Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fourth Chamber)

14 December 2018 *

(Plant protection products — Procedure for reviewing the approval of the active substance diflubenzuron — Article 21 of Regulation (EC) No 1107/2009 — Conclusion of the EFSA review — Partial publication of that conclusion — Article 63 of Regulation No 1107/2009 — Request for confidential treatment of certain sections — Protection of commercial interests — Refusal to grant confidential treatment — Interest in bringing proceedings)

In Case T-725/15,

Arysta LifeScience Netherlands BV, formerly Chemtura Netherlands BV, established in Amsterdam (Netherlands), represented by C. Mereu and K. Van Maldegem, lawyers,

applicant,

v

European Food Safety Authority (EFSA), represented by D. Detken and S. Gabbi, acting as Agents, and by R. Van der Hout and C. Wagner, lawyers,

defendant,

supported by

European Commission, represented initially by F. Moro and P. Ondrůšek, and subsequently by P. Ondrůšek and G. Koleva, acting as Agents,

intervener,

APPLICATION under Article 263 TFEU for the annulment of the decision of EFSA of 10 December 2015 relating to the publication of certain sections of the EFSA peer review on the review of the approval of the active substance diflubenzuron concerning the metabolite PCA,

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 29 November 2017,

gives the following

* Language of the case: English.

Judgment

I. Legal framework

A. EU legislation governing the procedure for the evaluation and approval of plant protection products and their active substances in the European Union

1. 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 system for authorising the placing of plant protection products on the market and contains provisions applicable to plant protection products and to the active substances contained 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 meet 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 the Directive and any conditions laid down in that annex are fulfilled. Articles 5 and 6 of that directive lay down the procedure for the inclusion of an active substance in the annex in question.

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 before 14 June 2011 in accordance with Article 6(3) of that directive.

2. 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 that directive. 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 applies to active substances for which there are clear indications that they do not have any harmful effects.

3. 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 Article 4 of Regulation No 1107/2009 lays down approval criteria for active substances in plant protection products.

10 Articles 7 to 13 of Regulation No 1107/2009 lay down the approval procedure for active substances. First of all, it is provided in Article 7 of that regulation that 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. Next, pursuant to Article 11 of that regulation, 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. Moreover, according to Article 12 of the same regulation, 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 communicated its conclusion to the applicant, the Member States and the Commission and made it available to the public. Last, in accordance with Article 13 of Regulation No 1107/2009, 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 shall be given the possibility to submit comments on the review report.

11 Article 21 of Regulation No 1107/2009 concerns review of the 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, it 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 this review procedure, it 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 it. Where it 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.

B. EU legislation on the active substance diflubenzuron

12 By Directive 2008/69/EC of 1 July 2008 amending Council 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.

13 Recital 5 of Directive 2008/69 reads as follows:

'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.'

14 Considering that it was appropriate to obtain further information on certain specific points concerning diflubenzuron in particular, the Commission, on 22 June 2010, adopted Directive 2010/39/EU amending Annex I to Council Directive 91/414 as regards the specific provisions relating to the active substances clofentezine, diflubenzuron, lenacil, oxadiazon, picloram and pyriproxyfen (OJ 2010 L 157, p. 7). According to recital 6 of Directive 2010/39:

'It is appropriate as regards diflubenzuron, to require that the notifier submit confirmatory data in respect of the potential toxicological relevance of the impurity and metabolite 4-chloroaniline (PCA).'

C. EU legislation on publication of EFSA conclusions and their confidential treatment

1. Regulation No 178/2002

15 Regulation No 178/2002 governs, inter alia, the transparency of EFSA's activities, the confidentiality of the information it receives and the communication to the public and to any interested parties of the results of its work.

16 In that regard, recital 40 of Regulation No 178/2002 states:

'The confidence of the Community institutions, the general public and interested parties in [EFSA] is essential. For this reason, it is vital to ensure its independence, high scientific quality, transparency and efficiency. Cooperation with Member States is also indispensable.'

17 According to recital 54 of Regulation No 178/2002:

'The independence of [EFSA] and its role in informing the public mean that it should be able to communicate autonomously in the fields falling within its competence, its purpose being to provide objective, reliable and easily understandable information.'

18 Article 23 of Regulation No 178/2002, headed 'Tasks of [EFSA]', provides:

'The tasks of [EFSA] shall be the following:

...

(j) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission;

...'

19 Article 38 of Regulation No 178/2002, entitled 'Transparency', provides:

'1. [EFSA] shall ensure that it carries out its activities with a high level of transparency. It shall in particular make public without delay:

...

(b) the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included;

(c) without prejudice to Articles 39 and 41, the information on which its opinions are based;

...

(e) the results of its scientific studies;

(f) the annual report of its activities;

(g) requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

...'

20 Article 39 of Regulation No 178/2002, 'Confidentiality', provides:

'1. By way of derogation from Article 38, [EFSA] shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public if circumstances so require, in order to protect public health.

...

3. The conclusions of the scientific opinions delivered by [EFSA] relating to foreseeable health effects shall on no account be kept confidential.

...'

21 Article 40 of Regulation No 178/2002, entitled 'Communications from EFSA', provides:

'1. [EFSA] shall communicate on its own initiative in the fields within its mission without prejudice to the Commission's competence to communicate its risk management decisions.

2. [EFSA] shall ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information, in particular with regard to the results of its work. In order to achieve these objectives, [EFSA] shall develop and disseminate information material for the general public.

3. [EFSA] shall act in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk communication process.

[EFSA] shall publish all opinions issued by it in accordance with Article 38.

...'

2. Regulation No 1107/2009

22 According to recital 12 of Regulation No 1107/2009:

'... Provisions should be included to ensure the transparency of the evaluation process.'

23 Article 12 of Regulation No 1107/2009, governing EFSA procedure when evaluating an active substance, provides for EFSA to make the draft assessment report sent to it by the rapporteur Member State available to the public after giving the applicant two weeks to request, pursuant to Article 63 of that regulation, that certain parts of the draft assessment report be kept confidential. After the expiry of the period for submitting written comments, EFSA must adopt a conclusion in which it states whether the active substance can be expected to meet the approval criteria provided for in Article 4 of that regulation; it must make that conclusion available to the public.

24 Article 63 of Regulation No 1107/2009, in Chapter VI, which is headed 'Public access to information', provides:

'1. A person requesting that information submitted under this Regulation is to be treated as confidential shall provide verifiable evidence to show that the disclosure of the information might undermine his commercial interests, or the protection of privacy and the integrity of the individual.

2. Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests or of privacy and the integrity of the individuals concerned:

(a) the method of manufacture;

(b) the specification of impurity of the active substance except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant;

(c) results of production batches of the active substance including impurities;

(d) methods of analysis for impurities in the active substance as manufactured except for methods for impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant;

(e) links between a producer or importer and the applicant or the authorisation holder;

(f) information on the complete composition of a plant protection product;

(g) names and addresses of persons involved in testing on vertebrate animals.

...'

II. Background to the dispute

25 The applicant, Arysta LifeScience Netherlands BV, formerly Chemtura 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 various crops, mainly apples, pears and mushrooms.

26 Diflubenzuron was included in Annex I to Directive 91/414 by Commission Directive 2008/69, in accordance with the procedure laid down in Article 11b of Regulation No 1490/2002.

27 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 others. According to those conclusions, products containing diflubenzuron satisfied, in general, the requirements of Article 5(1)(a) and (b) of Directive 91/414.

28 Considering that it was appropriate to obtain further information on certain specific points concerning diflubenzuron in particular, the Commission adopted Directive 2010/39. 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).

29 The applicant submitted the data in respect of the potential toxicological relevance of the impurity and metabolite 4-chloroaniline (PCA) as a residue of the use of diflubenzuron in June 2011. Those data were evaluated by the rapporteur Member State, the Kingdom of Sweden in this case, in the form of a draft assessment report. The rapporteur Member State circulated this draft report for comments to the applicant, the other Member States and EFSA.

30 Following consideration of the comments received, the Commission requested EFSA to organise a peer review and 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. On 22 August 2012, on the basis of an assessment of the representative uses of diflubenzuron as an insecticide on apples, pears and mushrooms and in forestry, it adopted its conclusions according to which potential exposure to the metabolite as a residue for consumers, residents or bystanders and workers should be considered a priori as a concern, since a threshold for a genotoxic carcinogen could not be assumed. Those conclusions were published on 7 September 2012.

31 On 16 July 2013, the Standing Committee on the Food Chain and Animal Health produced a revised review report for diflubenzuron. That committee essentially agreed with EFSA's conclusions of 22 August 2012.

32 The Commission subsequently, on 18 July 2013, formally informed the applicant that approval of diflubenzuron was being reviewed in line with Article 21 of Regulation 1107/2009. It conferred a mandate on EFSA to provide a conclusion in respect of that review. The deadline for that mandate was 28 August 2015.

33 In January 2014, the applicant submitted to the Kingdom of Sweden, as the rapporteur Member State for diflubenzuron, data aimed at addressing potential concerns about the metabolite. In 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 report'). The applicant, the other Member States and EFSA were given the opportunity to comment on that report.

34 The applicant submitted its views on the July 2014 report in the same month. The rapporteur Member State shared those views with all the Member States and EFSA in September 2014.

35 Following the commenting period, the rapporteur Member State supplemented the July 2014 report with two addendum reports. In the first addendum, issued in November 2014, 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 ('the July 2014 report'). So far as concerns consumers, however, the rapporteur Member State concluded that 'the risk for [them] cannot be sufficiently evaluated'.

36 On 12 March 2015, the Commission requested EFSA to provide its opinion on the potential exposure to PCA (4-chloroaniline, impurity and metabolite of diflubenzuron) as a residue and its potential toxicological relevance, and to examine if the Margin of Exposure approach had been correctly implemented by the rapporteur Member State by assessing the potential exposure to PCA as a residue under the representative use of diflubenzuron.

37 In the second addendum report, released in July 2015 following two peer review meetings in May and June 2015, the rapporteur Member State stated that 'it cannot be concluded that the estimated exposure of PCA is of low concern for consumers' ('the July 2015 addendum').

38 In order to respond to the substance of the July 2015 addendum, the applicant submitted scientific documentation to EFSA on 19 August 2015. By a letter of 24 August 2015, EFSA told the applicant that no further commenting by the notifier was foreseen during the peer review process, and that it could therefore not accept its request for a meeting. Furthermore, in the same letter, EFSA drew the applicant's attention to the fact that the Commission would invite it for comments on the EFSA conclusion at a later stage. In its conclusion of 27 August 2015 ('the contested conclusion'), EFSA considered that 'potential exposure to PCA as a residue (i.e. either for consumers or for workers and [residents or bystanders]) should be considered a priori as a concern since a threshold for a genotoxic carcinogen cannot be assumed'. In the same document, the following was also mentioned: '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 permit to conclude 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'.

39 Before publishing the contested conclusion on its website, EFSA, of its own initiative, asked the applicant to identify possible confidential information in the document, in accordance with Article 63 of Regulation No 1107/2009. In reply, by letters of 4 September 2015 and 11 September 2015, the applicant asked EFSA to confirm whether it had the power to make the contested conclusion publicly available and, in any event, to redact parts of the document for confidentiality reasons under that article. More specifically, it requested confidentiality for the names of the authors of the studies and reports, the correction of certain parts highlighted as factual mistakes, and the redaction of sections which, in its view, would undermine its commercial interests, notably regarding the properties and continued availability of diflubenzuron, or were based on conclusions of questionable scientific quality that were still under dispute and on which it had submitted comments to EFSA on 19 August 2015, which had not been taken into consideration.

40 By letter of 8 October 2015, EFSA granted the request for confidential treatment seeking the redaction of the names of the authors of studies and reports, in accordance with Article 63(2)(g) of Regulation No 1107/2009, and the request for the correction of certain material mistakes. However, it rejected the requests under paragraph 1 of that article for the redaction of sections containing information likely to undermine the applicant's commercial interests.

41 First of all, EFSA referred to Article 38(1) to Article 39(3) and to Article 40 of Regulation No 178/2002 as the legal basis conferring on it the power to make the contested conclusion publicly available. Next, it addressed the applicant's complaints of infringement of its rights of defence and of its right to be heard. In that regard, it reiterated that the applicant had been given the possibility to submit comments on the July 2014 report and would have the opportunity to state its views on the Commission's final decision. Last, regarding the applicant's request for the redaction of sections containing information likely to undermine its commercial interests, EFSA argued, in essence, that the mere risk that most of the information in it might tarnish the applicant's image was not sufficient to grant that information confidentiality, in view of its obligation to publish information likely to affect public health.

