JUDGMENT OF THE GENERAL COURT (Eighth Chamber)

7 March 2019 (*)

(Access to documents — Regulation (EC) No 1049/2001 — Documents relating to carcinogenicity studies conducted in connection with the renewal of the approval of the active substance glyphosate — Partial refusal to grant access — Exception relating to the protection of commercial interests — Overriding public interest — Regulation (EC) No 1367/2006 — Concept of information relating to emissions into the environment)

In Case T-329/17,

Heidi Hautala, residing in Finland,

Benedek Jávor, residing in Hungary,

Michèle Rivasi, residing in France,

Bart Staes, residing in Belgium,

represented by B. Kloostra, lawyer,

applicants,

v

European Food Safety Authority (EFSA), represented by D. Detken, J. Tarazona, F. Volpi and B. Vagenende, acting as Agents, assisted by R. van der Hout and C. Wagner, lawyers,

defendant,

supported by

Cheminova A/S, established in Harboøre (Denmark), represented by C. Mereu, lawyer,

and by

Monsanto Europe, established in Antwerp (Belgium),

and

Monsanto Company, established in Wilmington, Delaware (United States),

represented initially by M. Pittie, P. Honoré and N. Callens, and subsequently by P. Honoré, N. Callens and A. Helfer, lawyers,

interveners,

APPLICATION pursuant to Article 263 TFEU for the partial annulment of the EFSA decision of 14 March 2017 partially refusing access to twelve carcinogenicity studies on the active substance glyphosate, conducted in connection with the procedure for renewing the approval of that substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009

concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ 2009 L 309, p. 1).

THE GENERAL COURT (Eighth Chamber),

composed of A.M. Collins, President, M. Kancheva and G. De Baere (Rapporteur), Judges,

Registrar: P. Cullen, Administrator,

having regard to the written part of the procedure and further to the hearing on 13 September 2018,

gives the following

Judgment

Background to the dispute

Procedure for renewing the approval of the active substance glyphosate

1 Glyphosate is a chemical product used in pesticides which are plant protection products.

2 For the purposes of its inclusion as an active substance in Annex I to Council Directive 91/414/EC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1), glyphosate was the subject of an assessment report prepared by the Federal Republic of Germany, on the basis of which the European Commission adopted, on 29 June 2001, a review report on glyphosate which was made public on 21 January 2002.

3 Glyphosate was included on the list of active substances in Annex I to Directive 91/414 by Commission Directive 2001/99/EC of 20 November 2001 amending Annex I to Directive 91/414 to include glyphosate and thifensulfuron-methyl as active substances (OJ 2001 L 304, p. 14). The inclusion of glyphosate as an active substance was valid from 1 July 2002 to 30 June 2012.

4 After the Commission had received a request for renewal of the approval of glyphosate as an active substance, the inclusion of glyphosate on the list of active substances in Annex I to Directive 91/414 was temporarily extended until 31 December 2015 by Commission Directive 2010/77/EU of 10 November 2010 amending Directive 91/414 as regards the expiry dates for inclusion in Annex I of certain active substances (OJ 2010 L 293, p. 48).

5 Following the adoption of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414 (OJ 2009 L 309, p. 1), glyphosate was included in the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation No 1107/2009 as regards the list of approved active substances (OJ 2011 L 153, p. 1). The expiry date of the approval remained unchanged at 31 December 2015.

6 Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Directive 91/414 and establishing the list of those substances (OJ 2010 L 322, p. 10), designated the Federal Republic of Germany as Rapporteur Member State and the Slovak Republic as Co-rapporteur Member State for the procedure to renew approval of the active substance glyphosate.

7 For the purpose of the renewal of approval of the active substance glyphosate, in accordance with Regulation No 1141/2010, the Federal Republic of Germany submitted to the Commission and to the

European Food Safety Authority (EFSA) a draft 'renewal assessment report' ('the RAR') dated 18 December 2013, the public version of which was published by EFSA on 12 March 2014.

8 On 20 March 2015, the International Agency for Research on Cancer (IARC), an agency of the World Health Organization (WHO), published its findings concerning the carcinogenic potential of glyphosate. The IARC classified glyphosate as 'probably carcinogenic to humans' (Group 2 A).

9 On 29 April 2015, the Commission asked EFSA to examine the information contained in the IARC's findings and to include it in its own conclusions by 30 October 2015.

10 Since the assessment of the active substance glyphosate was delayed, the validity period for its approval was extended until 30 June 2016 by Commission Implementing Regulation (EU) 2015/1885 of 20 October 2015, amending Implementing Regulation No 540/2011 as regards the extension of the approval periods of the active substances 2,4-D, acibenzolar-s-methyl, amitrole, bentazone, cyhalofop butyl, diquat, esfenvalerate, famoxadone, flumioxazine, DPX KE 459 (flupyrsulfuron-methyl), glyphosate, iprovalicarb, isoproturon, lambda-cyhalothrin, metalaxyl-M, metsulfuron methyl, picolinafen, prosulfuron, pymetrozine, pyraflufen-ethyl, thiabendazole, thifensulfuron-methyl and triasulfuron (OJ 2015, L 276, p. 48).

11 The risk assessment of the active substance glyphosate carried out by the Rapporteur Member State in the RAR was submitted for a peer review by EFSA ('the peer review'). The conclusions of the peer review were adopted on 30 October 2015 and published on 12 November 2015.

12 In its conclusions in the peer review EFSA stated:

'Following a second mandate from the European Commission to consider the findings from the [IARC] regarding the potential carcinogenicity of glyphosate or glyphosate-containing plant protection products in the ongoing peer review of the active substance, EFSA concluded that glyphosate is unlikely to pose a carcinogenic hazard to humans and evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008.'

