatives to live vertebrate animal testing before requiring the performance of new in vivo studies to exclude the genotoxic potential of metabolite IN-JE127.

134 In particular, in the renewal process for FPS, EFSA and the Commission disregarded the 'last resort' principle in that they both identified a 'data gap' for an additional in vivo study evidencing bone marrow exposure to metabolite IN-JE127 without giving proper consideration to non-animal alternatives including the overall weight of evidence approach and without consideration of, firstly, the new in vitro (mammalian cell forward gene mutation) genotoxicity study submitted by DuPont which clearly shows negative results and, secondly, the additional modelling data produced by DuPont showing that metabolite IN-JE127 does not infiltrate to groundwater in concentrations exceeding 0.1 μg/L, which demonstrates that the new in vivo test requested by EFSA is unnecessary and therefore unjustified.

135 The Commission disputes the applicant's arguments.

136 In the present case, it should be noted from the outset that the applicant's allegations are based on the erroneous premiss that EFSA and the Commission required new in vivo studies to be carried out in order to exclude the genotoxic potential of the metabolite IN-JE127.

137 It should be emphasised that EFSA, in its revised conclusion of October 2016, noted a data gap in relation to the genotoxic profile of the metabolite IN-JE127 when observing that an in vivo study carried out on mammals had produced negative results and had not made it possible to confirm bone

marrow exposure. However, as noted by the Commission, EFSA did not request a new in vivo study in order to exclude the genotoxic potential of the metabolite IN-JE127, contrary to the claims of the applicant.

138 In those circumstances, that part of the first plea in law must be rejected and, therefore, the first plea in law in its entirety.

C. The second plea in law, alleging that the Commission wrongly relied on a new guidance document or made inconsistent use of guidance documents, in breach of the principle of legal certainty and the rights of defence of the applicant for renewal

139 This plea is divided into two parts. First, as regards the genotoxicity assessment of metabolite IN-JE127, the applicant claims that EFSA relied on guidance documents that had not been accepted or were not applicable at the time when the renewal dossier for FPS was submitted. Secondly, as regards the algae risk assessment, the applicant maintains that EFSA made inconsistent use of the guidance documents and approved a risk assessment that contradicted the available guidance document.

1. The genotoxicity assessment of metabolite IN-JE127

140 The applicant submits that the genotoxicity assessment of metabolite IN-JE127 was carried out on the basis of a guidance document that had not been approved and was not applicable at the time when the renewal dossier for FPS was submitted.

141 As such, according to the applicant, the contested regulation violates the principle of legal certainty as well as Article 12(2) and point 3.8.3 of Annex II to Regulation No 1107/2009 which expressly require the risk assessment to be carried out by EFSA 'using guidance documents available at the time of application [for approval or renewal]' and 'on the basis of [Union] or internationally agreed test guidelines'. Article 16(2) of Regulation No 1141/2010 confirms the application of that well-established rule in the context of the AIR-2 substance renewal programme, which includes FPS.

142 According to the applicant, even if the Commission intended to review the approval of FPS against the requirements of a new 'guidance document', such as EFSA scientific opinion of 3 October 2012 on genotoxicity testing strategies applicable to food and feed safety assessment ('the 2012 scientific opinion'), it was clearly required to afford the applicant for renewal an opportunity to address the new data requirements arising from that scientific opinion.

143 In the case of FPS, DuPont only became aware of the 'data gap' regarding the genotoxicity of metabolite IN-JE127 when EFSA issued its revised conclusion in October 2016, well after the end of the initial 'peer review' process for FPS. To address the new data requirement, DuPont immediately undertook two additional studies which confirmed the non-genotoxic profile of metabolite IN-JE127. DuPont informed the Commission of the results of those studies on 18 October 2016 and 13 January 2017. However, the Commission refused to consider those results prior to the adoption of the contested regulation, which amounts to an infringement of the principle of legal certainty and of the rights of the defence of the applicant for renewal.

144 The applicant adds that, even though the 2012 scientific opinion was published before submission of the FPS dossier, that does not, however, respond to the argument that EFSA relied on a scientific opinion which is even today still under review in accordance with the Commission's own mandate, and, accordingly, does not constitute an established and agreed methodology for risk assessment

available at the time of dossier submission. According to the applicant, pending the outcome of EFSA review, the Commission put on hold all regulatory decision-making on the possible renewal of substances for which only genotoxicity concerns were identified.

145 Moreover, according to the applicant, the 2012 scientific opinion was published only after the date of entry into force of Regulation No 1141/2010, on 28 December 2010. Since Article 16(2) of Regulation No 1141/2010 requires the use of 'the guidance documents available at the time of entry into force of this regulation', EFSA and the Commission should also on that basis have refrained from relying on that scientific opinion when reviewing FPS.

