Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fourth Chamber)

19 September 2019*

(Plant protection products — Active substance diflubenzuron — Review of approval — Article 21 of Regulation (EC) No 1107/2009 — Rights of the defence — *Ultra vires* — Manifest error of assessment — Procedure for renewal of approval — Article 14 of Regulation No 1107/2009 — Imposition, in the context of the review procedure, of additional restrictions limiting the use of the active substance at issue without waiting for the outcome of the renewal procedure — Proportionality)

In Case T-476/17,

Arysta LifeScience Netherlands BV, established in Amsterdam (Netherlands), represented by C. Mereu and M. Grunchard, lawyers,

applicant,

v

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

defendant,

APPLICATION under Article 263 TFEU for annulment of Commission Implementing Regulation (EU) 2017/855 of 18 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance diflubenzuron (OJ 2017 L 128, p. 10),

THE GENERAL COURT (Fourth Chamber),

composed of H. Kanninen, President, L. Calvo-Sotelo Ibáñez-Martín and I. Reine (Rapporteur), Judges,

Registrar: P. Cullen, Administrator,

having regard to the written part of the procedure and further to the hearing on 12 February 2019,

gives the following

* Language of the case: English.

Judgment

Legal framework

Directive 91/414/EEC

1 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) lays down the EU rules governing authorisation for the placing of these products on the market. It contains provisions applicable to plant protection products and to the active substances in those products.

2 Under Article 4 of Directive 91/414, governing the granting, review and withdrawal of authorisations of plant protection products, a plant protection product must fulfil certain criteria in order to be approved. In particular, a plant protection product is not authorised unless its active substances are listed in Annex I to that directive and any conditions laid down in that annex are satisfied. Articles 5 and 6 of Directive 91/414 lay down the procedure for the inclusion of an active substance in Annex I.

3 Directive 91/414 was repealed by Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Directives 79/117/EEC and 91/414 (OJ 2009 L 309, p. 1), with effect from 14 June 2011.

4 In accordance with the transitional measures laid down in Article 80(1)(a) of Regulation No 1107/2009, Directive 91/414 was to continue to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision had been adopted in accordance with Article 6(3) of that directive before 14 June 2011.

Regulation (EC) No 1490/2002

5 Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414 and amending Regulation (EC) No 451/2000 (OJ 2002 L 224, p. 23) concerns the continued evaluation of active substances.

6 Articles 10 to 13 of Regulation No 1490/2002 define the procedure for evaluating active substances. In that regard, a rapporteur Member State designated for each substance conducts an evaluation and draws up a report in which it makes a recommendation to the European Commission either to include the active substance in Annex I to Directive 91/414 or not to include it. The rapporteur Member State sends a draft assessment report to the European Food Safety Authority (EFSA). Once it has received the draft assessment report sent to it by the rapporteur Member State, EFSA circulates it to the Member States. EFSA evaluates the draft report and delivers its opinion to the Commission on whether the active substance can be expected to meet the safety requirements of Directive 91/414. After receipt of that opinion, the Commission submits a draft review report to the Standing Committee on the Food Chain and Animal Health established by Article 58 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1).

7 Article 11b of Regulation No 1490/2002 provides for the evaluation procedure for active substances with clear indications that they do not have any harmful effects.

Regulation No 1107/2009

8 According to recital 3 thereof, Regulation No 1107/2009 repealed and replaced Directive 91/414 with effect from 14 June 2011, in the light of the experience gained from the application of that directive and of recent scientific and technical developments.

9 According to Article 1(3) thereof, the purpose of Regulation No 1107/2009 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.

10 Article 4 of that regulation lays down approval criteria for active substances in plant protection products.

11 Under Article 5 of Regulation No 1107/2009, first approval is to be for a period not exceeding 10 years.

12 Articles 7 to 13 of Regulation No 1107/2009 set out the approval procedure for active substances. First of all, an application for the approval of an active substance or for an amendment to the conditions of an approval must be submitted by the producer of the active substance to a Member State, referred to as 'the rapporteur Member State'. It must be demonstrated that the active substance fulfils the approval criteria provided for in Article 4 (Article 7). Next, the rapporteur Member State prepares and submits to the Commission, with a copy to EFSA, a report, referred to as the 'draft assessment report', assessing whether the active substance can be expected to meet the approval criteria provided for in Article 4 (Article 11). Having received the draft assessment report from the rapporteur Member State, EFSA circulates it to the applicant and the other Member States. After the expiry of the period for the submission of written comments, EFSA adopts a conclusion in the light of current scientific and technical knowledge using guidance documents available at the time of application on whether the active substance can be expected to meet the approval criteria provided for in Article 4. It communicates its conclusion to the applicant, the Member States and the Commission and makes it available to the public (Article 12). Lastly, after receiving the conclusion from EFSA, the Commission presents a report, referred to as 'the review report', and a draft regulation to the Standing Committee on the Food Chain and Animal Health, taking into account the draft assessment report by the rapporteur Member State and the conclusion of EFSA. The applicant must be given the possibility to submit comments on the review report (Article 13).

13 Articles 14 to 20 of Regulation No 1107/2009 concern the renewal of approval of active substances. The approval of an active substance is renewed on application by a producer of the active substance to a Member State no later than three years before the expiry of the approval where it is established that the approval criteria provided for in Article 4 are satisfied (Article 14(1) and Article 15(1)). When applying for renewal of approval, the applicant must identify new data he intends to submit and demonstrate that they are necessary, because of data requirements or criteria which were not applicable at the time of the last approval of the active substance or because his request is for an amended approval (Article 15(2)). At the same time the applicant must submit a timetable of any new and ongoing studies (Article 15(2)). A regulation is to be adopted in accordance with the regulatory procedure referred to in Article 79(3) of Regulation No 1107/2009, providing that the approval of an active substance is renewed, subject to conditions and restrictions where appropriate, or that the approval of an active substance is not renewed (Article 20(1)).

14 Article 21 of Regulation No 1107/2009 concerns the review of approval of an active substance. Under that article, the Commission may review the approval of an active substance at any time. It must take into account the request of a Member State to review, in the light of new scientific and technical knowledge and monitoring data, the approval of an active substance. Where, in the light of new scientific and technical knowledge, the Commission considers that there are indications that the substance no longer satisfies the approval criteria provided for in Article 4, or further information

required has not been provided, it must inform the Member States, EFSA and the producer of the active substance, setting a period for the producer to submit its comments. In that review procedure the Commission may ask the Member States and EFSA for an opinion and EFSA is required to provide its opinion or the results of its work to the Commission. Where the Commission concludes that an active substance no longer fulfils the approval criteria provided for in Article 4, a regulation to withdraw or amend the approval must be adopted in accordance with the regulatory procedure referred to in Article 79(3) of Regulation No 1107/2009.

