JUDGMENT OF THE GENERAL COURT (Eighth Chamber)

7 March 2019 (*)

(Access to documents — Regulation (EC) No 1049/2001 — Documents relating to toxicity 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−716/14,

Anthony C. Tweedale, residing in Brussels (Belgium), represented by B. Kloostra, lawyer,

applicant,

supported by

Kingdom of Sweden, represented initially by A. Falk, C. Meyer-Seitz, U. Persson, N. Otte Widgren, E. Karlsson and L. Swedenborg, and subsequently by A. Falk, C. Meyer-Seitz, H. Shev, L. Swedenborg and F. Bergius, acting as Agents,

intervener,

v

European Food Safety Authority (EFSA), represented by D. Detken, J. Tarazona, C. Pintado and B. Vagenende, acting as Agents, assisted initially by R. Van der Hout and A. Köhler, and subsequently by R. Van der Hout and C. Wagner, lawyers,

defendant,

APPLICATION pursuant to Article 263 TFEU for the partial annulment of the EFSA decision of 16 October 2017 annulling and replacing the decision of 30 July 2014 and granting partial access to two toxicity studies on the active substance glyphosate, conducted in connection with the procedure to renew approval of that active 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

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 By letter dated 11 April 2014, sent by email the following day, the applicant, Mr Anthony C. Tweedale, 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).

9 That request concerned toxicity studies ASB2012-11499 and TOX95552393, ‘the two “key studies” used in order to set glyphosate’s acceptable daily intake (ADI)’ (‘the requested studies’).

10 The applicant’s request stated that ‘their public summaries in the RAR either [did] not exist or contain[ed] no details about its protocols or results, which [were] necessary to assess its reliability, which [was] not EFSA’s job alone’ and that ‘the requested information [was] the report written on this animal experiment, and any raw data or other auxiliaries to the experiment’.

11 By letter of 5 June 2014, EFSA refused access to the requested studies. EFSA stated that it had consulted the owners of the requested studies pursuant to Article 4(4) of Regulation No 1049/2001. It stated that it followed from the position of those owners and from its own assessment that those studies were covered by the exception provided by Article 4(2) of Regulation No 1049/2001, relating to the protection of commercial interests, including intellectual property rights, and that their full protection was also the direct consequence of their classification as 'confidential' under Article 63 of Regulation No 1107/2009. EFSA considered that disclosure of the requested studies would reveal the owners' know-how relating to scientific expertise and their commercial strategy, including their know-how for the dossier compilation, and would undermine their commercial interests.

12 EFSA added that, with respect to the balancing of interests and verification of the existence of an overriding public interest in disclosure of the requested studies, public interest in having access to the scientific information relating to the safety of the active substance glyphosate was manifestly and fully satisfied by the publication of the public version of the RAR (available on the EFSA website). EFSA refused to disclose the requested studies to the applicant pursuant to the exceptions provided for in Article 4(2) of Regulation No 1049/2001, read in conjunction with the provisions of that regulation on the confidential treatment of the commercial data received for scientific risk assessment, without prejudice to Regulation (EC) No 1367/2006.

13 By email of 24 June 2014, the applicant sent a confirmatory application asking EFSA to reconsider its position.

14 By decision of 30 July 2014, EFSA confirmed its refusal of access to the requested studies on the basis of Article 4(2) of Regulation No 1049/2001 and of Article 63 of Regulation No 1107/2009. It also stated that those studies did not constitute information which 'relates to emissions into the environment' for the purposes of Article 6(1) of Regulation No 1367/2006.

15 After the present action was brought, 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).

16 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.

17 Commission Implementing Regulation (EU) 2016/1056 of 29 June 2016 amending Implementing Regulation No 540/2011 as regards the extension of the approval period of the active substance glyphosate (OJ 2016 L 173, p. 52), extended the inclusion of glyphosate in the Annex to Regulation No 540/2011 until 31 December 2017, in view of the fact that the assessment of the substance and the decision on the renewal of its approval had been delayed.

18 On 16 October 2017, EFSA adopted a new confirmatory decision annulling and replacing the decision of 30 July 2014 and granting the applicant partial access to the requested studies.