42 On 12 October 2015, the applicant requested EFSA to review the decision rejecting its claims for confidential treatment under Article 63(1) of Regulation No 1107/2009 in respect of the contested conclusion. In support of that request, it complained that EFSA had, inter alia, acted contrary to Regulation No 178/2002. In its view, it is apparent from that regulation that EFSA's opinions must have 'high scientific quality'. That authority had formed the conclusion in question on the basis of the July 2015 addendum, which was itself based on questionable science and truncated information. Moreover, the applicant contended that, by wilfully ignoring its comments, EFSA had infringed its rights of defence and acted contrary to its obligation under that regulation to base its assessments on 'all the available scientific evidence'. Furthermore, in its view, there was no reliable evidence that the substance posed a risk to human or animal health.

43 On 10 December 2015, EFSA definitively rejected the applicant's requests for confidential treatment under Article 63)(1) of Regulation No 1107/2009 in respect of the contested conclusion ('the contested decision'). So far as concerns the applicant's complaints, based on the infringement of its rights of defence and of its right to be heard, it indicated that it had taken into account the information and comments provided by the applicant on 20 August 2015 and that its detailed position in respect of that information was contained in Annex I to the contested decision.

44 On 11 December 2015, the contested conclusion was published in its entirety on EFSA's website.

45 In the meantime, on 9 September 2015, the Commission invited the applicant to submit its comments on the contested conclusion. In the same letter, it stated that if, during the approval review for diflubenzuron, it submitted a revised draft review report to the Standing Committee on the Food Chain and Animal Health, the applicant would have the opportunity to submit its written comments on the subject. The applicant replied on 7 October 2015 and its comments were shared with the Member States sitting in the Standing Committee on the Food Chain and Animal Health.

III. Procedure and forms of order sought

46 By application lodged at the Registry of the General Court on 11 December 2015, the applicant brought the present action.

47 By separate document lodged at the Court Registry on the same day, the applicant applied for suspension of the operation of the contested decision.

48 By order of 15 December 2015, the President of the General Court granted the application for provisional suspension of the operation of the contested decision and ordered EFSA to remove the contested conclusion from its website immediately.

49 EFSA complied with that order that same day. However, on 7 January 2016, for a duration of 5 minutes, and from 13 to 14 January 2016, for approximately 24 hours, the contested conclusion was available online.

50 By order of 29 February 2016, the President of the General Court dismissed the application for interim relief lodged by the applicant, cancelled his order of 15 December 2015 and reserved the costs.

51 By document lodged at the Registry of the Court of Justice on 4 March 2016, the applicant appealed against the order of 29 February 2016.

52 By its provisional order of 11 March 2016, the Court of Justice upheld the application for suspension of the operation of the contested decision and ordered EFSA to refrain from publishing the contested conclusion and, should it have already published it, to remove it from its website by no later than 17.00 on 11 March 2016.

53 By its order of 14 June 2016, the Court of Justice dismissed the applicant's appeal and ordered it to pay the costs of the appeal proceedings.

54 By document lodged at the Registry of the General Court on 31 March 2016, the Commission applied for leave to intervene in support of EFSA. Leave was granted by decision of the President of the Fourth Chamber of the General Court of 2 May 2016.

55 Following a change in the composition of the Chambers of the Court, the present case was, by decision of 6 October 2016, reassigned to the Fourth Chamber and a new Judge-Rapporteur was designated.

56 Upon hearing the report of the Judge-Rapporteur, the General Court (Fourth Chamber) decided to open the oral procedure and to ask questions of the applicant by way of measures of organisation of procedure provided for in Article 89 of the Rules of Procedure of the Court. The applicant replied within the period prescribed.

57 By document lodged at the Court Registry on 18 October 2017, EFSA, on its own initiative, submitted its observations on the questions asked of the applicant. Those observations were added to the file and sent to the applicant by decision of the President of the Fourth Chamber of the Court of 14 November 2017.

58 By document lodged at the Court Registry on 22 November 2017, the applicant responded to EFSA's observations of 18 October 2017.

59 The parties presented oral argument and answered the questions put to them by the Court at the hearing on 29 November 2017.

60 During the hearing, the applicant lodged a letter of 8 July 2015, by which the Commission granted the request from EFSA of 29 June 2015 to obtain an extension of the deadline for delivering the conclusion on the assessment of risk of the active substance diflubenzuron under a review procedure. That letter was placed on the file during the hearing and EFSA and the Commission were invited to express their views on its admissibility and merits. During the hearing, EFSA indicated that the Commission's letter of 8 July 2015 was to be declared inadmissible on account of its belated submission and, in any event, irrelevant. The Commission did not express a view in that regard.

61 The applicant claims that the Court should:

– annul the contested decision;

– order EFSA to pay the costs of the proceedings.

62 EFSA contends that the Court should:

– reject the applicant's applications;

– order the applicant to pay, in addition to its own costs, the costs incurred by EFSA in the present proceedings.

63 The Commission contends that the Court should:

– reject the application as inadmissible or unfounded;

– order the applicant to pay the costs.

IV. Law

A. The interest in bringing proceedings

64 In its observations of 18 October 2017 on the questions asked of the applicant by way of measures of organisation of procedure, EFSA raised the issue of the applicant's interest in bringing proceedings on account of the preparatory nature of the contested conclusion. It argues that, after the adoption 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) and after the institution of proceedings concerning the legality of that implementing regulation before the Court (Case T-476/17), the applicant's interest in bringing the present proceedings no longer exists, assuming it ever even did.

65 In that regard, first, EFSA considers that the contested conclusion is a measure of preparatory nature in the proceedings which led to the adoption of Implementing Regulation 2017/855, such that allegations referring to compliance with the procedural requirements of the review procedure and to the correctness of the assessment made by the intervener, itself or other authorities involved in the review procedure can be raised in the context of the action concerning the legality of that implementing regulation brought in Case T-476/17. Second, it expresses uncertainty as to how the applicant would potentially benefit from the annulment of the contested decision. In its view, annulling that decision and removing the contested conclusion from its website would not make it possible to eliminate the alleged negative effects of their disclosure, in view of the characterisation of diflubenzuron as exercising genotoxic and carcinogenic properties in the implementing regulation, which is in force and available to the public.