Background to the dispute

15 The applicant, Arysta LifeScience Netherlands BV, is a company that develops, produces and sells agrochemical and specialty chemicals. Under the system provided for in Directive 91/414, it notified the active substance diflubenzuron, an insecticide used on pome fruit, citrus, cotton, mushrooms, ornamentals, forestry trees and in programmes to control mosquito larvae and gypsy moth populations.

Diflubenzuron approval procedure

16 By Directive 2008/69/EC of 1 July 2008 amending Directive 91/414 to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances (OJ 2008 L 172, p. 9), the Commission included the active substance diflubenzuron in Annex I to Directive 91/414 in accordance with the evaluation procedure provided for in Article 11b of Regulation No 1490/2002. According to the annex to Directive 2008/69, the approval of diflubenzuron was valid until 31 December 2018.

17 According to recital 5 of Directive 2008/69:

‘It has appeared from the various examinations made that plant protection products containing the active substances listed in the Annex to this Directive may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive [91/414], in particular with regard to the uses which have been examined and detailed in the Commission review report. It is therefore appropriate to include in Annex I to that Directive the active substances listed in the Annex to this Directive, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.’

18 On 22 June 2010, the Commission adopted Directive 2010/39/EU amending Annex I to Directive 91/414 as regards the specific provisions relating to the active substances clofentezine, diflubenzuron, lenacil, oxadiazon, picloram and pyriproxyfen (OJ 2010 L 156, p. 7). It is apparent from that directive that, on 16 July 2009, EFSA presented to the Commission the conclusions on the peer review for diflubenzuron, in accordance with Article 12a of Regulation No 1490/2002. Those conclusions were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 11 May 2010 in the format of the Commission review reports for diflubenzuron, among other substances. According to those conclusions, products containing diflubenzuron satisfied, in general, the requirements provided for in Article 5(1)(a) and (b) of Directive 91/414.

19 However, according to recital 5 of Directive 2010/39, it was appropriate to obtain further information on certain specific points as regards diflubenzuron, among other substances. According to recital 6 of that directive, the notifier, namely the applicant, was required to submit ‘confirmatory’ data in respect of the potential toxicological relevance of the impurity and metabolite 4-chloroaniline (‘PCA’).

20 The applicant submitted that information in June 2011. Those data were evaluated by the rapporteur Member State, in this case the Kingdom of Sweden, in the form of a draft assessment report. On 20 December 2011 the rapporteur Member State circulated that draft report for comments to the applicant, the other Member States and EFSA.

21 Following consideration of the comments received, the Commission consulted EFSA, asking it to deliver its conclusions on the risk from exposure to the metabolite via intake of, or exposure to, diflubenzuron for consumers, residents or bystanders and workers. Given the genotoxic properties of PCA identified on the basis of the confirmatory information, and given the carcinogenic properties of PCA and the absence of a threshold for acceptable exposure, EFSA identified, for the first time, a concern regarding potential exposure to PCA as a residue. Those conclusions were published in the *EFSA Journal* ((2012); 10(9): 2870) on 7 September 2012.

22 On 16 July 2013, the Standing Committee on the Food Chain and Animal Health produced a revised review report for diflubenzuron.

Diflubenzuron review procedure

23 On 18 July 2013, the Commission formally informed the applicant that approval of diflubenzuron was being reviewed in line with Article 21 of Regulation No 1107/2009. The Commission considered that, in the light of new scientific and technical knowledge, there were indications that the approval of the active substance diflubenzuron no longer fulfilled the approval criteria provided for in Article 4 of Regulation No 1107/2009 with respect to its potential harmful effect on human health through exposure to PCA as a residue. It invited the applicant to submit information as regards the potential exposure to PCA as a residue and, if exposure was confirmed, consideration of the potential toxicological relevance.

24 On 14 January 2014, the applicant submitted that information to the rapporteur Member State for diflubenzuron, namely the Kingdom of Sweden. On 23 July 2014, the rapporteur Member State released a draft report evaluating the updated data, in which it concluded that the potential exposure of consumers, workers and residents or bystanders to PCA from the representative use of diflubenzuron in pome fruits did not pose a risk ('the July 2014 draft report'). However, the rapporteur Member State considered it desirable to improve the sensitivity of the analytical methods in products of animal origin, especially milk and bovine animal products, in order to analyse residues of PCA at lower concentrations. On 23 July 2014, the rapporteur Member State submitted the results of its assessment, in the form of an addendum to the draft assessment report, to the other Member States, the Commission and EFSA. The applicant was also given an opportunity to comment on the July 2014 draft report.

25 Following the commenting period, the rapporteur Member State supplemented the July 2014 draft report with two addenda reports. In the first addendum, issued in November 2014 ('the November 2014 addendum'), the rapporteur Member State considered, in essence, that the potential exposure of workers and residents or bystanders to PCA from the representative use of diflubenzuron in pome fruits did not pose a risk. By contrast, as regards consumers, the rapporteur Member State concluded that the risk '[could] not be sufficiently evaluated', inter alia because there was no validated method to measure residues of PCA in ruminants, namely goats.

26 Following consideration of the comments received during the commenting period, the Commission consulted EFSA on the data submitted by the applicant as well as the assessment of those data by the rapporteur Member State regarding the potential exposure to PCA (4-chloroaniline, the impurity and metabolite of diflubenzuron) as a residue and consideration of the potential toxicological relevance. The Commission asked EFSA to provide its conclusions by the deadline of 28 August 2015.

27 In the second addendum report, released in July 2015 following two meetings in May and June 2015 ('the July 2015 addendum'), the rapporteur Member State found that 'it [could not] be concluded that the estimated exposure of PCA [was] of low concern for consumers'. It considered that before drawing conclusions on consumer safety it was necessary to examine residues of PCA in ruminants with an appropriate study design, according to valid guidelines. According to the rapporteur Member State's final conclusion, 'exposure to PCA should be considered a priori … a concern since a threshold for a genotoxic carcinogen cannot be assumed'.

28 On 19 August 2015, the applicant submitted a scientific paper to EFSA. By letter of 24 August 2015 EFSA informed the applicant that no further commenting by the notifier, in this case the applicant, was foreseen during the procedure in question before it. Furthermore, in the same letter EFSA drew attention to the fact that the Commission would invite the applicant to make comments on the EFSA conclusion at a later stage.