The applicants' request for access to documents

13 By letter of 15 March 2016, the applicants, Ms Heidi Hautala, Ms Michèle Rivasi, Mr Benedek Jávor and Mr Bart Staes, Members of the European Parliament, submitted to EFSA a request for access to documents pursuant to Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ 2001 L 145, p. 43), and to Regulation (EC) 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on access to information, public participation in decision-making and access to justice in environmental matters to Community institutions and bodies (OJ 2006 L 264, p. 13).

14 In their request, the applicants pointed out that, in March 2015, the IARC had concluded that glyphosate was potentially carcinogenic and that, nevertheless, in November 2015, the peer review concluded that glyphosate would be unlikely to pose a carcinogenic hazard to humans and that the evidence would not support classification of that substance with regard to its carcinogenic potential. The applicants also stated that EFSA had explained that its evaluation was based on a large body of evidence, including a number of studies which had not been assessed by the IARC, which was one of the reasons why EFSA and the IARC had reached different conclusions. Accordingly, they observed that the peer review was based on unpublished studies whose findings could not yet be verified or subjected to independent scrutiny.

15 Referring to the scientific controversy between EFSA and the IARC with regard to the carcinogenicity of glyphosate, the applicants' request related to all the documents which had been used during the peer review.

16 By letter of 11 April 2016, EFSA listed the documents covered by the applicants' request which were already published on its website. In view of the large number of studies covered by the applicants' request (approximately 1500), EFSA asked them to clarify the scope of their request.

17 By email of 25 April 2016 addressed to EFSA, the applicants specified the scope of their request. They stated that the request covered all the studies used by EFSA to assess the carcinogenicity of glyphosate and its representative formulation in their entirety, namely:

– the 14 studies on rodents included in the joint submission dossier, including the raw data;

– the historical control data used in those studies, in particular the historical control incidences for renal tumours and for haemangiosarcoma from the laboratories that performed the mouse carcinogenicity studies cited by EFSA;

– all studies that were assessed by EFSA concerning mechanisms of carcinogenicity such as genotoxicity and oxidative stress in relation to glyphosate and its representative formulation in their entirety.

18 By letter of 31 May 2016, EFSA pointed out that the applicants' request for access covered 182 studies, 100 of which were already available to the public, and enclosed a list of the 182 studies concerned. EFSA stated that, regarding the 82 studies which were not published, consisting of a large number of pages, it had to consult the study owners, in accordance with Article 4(4) of Regulation No 1049/2001, and that, pursuant to Article 6(3) of that regulation, it would provide the applicants with a status update by 22 June 2016 at the latest.

19 By decision of 7 October 2016, EFSA replied to the applicants' request for access to documents. EFSA stated that, after the request for access had been updated, it was found to relate to 75 unpublished studies and it granted partial access to those studies. It informed the applicants that it had decided to release the raw data and findings (aggregated in tables and figures) of those studies which could be deemed not to contain commercially sensitive or confidential information. It considered that disclosure of the other parts of the studies could undermine the commercial interests of their owners and that they were covered by Article 4(2), first indent, of Regulation No 1049/2001. It added that it had weighed up the interests at stake in accordance with Regulation No 1049/2001 and Regulation No 1367/2006, and had concluded that there was no overriding public interest in disclosure of the requested studies.

20 By letter of 9 December 2016, EFSA disclosed to the applicants the raw data and findings (aggregated in tables and figures) of the 75 unpublished studies.

21 By letter of 10 January 2017, the applicants filed a confirmatory application requesting EFSA to review its position. The applicants challenged EFSA's refusal to grant access to the parts of the 75 unpublished studies relating to 'material, experimental conditions and methods' and to 'results and discussion'.

22 By decision of 14 March 2017 ('the contested decision'), EFSA confirmed its decision to refuse access to parts of the 75 unpublished studies. First, EFSA considered that the parts of the studies relating to 'material, experimental conditions and methods', to 'statements of Good Laboratory Practice' and to 'results and discussion' were covered by Article 4(2), first indent, of Regulation No 1049/2001, since disclosure of that information might seriously harm the commercial and financial interests of the companies which had submitted the study reports for renewal of the approval of the active substance glyphosate. EFSA stated that it had balanced the applicants' interest in scrutinising and reproducing the scientific risk assessment undertaken by EFSA for the purpose of preparing its conclusions on the peer review against the interests of the study owners who had made a significant economic investment to undertake those studies. It concluded that the scientific scrutiny could be performed on the basis of the raw data and findings which had been disclosed to the applicants and the published documents.

23 Secondly, EFSA confirmed that there was no overriding public interest justifying disclosure. EFSA considered that the public interest in having a thorough knowledge of the work done on the peer review was met by the publication of a number of documents and by the organisation of events to explain, in particular, the differences with the assessments carried out by the IARC. The interest in the possibility of conducting a full review of the scientific reasoning and calculations in EFSA's output was met by the disclosure of the raw data and the findings of the studies.

24 Thirdly, EFSA considered that there was no overriding public interest in disclosure of the parts of the studies to which the applicants sought access on the basis of Article 6(1) of Regulation No 1367/2006, since those parts do not constitute information which 'relates to emissions into the environment' for the purposes of that provision.

25 Fourthly, EFSA considered that access to the parts of those studies was not necessary for the purpose of verifying the scientific risk assessment carried out in accordance with Regulation No 1107/2009.

26 Fifthly, EFSA confirmed its refusal to grant access to the names of the Member State experts involved in the scientific risk assessment of glyphosate, and to their declarations of conflicts of interest.

Events following the applicants' request for access to the documents

27 Since an opinion of the Committee for Risk Assessment of the European Chemicals Agency (ECHA) on the harmonised classification of glyphosate as regards its carcinogenicity was deemed necessary, on 17 March 2016, the rapporteur Member State submitted a dossier in accordance with Article 37 of 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), including for the hazard class on carcinogenicity.