19 In that decision, EFSA stated that the requested studies had been identified as the following:

– 1991, Brooker and Others, 'The Effect of Glyphosate on Pregnancy of the Rabbit (Incorporates Preliminary Investigations)', Huntingdon Research Centre, date: 1991-10-14, Reference TOX95552393,

– 1996, Coles and Others, ‘Glyphosate technical: oral gavage teratology study in the rabbit Safepharm Laboratories Limited’, Shardlow Business Park, dated 1996-07-04.

20 EFSA, taking into account the applicant’s arguments in this case, decided to give him access to the raw data and findings (aggregated in tables and figures) of the requested studies. It considered that the confidentiality claims put forward by the owners of those studies on the basis of Regulation No 1049/2001, read in conjunction with Article 63(2) of Regulation No 1107/2009, did not apply to that information.

21 However, EFSA considered, first, that the parts of the requested studies identified as coming under the list of information which could undermine the commercial interests of the owners of those studies for the purposes of Article 63(2) of Regulation No 1107/2009, should be protected in accordance with Article 4(2), first indent, of Regulation No 1049/2001. Secondly, EFSA considered that the information relating to ‘scientific know-how’ contained in the requested studies, namely the introduction, which contains administrative information on those studies, and the parts relating to materials and methods with information on batches and analytical methods, were also covered by the exception relating to the protection of commercial interests provided for in Article 4(2), first indent, of Regulation No 1049/2001. Thirdly, it considered that the annexes and other administrative parts of the requested studies, containing the regulatory certification of those studies by dedicated laboratories and including the statement of compliance with Good Laboratory Practice and the protocols followed by the study owners, were protected under that same provision.

22 EFSA also stated that the names and signatures contained in the requested studies, which were not already in the public domain, were covered by the exception provided for in Article 4(1)(b) of Regulation No 1049/2001.

23 In addition, EFSA stated 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. It considered that information passed on to the applicant satisfied the public’s need to be informed and made it possible to reproduce its assessment, whilst protecting the interests of the owners of the requested reports. According to EFSA, the raw data and findings were sufficient to examine carefully the evaluation of the results of the requested studies conducted during the assessment of glyphosate and the finding of ‘no observed adverse effect levels’ (NOAEL) selected and, combined with the information already published, were sufficient to verify their role in establishing the acceptable daily intake (ADI) proposed.

24 Finally, EFSA considered that the parts of the requested studies which were not disclosed did not contain information concerning emissions of plant protection products or their residues in the environment, or any information concerning emissions or releases of glyphosate into, or their effect on, the environment and that the presumption laid down in Article 6(1) of Regulation No 1367/2006 was therefore not applicable.

25 Furthermore, 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.

Procedure and forms of order sought

26 The applicant brought this action by application lodged at the Court Registry on 9 October 2014.

27 By document lodged at the Court Registry on 19 January 2015, EFSA requested that the proceedings be stayed pending final judgments in Case C−673/13 P, *Commission* v *Stichting Greenpeace Nederland and PAN Europe* and Case C−442/14, *Bayer CropScience and Stichting De Bijenstichting*. The applicant did not submit observations on that request.

28 By document lodged at the Court Registry on 22 January 2015, the Kingdom of Sweden applied for leave to intervene in the present proceedings in support of the form of order sought by the applicant.

29 By order of 14 April 2015, the President of the Fifth Chamber of the General Court granted the request for suspension of the proceedings, on the basis of the third paragraph of Article 54 of the Statute of the Court of Justice of the European Union and of Article 77(a) of the Rules of Procedure of the General Court of 2 May 1991.

30 As a result of changes in the composition of the Chambers of the General Court pursuant to Article 27(5) of the Rules of Procedure of the General Court, the Judge-Rapporteur was assigned to the Fourth Chamber, to which the present case was accordingly allocated.

31 Following delivery of the judgments of 23 November 2016, *Commission* v *Stichting Greenpeace Nederland and PAN Europe*, C−673/13 P, EU:C:2016:889, and of 23 November 2016, *Bayer CropScience and Stichting De Bijenstichting*, C−442/14, EU:C:2016:890, the proceedings were resumed.