29 In its conclusions of 27 August 2015, made public on 11 December 2015, EFSA considered that 'potential exposure to PCA as a residue (i.e. either for consumers or for workers and bystanders [or residents or both]) should be considered a priori … a concern since a threshold for a genotoxic carcinogen cannot be assumed' ('EFSA's 2015 conclusions'). The same document also stated as follows:

'An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not [enable it to be concluded] that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.'

30 On 9 September 2015, the Commission invited the applicant to submit its comments on EFSA's 2015 conclusions before 7 October 2015. The applicant replied within that time frame.

31 On 9 October 2015, the applicant asked the Commission to invite EFSA to review its comments and data submitted on 20 August and 7 October 2015 and to confirm that EFSA's conclusion would not be finalised until those comments had been reviewed. The Commission replied on 21 October 2015 and denied that request, stating that the applicant had had sufficient opportunity to provide comments, which had been considered in the review carried out by EFSA and by the Commission and the Member States. The Commission also stated that, according to the general procedure for submitting comments in the context of the procedure for reviewing the approval of an active substance, the applicant could submit comments only on the assessment made by the rapporteur Member State.

32 On 20 September 2016, the Commission communicated the draft review report to the applicant and invited it to submit its comments, which the applicant did by its email of 29 September 2016. In its draft review report the Commission proposed maintaining the approval of diflubenzuron but restricting it to use on non-edible crops only ('the draft review report'). The applicant disagreed with this restriction and recommended waiting or maintaining the current approval of diflubenzuron until the finalisation of the full re-evaluation of diflubenzuron within the renewal process which it had initiated on an unspecified date before December 2015. It also informed the Commission that a further study to clarify the genotoxicity of PCA would be available shortly and would be submitted to the rapporteur Member State for the renewal procedure for diflubenzuron.

33 On 11 November 2016, the applicant sent an email to the Commission criticising its approach to the evaluation of genotoxicity and carcinogenicity adopted by EFSA. The applicant underlined the issues identified by the European Crop Protection Association (ECPA) as regards that evaluation and referred to the Commission's intention to give a new mandate to EFSA to re-evaluate its approach to evaluating genotoxicity and carcinogenicity of active substances, impurity and metabolites.

34 On 8 December 2016, the Commission replied to the applicant's emails of 29 September and 11 November 2016. It informed the applicant, inter alia, that its comments on the draft review report had been made available to all Member States and that the Commission's services had analysed those comments in detail. The Commission then replied to the key points raised by the applicant.

35 On 8 March 2017, the applicant sent an email to the Commission informing it of the completion of the transgenic rodent toxicity study for PCA, called 'In Vivo Mutation Assay at the cII Locus in Big Blue® Transgenic F344 Rats and Micronuclei Analysis in Peripheral Blood' dated 28 February 2017 ('the TGR study'), and of its submission to the rapporteur Member State for the renewal procedure for diflubenzuron, attaching to that email a summary of the study. The applicant stated in particular that the results of the TGR study had confirmed that PCA was not acting via a genotoxic mode of action, which meant that EFSA's conclusion in the review procedure was not scientifically justified. In the same email, accepting that it was not possible to examine the TGR study as part of the review procedure due to the advanced stage of that procedure, the applicant asked the Commission to wait for the outcome of the review of the complete data package by the rapporteur Member State for the renewal procedure before taking any decision on diflubenzuron.

36 The Commission replied by email of 10 March 2017 stating that the summary of the TGR study would be made available to all Member States. It considered, inter alia, that the communication of the data provided by the applicant as part of the renewal procedure should not delay decision making in the context of the review under Article 21 of Regulation No 1107/2009.

37 On 20 March 2017, the applicant reiterated its request to postpone the discussion on diflubenzuron until finalisation of the review in the renewal procedure. The Commission refused that request on 3 May 2017. In particular, the Commission stated that it was in the interest of consumer safety that it had decided to act then and not to wait for a decision on the basis of the assessment of TGR study in the renewal procedure.

38 On 23 March 2017, the Standing Committee on Plants, Animals, Food and Feed gave a favourable opinion on the draft review report for diflubenzuron.

39 On 18 May 2017, the Commission adopted Implementing Regulation (EU) 2017/855 of 18 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance diflubenzuron (OJ 2017 L 128, p. 10; 'the contested regulation'). In that regulation it concluded that exposure of consumers to PCA could not be excluded except by imposing further restrictions and that the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 as regards the list of approved active substances (OJ 2011 L 153 p. 1) should be amended accordingly to restrict use of diflubenzuron to non-edible crops.

Diflubenzuron renewal procedure

40 On an unspecified date before December 2015, the applicant submitted an application for renewal of the approval of diflubenzuron before the December 2015 deadline, in accordance with Article 15 of Regulation No 1107/2009.

41 The rapporteur Member State appointed for the review of diflubenzuron was Greece.

42 On 29 July 2016, Greece declared the dossier of diflubenzuron admissible, in accordance with Article 8(1) of Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation No 1107/2009 (OJ 2012 L 252, p. 26). That dossier included the TGR study. The conclusion of that study is as follows:

'The results of the [TGR] study discussed in this document provide reliable and robust evidence that PCA is not a genotoxic carcinogen and that tumourigenicity is a consequence of chronic haematotoxicity with clear NOAEL [no observed adverse effect level] (0.5 mg/kg bw/day). The Big Blue® mutant frequency data provided in this report also ameliorate any concerns regarding positive results previously reported in both the Salmonella and mammalian cell mutation assays and demonstrate that sequence mutations are not a factor in the carcinogenicity of either PCA or aniline.'

43 It is apparent from the minutes of the meeting of 19 January 2017 between the applicant and the Greek authorities that the latter had confirmed that completion of the renewal assessment report was planned for October 2017. Later, at an unspecified date, the Greek authorities informed the Commission that the report would be ready in January 2018. At the time it drafted its defence the Commission considered that the approval period of diflubenzuron in the context of the renewal procedure was likely to be extended by at least six months, that is to say until 30 June 2019. Nevertheless, in its response to a question asked by the Court by way of measures of organisation of procedure, the Commission noted that the draft report had been submitted by Greece only on 20 March 2018, so that approval of the active substance diflubenzuron was extended until 31 December 2019 for reasons beyond the control of the applicant, in accordance with Commission Implementing Regulation (EU) 2018/1796 of 20 November 2018 amending Implementing Regulation No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorpyrifos, chlorpyrifos-methyl, clofentezine, dicamba, difenoconazole, diflubenzuron, diflufenican, dimoxystrobin, fenoxaprop-p, fenpropidin, lenacil, mancozeb, mecoprop-p, metiram, nicosulfuron, oxamyl, picloram, pyraclostrobin, pyriproxyfen and tritosulfuron (OJ 2018 L 294, p. 15).