28 In view of the time required to assess such a dossier, the approval period for the active substance glyphosate was extended until 6 months from the date of receipt by the Commission of the opinion of the ECHA Committee for Risk Assessment and, in any event, until 31 December 2017 at the latest, by Commission Implementing Regulation (EU) 2016/1056 of 29 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate (OJ 2016, L 173, p. 52). In the meantime, the conditions for approval of the active substance were amended in the light of new scientific and technical knowledge by Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate (OJ 2016, L 208, p. 1).

29 The ECHA Committee for Risk Assessment adopted its opinion on 15 March 2017 and forwarded it to the Commission on 15 June 2017. In its opinion, the ECHA Committee for Risk Assessment concluded by consensus that, on the basis of the information currently available, no hazard classification for carcinogenicity was justified for glyphosate.

30 Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate in accordance with Regulation No 1107/2009 and amending the Annex to Commission Implementing Regulation No 540/2011 (OJ 2017 L 333, p. 10), renewed the approval of glyphosate until 15 December 2022, subject to the conditions laid down in Annex I.

31 In that respect, recitals 19 and 20 of Implementing Regulation 2017/2324 state:

'19 While a large amount of information on the active substance glyphosate already exists and has been assessed leading to the conclusion that the approval of the active substance glyphosate should be renewed, additional information on glyphosate is being published at an exceptionally high rate compared to other active substances. Therefore possibilities of rapid future developments in science and technology should be taken into account when deciding on the length of the approval period of

glyphosate, also bearing in mind the fact that glyphosate is one of the most widely used herbicides in the Union.

20 In light of these specificities and other legitimate factors referred to in the recitals above and bearing in mind the need to ensure a level of safety and protection consistent with the high level of protection that is sought within the Union, from a risk management perspective it is appropriate to provide for a renewal of the approval of glyphosate for a period of five years ensuring a priority re-assessment of glyphosate over other active substances.'

Procedure and forms of order sought

32 The applicants brought this action by application lodged at the Court Registry on 24 May 2017.

33 In the defence, lodged at the Court Registry on 15 September 2017, EFSA requested a stay of proceedings pending final judgment in Case T−716/14, *Tweedale* v *EFSA*. By decision of 26 September 2017, the President of the Fourth Chamber of the General Court decided not to stay proceedings at that stage.

34 By document lodged at the Court Registry on 21 September 2017, Cheminova A/S sought leave to intervene in the proceedings in support of the form of order sought by EFSA.

35 By document lodged at the Court Registry on 21 September 2017, Monsanto Europe and Monsanto Company also sought leave to intervene in the proceedings in support of the form of order sought by EFSA.

36 By documents lodged at the Court Registry on 18 October 2017, the applicants requested confidential treatment of the application vis-à-vis Cheminova, Monsanto Europe and Monsanto Company.

37 By order of 30 November 2017, the President of the Fourth Chamber of the General Court granted Cheminova, Monsanto Europe and Monsanto Company leave to intervene. Since the interveners had raised no objections to the requests for confidential treatment, a non-confidential version of the application was provided to them.

38 By document lodged at the Court Registry on 26 January 2018, Monsanto Europe and Monsanto Company waived their right to lodge a statement in intervention. Cheminova did not lodge a statement in intervention.

39 By decision of the President of the General Court, the present case was assigned to a new Judge-Rapporteur, sitting in the Eighth Chamber.

40 The parties presented oral arguments and replied to the Court's oral questions at the hearing on 13 September 2018.

41 The applicants claim that the Court should:

– annul in part the contested decision;

– order EFSA to pay the costs.

42 EFSA contends that the Court should:

– dismiss the action;

– order the applicants to pay the costs.

Law

43 As a preliminary point, it should be stated that the present action concerns only the 12 'most crucial' studies for the peer review and its conclusion that glyphosate is unlikely to pose carcinogenic hazard to humans, that is to say, 12 of the 75 unpublished studies to which EFSA has partially refused access, and which are listed in the annex to the application ('the requested studies').

44 At the hearing, the applicants confirmed that they sought disclosure only of the parts 'material, experimental conditions and methods' and 'results and discussion' of the requested studies.

45 In support of their application, the applicants raise six pleas in law.

46 The first plea alleges, in essence, infringement of Article 4(2), first indent, of Regulation No 1049/2001 and of Article 6(1) of Regulation No 1367/2006, in that the requested studies may be classified as information which 'relates to emissions into the environment' for the purposes of the latter provision.

47 The second plea alleges infringement of Article 2(4) and Article 4(2), first indent, of Regulation No 1049/2001, and of Article 41 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), in that EFSA has failed to demonstrate that there is any actual harm or risk of actual harm to the commercial interests of the study owners, and also infringement of Article 4(4)(d) of the Convention on access to information, public participation in decision-making and access to justice in environmental matters, signed in Aarhus on 25 June 1998 and adopted on behalf of the European Community by Council Decision 2005/370/EC of 17 February 2005 (OJ 2005, L 124, p. 1, 'the Aarhus Convention'), in that EFSA has failed to identify a specific legitimate economic interest.

48 The third plea alleges the misapplication of Article 63(2) of Regulation No 1107/2009.

49 The fourth plea alleges infringement of Article 4(2) of Regulation No 1049/2001 in that EFSA did not recognise that there was an overriding public interest in the disclosure of the requested studies.

50 The fifth plea alleges infringement of Article 4(2), first indent, of Regulation No 1049/2001 in that EFSA omitted to weigh the interest of the public in having access to the environmental information in the requested studies against the interest of companies in protecting their commercial interests and/or let the economic interest of those companies prevail.