146 The Commission disputes the applicant's arguments.

147 As regards this part of the second plea, it should be noted at the outset that it is ineffective.

148 A potential infringement of Regulation No 1107/2009, of Regulation No 1141/2010, of the principle of legal certainty or of the rights of the defence concerning this aspect of the proceedings cannot result in the annulment of the contested regulation. It should be noted in that regard that, as the Commission maintains, without the finding concerning the lack of data on the genotoxic potential of metabolite IN-JE127, referred to in recital 10 of the contested regulation, the Commission would still have reached the same conclusion, as there was a high risk of groundwater exposure to a number of other FPS metabolites and a high risk to aquatic organisms. In the contested regulation, that ground is presented as an additional, even superfluous, ground.

149 In any event, as regards the applicant's argument that EFSA relied on the scientific opinion of 2012 in breach of the rule that risk assessments must be carried out on the basis of the guidance documents applicable on the date of submission of the dossier, it should be noted, as observed by the Commission, that the first version of that opinion was published on 30 September 2011, as stated on the first page.

150 Accordingly, it cannot be argued that the risk assessments were carried out on the basis of a guidance document published after the complete submission of the renewal dossier, which dates from May 2012.

151 Furthermore, it should be noted, as stated in the Commission's reply to the Court's questions, that the 2012 scientific opinion was not formally adopted by the Commission as a guidance document in accordance with Article 77 of Regulation No 1107/2009. Rather, it is a scientific opinion that EFSA uses to assess genotoxicity aspects in the context of food and feed law.

152 According to the Commission, EFSA's scientific opinions represent the most recent scientific knowledge in a given field, in this instance in the field of genotoxicity, as far as food and feed safety assessments are concerned.

153 In that respect, it should be noted that Article 12(2) of Regulation No 1107/2009 states expressly that EFSA is to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of the same regulation, 'in the light of current scientific and technical knowledge'.

154 In those circumstances, EFSA cannot be criticised for having carried out a risk assessment on the basis of the scientific opinion of 2012, which confines itself to summarising the most recent scientific knowledge in the field of genotoxicity and the first version of which was, moreover, published before the complete submission of the renewal dossier.

155 As regards the applicant's argument that the 2012 scientific opinion could not be used because it was published after the date of entry into force of Regulation No 1141/2010, on 28 December 2010, it is sufficient to note, as stated in paragraph 151 above, that that scientific opinion was not formally

adopted by the Commission as a guidance document in accordance with Article 77 of Regulation No 1107/2009. Article 16(2) of Regulation No 1141/2010 is, therefore, inapplicable to the present case. Consequently, that argument must also be rejected.

156 As regards, lastly, the argument that, even if the Commission intended to review the approval of FPS on the basis of the requirements set out in a new 'guidance document', it was clearly required to afford the applicant for renewal an opportunity to address the new data requirements arising from that new 'guidance document', it must be held that that argument cannot succeed either.

157 It is certainly regrettable that the 'data gap' concerning the genotoxicity of metabolite IN-JE127 was only brought to the attention of the renewal applicant for renewal when EFSA published its revised conclusions in October 2016, well after the end of the initial 'peer review' process for FPS. However, as noted above, contrary to the applicant's contention, that 'data gap' is not based on a new data requirement arising from a new 'guidance document'. On the contrary, it is based on a scientific opinion which confines itself to summarising the most recent scientific knowledge in the field of genotoxicity and the first version of which was published before the submission of the renewal dossier.

158 In the light of the foregoing, the present part of the second plea in law must be rejected.

2. The algae risk assessment

159 As regards the algae risk assessment, the applicant submits, in essence, that the manner in which EFSA performed the algae risk assessment for FPS was, first, inconsistent, in comparison with the approach taken in the risk assessment for aquatic plants, and, secondly, manifestly flawed, in so far as EFSA departed from its own guidance document on the risk assessment for aquatic organisms and the relevant guidelines of the Organisation for Economic Cooperation and Development (OECD).

160 The applicant maintains that EFSA performed a comprehensive higher tier assessment for aquatic plants, finding safe uses, but only a Tier 1 assessment for algae, resulting inevitably in the identification of an alleged 'high risk' to algae. According to the applicant, if EFSA had followed a consistent approach for both algae and aquatic plants, in other words, reducing the value of the assessment factor and taking into account the reference value for growth rate, safe uses would have been identified also for algae.

161 In any event, according to the applicant, as soon as it became aware of EFSA's unexpected approach, the applicant for renewal conducted an additional algal study for inclusion in the species sensitive distribution that made it possible, together with the available data set, to identify safe uses for algae. Again, however, the Commission refused to consider that study, because it had been produced after the end of the peer review, in breach of the general principles of EU law relied on by the applicant.

162 The Commission disputes the applicant's arguments.

163 In the present case, it should be pointed out that, on the basis of the elements contained in the dossier and the reply provided by the Commission in that regard to the questions of the Court, a certain difference can be observed in the approach followed by EFSA in the assessment carried out in relation to algae and that carried out in relation to aquatic plants. More specifically, EFSA agreed to reduce the value of the assessment factor for aquatic plants finding safe uses, but refused to reduce the value of the assessment factor for algae resulting in the identification of a high risk. In addition, EFSA used, as observational endpoint in the algae risk assessment, the biomass, instead of the growth rate, which, according to the applicant, would have allowed it to establish safe uses in a number of relevant

environmental scenarios referred to as 'FOCUS', measuring the vulnerability of groundwater to contamination as a result of the use of an active substance, whereas it used the growth rate value for the risk assessment for aquatic plants.