Procedure and forms of order sought

44 By application lodged at the Court Registry on 27 July 2017, the applicant brought the present action.

45 By separate document lodged at the Court Registry on 4 September 2017, the applicant brought an application for interim measures seeking suspension of the operation of the contested regulation.

46 By order of 22 June 2018, *Arysta LifeScience Netherlands* v *Commission* (T-476/17 R, EU:T:2018:407), the President of the General Court dismissed the application for interim measures and reserved the costs.

47 On a proposal from the Judge-Rapporteur, the Court (Fourth Chamber) decided to open the oral part of the procedure and, by way of measures of organisation of procedure, as provided for in Article 89 of its Rules of Procedure, put questions to the parties. The parties replied within the prescribed period.

48 The parties presented oral arguments and answered the questions put to them by the Court at the hearing on 12 February 2019.

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.

Law

51 In support of its action the applicant relies, in essence, on four pleas in law, alleging, first, a manifest error of assessment, second, *ultra vires*, third, infringement of the rights of the defence and failure to observe the principle of good administration, and fourth, failure to observe the principle of proportionality.

The alleged new pleas

52 During the hearing the Commission stated that the applicant had appeared to raise, during the course of the hearing, two new pleas — the first being the insufficient scientific basis for initiating the diflubenzuron review procedure in accordance with Article 21 of Regulation No 1107/2009 and the second being failure to observe the precautionary principle. According to the Commission, those pleas should be declared inadmissible.

53 Upon invitation to reply to the Commission's claims, the applicant stated, first, that it did not challenge the reasons for the Commission having initiated the review procedure in question, but rather the way in which the procedure had been conducted. Second, as regards the precautionary principle, it argues that it had invoked that principle in reply to the Commission's defence without raising a separate plea alleging failure to observe that principle.

54 It should also be noted, as demonstrated by the oral presentation of the applicant's representative during the hearing, that the applicant's observations on the scientific basis for initiating the diflubenzuron review procedure in accordance with Article 21 of Regulation No 1107/2009 had been provided in response to an invitation by the Court, in the context of the measures of organisation of procedure, to state its views, at the hearing, on the relevance in the present case of the reasoning set out in paragraphs 88 to 90 of the judgment of 17 May 2018, *BASF Agro and Others* v *Commission* (T-584/13, EU:T:2018:279).

55 As regards the applicant's observations on the precautionary principle, it must be noted that the applicant's representative made these during the hearing in response to two questions from the Court.

56 It is apparent from the foregoing that the arguments raised by the applicant during the hearing are arguments in support of the existing pleas and therefore admissible.

57 It is appropriate to begin by examining the third plea.

The third plea in law, alleging infringement of the rights of the defence and failure to observe the principle of sound administration

58 The applicant claims that it was not able to present properly and effectively its own views throughout the review process. In that regard, the applicant states that it was given the chance to comment on the July 2014 draft report, in which the rapporteur Member State for the review of diflubenzuron (Sweden) concluded that PCA did not pose a risk. However, the applicant was not given a chance to comment after Sweden had changed its conclusions in the November 2014 and July 2015 addenda, holding that the risk for consumers could not be evaluated sufficiently (November 2014 addendum) and thus that it

could not be concluded that the estimated exposure of PCA was of low concern for consumers (July 2015 addendum). The applicant considers that the conclusions adopted in the November 2014 and July 2015 addenda related to a time of critical decision making in the diflubenzuron review procedure and that it would be more difficult to have those conclusions changed in a subsequent procedure.

59 The Commission disputes the applicant's arguments.

60 It should be borne in mind that observance of 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, judgment of 15 June 2006, *Dokter and Others*, C-28/05, EU:C:2006:408, paragraph 74 and the case-law cited).

61 In accordance with the second paragraph of Article 21(1) of Regulation No 1107/2009, the Commission must, during the review of the approval of an active substance, set a period for the producer of the substance to submit its comments.

62 In the present case, during the procedure for reviewing diflubenzuron the applicant was able to submit comments four times: first, on the Commission's letter of 18 July 2013 informing the applicant that approval of diflubenzuron was being reviewed in line with Article 21 of Regulation No 1107/2009 (see paragraphs 23 and 24 above), second, on the July 2014 draft report by the rapporteur Member State (see paragraph 24 above), third, on EFSA's 2015 conclusions (see paragraph 30 above) and, fourth, on the draft review report (see paragraph 32 above).

63 Accordingly, assessing the procedure for reviewing diflubenzuron as a whole, the Commission cannot be reproached for not giving the applicant the proper opportunity to submit its views during the course of that procedure.

64 Nevertheless, the applicant criticises the Commission for not having invited it to submit comments on the November 2014 and July 2015 addenda, which were materially different from the July 2014 draft report by the rapporteur Member State. In the July 2014 draft report the rapporteur Member State had concluded that the potential exposure of consumers, workers and residents or bystanders to PCA from the representative use of diflubenzuron in pome fruits did not pose a risk (see paragraph 24 above). By contrast, in the November 2014 and July 2015 addenda the rapporteur Member State held that the risk for consumers could not be evaluated sufficiently (see paragraph 25 above) and thus it could not be concluded that the exposure of PCA was of low concern for them, since a threshold for a genotoxic carcinogen could not be assumed (see paragraph 27 above).

65 In the first place, it should be noted that the conclusions drawn both in the July 2014 draft report and in the November 2014 and July 2015 addenda were part of just one stage in the diflubenzuron review procedure, namely the assessment by the rapporteur Member State of the information submitted by the applicant regarding the potential exposure of consumers to PCA as a residue (see paragraphs 24, 25 and 27 above). In the present case, as was noted in paragraph 62 above, the applicant was heard both before and after that stage.

66 However, the applicant considers that the submission of its comments at a later stage in the procedure, namely after the rapporteur Member State's assessment, was too late to be able to dismiss the concerns raised in those documents.

67 In that regard, it must be noted that the applicant does not provide any real evidence to support its claim that it would not be possible to change the conclusions drawn in the July 2015 addendum during a later stage in the procedure.

68 In the second place, it should be noted that, despite their materially different character as compared with the July 2014 draft report on potential exposure of consumers to PCA, the conclusions drawn by the rapporteur Member State in the November 2014 and July 2015 addenda (see paragraphs 25 and 27 above) cannot be considered to have raised a new concern that was previously unknown to the applicant and on which the applicant was entitled to be heard once again before the adoption of those addenda.