51 The sixth plea alleges infringement of Articles 2 and 4 of Regulation No 1049/2001 and Article 41 of Regulation No 178/2002, in that EFSA denied the general interest and the applicants' interest in disclosure of the requested studies.

52 By the first plea, the applicants claim that EFSA infringed Article 4(2) of Regulation No 1049/2001 and Article 6(1) of Regulation No 1367/2006 by failing to recognise that the requested studies could have been be classified as information which 'relates to emissions into the environment' for the purposes of the latter provision.

53 The applicants argue that the requested studies are part of the RAR and contain information on the release of glyphosate into the environment. The concept of information which 'relates to emissions into the environment' for the purposes of Article 6(1) of Regulation No 1367/2006 covers foreseeable emissions into the environment. It includes information on the effects of emissions, entitling the public to check whether the assessment of those effects has been carried out properly.

54 They state that the requested studies are a key element in the conclusion of the peer review that glyphosate should not be classified as carcinogen category 1 A or 1 B; if it were so classified, it could not be approved as an active substance for the purposes of Article 4 of Regulation No 1107/2009, read in conjunction with

point 3.6.3. of Annex II thereto. Those studies do not concern hypothetical emissions, and are intended to assess the effects of glyphosate emissions on human health and to determine whether glyphosate poses a carcinogenic risk for humans.

55 The applicants maintain that the concept of information which 'relates to emissions into the environment' in Article 6(1) of Regulation No 1367/2006 should not be interpreted restrictively. They consider that all the requested studies fall within that concept.

56 Article 4(2) of Regulation No 1049/2001 provides:

'2. The institutions shall refuse access to a document where disclosure would undermine the protection of:

– commercial interests of a natural or legal person, including intellectual property,

– court proceedings and legal advice,

– the purpose of inspections, investigations and audits,

unless there is an overriding public interest in disclosure.'

57 Recital 15 of Regulation No 1367/2006 states:

'Where Regulation […] No 1049/2001 provides for exceptions, these should apply subject to any more specific provisions in this Regulation concerning requests for environmental information. The grounds for refusal as regards access to environmental information should be interpreted in a restrictive way, taking into account the public interest served by disclosure and whether the information requested relates to emissions in the environment. The term "commercial interests" covers confidentiality agreements concluded by institutions or bodies acting in a banking capacity.'

58 Article 6(1) of Regulation No 1367/2006 provides:

'As regards Article 4(2), first and third indents, of Regulation […] No 1049/2001, with the exception of investigations, in particular those concerning possible infringements of Community law, an overriding public interest in disclosure shall be deemed to exist where the information requested relates to emissions into the environment. As regards the other exceptions set out in Article 4 of Regulation […] No 1049/2001, the grounds for refusal shall be interpreted in a restrictive way, taking into account the public interest served by disclosure and whether the information requested relates to emissions into the environment.'

59 Article 6 of Regulation No 1367/2006 adds specific rules on requests for access to environmental information to Regulation No 1049/2001 (judgment of 14 November 2013, *LPN and Finland* v *Commission*, C−514/11 P and C−605/11 P, EU:C:2013:738, paragraph 79).

60 As regards the concept of information which 'relates to emissions into the environment' for the purposes of Article 6(1) of Regulation No 1367/2006, it must be recalled that the Court of Justice stated that it was clear from recital 2 of Regulation No 1049/2001 that openness enables the EU institutions to have greater legitimacy and to be more effective and more accountable to EU citizens in a democratic system and that, by allowing divergences between various points of view to be openly debated, it also contributes to increasing those citizens' confidence in those institutions (judgment of 4 September 2018, *ClientEarth* v *Commission*, C−57/16 P, EU:C:2018:660, paragraph 75).

61 For those purposes, Regulation No 1049/2001 is intended, as is apparent from recital 4 and from Article 1, to give the fullest possible effect to the right of public access to documents of the institutions. Similarly, the aim of Regulation No 1367/2006, as is provided for in Article 1, is to ensure the widest possible systematic availability and dissemination of the environmental information held by the institutions and

bodies of the European Union (see judgment of 23 November 2016, *Commission* v *Stichting Greenpeace Nederland and PAN Europe*, C−673/13 P, EU:C:2016:889, paragraph 52 and the case-law cited; judgment of 4 September 2018, *ClientEarth* v *Commission*, C−57/16 P, EU:C:2018:660, paragraph 98).

62 Therefore, it is only in so far as they derogate from the principle of the widest possible public access to those documents, by restricting such access, that exceptions to that principle, in particular those provided for in Article 4 of Regulation No 1049/2001, must, according to the Court's settled case-law, be interpreted and applied strictly. The need for such a restrictive interpretation is, moreover, confirmed by recital 15 of Regulation No 1367/2006 (see judgment of 23 November 2016, *Commission* v *Stichting Greenpeace Nederland and PAN Europe*, C−673/13 P, EU:C:2016:889, paragraph 53 and the case-law cited).

63 However, by establishing a presumption that the disclosure of information which 'relates to emissions into the environment', with the exception of information relating to investigations, is deemed to be in the overriding public interest, compared with the interest in protecting the commercial interests of a particular natural or legal person, with the result that the protection of those commercial interests may not be invoked to preclude the disclosure of that information, the first sentence of Article 6(1) of Regulation No 1367/2006 derogates from the rule requiring the weighing up of the interests laid down in Article 4(2) of Regulation 1049/2001. Nonetheless, the first sentence of Article 6(1) thus allows actual implementation of the principle that the public should have the widest possible access to information held by the institutions and bodies of the European Union, with the result that a narrow interpretation of that provision cannot be justified (judgment of 23 November 2016, *Commission* v *Stichting Greenpeace Nederland and PAN Europe*, C−673/13 P, EU:C:2016:889, paragraph 54).