66 In its response of 22 November 2017 to EFSA's observations, the applicant disputes EFSA's claims regarding the inadmissibility of the action for lack of purpose. It is of the view that it retains an interest in obtaining the annulment of the contested decision in that, by the present action, it intends to have the contested conclusion published on its website with sections redacted. In its view, it could thereby prevent the impact of the disclosure of the contested conclusion on the sale of the substance as an insecticide in non-edible crops and potentially bring an action for damages. It also considers that the present action and the action brought against Implementing Regulation 2017/855 in Case T-476/17 have different objectives.

67 It should be observed that an action for annulment brought by a natural or legal person is admissible only in so far as that person has an interest in the contested measure being annulled. Such an interest requires that the annulment of that act must be capable, in itself, of having legal consequences and that the action may therefore, through its outcome, procure an advantage to the party which brought it. An applicant's interest in bringing proceedings must be vested and current. It may not concern a future and hypothetical situation. That interest must, in the light of the purpose of the action, exist at the stage of lodging the action, failing which the action will be inadmissible, and continue until the final decision, failing which there will be no need to adjudicate (judgment of 17 September 2015, *Mory and Others* v *Commission*, C-33/14 P, EU:C:2015:609, paragraphs 55 to 57).

68 Therefore, the plea of inadmissibility raised in the present case by EFSA can only be rejected as unfounded, without it being necessary to rule on the admissibility both of EFSA's observations regarding the questions asked of the applicant by way of measures of organisation of procedure (see paragraph 57 above) and of the applicant's responses to those observations.

69 When it brought the present action, the applicant had an interest in bringing proceedings since annulment of the contested decision was liable to procure it an advantage, in so far as that decision, having rejected the requests for confidential treatment under Article 63(1) of Regulation No 1107/2009 made by the applicant in respect of the contested conclusion, led to the publication of

a version of that conclusion containing sections for which the applicant had requested confidential treatment. In those circumstances, the applicant could, in the event of annulment of that decision, have, as a first step, the conclusion in question removed from EFSA's website, for example, and, as a second step, have it published in a form reiterating in full or in part its requests for confidentiality that EFSA had previously rejected.

70 Contrary to what EFSA argues, the applicant's interest in bringing proceedings does not disappear on account, first, of the adoption of Implementing Regulation 2017/855, which authorises uses of diflubenzuron as an insecticide only on non-edible crops and, second, of the bringing of the action challenging the legality of that implementing regulation before the Court.

71 The contested decision is a measure by which EFSA decided to reject the requests for confidential treatment under Article 63(1) of Regulation No 1107/2009 made by the applicant in respect of the contested conclusion. That decision continues to produce effects. The conclusion in question is still accessible to the public. In addition, the applicant is right to argue that it retains an interest in seeking annulment of that decision in order to obtain inter alia a finding, by the EU judicature, that an unlawful act has been committed against it, so that such a finding can then be the basis for any action for damages aimed at properly restoring the damage allegedly caused to his commercial interests by the publication of the contested conclusion (see, to that effect, judgment of 17 July 2014, *Westfälisch-Lippischer Sparkassen- und Giroverband* v *Commission*, T-457/09, EU:T:2014:683, paragraph 137).

72 Neither the adoption of Implementing Regulation 2017/855 nor the result of the action pertaining to the legality of that implementing regulation brought in Case T-476/17 can procure such an advantage for the applicant, given that they have no impact on the question of whether EFSA was justified, in the contested decision, in rejecting the requests for confidential treatment under Article 63(1) of Regulation No 1107/2009 made by the applicant in respect of the contested conclusion.

73 Indeed, as EFSA indicates, Implementing Regulation 2017/855 makes specific reference to the characterisation of the active substance diflubenzuron as exercising genotoxic and carcinogenic properties, a characterisation which coincides with that mentioned in the contested conclusion. It is also true that that information is made available to the public by the publication of that implementing regulation. However, that circumstance alone does not make it possible to conclude that the alleged negative effects of the disclosure of the conclusion in question have been eliminated. It must be stated that the present action and the action on the legality of that implementing regulation have different objectives and must thus be assessed autonomously, following a separate examination. In the case at hand, the applicant claims that the disclosure of information on the basis of which EFSA adopted that conclusion undermines its commercial interests. However, the matter dealt with in the action relating to the legality of the same implementing regulation is whether the Commission committed a manifest error of assessment in considering that the active substance exercised genotoxic and carcinogenic properties. In those circumstances, it is also of no relevance that there is an overlap between the applicant's arguments in the present action and in the action relating to the legality of the implementing regulation in question.

74 Having regard to the foregoing considerations, it must be concluded that the applicant retains an interest in bringing proceedings.

B. Substance

75 The applicant puts forward five pleas in law in support of the action. The first plea, in its first branch, alleges misuse of powers by EFSA, in that it adopted the contested decision without an appropriate legal basis, and, in its second branch, alleges infringement of Regulation 1107/2009 and of the fundamental right to the protection of business secrets, and of Articles 38 and 40(3) of Regulation

No 178/2002. The second plea alleges, first, misuse of powers by EFSA, in that it adopted an act relating to the classification of chemical products, which falls within the competence of the European Chemicals Agency (ECHA), and, second, a manifest error of appraisal, in that EFSA based the contested conclusion on truncated information without taking account of the applicant's comments. The third plea alleges infringement of the rights of defence and of the principle of sound administration. The fourth plea alleges breach by EFSA of its duties under Regulation No 178/2002. The fifth plea is based on an infringement of the principle of legitimate expectations, in that the Commission led the applicant to entertain legitimate expectations that its comments would be taken into consideration before the contested conclusion was published.

1. The first branch of the first plea, alleging misuse of powers by EFSA

76 The applicant considers that, in adopting the contested decision and publishing the contested conclusion, EFSA committed a misuse of powers. In its view, while there is a legal basis for EFSA to publish its conclusion in the context of an original assessment, there is no such basis for it to publish a conclusion adopted in the context of a review conducted under Article 21 of Regulation No 1107/2009.

77 EFSA contests the applicant's arguments.

78 As a preliminary point, it must be stated that Article 21 of Regulation No 1107/2009, which governs the process of reviewing an active substance, under which EFSA adopted the conclusion at issue, does not specify whether, or how, an opinion of EFSA adopted under such a review process must be disclosed. However, Article 12 of the same regulation, which governs the initial assessment of an active substance, makes express provision for EFSA's obligation to make its conclusions available to the public.

79 In those circumstances, it is appropriate to verify whether, as the applicant claims, the EU legislature intended to exclude the publication of EFSA opinions adopted in the context of a review process by expressly providing that EFSA is obliged to make available to the public its conclusions adopted in the context of an initial assessment of an active substance.