69 According to the November 2014 and July 2015 addenda, the concerns as regards consumers' exposure to PCA are based on the genotoxicity of PCA and the fact that it is impossible to evaluate sufficiently the risk of consumers being exposed to that substance. It is apparent from the file that the concerns about the genotoxic properties of PCA had been well known to the applicant for a number of years. For example, after EFSA referred to the concerns about potential exposure to PCA as a residue in 2012 (see paragraph 21 above), the applicant was invited, in 2013, in accordance with Article 21 of Regulation No 1107/2009, to provide relevant information by January 2014 at the latest (see paragraph 23 above).

70 In that regard, the applicant makes a distinction between, on the one hand, identification of a 'concern' in 2012 (see paragraph 21 above), and, on the other hand, the determination of a 'risk' in 2014 (see paragraph 25 above). Asked during the hearing to clarify that argument, the applicant stated that a 'concern' existed when the Commission commenced the review procedure under Article 21 of Regulation No 1107/2009, that is in 2013 (see paragraph 23 above). According to the applicant, such a concern would nevertheless not have been sufficient in 2015 to continue and finalise that procedure. Accordingly, in the present case, that concern became a 'risk' following the adoption by the rapporteur Member State of the November 2014 addendum (see paragraph 25 above), with the result that, at that moment, the applicant should have been able to exercise its rights of defence.

71 As regards the applicant's argument that there is a difference, in the present case, between two concerns — the first identified in 2012 by EFSA (see paragraph 21 above) and the second acknowledged in 2014 by the adoption of the November 2014 addendum (see paragraph 25 above) — it must be noted that the subject matter of the two concerns is the same. Indeed, it is apparent from the November 2014 addendum that the concern was still with regard to potential exposure to PCA as a residue (see paragraph 25 above), a concern that had already been identified by EFSA in 2012 (see paragraph 21 above).

72 Moreover, as regards the formal denominations of 'concern' or 'risk' in the relevant documents, it should be noted that what is important for the approval of an active substance, as the Commission stated, in essence, during the hearing, is whether or not 'it may be expected, in the light of current scientific and technical knowledge', that plant protection products containing the active substance satisfy the conditions set out in Article 4 of Regulation No 1107/2009.

73 The applicant did not provide a more detailed explanation of exactly how the two concerns — the first identified in 2012 by EFSA and the second acknowledged in 2014 by the adoption of the November 2014 addendum — were different and why they should be distinguished by their denomination. Its arguments as to a difference between those concerns and as to their formal denomination in the relevant documents cannot, therefore, be accepted.

74 Lastly, in the third place, as the Commission states, in order to justify its right to be heard specifically on the conclusions in the November 2014 and July 2015 addenda, the applicant provides no new relevant scientific information liable to disprove those conclusions.

75 That finding cannot be called into question by the applicant's reference, first, to its comments of 19 August 2015 on the July 2015 addendum and, second, to the TGR study. As the applicant stated during the hearing, its comments of 19 August 2015 did not concern the genotoxity of PCA, while, according to the conclusion in the July 2015 addendum 'exposure to PCA should be considered a

priori … a concern since a threshold for a genotoxic carcinogen cannot be assumed'. The TGR study, for its part, is not relevant for the purposes of demonstrating the need to hear the applicant after the adoption of the July 2015 addendum since the applicant first communicated information on the existence of that study only in September 2016 and submitted the summary of that study only on 8 March 2017.

76 Consequently, the third plea in law must be rejected and the other pleas in law examined. In that regard the Court will first analyse the second plea in law, alleging *ultra vires*.

The second plea in law, alleging ultra vires

77 The applicant claims that the Commission adopted the contested regulation *ultra vires* by proposing to classify PCA as an *in vivo* genotoxic agent during the review process. The applicant states that the European Chemicals Agency (ECHA) is the authority legally responsible for classification or re-classification of substances, according to 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).

78 The applicant notes that, in accordance with Regulation No 1272/2008, the classification process must start with a proposal from a competent authority of a Member State to ECHA and that that process provides for the active participation of the concerned party, providing for additional procedural guarantees such as the right to be consulted and to be granted opportunities to provide comments to the ECHA's Risk Assessment Committee (RAC).

79 The Commission disputes the applicant's arguments. It contends that the present plea is ineffective and that, in any event, the contested regulation was not adopted *ultra vires*.

80 It should be noted that it is not apparent from the contested regulation that the Commission or EFSA formally classified the metabolite PCA as a genotoxic agent or that they formally proposed to classify it as such in the context of the procedure for reviewing the active substance diflubenzuron under Article 21(2) of Regulation No 1107/2009.

81 The Commission states that genotoxicity is not a separate hazard class and that information on the genotoxic potential of a substance is only one factor contributing to the possible classification of that substance in the hazard classes 'germ cell mutagenicity' or 'carcinogenicity'. The Commission submits that PCA is already classified as a carcinogen category 1B and that that fact is not disputed by the applicant.

82 In that regard, it must be noted that both EFSA's 2015 conclusions and the contested regulation simply indicate that PCA has genotoxic properties.

83 In the light of the foregoing, the second plea in law, alleging *ultra vires*, must be rejected on the ground that it has no factual basis.

The first plea in law, alleging a manifest error of assessment, and the fourth plea in law, alleging failure to observe the principle of proportionality

84 The first plea in law, alleging a manifest error of assessment, will be examined together with the fourth plea in law, alleging failure to observe the principle of proportionality. The plea alleging failure to observe the principle of proportionality and that alleging a manifest error of assessment overlap in so

far as the applicant claims, inter alia, in the context of the latter plea that there was an error stemming from the unreasonable and disproportionate nature of adopting the contested regulation without waiting for the outcome of the diflubenzuron renewal procedure.

Preliminary remarks on the scope of judicial review

85 According to case-law, if the Commission is to be able to pursue effectively the objectives assigned to it by Regulation No 1107/2009, 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.

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

87 As regards the assessment by the EU Courts 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, judgment of 12 December 1996, *AIUFFASS and AKT* v *Commission*, T-380/94, EU:T:1996:195, paragraph 59). 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).

88 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).

89 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).

The manifest errors of assessment

90 The applicant criticises the Commission for having made two main errors, the first by adopting the contested regulation without waiting for the outcome of the diflubenzuron renewal procedure, and the second by not carefully and impartially examining all the relevant elements and factors of the case.