64 That means that an EU institution, hearing a request for access to a document, cannot justify its refusal to divulge it on the basis of the exception relating to the protection of the commercial interests of a particular natural or legal person, provided for in Article 4(2), first indent, of Regulation No 1049/2001, where the information contained in that document constitutes information which 'relates to emissions into the environment' for the purposes of Article 6(1) of Regulation No 1367/2006.

65 It should be recalled that, in the present case, EFSA, in the contested decision, justified its refusal to disclose certain parts of the requested studies on the basis of Article 4(2), first indent, of Regulation No 1049/2001, by invoking the protection of the commercial interests of the owners of the requested reports.

66 The applicants describe the requested reports as the 12 'most crucial' studies for the peer review and its conclusion that glyphosate is unlikely to pose any carcinogenic hazard to humans.

67 It is common ground between the parties that these are 12 studies carried out in a laboratory on rats and mice, aimed at detecting the long term toxic effects and carcinogenicity of glyphosate.

68 The applicants state that 11 of the 12 requested studies were part of the RAR and that five of them were also part of the initial assessment report that led, in 2001, to the first inclusion of glyphosate on the list of active substances in Annex I to Directive 91/414. One of the requested studies, the Lankas study of 1981, was part of the first assessment report, but was not taken into account in the carcinogenicity assessment in the RAR.

69 It is also common ground that the requested studies enabled EFSA to conclude that glyphosate did not pose a carcinogenic hazard to humans.

70 The parties agree that the differences between the IARC and EFSA conclusions lie in the unpublished studies underlying the peer review which were not available for the IARC's independent scrutiny. That is apparent, in particular, from an EFSA press release of 12 November 2015, entitled 'Glyphosate: EFSA updates toxicological profile', in which it is stated that 'the evaluation considered a large body of evidence, including a number of studies not assessed by the IARC which is one of the reasons for reaching different conclusions.'

71 First, it should be pointed out, as the applicants maintain without being challenged by EFSA, that an active substance which is classified as carcinogenic cannot be approved or re-approved.

72 Article 14(1) of Regulation No 1107/2009 provides that the approval of an active substance will be renewed if the approval criteria set out in Article 4 of that regulation have been satisfied. With regard to the approval criteria for active substances, Article 4(1) of Regulation No 1107/2009 states:

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

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

73 Point 3.6.3 of Annex II to Regulation No 1107/2009, on ‘impact on human health’, states:

‘An active substance, safener or synergist shall only be approved, if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation […] No 1272/2008, as carcinogen category 1 A or 1 B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.’

74 Consequently, an active substance will be approved only if, on the basis of the assessment of the carcinogenicity testing carried out, it is not classified as carcinogen category 1 A or 1 B, in accordance with the provisions of Regulation No 1272/2008.

75 Article 4(7) of Regulation No 1107/2009 makes provision for a derogation from Article 4(1) of that regulation. Essentially, it provides that, where an active substance is necessary to control a serious danger to plant health, it may be approved for a limited period, even if it does not satisfy the criteria laid down in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, provided that its use is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. However, that provision expressly states that that derogation does not apply to active substances which are or have to be classified in accordance with Regulation No 1272/2008 as carcinogenic category 1 A or carcinogenic category 1 B without a threshold.

76 Furthermore, it should be recalled that it is apparent in particular from the recitals of Implementing Regulation 2017/2324 that, once the approval of glyphosate had been renewed, the divergences between the findings of the IARC and of EFSA with regard to the carcinogenic potential of glyphosate delayed the adoption of the decision on the renewal of the approval of glyphosate. Recital 12 of Implementing Regulation 2017/2324 states, inter alia, that the opinion of the ECHA Committee for Risk Assessment on the harmonised classification of glyphosate as regards its carcinogenicity was sought before a decision was taken on the renewal of the approval, because such an opinion might be relevant for the approval based on the criteria set out in Regulation No 1107/2009.

77 The uncertainties concerning in particular the carcinogenicity of glyphosate, highlighted in the recitals of Implementing Regulation 2017/2324, led the Commission to introduce restrictions on the renewal of the approval of that active substance, particularly with regard to the conditions of use of glyphosate and the length of the approval period.

78 Consequently, the renewal of the approval of the active substance glyphosate was conditional on the outcome of the requested studies, the purpose of which was to determine whether that substance must be classified as carcinogenic.

79 Secondly, the view should also be taken that the requested studies are intended to determine the effects of exposure to glyphosate on human health.

80 Article 3 of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances in accordance with Regulation No 1107/2009 (OJ 2013 L 93, p. 1) provides that Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation No 1107/2009 (JO 2011, L 155, p. 1) is to apply to procedures concerning the renewal of approval of an active substance commenced before 31 December 2013. Therefore, Regulation No 544/2011 applies to the procedure concerning the renewal of approval of glyphosate (see paragraph 4 above).

81 The Annex to Regulation No 544/2011 sets out the data requirements for active substances, pursuant to Article 8(1)(b) of Regulation No 1107/2009.

82 With regard to long term toxicity and carcinogenicity, point 5.5 of the Annex to Regulation No 544/2011 provides:

‘Aim of the test

The long-term studies conducted and reported, taken together with other relevant data and information on the active substance, must be sufficient to permit the identification of effects, following repeated exposure to the active substance, and in particular must be sufficient to:

– identify adverse effects resulting from exposure to the active substance,

– identify target organs, where relevant,

– establish the dose-response relationship,

– identify changes in toxic signs and manifestations observed, and

– establish the NOAEL [no-observed adverse effect levels].