164 However, it should be noted that the risk assessment for all aquatic organisms was based principally on EFSA guidance document on the risk assessment for aquatic organisms of 2002, which was the officially applicable document at the time when the renewal dossier for FPS was submitted in May 2012. By contrast, the new EFSA guidance document, namely the EFSA guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters of 5 August 2013, referred to by the applicant, is applicable to applications submitted from 1 January 2015, that is to say, after the assessment of FPS.

165 With regard to the latter document, the Commission notes that, during the transitional period for the application of that new document, case-by-case assessments were carried out and EFSA organised expert meetings whenever there was disagreement about the approach used during the observation phase of the assessments. Before 1 January 2015, applicants already provided data and risk assessments that followed some of the recommendations in that guidance document, in accordance with the scientific opinion published in 2013 that served as a basis for that guidance document.

166 According to the case-law, in order to establish that the Commission has made a manifest error in assessing complex facts such as to justify the annulment of a 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). Subject to that review of plausibility, it is not the Court's role to substitute its assessment of complex facts for that made by the institution which adopted the act (judgment of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 152).

167 First, EFSA and the experts have provided detailed technical justification for any differences between the approaches taken for algae and for aquatic plants, and the explanations provided by the Commission in that respect are sufficiently credible. The Commission explained, inter alia, that the reduction of the assessment factor for aquatic plants, combined with the use of the reference value for growth rate, was suggested as an alternative by the experts because the species *lemna gibba* had proved to be extremely more sensitive than the other species used in the test. By contrast, there was not such a great difference in sensitivity among the species used in the algae test and, consequently, the same reduction of the assessment factor could not be adopted.

168 Secondly, the evidence furnished by the applicant is insufficient to render implausible the contested regulation, which is in particular based on the assessments of EFSA. In those circumstances, it must be held that it is not the Court's role to substitute its assessment of complex facts for that made by the institution which adopted the act.

169 Furthermore, as regards the additional study provided by the applicant, which, according to the latter, made it possible, together with all the available data, to identify safe uses for algae, but which was not taken into account by the Commission, it is sufficient to note that it was submitted on 13 January 2017, that is to say, after EFSA's scientific conclusions had been finalised and almost at the end of the renewal process. In those circumstances and in the absence of provisions in Regulation No 1141/2010 allowing submission of additional data at such a late stage of the assessment, it must be held that the Commission was fully entitled to refuse to take that study into account.

170 In the light of the foregoing, the present part of the second plea in law must be rejected and, therefore, so must the second plea in law in its entirety.

D. The third plea in law, alleging that the Commission failed to carry out a complete risk assessment, in breach of a number of provisions of EU law and of the rights of defence of the applicant for renewal

171 The applicant claims that the Commission failed to make a complete risk assessment, in breach of Article 13(1) of Regulation No 1107/2009 and Article 17(1) of Regulation No 1141/2010.

172 The applicant claims that, when deciding on substance renewal, the Commission may not exclusively base its decision on EFSA's conclusions, but is under an obligation to also take into account the conclusions reached by the RMS, the comments made by the applicant for renewal and by the other Member States on the RMS' risk assessment, and any other relevant scientific evidence available to it. This includes, in particular, any further data, studies or position papers submitted by an applicant – even after the publication of the EFSA conclusion – to address specific 'data gaps' or 'concerns' which the applicant could not reasonably have foreseen at the time of dossier submission, despite its dossier being in full compliance with the prevailing data requirements and applicable guidance at the time of submission.

173 In the present case, the Commission based the contested regulation exclusively on the EFSA conclusion and failed to consider any other scientific evidence submitted by the applicant for renewal confirming the safety of FPS.

174 The applicant submits that no provision contained in Regulation No 1107/2009 prohibits the Commission from considering additional data made available after the peer review has ended. On the contrary, as confirmed by the Court of Justice, it is the Commission's duty to ensure a comprehensive risk assessment and thus, where necessary, to request and consider additional data prior to taking a decision on approval or renewal. The Commission itself recognised in previous proceedings before the EU Ombudsman that Regulation No 1107/2009 allows it to request and consider additional data during the review process.

175 According to the applicant, the mere possibility to 'comment' clearly does not suffice to ensure that a comprehensive review is conducted and that the applicant's rights of the defence are duly respected. The limitation to comments only, for example, when evaluating EFSA conclusions, does not allow the applicant to submit new studies and data that may genuinely address any concerns or data gaps.