– The alleged error of unreasonably and disproportionately adopting the contested regulation without waiting for the outcome of the diflubenzuron renewal procedure

91 The applicant claims that the Commission unreasonably and disproportionately adopted the contested regulation in so far as it closed the diflubenzuron review procedure without waiting for the outcome of the procedure for renewal of approval for that substance under Article 14 of Regulation No 1107/2009.

92 In that regard, the applicant itself states that it does not criticise the fact that the Commission ran two parallel procedures, both assessing the genotoxic potential of PCA as a residue. What it criticises the Commission for, in essence, is the failure to take into account in the context of the review procedure new and available data, and in particular the TGR study which confirmed that there was no genotoxic potential, which should have led the Commission to suspend the diflubenzuron review procedure pending the outcome of the renewal procedure.

93 In that regard, first, it must be noted that Regulation No 1107/2009 makes no provision in respect of the relationship between the review procedure and the renewal procedure, governed respectively by Articles 21 and 14 to 20 thereof.

94 Next, it should be noted that on 8 March 2017, in the context of the review procedure, the applicant sent the Commission a 'Data Summary' of the TGR study and not the study itself. The applicant does not contradict this fact. In its responses to the measures of organisation of procedure, the Commission stated that because it received only a summary of the TGR study it had not had the opportunity to examine it before the close of the review procedure. It is apparent from the file that that study itself was presented in the context of the ongoing procedure for possible renewal of the approval of diflubenzuron (see paragraph 42 above).

95 Nevertheless, the Commission considered that, in any event, it was disproportionate and inconsistent with the provisions of Regulation No 1107/2009 and with its aim to ensure a high level of protection of human health to wait for the outcome of the diflubenzuron renewal procedure.

96 It is apparent from the Commission's letter of 3 May 2017, sent to the applicant in reply to its letter of 20 March 2017, that it was 'in the interest of consumer safety' that it decided not to wait for the outcome of the diflubenzuron renewal procedure. In the same letter, the Commission also noted that the concerns regarding PCA dated back to 2009 when EFSA noted a data gap in that regard and that the applicant had had the opportunity to submit relevant data, first, in the framework of the assessment of confirmatory information as regards the potential toxicological relevance of the impurity and of PCA as a residue of the use of diflubenzuron (EFSA's 2012 conclusions) and, second, during the review of the approval of diflubenzuron (EFSA's 2015 conclusions).

97 It should be noted that the arguments raised by the applicant neither call into question the Commission's decision to prioritise consumer safety by not waiting for the outcome of the diflubenzuron renewal procedure, nor demonstrate that such a decision is unreasonable and disproportionate.

98 First, the applicant claims that the Commission's decision not to wait for the outcome of the diflubenzuron renewal procedure runs the real risk of imposing a disproportionate burden on the applicant, as well as on downstream undertakings and consumers. According to the applicant, if the outcome of the diflubenzuron renewal procedure were that the TGR study confirms that PCA has no genotoxic potential the contested regulation would have to be amended to reverse its legal consequences. That would involve not only the downstream undertakings, consumers and itself having to reverse the measures they took to conform to the now obsolete contested regulation but also time and effort being spent by the relevant authorities in rectifying the situation.

99 In that regard, it should be borne in mind that Article 168(1) TFEU requires that a high level of human health protection be ensured in the definition and implementation of all EU policies and activities. The protection of human health takes precedence over economic considerations, with the result that it may justify adverse economic consequences, even those which are substantial, for certain traders (see, to that effect, order of 12 July 1996, *United Kingdom* v *Commission*, C-180/96 R, EU:C:1996:308, paragraph 93, and judgment of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraphs 456 and 457).

100 It is apparent from the contested regulation that, according to the Commission, the information submitted in the review process did not demonstrate that the risk of potential exposure of consumers to PCA as a residue was acceptable. In particular, it stated that the presence of PCA in the metabolic pathway had been demonstrated in some plants and livestock and could not be excluded in others. Moreover, according to the Commission, studies indicated a significant transformation of diflubenzuron residues into PCA under conditions similar or equal to food sterilisation processes, and such transformation could not be excluded for household processing practices. The Commission concludes that the exposure of consumers to PCA cannot be excluded and that the use of diflubenzuron should be limited to non-edible crops only, and crops treated with diflubenzuron should not enter the food and feed chain.

101 Accordingly, the Commission cannot be criticised for having put consumer safety before the possible economic or organisational interests of the applicant, downstream undertakings, consumers and competent authorities.

102 Second, the applicant alleges that the renewal of the approval of diflubenzuron was subject to strict deadlines so that the outcome of that procedure should have been known in October 2017, namely five months after the adoption of the contested regulation, and that there was thus no reason to push for the conclusion of the review under Article 21 of Regulation No 1107/2009. In addition, in reply to the Commission's prediction, which it submitted during the present proceedings before the Court, as to the date on which the diflubenzuron renewal procedure would close, namely 30 June 2019, the applicant notes that Article 3 of the contested regulation provides that any grace period granted by Member States in accordance with Article 46 of Regulation No 1107/2009 is to expire by 8 September 2018 at the latest. The applicant is of the opinion that the existence of such a transitional period granted to the Member States in particular when they withdraw or amend the authorisation of an active substance means that it may be that it becomes clear only nine months after the end of that deadline that there was in fact no need to have taken any measures.

103 In that regard, despite the fact, as the Commission states, that the diflubenzuron renewal procedure was subject to a precise timetable (it having to be closed by 31 December 2018 at the latest, that being the date the initial approval of diflubenzuron was to expire) it must be noted that, in accordance with Article 17 of Regulation No 1107/2009, where, for reasons beyond the applicant's control, it appears that the approval is likely to expire before a decision has been taken on renewal, the Commission is to adopt a decision extending the approval period until the end of the renewal procedure.

104 That provision has the effect of allowing the procedure for the renewal of approval of the active substance to be extended on account of reasons arising in the course of the procedure itself that were previously unknown. Thus, before the adoption of the contested regulation, it was not certain that the diflubenzuron renewal procedure would end before 31 December 2018 or even before 30 June 2019.

105 In any event, as regards the applicant's argument that the diflubenzuron renewal procedure was expected to have finished in October 2017, it must be noted that it is apparent from the file that at that date only the result of the assessment of that substance by the rapporteur Member State, namely Greece, could have been expected and not the final result of the renewal procedure.

106 As a result, in the context of an uncertain timetable for the diflubenzuron renewal procedure, described in paragraph 43 above, the Commission cannot be criticised for having put consumer safety first.

107 Third, the applicant expresses doubts as to the existence of real concerns by the Commission as regards the risk of consumer exposure to PCA. In that regard, the applicant states that no measure had been taken during the two and a half years preceding the contested regulation, even though the same alleged risk had been identified in November 2014.