Similarly, the carcinogenicity studies taken together with other relevant data and information on the active substance, must be sufficient to permit the hazards for humans, following repeated exposure to the active substance, to be assessed, and in particular must be sufficient:

– to identify carcinogenic effects resulting from exposure to the active substance,

– to establish the species and organ specificity of tumours induced,

– to establish the dose-response relationship, and

– for non-genotoxic carcinogens, to identify the maximum dose eliciting no adverse effect (threshold dose).’

83 In the light of the foregoing considerations, it is necessary to examine whether the information contained in the requested studies constitutes information which ‘relates to emissions into the environment’ for the purposes of Article 6(1) of Regulation No 1367/2006, which EFSA disputes.

84 In the first place, EFSA contends that the requested studies do not concern actual or foreseeable emissions into the environment or the effects of such emissions.

85 According to the case-law of the Court of Justice, it is apparent, in essence, from Article 1(1)(b) of Regulation No 1367/2006, read in conjunction with Article 2(1)(d), that the objective of that regulation is to ensure access to information concerning factors, such as emissions affecting or likely to affect elements of the environment, in particular air, water and soil. That is not the case as regards purely hypothetical emissions (see judgment of 23 November 2016, *Commission* v *Stichting Greenpeace Nederland and PAN Europe*, C−673/13 P, EU:C:2016:889, paragraph 72 and the case-law cited).

86 However, the concept of information which 'relates to emissions into the environment' cannot be limited to information concerning emissions actually released into the environment when the plant protection product or active substance in question is used on plants or soil, where those emissions depend, inter alia, on the quantities of product actually used by farmers and the exact composition of the final product marketed (judgment of 23 November 2016, *Commission* v *Stichting Greenpeace Nederland and PAN Europe*, C−673/13 P, EU:C:2016:889, paragraph 73).

87 Thus, that concept also covers information on foreseeable emissions into the environment from the plant protection product or active substance in question, under normal or realistic conditions of use of that product or substance, namely the conditions under which the authorisation to place that product or substance on the market was granted and which prevail in the area where that product or substance is intended to be used (see judgment of 23 November 2016, *Commission* v *Stichting Greenpeace Nederland and PAN Europe*, C−673/13 P, EU:C:2016:889, paragraph 74 and the case-law cited).

88 Although the placing on the market of a product or substance is not sufficient in general for it to be concluded that that product or substance will necessarily be released into the environment and that information concerning the product or substance 'relates to emissions into the environment', the situation is different as regards a product such as a plant protection product, and the substances which that product contains, which, in the course of normal use, are intended to be released into the environment by virtue of their very function. In that case, foreseeable emissions, under normal or realistic conditions of use, from the product in question or from the substances which that product contains, into the environment are not hypothetical and are covered by the concept of 'emissions into the environment' for the purposes of the first sentence of Article 6(1) of Regulation No 1367/2006 (see judgment of 23 November 2016, *Commission* v *Stichting Greenpeace Nederland and PAN Europe*, C−673/13 P, EU:C:2016:889, paragraph 75 and the case-law cited).

89 Consequently, an active substance contained in plant protection products, such as glyphosate, in the course of normal use, is intended to be discharged into the environment by virtue of its function, and its foreseeable emissions cannot, therefore, be regarded as purely hypothetical.

90 In any event, glyphosate emissions cannot be classified as merely foreseeable emissions. As was stated in paragraph 78 above, the renewal of the approval of the active substance glyphosate was conditional on the outcome of the requested studies.

91 It should be recalled, in that respect, that glyphosate has been listed as an active substance since 1 July 2002. Since that date, glyphosate has been authorised in Member States and has actually been used in plant protection products. As recital 19 of Implementing Regulation 2017/2324 states, glyphosate is one of the most widely used herbicides in the European Union (see paragraph 31 above).

92 Glyphosate emissions into the environment are therefore a reality. That active substance is present particularly as residues in plants, water and food.

93 Hence, the requested studies are studies which are intended to establish the carcinogenicity of an active substance which is actually present in the environment.

94 Therefore, EFSA cannot argue that the requested studies do not concern actual emissions or the effects of actual emissions.

95 In the second place, EFSA submits that the requested studies do not relate to emissions; their aim is not to set the intended use of glyphosate, and a mere link, even a direct link, with emissions into the environment does not suffice for those studies to be covered by Article 6(1) of Regulation No 1367/2006.

96 It is true that the Court of Justice has already held that, although it was not necessary to apply a restrictive interpretation of the concept of information which 'relates to emissions into the environment', that concept may not, in any event, include information containing any kind of link, even direct, to emissions into the environment. If that concept were interpreted as covering such information, it would to a large extent deprive the concept of 'environmental information', as defined in Article 2(1)(d) of Regulation No 1367/2006, of any meaning. Such an interpretation would deprive of any practical effect the possibility, laid down in Article 4(2), first indent, of Regulation No 1049/2001, for the institutions to refuse to disclose environmental information on the ground, inter alia, that such disclosure would have an adverse effect on the protection of the commercial interests of a particular natural or legal person and would jeopardise the balance which the EU legislature intended to maintain between the objective of transparency and the protection of those interests. It would also constitute a disproportionate interference with the protection of business secrecy ensured by Article 339 TFEU (judgment of 23 November 2016, *Commission* v *Stichting Greenpeace Nederland and PAN Europe*, C−673/13 P, EU:C:2016:889, paragraph 81).

97 However, it must be recalled that, according to the case-law cited in paragraph 62 above, the objective of Regulation No 1367/2006, according to Article 1, is to ensure the widest possible systematic availability and dissemination of environmental information. It is clear, in essence, from recital 2 of that regulation that the purpose of having access to environmental information guaranteed by that regulation is to promote more effective public participation in the decision-making process, thereby increasing, on the part of the competent bodies, the accountability of decision-making and contributing to public awareness and support for the decisions taken (judgments of 23 November 2016, *Commission* v *Stichting Greenpeace Nederland and PAN Europe*, C−673/13 P, EU:C:2016:889, paragraph 80, and of 4 September 2018, *ClientEarth* v *Commission*, C−57/16 P, EU:C:2018:660, paragraph 98).