80 According to settled case-law, in interpreting a provision of EU law, it is necessary to consider not only its wording but also the context in which it occurs, the objects of the rules of which it is part (judgment of 17 November 1983, *Merck*, 292/82, EU:C:1983:335, paragraph 12), and the provisions of EU law as a whole (judgments of 6 October 1982, *Cilfit and Others*, 283/81, EU:C:1982:335, paragraph 20, and of 6 October 2005, *Sumitomo Chemical and Sumika Fine Chemicals* v *Commission*, T-22/02 and T-23/02, EU:T:2005:349, paragraph 47).

81 In that regard, it must be observed that, as EFSA indicated in the contested decision, there is no provision in Regulation Nos 1107/2009 or 178/2002 that explicitly prohibits EFSA from publishing its opinions adopted in the context of a review process. It must be stated, moreover, that there is nothing in those regulations to suggest that the EU legislature had intended to prohibit EFSA from making such opinions available to the public. Such a prohibition cannot be inferred solely from the absence of an obligation, in the text of Article 21 of Regulation No 1107/2009, to make such opinions available.

82 It is apparent, however, from a combined reading of Regulation Nos 1107/2009 and 178/2002 that EFSA is subject to transparency requirements which assume, in principle, that the public is informed of the results of its activities and thus can have access to its opinions adopted in the context of a review process. As EFSA indicated in its letter of 8 October 2015, it is those provisions which confer the power to publish such opinions. Thus, Article 38 of Regulation No 178/2002, entitled 'Transparency', provides that EFSA is to ensure that it carries out its activities with a high level of transparency. It is apparent, in particular, from Article 38(1)(b) and from Article 40(2) and (3), second

subparagraph, of that regulation that the opinions of EFSA are, in principle, made public. Article 39(3) of the same regulation provides that the conclusions of the scientific opinions delivered by EFSA relating to foreseeable health effects are on no account to be kept confidential. As regards, more specifically, the placing on the market of plant protection products, Article 63 of Regulation No 1107/2009, the sole provision contained in the chapter of that regulation entitled 'Public access to information', provides, inter alia, that '[a] person requesting that information submitted under this Regulation is to be treated as confidential shall provide verifiable evidence to show that the disclosure of the information might undermine his commercial interests, or the protection of privacy and the integrity of the individual'. It follows from a reading *a contrario* of that provision that confidential treatment of such information is the exception, whereas public access to that information is the rule.

83 Consequently, EFSA cannot be criticised for having considered, in the contested decision, that its power to publish the contested conclusion stemmed, inter alia, from the combined reading of Articles 38 to 40 of Regulation No 178/2002 and of Article 63 of Regulation No 1107/2009.

84 That finding is not called into question by the applicant's arguments.

85 The applicant's argument that it is contrary to legal certainty that EFSA can accord itself a right to publish even though that right is not expressly provided for in the applicable derived legislation, such that economic operators will not necessarily be in a position to know whether they will have the right to request confidential treatment, is therefore unfounded.

86 In that regard, it is sufficient to state that, in the case at hand, it is undisputed that, before publishing the contested conclusion, EFSA invited the applicant to present and reason its requests for confidentiality (see paragraph 39 above). Therefore, the applicant cannot blame EFSA for its not knowing that it had the right to request confidential treatment.

87 In view of the foregoing, it is necessary to reject the first branch of the first plea, alleging that there is no legal basis to publish the opinion of EFSA provided for in Article 21(2) of Regulation No 1107/2009.

2. The second branch of the first plea, assessed together with the second to fifth pleas

88 It is appropriate to assess the second branch of the first plea, alleging infringement of Regulation No 1107/2009 and of the fundamental right to the protection of business secrets, and of Articles 38 and 40(3) of Regulation No 178/2002, in conjunction with the second plea, alleging misuse of powers by EFSA, in that it adopted an act relating to the classification of chemical products, and a manifest error of appraisal in that EFSA based its conclusion on truncated information without taking account of the applicant's comments, the third plea, alleging infringement of the rights of defence of the applicant and of the principle of sound administration, the fourth plea, alleging breach by EFSA of its duties under Regulation No 178/2002, and the fifth plea, alleging infringement of the principle of protection of legitimate expectations. By that branch and by those pleas, the applicant essentially argues that the contested conclusion, published following the adoption of the contested decision, is based on an erroneous assessment of the active substance diflubenzuron from a procedural and scientific perspective vitiated by an infringement of the right of the applicant to be heard and of its legitimate expectations. In those circumstances, the publication of the contested conclusion would result in false or incorrect information on the applicant's products being revealed and in third parties being deprived a full and contradictory assessment of the substance diflubenzuron and its metabolite, thereby harming the commercial interests and reputation of the applicant.

(a) Preliminary observations

89 By the second branch of the first plea and the second to fifth pleas, the applicant essentially requests the Court to find that the publication of the contested conclusion undermines its commercial interests and reputation on account, first, of the scientifically incorrect nature of the assessment of the active substance diflubenzuron it contains and, second, of the non-observance of the rights of defence, of the principle of sound administration and of the principle of protection of legitimate expectations in the adoption of that conclusion. The applicant therefore seeks specifically to have the Court review the legality of the conclusion in question and the observance of certain procedural guarantees during the adoption of it and to circumvent the applicable admissibility rules.

90 In that regard, it should be recalled that, as such, the contested conclusion is part of the review process referred to in Article 21 of Regulation No 1107/2009. That process is ended by the adoption of a decision of the Commission to maintain, withdraw or amend the active substance at issue. An EFSA conclusion such as the conclusion in question therefore does not reflect the definitive position on that active substance in the review. The Commission alone has the power to take a definitive position on that matter. It is not apparent from a reading of Article 21 of Regulation No 1107/2009 that the Commission is obliged to follow EFSA opinions. In those circumstances, that conclusion must be regarded as constituting a preparatory act that cannot be subject to review by the Court, it being possible to invoke, where appropriate, the allegedly incorrect nature of the conclusion in question or the existence of a misuse of powers or a breach of procedural guarantees vitiating it in the context of an action against the decision of the Commission.

91 It follows that the second branch of the first plea and the second to fifth pleas must be rejected as inadmissible to the extent that the applicant requests the Court to review the legality of the contested conclusion and observance of certain procedural guarantees during the adoption of it.