108 In that regard, it must be noted, first, that it is apparent from the file that in November 2014 the rapporteur Member State for the review of diflubenzuron, namely Sweden, had issued only the first addendum, which had supplemented the July 2014 draft report (see paragraphs 24 and 25 above). It is only in July 2015 that Sweden adopted the final assessment report which, about one month later, was endorsed by EFSA's conclusions (see paragraphs 27 and 29 above). As for the latter, it is apparent from the contested regulation that EFSA submitted its conclusions to the Commission only on 11 December 2015. As a result, the Commission correctly clarifies that only approximately one and a half years — not two and a half years — had elapsed between the risk of consumer exposure to PCA as residues being identified and the contested regulation being adopted.

109 Next, it should be assessed whether the period of one and a half years is liable to call into question the existence of real concerns linked to consumer safety, relied on by the Commission as the reason for not waiting for the outcome of the diflubenzuron renewal procedure.

110 In the present case, it must be noted that the Commission sets out various reasons why the review of diflubenzuron took nearly a year and a half. Indeed, first, it refers to several meetings of the Standing Committee on the Food Chain and Animal Health, namely 4 meetings in 2015, 10 meetings in 2016 and 4 meetings in 2017, which had been organised to find solutions that would command the widest possible support within the Committee. Second, it recalls its international obligations which require it, inter alia, to notify a draft to the World Trade Organisation (WTO), give a period of 60 days for comments and then respond to the comments received. Third, the Commission is fully entitled to observe that the applicant's actions also contributed to the duration of the review of diflubenzuron after EFSA's 2015 conclusions, particularly its challenge to EFSA's decision to publish those conclusions.

111 It is also necessary to point out the complexity of the issues examined by the Commission in the procedure for reviewing the approval of diflubenzuron. This is demonstrated in particular by the scientific nature of those issues and the several meetings organised by the Commission before adopting the contested regulation.

112 In the light of the foregoing, and since the applicant has submitted no specific evidence to call into question, first, the reasons relied on by the Commission and mentioned in paragraph 110 above and, second, the complexity of the issues reviewed by the Commission, the period of one and a half years which elapsed between the adoption of the contested regulation and the identification, by the rapporteur Member State and EFSA, of the risks associated with the exposure of consumers to PCA

cannot be considered unreasonable. Accordingly, the applicant has failed to show that there are no real concerns linked to consumer safety with the result that the Commission cannot be criticised for not having waited for the outcome of the diflubenzuron renewal procedure.

113 Fourth, the applicant relies on the case of another active substance, namely chlorpyrifos, in which the Commission decided to close the review procedure under Article 21 of Regulation No 1107/2009 because the substance was subject to a complete re-assessment for possible renewal.

114 It must be stated, as the Commission notes, that the circumstances surrounding the procedures for chlorpyrifos and diflubenzuron are not the same. In the first place, it is apparent from Commission Regulation (EU) 2016/60 of 19 January 2016, amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorpyrifos in or on certain products (OJ 2016 L 14, p. 1), that the maximum residue levels (MRLs) for chlorpyrifos had been set, whereas for diflubenzuron, as is apparent from recital 14 of the contested regulation, the Commission found that it was not possible to set toxicological reference values for PCA and, consequently, no safe residue levels could be identified.

115 In the second place, it is apparent from Regulation 2016/60 that the MRLs for chlorpyrifos were adapted after new verified information was received. That information included both EFSA's recommendation to lower those maximum levels for certain products and the European Union reference laboratories' conclusion that for certain commodities technical development requires the setting of specific limits of determination. By contrast, in the present case, the TGR study, relied on by the applicant in order to request the suspension of the diflubenzuron review procedure until that study had been evaluated in the context of the renewal procedure, contained new scientific data which had not been evaluated at all either during the review procedure or as part of the renewal procedure, before the adoption of the contested regulation.

116 Fifth, in response to the Commission's argument that a study such as the TGR study had been requested in 2009 and should have been submitted in 2011, the applicant claims, first, that the TGR study was not specifically requested in 2009 by the competent authorities and, second, that it could not have been requested in 2009, in any event, given the date on which the Organisation for Economic Co-operation and Development ('OECD') Guidelines No 488 regarding transgenic rodent somatic and germ cell gene mutation assays were adopted, that being 28 July 2011.

117 In that regard, it should be noted that, in 2009, in connection with the original approval for diflubenzuron, the Commission asked the applicant to submit confirmatory data in respect of the potential toxicological relevance of the impurity and PCA as a residue of the use of diflubenzuron. Yet it must be noted that 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 provided for in Article 4 of Regulation No 1107/2009 are met lies, in principle, with the notifier. Thus, 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 (judgment of 17 May 2018, *BASF Agro and Others* v *Commission*, T-584/13, EU:T:2018:279, paragraphs 86 and 88). In that regard, it is apparent more specifically from recital 10 of Regulation No 1107/2009 that substances should be included in plant protection products 'only … where it has been demonstrated', in particular, that they are not expected to have any harmful effect on human health (see, to that effect, judgment of 17 May 2018, *BASF Agro and Others* v *Commission*, T-584/13, EU:T:2018:279, paragraph 87). Moreover, in principle, a party who relies on a legal provision must prove that the conditions of application of that provision are met (judgment of 17 May 2018, *BASF Agro and Others* v *Commission*, T-584/13, EU:T:2018:279, paragraph 88).

118 Even if, as the applicant claims, the adoption of the OECD Guidelines No 488 on transgenic rodent somatic and germ cell gene mutation assays, adopted on 28 July 2011, were necessary in order to conduct and present the results of the TGR study, it is sufficient to state that the applicant does not note any circumstances which would have prevented it from presenting the results of studies for the testing of chemicals as from 28 July 2011.

119 In addition, it is not apparent from Regulation No 1107/2009 that the competent authorities involved in the procedure for the approval of an active substance are obliged to identify the relevant information to be provided by the interested party. Such an obligation is also not provided for in the context of a review procedure under Article 21 of that regulation, with the result that the applicant's argument, put forward during the hearing, that the necessity of the TGR study was only identified for the first time in EFSA's 2015 conclusions, which were adopted in the context of the diflubenzuron review procedure, is irrelevant.

120 Accordingly, the Commission cannot be criticised for not having required the presentation of a specific study in 2009, such as the TGR study, in the context of the approval of diflubenzuron.