98 In order to be able to ensure that the decisions taken by the competent authorities in environmental matters are justified and to participate effectively in decision-making in environmental matters, the public must have access to information enabling it to ascertain whether the emissions were correctly assessed and must be given the opportunity reasonably to understand how the environment could be affected by those emissions. The Court of Justice concluded that it was necessary to include in the concept of information which 'relates to emissions into the environment' information enabling the public to check whether the assessment of actual or foreseeable emissions, on the basis of which the competent authority authorised the product or substance in question, was correct, and the data relating to the effects of those emissions on the environment (judgment of 23 November 2016, *Commission* v *Stichting Greenpeace Nederland and PAN Europe*, C−673/13 P, EU:C:2016:889, paragraph 80).

99 It is apparent from that case-law that the concept of information which 'relates to emissions into the environment' for the purposes of Article 6(1) of Regulation No 1367/2006 is not limited to information which makes it possible to assess the emissions as such, but also covers information relating to the effects of those emissions.

100 In that regard, the Court of Justice has provided guidelines in its interpretation of the concept of 'information on emissions into the environment' for the purposes of the second subparagraph of Article 4(2) of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ 2003 L 41, p. 26).

101 The second subparagraph of Article 4(2) of Directive 2003/4 is intended to transpose Article 4(4)(d) of the Aarhus Convention, the provisions of which form an integral part of the EU legal order (see judgment of 15 March 2018, *North East Pylon Pressure Campaign and Sheehy*, C−470/16, EU:C:2018:185, paragraph 46 and the case-law cited). That convention has primacy over secondary EU legislation which

must be interpreted, as far as possible, in accordance with it (see, by analogy, judgment of 11 July 2018, *Bosphorus Queen Shipping*, C−15/17, EU:C:2018:557, paragraph 44).

102 Account must be taken of the Aarhus Convention for the purposes of interpreting Directive 2003/4 (judgment of 23 November 2016, *Bayer CropScience and Stichting De Bijenstichting*, C−442/14, EU:C:2016:890, paragraph 54) and Regulation No 1367/2006 (judgment of 23 November 2016, *Commission* v *Stichting Greenpeace Nederland and PAN Europe*, C−673/13 P, EU:C:2016:889, paragraph 61).

103 It should be pointed out that Article 4(2)(d) of Directive 2003/4 and Article 6(1) of Regulation No 1367/2006 are intended to implement the same provision of the Aarhus Convention.

104 As Advocate General Szpunar stated in point 40 of his Opinion in *Saint-Gobain Glass Deutschland* v *Commission* (C−60/15 P, EU:C:2016:778), it is desirable to ensure consistency in the interpretation of those two acts (Directive 2003/4 and Regulation No 1367/2006) in so far as they implement the same provisions of the Aarhus Convention. In the absence of explicit indication to the contrary, it can be reasonably assumed that the EU legislature intended to implement the Aarhus Convention uniformly in EU law, both for Member States and for the EU institutions.

105 Therefore, the view should be taken that the interpretation adopted by the Court of Justice in the judgment of 23 November 2016, *Bayer CropScience and Stichting De Bijenstichting* (C−442/14, EU:C:2016:890), of the concept of 'information relating to emissions into the environment' for the purposes of Article 4(2)(d) of Directive 2003/4 also applies to the concept of information which 'relates to emissions into the environment' for the purposes of Article 6(1) of Regulation No 1367/2006.

106 The Court of Justice has held that the public must have access not only to information on emissions as such, but also to information concerning the medium to long-term consequences of those emissions on the state of the environment, such as the effects of those emissions on non-targeted organisms. The public interest in accessing information on emissions into the environment is specifically to know not only what is, or foreseeably will be, released into the environment, but also to understand the way in which the environment could be affected by the emissions in question (see, by analogy, judgment of 23 November 2016, *Bayer CropScience and Stichting De Bijenstichting*, C−442/14, EU:C:2016:890, paragraph 86).

107 It follows that the concept of information which 'relates to emissions into the environment' for the purposes of Article 6(1) of Regulation No 1367/2006 must be interpreted as covering not only information on emissions as such, namely information concerning the nature, composition, quantity, date and place of those emissions, but also data concerning the medium to long-term consequences of those emissions on the environment (see, by analogy, judgment of 23 November 2016, *Bayer CropScience and Stichting De Bijenstichting*, C−442/14, EU:C:2016:890, paragraph 87).

108 In that regard it should be recalled that, according to point 5.5 of the Annex to Regulation No 544/2011, on long-term toxicity and carcinogenicity studies, the long-term studies must be 'sufficient to permit the identification of effects, following repeated exposure to the active substance' and 'identify adverse effects resulting from exposure to the active substance'. The carcinogenicity studies must be sufficient 'to permit the hazards for humans, following repeated exposure to the active substance, to be assessed' and 'to identify carcinogenic effects resulting from exposure to the active substance'.

109 The requested studies are intended to establish whether glyphosate has carcinogenic effects and therefore to determine the effects on human health of that active substance to which humans are exposed as a result of its actual use since it was first approved.

110 In the third place, EFSA argues that the conditions of exposure used in the laboratory tests are not comparable to the range of exposure of humans and the environment. EFSA states that the studies are based on oral exposure which is different from the predictable exposure of residents and bystanders due to inhalation or dermal exposure. The doses used are not linked to the expected emissions.