176 The Commission disputes the applicant's arguments.

177 In that respect, it should first of all be recalled that, in accordance with settled case-law, where the institutions of the European Union have a broad power of appraisal, respect for the rights guaranteed by the legal order of the European Union in administrative procedures is of even more fundamental importance. Those guarantees include, in particular, the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case (see judgment of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 171 and the case-law cited).

178 It follows 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).

179 In the light of the factors mentioned above, it should be noted that the renewal procedure for FPS lasted from May 2012 to July 2017, that is to say more than five years.

180 First, as regards the alleged infringement of Article 13(1) of Regulation No 1107/2009 and Article 17(1) of Regulation No 1141/2010, it is sufficient to note that those provisions state (i) merely that the Commission is to draft a review report and a draft regulation taking into account the draft assessment report by the RMS and the EFSA conclusion and (ii) that the applicant for renewal is to be given the possibility to submit comments. It cannot be argued that those provisions have been infringed.

181 As regards, in particular, the RMS report, although it is true that the latter concluded that the renewal dossier was complete and supported the renewal of the approval of FPS, the fact remains that it highlighted a number of problems relating, in particular, to groundwater metabolites and risk to aquatic organisms. As regards, more specifically, the risk assessment for aquatic organisms, the RMS recommended expert discussion, as is apparent from section 3.1.8 of Volume 1 of the report.

182 With regard to the applicant for renewal being afforded the possibility to submit comments, it must be held that the Commission's handling of the procedure does not constitute a breach of the applicant's rights of defence or right to be heard.

183 According to settled case-law in that regard, respect for the rights of the defence is, in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of EU law which must be guaranteed even in the absence of any rules governing the proceedings in question. That principle requires that the addressees of decisions which significantly affect their interests be placed in a position in which they may effectively make known their views (see, to that effect, judgments of 15 June 2006, *Dokter and Others*, C-28/05, EU:C:2006:408, paragraph 74, and of 9 September 2008, *Bayer CropScience and Others* v *Commission*, T-75/06, EU:T:2008:317, paragraph 130). The right to be heard in an administrative procedure taken against a specific person is a corollary of the rights of the defence, which must be observed even in the absence of any rules governing the procedure in question (see, to that effect, judgment of 11 September 2002, *Alpharma* v *Council*, T-70/99, EU:T:2002:210, paragraph 388 and the case-law cited).

184 In the present case, it is important to note that the applicant was able to submit its comments in good time. As noted in paragraphs 4 to 33 above, it is apparent from the documents before the Court that the Commission received the applicant's comments on the RMS assessment report and on the EFSA conclusion and review report. Furthermore, the applicant was heard by the Commission at the meeting of 24 June 2015, at which the assessment of the renewal of FPS was discussed.

185 It follows that the applicant was invited to make comments and that it did make comments, both in writing and at the hearing with the Commission's services. In those circumstances, it must be held that the applicant has effectively exercised its rights of defence.

186 In the second place, as regards the applicant's argument that the Commission did not take into consideration any other scientific evidence submitted by the applicant for renewal and confirming the safety of FPS, it must be held, as observed by the Commission, that, under Article 16(4) of Regulation No 1141/2010, new data submitted without having been requested or submitted at the end of the approval process and after the peer review could not be taken into consideration by the Commission.

187 Although it is true that no provision in Regulation No 1107/2009 expressly prohibits the Commission from examining additional data submitted after the end of the peer review, it should be noted that, according to recital 14 of that regulation, 'to speed up the approval of active substances, strict deadlines should be established for the different procedural steps'. Regulation No 1107/2009 indeed provides for fairly strict time limits for each stage of the approval process. In that respect, it should be noted that Regulation No 1141/2010 adopts the same approach to structure the renewal process.

188 It must also be considered that an indefinite extension of the time limit for the evaluation of an active substance would be contrary to the objective pursued by Regulation No 1107/2009 of ensuring a high level of protection of human and animal health and the environment.

189 In those circumstances, the Commission cannot be criticised for refusing to examine additional data submitted after the end of the peer review.

190 Furthermore, it should be noted that, as stated in recital 19 of the contested regulation, the applicant may submit a new application for approval, in which any new data or scientific studies produced to address the concerns identified in the relevant renewal procedure can be submitted.

191 In the light of the foregoing circumstances, it must be concluded that the contested regulation does not infringe Article 13(1) of Regulation No 1107/2009, Article 17(1) of Regulation No 1141/2010 or the applicant's rights of defence or right to be heard. The third plea in law must therefore be rejected.

E. The fourth plea in law, alleging infringement of the principle of proportionality

192 The applicant claims that the contested regulation infringes the general principle of proportionality enshrined in Article 5(4) TEU as it is disproportionate in relation to the objective of Regulation No 1107/2009, which is to ensure that all substances in plant protection products go through a risk assessment process to ensure that only substances harmless to human or animal health can remain on the EU market.