32 By decision of 8 December 2016, the President of the Fourth Chamber of the General Court granted the intervention of the Kingdom of Sweden, which lodged its Statement in Intervention on 28 February 2017. The applicant and EFSA lodged their observations on that statement within the prescribed time limit.

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

34 By letter lodged at the Court Registry on 19 October 2017, EFSA notified the General Court of the adoption of the decision of 16 October 2017.

35 By document lodged at the Court Registry on 22 December 2017, the applicant modified the form of order sought in order also to seek annulment of the decision of 16 October 2017.

36 EFSA and the Kingdom of Sweden lodged their observations on the statement modifying the form of order sought on 9 February and 19 March 2018 respectively.

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

38 In the statement modifying the form of order sought, the applicant, supported by the Kingdom of Sweden, claims that the Court should:

– annul the decisions of 30 July 2014 and 16 October 2017;

– order EFSA to pay the costs.

39 EFSA contends that the Court should:

– dismiss the action;

– order the applicant to pay the costs.

40 At the hearing, the applicant discontinued his application for annulment of EFSA's decision of 30 July 2014. The applicant also indicated that he was not seeking disclosure of the names and signatures of the persons referred to in the requested studies. Therefore, the present action must be viewed as an application for partial annulment of the decision of 16 October 2017 ('the contested decision').

Law

41 In support of the action, the applicant raises two pleas in the application and four new pleas in the statement modifying the form of order sought.

42 The first plea alleges 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.

43 The second plea alleges infringement of Article 4(2) of Regulation No 1049/2001 and of Article 4 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 did not assess the actual risk of harm caused to the commercial interests relied upon by the disclosure of the requested studies.

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

45 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.

46 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.

47 The sixth plea alleges infringement of Articles 2 and 4 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 EFSA and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1) in that EFSA denied the general interest and the applicant's interest in disclosure of the requested studies.

48 By the first plea, the applicant claims 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 be classified as information which 'relates to emissions into the environment' for the purposes of the latter provision.

49 According to the applicant, the application of the exception to disclosure based on the protection of commercial interests, laid down in Article 4(2), first indent, of Regulation No 1049/2001, must be waived owing to an overriding public interest. Under Article 6(1) of Regulation No 1367/2006, an overriding public interest in disclosure is deemed to exist where the information requested 'relates to emissions into the environment'. The studies requested constitute, with regard to glyphosate, information which 'relates to emissions into the environment' for the purposes of that provision, and they should therefore have been disclosed.

50 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.'

51 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.’

52 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.’

53 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).

54 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).

55 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).

56 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).

57 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).

58 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 for the purposes of 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.

59 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.

60 The requested studies were characterised by the applicant, in his request for access to the documents, as 'the two "key studies" used in order to set glyphosate's [ADI]'. They are two developmental toxicity studies used in the request to renew the approval of the active substance glyphosate.

61 It is common ground between the parties that both of those studies were carried out in a laboratory on pregnant rabbits by gavage with high doses of glyphosate. The purpose of those studies was to assess the effects on the embryo and development of the foetus in case of exposure to the active substance glyphosate and to establish the dose with no observed adverse effect levels (NOAEL) for maternal toxicity and the development of the foetus.

62 The parties also agree that, on the basis of the requested studies, the NOAEL was set at 50 mg per kilogramme of body weight per day ('mg/kg bw/day') and that the ADI for glyphosate, calculated on the basis of the NOAEL by applying a safety factor of 100, was set in the RAR at 0.5 mg/kg bw/day.

63 Article 3(2)(j) of Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414 (OJ 2005 L 70, p. 1), defines the ADI as being 'the estimate of the amount of substances in food expressed on a body weight basis, that can be ingested daily over a lifetime, without appreciable risk to any consumer on the basis of all known facts at the time of evaluation, taking into account sensitive groups within the population (e.g. children and the unborn)'.

64 It follows from part 2.6 of volume 1 of the RAR, relating to the effects on human and animal health of the active substance glyphosate, that the NOAEL established from the requested studies also made it possible to establish the 'acute reference dose' (ARfD), set by applying a safety factor of 100 to 0.5 mg per kilogramme of body weight.