92 However, in so far as the applicant also claims under the second branch of the first plea that the contested decision, by which EFSA rejected its requests for confidential treatment based on Article 63(1) of Regulation No 1107/2009 in respect of the contested conclusion, is vitiated by an infringement of that article, it is appropriate to verify whether that article is applicable and, if so, whether it has been infringed in this case.

(b) The applicability of Article 63 of Regulation No 1107/2009

93 EFSA considers that Article 63 of Regulation No 1107/2009, which deviates from the rule providing for the making available of information to the public under that regulation, applies only to 'information submitted under [that] Regulation'. That provision therefore does not authorise confidentiality requests pertaining to information produced by EFSA, such as the contested conclusion. In support of EFSA's position, the intervener adds that it is not the purpose of paragraph 1 of that article to withhold from the public scientific findings made by EFSA on the basis of submitted data or other information.

94 The applicant disputes the interpretation of Article 63 of Regulation No 1107/2009 proposed by EFSA and by the intervener. In its view, a proper literal reading of that provision would be that it covers any information, whether or not submitted by the applicant. It adds that the information for which confidential treatment was requested in the case at hand and which was highlighted in yellow in the document it submitted to EFSA on 4 September 2015 was, and was based on, information submitted by it.

95 So far as concerns EFSA's argument that it is only information that has been submitted by the applicant for which confidential treatment could be requested pursuant to Article 63(1) of Regulation No 1107/2009, it should be recalled that that provision provides that confidential treatment may be requested for 'information submitted under [that] Regulation'. It must, however, be pointed out that a

comparative examination of the various language versions of that provision shows that they present significant differences in that respect. Thus, inter alia the Italian and Spanish versions suggest that only the person who has submitted information may request confidential treatment, whereas the English, French and German versions do not stipulate that the 'information submitted under [that] Regulation' must necessarily come from the person requesting confidential treatment for it.

96 According to the case-law, where there are differences between the different language versions of a provision, the EU Court cannot rely on an interpretation which is exclusively textual (judgment of 22 October 2015, *Hedqvist*, C-264/14, EU:C:2015:718, paragraph 47). It must, on the contrary, interpret that provision by reference to the purpose and general scheme of the rules of which it forms part (judgment of 22 March 2012, *Génesis*, C-190/10, EU:C:2012:157, paragraph 42).

97 In that regard, it is apparent from recital 41 of Regulation No 1107/2009 that that regulation specifies the provisions applicable to access to the information contained in the 'documents in the possession' of the Member States, of the Commission and of EFSA and to the confidentiality of those documents. As has been noted in paragraph 82 above, Article 63 of Regulation No 1107/2009 is the sole provision contained in the chapter of that regulation entitled 'Public access to information'. Therefore, it is appropriate to interpret that provision in the light of recital 41 of Regulation No 1107/2009, from which it is not apparent that the EU legislature intended to restrict a request for confidential treatment solely to the information originating from the person requesting its confidential treatment. Such an interpretation is also apparent from Article 39(1) of Regulation No 178/2002, which is the general provision laying down restrictions on public access to the information in EFSA's possession according to which EFSA is not to divulge to third parties 'confidential information that it receives for which confidential treatment has been requested and justified'.

98 Moreover, it must be stated that Article 63 of Regulation No 1107/2009 seeks to protect commercial interests, privacy and the integrity of the individual who requests confidential treatment for information submitted pursuant to that regulation. It cannot be ruled out, however, that those interests might be undermined by the disclosure of information submitted by a person other than the one who requested confidential treatment for it.

99 It is true, as EFSA notes, that confidential treatment of information submitted under Regulation No 1107/2009 is the exception, whereas public access to that information is the rule. However, that argument pertains to the derogative nature of the confidential treatment of such information and not to the identity of the persons who can make a request for confidential treatment. It cannot be concluded, therefore, that a person may request confidential treatment only for the information that he has submitted.

100 Accordingly, it is necessary to reject as unfounded EFSA's argument that the applicant can only claim that the disclosure of information it submitted to EFSA might undermine its commercial interests.

101 Similarly, the argument of EFSA and of the intervener that the contested conclusion cannot constitute information submitted under Regulation No 1107/2009 cannot be accepted.

102 First, assessments of active substances by EFSA are, in principle, based on information submitted to that authority. In the case at hand, it is apparent from the mandate conferred by the Commission on EFSA during the process of reviewing diflubenzuron that the Commission requested that authority to organise a peer review of the data submitted by the applicant as well as the assessment of those data by the rapporteur Member State regarding the potential exposure to the metabolite as a residue and consideration of the potential toxicological relevance. It follows that the contested conclusion adopted in response to that mandate was based on the information submitted by the applicant and by the rapporteur Member State. Therefore, the assessment contained in that conclusion cannot be regarded

as being isolated from the information on which it was based. Moreover, EFSA and the intervener do not dispute that the assessment provided by EFSA in the contested conclusion was essentially based on the assessment by the rapporteur Member State, as the applicant indicates.

103 Second, as is apparent from recital 41 of Regulation No 1107/2009, the confidentiality rule applies to the 'documents in the possession' of the competent authorities. Given that the assessment produced by EFSA is in its possession and in the absence of any other argument, the Court sees no reason to consider that the confidentiality rule could not also be applied to such an assessment.

104 In the light of the foregoing, it should be concluded that Regulation No 1107/2009 applied to information for which the applicant requested confidential treatment.

(c) The alleged breach of the confidentiality rule contained in Article 63 of Regulation No 1107/2009

105 The applicant claims that EFSA infringed Article 63 of Regulation No 1107/2009 in so far as it published the contested conclusion. It considers that the publication of the conclusion in question undermines its commercial interests and its reputation on account, first, of the scientifically incorrect nature of the assessment of the active substance diflubenzuron it contains and, second, of the non-observance of its rights of defence, of the principle of sound administration and of the principle of protection of legitimate expectations in the adoption of that conclusion.

106 EFSA counters that the correctness of the contested conclusion and its impact with regard to the review procedure under Article 21 of Regulation No 1107/2009 are of no relevance to the contested decision, by which it only rejected the requests for confidential treatment based on Article 63(1) of Regulation No 1107/2009 made by the applicant in respect of the conclusion referred to. It also states that the disclosure of the information contained in that conclusion does not affect the applicant's commercial interests. In its view, before that disclosure, the reputation of the active substance diflubenzuron had already been compromised by Directive 2010/39, by the 2012 EFSA conclusion and by the decision of the Commission which triggered the review of that substance under Article 21 of Regulation No 1107/2009.