193 First of all, the applicant insists that there is no evidence of FPS being harmful.

194 In the first place, as regards the alleged toxicity of groundwater metabolites, the applicant observes that there is at present no legal or scientific basis to presume the relevance of the three FPS metabolites (IN-JV460, IN-KC576 and IN-KY374) which are expected to exceed the concentration limit of 0.1 μg/L. Moreover, the additional studies produced by DuPont show that metabolite IN-JE127 is non-genotoxic and does not appear in groundwater in concentrations exceeding 0.1 μg/L.

195 In the second place, as regards the risk to aquatic organisms – in particular to algae and aquatic plants – according to the applicant, several available higher tier studies show that safe uses can be identified for aquatic plants by means of appropriate refinements consistent with EFSA's guidance on risk assessment for aquatic organisms and relevant OECD guidelines.

196 The applicant claims that the disproportionate nature of the contested regulation is also evident from the fact that FPS has one of the safest regulatory profiles among existing herbicide products and wishes to draw particular attention to the consequences of the contested regulation and, more precisely, to the loss that would be suffered by the applicant and also by farmers as a result of being deprived of an important substance for weed control in crops, given that EFSA has identified a number of uses for which there are presently no or insufficient alternatives to FPS-based products.

197 In any event, the applicant submits that the Commission could have chosen alternative approaches with less serious consequences instead of adopting a decision not to renew the approval of FPS.

198 The applicant would have liked to be able to avail of the confirmatory data procedure ('CDP') laid down in Article 6(f) of Regulation No 1107/2009 allowing the Commission to approve or renew the approval of a plant protection product substance subject to the requirement to submit confirmatory data in order to address outstanding 'data gaps'. The applicant disputes the Commission's assertion that the CDP can only be used to address unexpected data gaps resulting from new or amended guidelines. The CDP should also allow the submission of information that 'is considered to be confirmatory in nature, as required to increase confidence in the decision'. The applicant considers that it was appropriate to make use of the CDP to allow the demonstration of bone marrow exposure to metabolite IN-JE127 in the mouse genotoxicity study, as this new data requirement resulted from a

new scientific opinion that was not available at the time of dossier submission or to address, as necessary in light of the ECHA's decision on hazard classification, the toxicity profile of the three allegedly 'relevant' FPS metabolites.

199 In that regard, the applicant submits that the Commission has in the past renewed the approval of many substances despite there being many more metabolites of concern. For example, thifensulfuron-methyl (AIR-2) was renewed with no less than six metabolites of concern. Furthermore, none of the three main soil metabolites of FPS was detected in groundwater in a comprehensive pesticide monitoring programme carried out in Denmark from 2013 to 2016.

200 As for the metabolite IN-JE127, the Commission itself admits in the revised Review Report on FPS that human exposure to this metabolite is expected to be 'very low'.

201 According to the applicant, the 'two classifications suggested (C2 and R2)' are similarly incapable of differentiating the case of FPS from that of other substances as far as the use of the CDP is concerned. The applicant claims that the Commission frequently uses the CDP to request confirmatory data on metabolites, including in cases where the parent substance is proposed to be classified for certain hazards by EFSA. In the case of FPS, the Commission moreover stated that the ECHA should be mandated to review the additional toxicity studies produced by the applicant for renewal.

202 The applicant states that the use of the CDP was also strongly advocated by several Member States.

203 Lastly, even on the assumption that there is an actual risk for aquatic plants, the applicant disputes the 'high risk for all uses' and considers that ecotoxicology concerns are best managed at Member State level at the time of the evaluation of the plant protection products, since the Member States may decide on specific restrictions which may be less restrictive than an outright ban on the use of FPS, such as no-spray buffer zones around aquatic areas. In that regard, the applicant highlights that that view is shared by the RMS, which expressly suggested that the additional higher tier studies submitted by DuPont after the publication of the renewal assessment report (including the algae recovery study), which were not taken into account in the risk assessment, 'may be further considered at the Member State level'.

204 The Commission disputes the applicant's arguments.

205 In the present case, it should be noted, first of all, that the arguments concerning the alleged lack of evidence of FPS being harmful and the obligation on EFSA and the Commission to take into account the new studies provided by the applicant for renewal have already been rejected in the context of the second and third pleas in law and, consequently, are not dealt with in the present plea alleging infringement of the principle of proportionality.

206 Next, it should be recalled that, according to settled case-law, the principle of proportionality, which is one of the general principles of European Union law, requires that measures adopted by the institutions must not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question; where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (judgments of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 411, and of 7 March 2013, *Acino* v *Commission*, T-539/10, not published, EU:T:2013:110, paragraph 85; see also, to that effect, judgment of 18 November 1987, *Maizena and Others*, 137/85, EU:C:1987:493, paragraph 15).

207 Nevertheless, it should be noted that, 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

conferred on it by Articles 40 to 43 TFEU in that field. In the present case, the contested regulation is based on Regulation No 1107/2009 the legal basis of which is, inter alia, Articles 43 and 114 TFEU. 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).

208 The applicant claims that the Commission could have chosen alternative approaches with less serious consequences, such as making use of the CDP, rather than adopting a decision not to renew the approval of FPS.