65 Article 3(2)(i) of Regulation (EC) No 396/2005 defines 'acute reference dose' as 'the estimate of the amount of substance in food, expressed on a body weight basis, that can be ingested over a short period of time, usually during one day, without appreciable risk to the consumer on the basis of the data produced by appropriate studies and taking into account sensitive groups within the population (e.g. children and the unborn)'.

66 First, it should be pointed out that the requested studies, which were described as '"key studies" used in order to set glyphosate's [ADI]', constitute necessary information which must appear in the renewal dossier.

67 Article 7(1) of Regulation No 1107/2009 provides that an application for the approval of an active substance is to be submitted by the producer of that active substance to the rapporteur Member State, together with, inter alia, a summary and a complete dossier as provided for in Article 8(1) and (2) of Regulation No 1107/2009.

68 Point 3.1 of Annex II to Regulation No 1107/2009 states, inter alia, that ‘the dossiers submitted pursuant to Article 7(1) shall contain the information needed to establish, where relevant, [ADI], Acceptable Operator Exposure Level (AOEL) and [ARfD].

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

70 Under Article 3(23) of Regulation No 1107/2009, ‘tests and studies’ means ‘investigations or experiments whose purpose is to determine the properties and behaviour of an active substance or of plant protection products, predict exposure to active substances and/or their relevant metabolites, determine safe levels of exposure and establish conditions for the safe use of plant protection products’.

71 In addition, 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).

72 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.

73 With regard to the toxicological and metabolism studies, point 5 of the Annex to Regulation No 544/2011 provides, inter alia, in its introduction:

‘(i) The information provided, taken together with that provided for one or more preparations containing the active substance, must be sufficient to permit an evaluation to be made as to the risks for man, associated with the handling and use of plant protection products containing the active substance, and the risk for man arising from residual traces remaining in food and water. In addition, the information provided must be sufficient to:

– decide whether, or not, the active substance can be approved,

– specify appropriate conditions or restrictions to be associated with any approval,

– classify the active substance as to hazard,

– establish a [ADI] level for man,

– establish [AOEL],

– […]’

74 More specifically, with regard to the developmental toxicity studies, of which the requested studies form part, point 5.6.2 of the Annex to Regulation No 544/2011 states:

‘The studies reported, taken together with other relevant data and information on the active substance, must be sufficient to permit effects on embryonic and foetal development, following repeated exposure to the active substance, to be assessed, and in particular must be sufficient:

– to identify direct and indirect effects on embryonic and foetal development resulting from exposure to the active substance,

[…]

– to establish the NOAEL.’

75 It follows that, by making it possible to determine, inter alia, the ADI and ARfD for glyphosate, which represent the estimated quantity in food that may be ingested daily or over a lifetime without appreciable risk to the health of the consumer, the requested studies form part of the process of assessing the risks of the active substance for human health for the purposes of renewing the approval of glyphosate.

76 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.

77 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.

78 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).

79 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).

80 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).

81 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).

82 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.

83 In any event, glyphosate emissions cannot be classified as merely foreseeable emissions. The requested studies formed part of the dossier for the renewal of approval of the active substance glyphosate.

84 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.

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

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

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

88 In the second place, EFSA contends that the requested studies were conducted in order to determine the dangerous properties of glyphosate and not to establish the level of emissions which might be authorised and that, therefore, their purpose is not to assess the actual or foreseeable emissions. A link with emissions into the environment is not sufficient for those studies to be covered by Article 6(1) of Regulation No 1367/2006.

89 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).

90 However, it must be recalled that, according to the case-law cited in paragraph 57 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).

91 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).

92 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.

93 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).

94 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).

95 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).

96 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.

97 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.

98 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.

99 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).

100 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).

101 In that regard, by making it possible to set the NOAEL and the ADI for glyphosate, that is to say, the maximum dose for exposure to the active substance for which no adverse effects are observed and the

estimated quantity of the substance that may be ingested daily over a lifetime without appreciable risk to the consumer, the view must be taken that the requested studies, in accordance with the definition in Article 3(23) of Regulation No 1107/2009, made it possible to 'determine safe levels of exposure' and to 'establish conditions for the safe use of plant protection products'.