107 EFSA also contends that the conclusion at issue needed to be made available to the public in the interests of the protection of public health. In support of its argument, it refers to its letter of 8 October 2015 in which it had already set out to the applicant overriding reasons in the public interest by virtue of which it was necessary to inform the public and interested parties as to the risk posed by the substance at issue to workers, bystanders or residents and consumers.

108 In that regard, it should be noted that Article 63 of Regulation No 1107/2009 does not define the concept of commercial interests and is not limited to the types of information mentioned in paragraph 2 thereof considered a priori to undermine those interests, with the result that it may be applied to a multitude of types of information, the sole criterion being that the person requesting confidential treatment provide 'verifiable evidence' showing in a concrete manner that the disclosure of that information might undermine his commercial interests.

109 As EFSA indicates, however, the incorrectness of information does not constitute, as such, a relevant criterion for determining whether the disclosure of that information is likely to undermine commercial interests. That issue is separate from that of the correctness of information. A piece of information may be correct and yet undermine an applicant's commercial interests on account of its disclosure. Conversely, the disclosure of false information does not necessarily harm those interests.

110 So far as concerns the alleged non-observance of the applicant's rights of defence, of the principle of sound administration and of the principle of protection of legitimate expectations in the adoption of the contested conclusion, it should be stated that the applicant does not in any manner explain how those potential procedural irregularities are, as such, likely to establish an undermining of its commercial interests on account of the publication of the contested conclusion.

111 Therefore, the scientifically incorrect nature of the contested conclusion, first, and the non-observance of the applicant's rights of defence, of the principle of sound administration and of the principle of protection of legitimate expectations in the adoption of that conclusion, second, do not constitute, as such, criteria relevant to Article 63 of Regulation No 1107/2009.

112 Invited, by way of measures of organisation of procedure, to specify the documents in the file serving as the basis for its claim that the publication of the contested conclusion undermined or was likely to undermine its commercial interests, the applicant indicated that 'verifiable evidence' was to be found in the contents of the letters sent by it or on behalf of it, attached as Annexes A.7 and A.9 to the application, as well as in the report on the contested conclusion, attached as Annex C.2 to the reply, where the information the disclosure of which 'might undermine' its interests was highlighted in yellow.

113 In that regard, so far as concerns Annex A.7, it must be recalled that, pursuant to Article 21 of the Statute of the Court of Justice and Article 76(d) of the Rules of Procedure, the essential facts and law on which an application is based must be apparent from the text of the application itself, even if only stated briefly. Whilst the body of the application may be supported and supplemented on specific points by references to extracts from documents annexed thereto, a general reference to other documents, even those annexed to the application, cannot make up for the absence of the essential arguments in law which, in accordance with the abovementioned provisions, must appear in the application (see, to that effect, judgment of 17 September 2007, *Microsoft* v *Commission*, T-201/04, EU:T:2007:289, paragraph 94).

114 It is not for the Court to seek and identify in the annexes the relevant arguments in support of the action and, given that that reference does not determine precisely, among the matters contained in those annexes, those that support the applicant's assertions (see, to that effect, judgment of 17 September 2007, *Microsoft* v *Commission*, T-201/04, EU:T:2007:289, paragraphs 94 and 99).

115 The applicant has in no way explained, however, how Annex A.7, which contained its observations of 19 August 2015 submitted of its own motion on the July 2015 addendum, might demonstrate harm to its commercial interests, or identified the sections of that annex capable of establishing such harm, whereas that 29-page document does not appear from the outset such as to constitute evidence of that. The Court will therefore not take into consideration the mere reference to Annex A.7 in order to examine the existence of harm to the applicant's commercial interests.

116 With regard to Annexes A.9 and C.2, which should be considered together, in so far as the letter in Annex A.9 (the applicant's response to EFSA's request to identify possible confidential information) refers to the document contained in Annex C.2 (the text of the contested conclusion highlighted in yellow), it must be stated that the information contained in it does not enable identification of concrete elements capable of establishing any undermining of the applicant's commercial interests within the meaning of Article 63(2) of Regulation No 1107/2009. In claiming that the parts of that conclusion highlighted in yellow irreparably harms the reputation of its products and, therefore its commercial interests, the applicant merely challenges the correctness of that conclusion and the observance of certain procedural guarantees during the adoption of it. However, it has been found in paragraph 90 above that the conclusion in question must be regarded as constituting a preparatory act that cannot be subject to review by the Court.

117 Invited once again, during the hearing, to identify which part of the file would explain and demonstrate the link between the quality of the information and the potential harm to its commercial interests, the applicant indicated that possible consequences of classification of a product as genotoxic might be, first, that farmers will no longer want to use such a product, second, that other authorities around the world will rely on such a classification to refuse authorisations, third, that non-governmental organisations will use the information disclosed in the publication of their own articles and thereby disseminate allegedly inaccurate information, and, fourth, that authorisation of the product will be restricted in the final decision, which has in fact occurred with diflubenzuron.

118 None of the claims set out in paragraph 117 above, however, is relevant to calling into question the finding made in paragraph 109 above according to which 'the incorrectness of information does not constitute, as such, a relevant criterion for determining whether the disclosure of that information is likely to undermine commercial interests'.

119 Moreover, the applicant argues that the genotoxic nature of diflubenzuron reveals to the public certain properties of the product and that its disclosure must thus be regarded as equivalent to that of data on the composition of the active substance or on the specification of impurity, enumerated in the list contained in paragraph 2 of Article 63 of Regulation No 1107/2009.

120 It is true that the specification of impurity of the active substance is mentioned among the examples set out in the non-exhaustive list of Article 63(2) of Regulation No 1107/2009, which are, in principle, deemed to undermine the protection of commercial interests. More precisely, the specification of impurity of the active substance is referred to in paragraph 2(b). However, that provision contains an exception whereby the impurities that are considered to be inter alia toxicologically relevant are excluded from that protection.

121 Furthermore, the exception provided for in Article 63(2)(b) of Regulation No 1107/2009 applies in the case at hand. It is apparent from the mandate conferred by the Commission on EFSA during the process of reviewing diflubenzuron that the Commission requested EFSA to organise a peer review 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 the metabolite as a residue and consideration of the potential toxicological relevance.