209 In that respect, it should be noted that Article 6(f) of Regulation No 1107/2009 does indeed provide that approval may be subject to conditions and restrictions such as the submission of further confirmatory information to Member States, the Commission and EFSA, where new requirements are established during the assessment process or as a result of new scientific and technical knowledge. Point 2.2 of Annex II to Regulation No 1107/2009 provides for the possibility, in exceptional cases, that approval of the active substance may be granted even though certain information has not yet been submitted 'where the data requirements have been amended or refined after the submission of the dossier' or 'where the information is considered to be confirmatory in nature, as required to increase confidence in the decision'.

210 Under those provisions, it is not possible to make use of the CDP where the data should have been included in the renewal dossier at the time it was submitted and where adequate guidance is available to perform the assessment required. Those provisions may not be used to fill data gaps detected during the approval process. Furthermore, those provisions do not allow for the approval of active substances for which the absence of harmful effect on human or animal health or the absence of unacceptable effects on the environment or on groundwater have not been demonstrated.

211 In the first place, as regards the risk to groundwater, it has already been noted in the context of the examination of the first plea that, in view of the effects observed in the studies carried out on FPS, where certain properties related to carcinogenicity and toxicity for reproduction raised concerns, the Commission, in accordance with the precautionary principle and in its capacity as risk manager, considered, without committing a manifest error of assessment, that the presence of the three FPS metabolites (IN-JV460, IN-KC576 and IN-KY374) in groundwater was a cause of concern.

212 In the second place, as regards the risk to aquatic organisms, experts from EFSA and the Member States, after examining all the available data and possible refinement of the risk assessment, concluded that the risk was high. Section 9.2 of the EFSA conclusion states:

'A high risk is identified for aquatic organisms using biomass based endpoint in nine out of nine scenarios at FOCUS step 3 from exposure to [FPS] salts for all representative uses (the risk assessment was driven by algae). No suitable refinements are currently available.'

213 Moreover, as regards the applicant's argument that it would be preferable to address ecotoxicology concerns at Member State level at the time of the evaluation of the plant protection products, since the Member States may decide on specific restrictions, it must be found, as observed by the Commission, that that solution would be acceptable in cases where there is at least some concrete information to show that there is at least one safe scenario for one representative use, taking into account possible mitigation measures. However, such a solution is not conceivable in a case such as the present one, where a high risk is concluded for all uses, taking into account the outcome of a comprehensive assessment carried out by experts.

214 Accordingly, the Commission was right not to make use of the CDP.

215 In those circumstances, having regard to the broad discretion which the Commission must be recognised as enjoying in order to be able to pursue effectively the objective assigned to it by Regulation No 1107/2009 and taking account of the complex technical assessments which it must undertake, it must be held that the contested regulation does not appear manifestly disproportionate as regards the risk to groundwater and as regards the risk to aquatic organisms.

216 The fourth plea in law must therefore be rejected.

F. The fifth plea in law, alleging infringement of the principle of non-discrimination

217 The applicant submits that the contested regulation infringes the principle of non-discrimination since the Commission dealt with similar cases differently. According to the applicant, the Commission failed to follow a consistent approach and to regulate FPS in the same way as other plant protection product substances with regard to, first, the genotoxicity assessment of plant protection product substances and their metabolites, second, the issue of groundwater contamination by plant protection product substances and their metabolites and, third, the management of ecotoxicology issues.

218 In particular, the applicant claims that, in relation to genotoxicity, the Commission refrained from taking any decision on the approval or renewal of substances for which only genotoxicity concerns were identified, pending EFSA's review of its approach to the genotoxicity assessment and, moreover, the CDP was used in other cases and could also have been used for the metabolite IN-JE127, but it was not. Furthermore, in relation to groundwater contamination, the applicant claims that the Commission approved substances the concentrations of which were expected to exceed 0.1 μg/L, but did not approve FPS. In relation to the risk to aquatic plants, the applicant submits that the Commission has approved substances presenting a high risk to aquatic organisms. According to the applicant, virtually all AIR-2 renewal decisions adopted by the Commission to this date included a requirement for EU Member States to perform an aquatic risk assessment.

219 The Commission disputes the applicant's arguments.

220 In that regard, it should be recalled that point 6.3.2 of the Communication from the Commission on the precautionary principle of 2 February 2000, entitled 'Non-discrimination', reads as follows:

'The principle of non-discrimination means that comparable situations should not be treated differently and that different situations should not be treated in the same way, unless there are objective grounds for doing so.

Measures taken under the precautionary principle should be designed to achieve an equivalent level of protection without invoking the geographical origin or the nature of the production process to apply different treatments in an arbitrary manner.

Measures should not be discriminatory in their application.'

221 In the present case, first of all, it must be found that the applicant has not succeeded in establishing that the Commission suspended the adoption of any decision concerning the approval or renewal of substances for which only genotoxicity concerns have been identified. The minutes of the meeting of the Standing Committee on Plants, Animals, Food and Feed of 6 and 7 October 2016 concerning the active substance picoxystrobin, cited by the applicant, in no way confirm that that is the case.