111 Admittedly, in the present case, there is no dispute that the requested studies were carried out in a laboratory on rats and mice with high doses of glyphosate which do not correspond to those with which a human being is faced during normal use of that substance.

112 However, the Court of Justice has held that what mattered was not so much that the data in question come from studies performed entirely or in part in the field or in laboratories or even from a translocation examination, but that the purpose of those studies is to assess 'emissions into the environment' for the purposes of Article 6(1) of Regulation No 1367/2006, that is to say, the actual or foreseeable emissions of the product or substance in question into the environment under circumstances representing normal or realistic conditions of use of that product or substance, or to analyse the effects of those emissions (see, by analogy, judgment of 23 November 2016, *Bayer CropScience and Stichting De Bijenstichting*, C−442/14, EU:C:2016:890, paragraph 89).

113 Therefore, data from tests whose objective is to study the effects of the use of a dose of the product or substance in question which is significantly above the maximum dose for which the marketing authorisation is granted and which is to be used in practice, or a dose in a much higher concentration, do not, in particular, constitute information which 'relates to emissions into the environment', since that information relates to emissions which are not foreseeable under normal or realistic conditions of use (see, by analogy, judgment of 23 November 2016, *Bayer CropScience and Stichting De Bijenstichting*, C−442/14, EU:C:2016:890, paragraph 90).

114 By contrast, information which 'relates to emissions into the environment' covers studies which seek to establish the toxicity, effects and other aspects of a product or substance under the most unfavourable realistic conditions which could possibly occur, and studies carried out in conditions as close as possible to normal agricultural practice and conditions which prevail in the area where that product or substance is to be used (see, by analogy, judgment of 23 November 2016, *Bayer CropScience and Stichting De Bijenstichting*, C−442/14, EU:C:2016:890, paragraph 91).

115 It follows that, for the studies to be classified as information which 'relates to emissions into the environment' for the purposes of Article 6(1) of Regulation No 1367/2006, what matters is not so much the conditions in which those studies were carried out, in particular whether or not they were carried out in a laboratory, but their purpose.

116 Thus, EFSA cannot validly argue that the requested studies are not related to the intended uses and are purely theoretical on the basis that the conditions of exposure used for the laboratory test are not comparable to the range of exposure of humans.

117 That would mean that the requested studies have determined that glyphosate is non-carcinogenic for humans by using purely hypothetical data which have nothing to do with the manner in which humans will be exposed to glyphosate when using it.

118 In that regard, it should be recalled that the purpose of the requested studies is to determine whether glyphosate must be classified as carcinogenic for humans, in which case the active substance could not be renewed.

119 Thus, EFSA's argument that the conditions in which the requested studies were carried out are not linked to emissions is irrelevant. What matters is not the conditions in which the requested studies were carried out, but their purpose, which is to determine the carcinogenic effects of exposing humans to glyphosate and therefore to determine the toxicity of glyphosate under the most unfavourable realistic conditions which could possibly occur.

120 Therefore, since the purpose of the requested studies is to determine the carcinogenic effects of glyphosate and therefore the effects on human health and the threat to humans of an active substance which is actually released into the environment, they must be regarded as information which 'relates to emissions into the environment' for the purposes of Article 6(1) of Regulation No 1367/2006.

121 Under the case-law cited in paragraph 97 above, according to which the public must be given the opportunity reasonably to understand how the environment could be affected by those emissions, the view must therefore be taken that the applicants' access to the requested studies will enable them to understand the manner in which human health could be affected by glyphosate being released into the environment.

122 It follows from the foregoing that the requested studies must be regarded as constituting information which 'relates to emissions into the environment' for the purposes of Article 6(1) of Regulation No 1367/2006.

123 Therefore, pursuant to that provision, an overriding public interest in disclosing the studies is deemed to exist, and EFSA could not refuse to disclose them on the ground that that would have an adverse effect on the protection of the commercial interests of the owners of the requested studies for the purposes of Article 4(2), first indent, of Regulation No 1049/2001.

124 Consequently, EFSA's argument that disclosure of the requested studies is not necessary, since its assessment can be scrutinised using documents that have already been published, is irrelevant.

125 In the light of all of the foregoing, the first plea in law should be upheld, and therefore the contested decision should be annulled in so far as EFSA refused access to the parts 'material, experimental conditions and methods' and 'results and discussion' of the requested studies, without there being any need to examine the other pleas in law raised by the applicants.

Costs

126 Under Article 134(1) of the Rules of Procedure of the General Court, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since EFSA has been unsuccessful, it must be ordered to bear its own costs and to pay those incurred by the applicants, in accordance with the form of order sought by the applicants.

127 In addition, under Article 138(3) of the Rules of Procedure, the Court may decide that an intervener, other than those referred to in Article 138(1) and (2) of those Rules, is to bear its own costs. In the present case, the Court has decided that Cheminova, Monsanto Europe and Monsanto Company, having intervened in the present action in support of the form of order sought by EFSA, are to bear their own costs.

On those grounds,

THE GENERAL COURT (Eighth Chamber)

hereby:

1. **Annuls the decision of the European Food Safety Authority (EFSA) of 14 March 2017, in so far as EFSA refused access to the parts 'material, experimental conditions and methods' and 'results and discussion' of 12 carcinogenicity studies on the active substance glyphosate;**

2. **Orders EFSA to bear its own costs and pay the costs incurred by Ms Heidi Hautala, Ms Michèle Rivasi, Mr Benedek Jávor and Mr Bart Staes;**

3. **Orders Cheminova A/S, Monsanto Europe and Monsanto Company to bear their own costs.**

Collins Kancheva De Baere

Delivered in open court in Luxembourg on 7 March 2019.

E. Coulon A.M. Collins

Registrar President

---

* Language of the case: English.