122 In its letter of 8 October 2015, which must be read together with the contested decision, adopted in response to the applicant's letter of 12 October 2015 challenging that letter of 8 October 2015, EFSA noted that the Standing Committee on the Food Chain and Animal Health had concluded that potential exposure to PCA as a residue ought to be considered a priori as a concern since a threshold for a genotoxic carcinogen could not be assumed. As EFSA indicates, without being challenged in that regard by the applicant, genotoxicity may result in cancer, but also in damage of the genome in the germ cells and thereby cause malformations and development toxicity.

123 In those circumstances, it cannot be denied that the impurities at issue are toxicologically relevant.

124 The applicant also states that Article 63 of Regulation No 1107/2009 seeks to achieve a balance between ensuring adequate risk assessment guaranteed in part by the transparency of the substance review process on the one hand, and the protection of business secrets on the other. In that regard, it cites case-law according to which, where a publication may divulge business secrets, it is only where lack of disclosure could cause an immediate danger to human health or the environment that publication would be warranted.

125 In that context, it should be recalled that, in order that information be of the kind to fall within the ambit of the obligation of professional secrecy, it is necessary, first of all, that it be known only to a limited number of persons. It must then be information whose disclosure is liable to cause serious harm to the person who has provided it or to third parties. Finally, the interests liable to be harmed

by disclosure must, objectively, be worthy of protection. The assessment as to the confidentiality of a piece of information thus requires the legitimate interests opposing disclosure of the information to be weighed against the public interest that the activities of the EU institutions take place as openly as possible (judgment of 30 May 2006, *Bank Austria Creditanstalt* v *Commission*, T-198/03, EU:T:2006:136, paragraph 71).

126 As EFSA and the Commission indicate, it is necessary to take account of the fact that, during the assessment of the confirmatory data submitted by the applicant in June 2011 (see paragraphs 28 to 30 above), the conclusion on the genotoxic potential of the metabolite PCA was already prepared in August 2012 and disclosed to the public in September 2012. In its conclusion, approved on 22 August 2012 and published on 7 September 2012, EFSA concluded that '[b]ased on genotoxicity studies submitted by the [applicant] the weight of evidence suggest[ed] that PCA [wa]s an *in vivo* genotoxic agent' and that 'potential exposure to the metabolite as a residue for consumers, residents [or] bystanders and workers should be considered a priori as a concern, since a threshold for a genotoxic carcinogen could not be assumed'.

127 It follows that the claim that PCA was an *in vivo* genotoxic agent came into the public domain in September 2012. Thus, that information was known beyond a restricted circle of persons.

128 Consequently, as the first of the three cumulative conditions described in paragraph 125 above has not been fulfilled, it is necessary to reject the complaint based on breach of professional secrecy.

129 That conclusion cannot be called into question by the argument of the applicant that there were differences between the EFSA conclusion of 22 August 2012 and the contested conclusion regarding the finality of the concerns raised. Even assuming that there were such differences, they have no impact on the finding that PCA's disclosure as an *in vivo* genotoxic agent took place in September 2012.

130 In the light of the foregoing, it must be concluded that the applicant has not provided 'verifiable evidence' proving that the disclosure of the contested conclusion might undermine its commercial interests.

131 Moreover, in rejecting the applicant's requests for confidential treatment, EFSA relied on Article 39(3) of Regulation No 178/2002, which provides that the conclusions of the scientific opinions delivered by EFSA relating to foreseeable health effects are on no account to be kept confidential. In that regard, it noted that the contested conclusion had identified the adverse effects on health of the use of the metabolite PCA for consumers, workers and residents or bystanders. That reasoning rightly holds that EFSA could not grant confidential treatment to the sections of that conclusion that related to the foreseeable health effects of the active substance at issue. EFSA was therefore entitled to rely on that provision.

132 In any event, the applicant does not demonstrate that, in responding to its requests for confidential treatment in respect of the contested conclusion, EFSA committed a manifest error of assessment in the weighing up of the interests involved.

133 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).

134 It is apparent from the letter of EFSA of 8 October 2015, sent in response to the requests for confidentiality made by the applicant on 4 and 11 September 2015, that the contested conclusion identified the adverse effects on health of the use of the metabolite PCA for consumers, workers and residents or bystanders. That position was confirmed in the contested decision, which had been adopted in response to the letter of the applicant of 12 October 2015 challenging the letter of EFSA of 8 October 2015. EFSA considered that the decision of the Commission to start a review of the approval of the active substance diflubenzuron clearly reflected the existence of a risk already highlighted by EFSA in its 2012 conclusion and acknowledged by the Standing Committee on the Food Chain and Animal Health in its revised report of 16 July 2013. In that context, on the basis of a combined reading of Article 4 and Article 21(1), second subparagraph, of Regulation No 1107/2009, EFSA noted that the identification of a risk concern for human or animal health was a fundamental prerequisite for triggering the review of the approval of an active substance.

135 In those circumstances, EFSA cannot be criticised for having disclosed the contested conclusion in the interests of protecting public health, thereby giving precedence to the requirements related to the protection of those interests over economic interests.

136 The letter of the Commission of 8 July 2015 submitted by the applicant during the hearing cannot change that conclusion. Even if that letter were to be declared admissible, it would have to be stated that it concerns only a procedural aspect of the review of the active substance diflubenzuron, namely, the extension, until 28 August 2015, of the deadline set for EFSA to submit its conclusion on that substance. As such, that letter relates to the review procedure the legality of which is not the subject of the present proceedings.

137 In the light of all the foregoing considerations, it must be concluded that the applicant has not established that EFSA breached the confidentiality rule contained in Article 63 of Regulation No 1107/2009. Accordingly, it is necessary to reject the second branch of the first plea, assessed together with the second to fifth pleas, and to dismiss the action as a whole.

V. Costs

138 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 EFSA in both the present action and the application for interim measures, in accordance with the form of order sought by the latter.

139 The Commission is to bear its own costs, in accordance with Article 138(1) of the Rules of Procedure.

On those grounds,

THE GENERAL COURT (Fourth Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders Arysta LifeScience Netherlands BV to bear its own costs and to pay those incurred by the European Food Safety Authority (EFSA) in the present action and in the proceedings for interim measures;**

3. **Orders the European Commission to bear its own costs.**

Kanninen Calvo-Sotelo Ibáñez-Martín Reine

Delivered in open court in Luxembourg on 14 December 2018.

E. Coulon
Registrar

H. Kanninen
President

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