121 In the absence of other arguments calling into question the Commission's decision to give priority to consumer safety and to continue the review procedure without waiting for the outcome of the diflubenzuron renewal procedure, it must be stated that the Commission did not commit a manifest error of assessment in finding, first, that that interest justified such a decision and, second, that that decision was proportionate.

– The alleged error of failing to examine carefully and impartially all the relevant elements and factors of the case

122 The applicant claims that the Commission failed to carry out its assessment with care and impartiality as regards all the relevant elements and factors of the case. In that respect, it puts forward several arguments.

123 First, the applicant claims that it is unfairly accused of failing to submit enough information in its complete dossier. In that context, the applicant considers that it could not respond to a concern that had not been identified and for which no information was needed. According to the applicant, the concern about PCA as a residue was first raised as a risk in the July 2015 addendum. In that regard, the applicant makes a distinction between a 'concern' identified in 2012 and the finding of a 'risk' in 2014.

124 It should be noted that it was concluded in paragraphs 68 and 71 above that the conclusions drawn by the rapporteur Member State in the November 2014 and July 2015 addenda (see paragraphs 25 and 27 above) should not be considered to have raised a new concern about which the applicant had not already been aware for several years, irrespective of its formal designation in the relevant documents as 'concern' or 'risk'. It is apparent from the file that EFSA had raised concerns about potential exposure to PCA as a residue as early as 2012. As a result, the applicant could not, even in 2012, have been unaware of the concerns regarding exposure to PCA as a residue, and it was for the applicant, as from 2012, to provide sufficient information in that regard.

125 In any event, as was already stated in paragraph 62 above, the applicant was again able to submit its arguments after the July 2015 addendum twice, namely on 7 October 2015, in respect of EFSA's 2015 conclusions (see paragraph 30 above), and on 29 September 2016, in respect of the draft review report (see paragraph 32 above).

126 Moreover, it appears that, for the first time in the present proceedings, during the hearing, the applicant criticised the Commission for not having taken into consideration its comments submitted to EFSA on 20 August 2015 on the ground that it had had sufficient opportunity to provide comments during the previous procedure (see paragraph 31 above), and that it could submit comments only once on the assessment carried out by the rapporteur Member State (see paragraph 31 above). In that regard, the applicant states that those comments could not be provided before July 2015 because it was only in July 2015 that the rapporteur Member State had considered that the question of residues posed problems (see paragraph 27 above). Without it being necessary to rule on its admissibility, that argument of the applicant must be rejected as unfounded in the light of the conclusions drawn in paragraphs 74, 75, 124 and 125 above.

127 Second, the applicant considers that the Commission itself did not know how to assess genotoxicity and that there is no consensus between EFSA and the European Medicines Agency (EMA) on the genotoxic and carcinogenic properties of PCA.

128 As regards the Commission's assessment of genotoxicity, the applicant relies on a request for clarification and consideration of several aspects related to the assessment of genotoxicity, submitted by the Commission to EFSA, that it claims demonstrates strong divergences in opinion between some Member States, EFSA and applicants on this issue.

129 In that regard, the Commission argues, without being contradicted by the applicant, that the request submitted to EFSA, referred to in paragraph 128 above, concerns a very limited and highly technical aspect of how different genotoxicity assessments are followed up, that is to say, how best *in vitro* tests should be followed up with *in vivo* tests in a consistent and more standardised manner.

130 As regards the opinions of EFSA and EMA on the genotoxic and carcinogenic properties of PCA, the applicant relies on the EMA report, dated 23 July 2015, from which it is apparent that a threshold of exposure to PCA can be set and that an assessment can therefore be performed.

131 However, it must be noted that it is apparent from the 'Comments on the rationale for a non-divergent position between EFSA conclusions on 4-chloroaniline (PCA) and EMA's CHMP/ICH conclusions', annexed to the file, that the two agencies confirmed, first, that there was fundamentally no divergent scientific view between them since both agencies considered that PCA should be assessed as genotoxic and carcinogenic based on the data available at the time and, second, that the different approaches used by the two agencies are explained by the different contexts in which PCA had to be assessed.

132 The EMA report relied on by the applicant to demonstrate that EMA's position on exposure to PCA was different to that of EFSA cannot call into question the positions of EFSA and EMA set out in the document referred to in paragraph 131 above. In that regard, it is sufficient to note that that document post-dates the EMA report in question, which is dated 23 July 2015. According to the clarifications provided by the Commission in the context of the measures of organisation of procedure, and which are not contested by the applicant, EFSA and EMA had agreed on the final version of the document referred to in paragraph 131 above on 10 December 2015.

133 Accordingly, the Commission cannot be criticised on the ground that it did not take account of possible lack of consensus between EFSA and EMA on the genotoxic and carcinogenic properties of PCA.

134 Third, the applicant states that, unlike the assessment of diflubenzuron as a plant protection product, the assessment of diflubenzuron as a biocide revealed no grounds for concern as regards the level of metabolite for workers, residents and bystanders.

135 As the Commission states in its replies to the questions asked by way of measures of organisation of procedure, it is apparent from Commission Directive 2013/6/EU of 20 February 2013 amending Directive 98/8/EC of the European Parliament and of the Council to include diflubenzuron as an active substance in Annex I thereto (OJ 2013 L 48, p. 10) — the directive setting the conditions for the approval of diflubenzuron as a biocide — that the risk assessments carried out at EU level did not assess all exposure scenarios and potential uses, such as outdoor use, use by non-professionals and exposure of livestock. It follows that, unlike the assessment of diflubenzuron as a plant protection product, the assessment of diflubenzuron as a biocide did not concern the uses giving rise to exposure of consumers via food products or animal feed.

136 Accordingly, the Commission cannot be criticised for not having taken into account with care and impartiality the assessment of diflubenzuron as a biocide in the assessment of diflubenzuron as a plant protection product during the review procedure.

137 Consequently, the first and fourth pleas in law must be rejected.

138 In the light of all the foregoing, the action must be dismissed in its entirety.

Costs

139 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. In the case at hand, since the applicant has been unsuccessful, it must be ordered to bear its own costs and to pay those incurred by the Commission in the present action and in the proceedings for interim measures in accordance with the form of order sought by the latter.

On those grounds,

THE GENERAL COURT (Fourth Chamber),

hereby:

1. **Dismisses the action;**

2. **Declares that Arysta LifeScience Netherlands BV is to bear its own costs and orders it to pay those incurred by the European Commission in the present action and in the proceedings for interim measures.**

Kanninen Calvo-Sotelo Ibáñez-Martín Reine

Delivered in open court in Luxembourg on 19 September 2019.

E. Coulon
Registrar

A. M. Collins
President

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