222 As regards the argument that the Commission treated comparable situations differently, it must be found that the applicant has not succeeded in establishing that the cases it mentions may be regarded as comparable to FPS. It must be noted, as is apparent from the Commission's reply to the questions put by the Court, that the characteristics identified in the scientific review process for the other

substances mentioned are, in all cases, at least partially different from FPS. It should be noted, for example, that, unlike the other substances mentioned, a high risk for algae in all scenarios and for all uses was identified for FPS.

223 In addition, it must be held that, having regard in particular to the specific nature of each review procedure, which makes comparisons extremely difficult, and also to the Commission's discretion as to how it conducts investigations of such a technical and complex nature, the applicant has failed to establish that the differences in the manner in which the evaluation procedures subject to comparison took place were not objectively justified (see, to that effect, judgment of 19 January 2012, *Xeda International and Pace International* v *Commission*, T-71/10, not published, EU:T:2012:18, paragraph 139 and the case-law cited).

224 Consequently, the active substances referred to by the applicant are not comparable to the evaluation of FPS, even though the concerns raised display similarities with the present procedure.

225 Lastly, as regards the argument that the CDP was used in other cases and could also have been used for the metabolite IN-JE127, it is sufficient to note, as was pointed out in paragraphs 208 to 214 above, that the Commission was right not to use the CDP in the case of FPS. It is not possible, in accordance with the applicable provisions, to use that procedure where the data must be included in the renewal dossier at the time of its submission and where adequate guidance is available to perform the required assessment. Furthermore, those provisions do not allow for the approval of active substances for which the absence of harmful effect on human or animal health or the absence of unacceptable effects on the environment or on groundwater have not been demonstrated.

226 In the light of all of the foregoing, the fifth plea must be rejected.

G. The sixth plea in law, alleging infringement of the principles of sound administration and of the protection of legitimate expectations

227 The applicant submits that the Commission infringed the general duty of sound administration, which obliges it to guarantee that the review and the decision-making process are carried out in a transparent manner and according to the applicable provisions.

228 According to the applicant, the Commission initially took the view that FPS fell under the interim endocrine disrupting criteria and invited DuPont to apply immediately for a possible approval by derogation under Article 4(7) and point 3.6.5 of Annex II to Regulation No 1107/2009. However, the Commission reversed its stance in the second draft review report and decided that, in the case of FPS, the interim endocrine disrupting criteria could not be applied.

229 According to the applicant, that circumstance led DuPont to invest significant time and resources in the preparation of two derogation dossiers which eventually proved entirely useless because of the Commission's abrupt change of course.

230 If, indeed, the Commission considered that the two other concerns identified in the March 2015 Review Report were sufficient as grounds for a non-renewal decision, it could have simply relied on those concerns, without referring to the interim endocrine disrupting criteria, and would not have stated that the substance could be approved by derogation.

231 The Commission's change of course had significant implications since the applicant for renewal was effectively denied the possibility of approval by derogation. That conduct amounted to an infringement of the principle of sound administration and of the protection of legitimate expectations

of the applicant for renewal, as conveyed by the Commission, that it would be able to secure, at least, a limited form of approval on the basis of the derogations to the interim endocrine disrupting criteria set out in Regulation No 1107/2009.

232 The applicant also claims that FPS forms part of the divestment which the Commission itself imposed in the context of the Dow/DuPont merger to create an effective competitor to Dow/DuPont in the European Economic Area (EEA) market for broadleaf cereal herbicides. By adopting the contested regulation withdrawing FPS from the market, the Commission was therefore effectively undermining the competition policy objectives underlying the divestment which it itself imposed on Dow/DuPont. Indeed, the contested regulation would remove FMC as an effective competitor to Dow/DuPont, therefore reinforcing Dow/DuPont's dominance in the EEA market for broadleaf cereal herbicides to the detriment of Dow/DuPont's competitors and EU farmers. That is precisely the situation which the Commission intended to avoid when it required DuPont to divest FPS to FMC. According to the applicant, that inconsistency in the Commission's policy also amounts to an infringement of the principle of sound administration.

233 The Commission disputes the applicant's arguments.

234 In that regard, it should be noted that, according to the case-law relating to the principle of sound administration, where the EU institutions have a broad discretion, respect for the safeguards established by the EU legal order in administrative procedures is of even more fundamental importance. Those guarantees include, in particular, the duty of care, that is, the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case (judgments of 21 November 1991, *Technische Universität München*, C-269/90, EU:C:1991:438, paragraph 14; of 27 September 2012, *Applied Microengineering* v *Commission*, T-387/09, EU:T:2012:501, paragraph 76; and of 16 September 2013, *ATC and Others* v *Commission*, T-333/10, EU:T:2013:451, paragraph 84).

235 It has also been held that, in order for a breach of the duty of care to constitute a manifest and grave disregard of the limits on the discretion enjoyed by an institution, there must have been a complete failure to satisfy the duty of care, a simple failure to appreciate properly the extent of the obligations arising from that duty not sufficing (judgment of 23 September 2015, *Hüpeden* v *Council and Commission*, T-206/14, not published, EU:T:2015:672, paragraph 48).

236 In the present case, it should be recalled that, on the basis of the EFSA conclusion, the Commission published a draft review report on FPS on 18 March 2015, in which it proposed to withdraw the approval of FPS. The Commission proposal was based on three key concerns, namely:

– the interim endocrine disrupting criteria, which were considered to be fulfilled on the basis of the EFSA classification proposal for FPS as a category 2 carcinogen and as a reproductive toxicant category 2;

– the risk of groundwater exposure, above the maximum concentration limit of 0.1 μg/L, to three FPS metabolites (IN-JV460, IN-KC576 and IN-KY374);

– a risk to aquatic organisms.

237 On the same day, the Commission informed DuPont that internal discussions were still ongoing regarding the use of the EFSA classification proposals in regulatory decision-making, especially with regard to the interim endocrine disrupting criteria, so that the review report might have to be revised depending on the outcome of those discussions.

238 Some time after the publication of the draft review report on FPS, the Commission invited DuPont, by email of 29 May 2015, based on the finding that FPS met the interim endocrine disrupting criteria, to submit considerations for possible approval by derogation according to the provisions of Article 4(7) and point 3.6.5 of Annex II to Regulation No 1107/2009.

239 On 26 June and 13 July 2015, DuPont submitted two additional derogation dossiers evidencing the agricultural indispensability of FPS as well as the negligible exposure to FPS of all categories of users of FPS-based products. In January 2016, the European Commission mandated EFSA to review the two derogation dossiers submitted by DuPont.

240 On 3 October 2016, EFSA resumed its evaluation of the main renewal dossier and delivered a revised version of its conclusion.

241 Following the publication of the revised EFSA conclusion, the Commission issued a revised version of its draft review report on 22 December 2016, in which it maintained its proposal to withdraw the approval of FPS. However, the Commission revised the statement of reasons supporting the proposed non-renewal, no longer stating that the interim endocrine disrupting criteria should be applied.

242 In the light of those circumstances, it must be found that the applicant has not succeeded in establishing that the Commission did not examine carefully and impartially, in a fair manner and within a reasonable time, the aspects concerning the interim endocrine disrupting criteria. On the contrary, the Commission, first, identified the interim endocrine disrupting criteria as a concern and, secondly, stated that internal discussions were still ongoing within the Commission and that the review report might be revised depending on the outcome of those discussions. In addition, after a more detailed examination of the dossier, the Commission decided to present a revised version of its draft review report, in which, while maintaining its proposal to withdraw the approval of FPS, it declined to apply the interim endocrine disrupting criteria.

243 Moreover, it was at the applicant's own request that the Commission amended the draft review report and, in that context, that the Commission reached the conclusion that its proposal to withdraw the approval of FPS remained valid for some of the reasons initially put forward.

244 In those circumstances, the applicant's argument that the Commission infringed the principle of sound administration as regards the interim endocrine disrupting criteria, must, in any event, be rejected.

245 As regards the alleged violation of the principle of the protection of legitimate expectations, it has consistently been held that any individual whom an institution of the European Union has led to entertain legitimate expectations by giving him or her precise assurances may rely on that principle (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).

246 In that regard, it is sufficient to note that the applicant does not refer to any assurance given to it by the Commission that it had obtained a limited form of approval on the basis of the derogations to the interim endocrine disrupting criteria set out in Regulation No 1107/2009. In those circumstances, the complaint alleging infringement of the principle of the protection of legitimate expectations must be rejected.

247 Furthermore, as regards the applicant's claim that the contested regulation is incompatible with EU competition law, suffice it to note, as observed by the Commission, that the contested regulation does not take account of the competitive positions of actual or potential producers of plant protection products containing FPS. The effect of the contested regulation is to remove plant protection products containing FPS from the EU market, not to change the competitive positions of undertakings on it.

248 Therefore, the Commission did not gravely and manifestly disregard the limits of its discretion having regard to the principle of sound administration concerning the duty of care.

249 In the light of the foregoing, the sixth plea in law must be rejected and the action must be dismissed in its entirety.

V. Costs

250 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 applicant has been unsuccessful, it must be ordered to bear its own costs and pay those of the Commission, in accordance with the form of order sought by the Commission, including the costs relating to the substitution procedure and the proceedings for interim measures.

On those grounds,

THE GENERAL COURT (Fifth Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders FMC Corporation to bear its own costs and to pay the costs incurred by the European Commission, including those relating to the substitution procedure and the proceedings for interim measures.**

Spielmann Spineanu-Matei Mastroianni

Delivered in open court in Luxembourg on 17 March 2021.

E. Coulon
Registrar

M. van der Woude
President

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