102 In addition, it is apparent from point 5 of the Annex to Regulation No 544/2011 that the requested studies, by making it possible to set the ADI for glyphosate, constitute information which allows for an 'evaluation to be made as to the risks for man, associated with the handling and use of the active substance' and the 'risk for man arising from residual traces remaining in food and water'. More specifically, the purpose of the requested studies, as developmental toxicity studies, according to point 5.6.2 of the Annex to Regulation No 544/2011, is 'to permit effects on embryonic and foetal development, following repeated exposure to the active substance, to be assessed'.

103 The view must therefore be taken that the requested studies, by establishing the NOAEL on the basis of which the ADI and the ARfD were calculated, made it possible to determine the limits within which glyphosate, when present in food, does not present any risk in the medium to long term for human health and therefore set the various values relating to the consequences of glyphosate emissions on human health.

104 Furthermore, as the Kingdom of Sweden points out, the ADI represents a threshold for long-term safe exposure for consumers. Thus, if the use or residues of a plant protection product cause the ADI to be exceeded, they will be regarded as harmful to human health.

105 In that regard, EFSA acknowledges that the ADI forms part of the risk assessment process for the approval of an active substance, which requires that the conditions set out in Article 4 of Regulation No 1107/2009 are satisfied. It states that, to that end, it is necessary to assess whether the active substance or its residues have harmful effects on human health. EFSA states that, in a first step, the toxicological reference value used to assess the long term exposure of humans is the ADI, calculated on the basis of the NOAEL, and that, in a second step, the exposure to the active substance and its residues is assessed and compared with the ADI.

106 It is apparent from the peer review and it is common ground between the parties that, on the basis of the requested studies, the ADI for glyphosate went from 0.3 mg/kg bw/day at the time of the first approval of glyphosate to 0.5 mg/kg bw/day at the time of the renewal of the approval of that active substance.

107 An increase in the ADI implies the possibility of an increase in the glyphosate residues regarded as not being harmful to health. As the Kingdom of Sweden points out, an increase in the ADI means that the relevant authorities will accept higher glyphosate levels in food.

108 In the third place, EFSA argues that the doses administered to vertebrate animals in a laboratory are not the same as the doses with which human beings will come into contact when using the substance and that those studies carried out in a laboratory are unrelated to the intended manner of use and do not correspond to realistic conditions. The conditions of exposure used in the laboratory studies are not comparable to the range of exposure of humans and the environment to spraying with glyphosate in accordance with good agricultural practice.

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

110 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).

111 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).

112 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).

113 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.

114 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 high doses used in the requested studies in order to set the ADI do not correspond to those actually released into the environment.

115 That would mean that the requested studies set the NOAEL for human beings, from which the ADI was calculated using purely hypothetical data which have nothing to do with the manner in which human beings will be exposed to glyphosate when using it.

116 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 define the NOAEL, used as a basis for establishing the ADI and the ARfD. It follows that the purpose of the requested studies is to determine the limits beyond which exposure to the active substance glyphosate presents risks to human health.

117 Therefore, by making it possible to define the maximum dose for exposure to glyphosate beyond which the residues of the active substance will be regarded as harmful to human health, the requested studies are studies which seek to determine the toxicity of glyphosate under the most unfavourable realistic conditions which could possibly occur.

118 In addition, under the case-law cited in paragraph 91 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 be taken that the applicant's access to the requested studies would enable him to understand the manner in which human health could be affected by glyphosate being released into the environment.

119 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.

120 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.

121 Consequently, EFSA's argument that access to the complete studies is not necessary, since the parts of the requested studies that were disclosed make it possible to verify the result of the studies or the assessment carried out, is irrelevant.

122 Moreover, in the contested decision, in the context of the exception laid down in Article 4(2), first indent, of Regulation No 1049/2001, EFSA stated that Article 63(2) of Regulation No 1107/2009 contained a non-exhaustive list of sensitive information the disclosure of which was in principle deemed to undermine the protection of the commercial interests of the persons concerned. It considered that the parts of the studies identified as coming under that list had to be protected in accordance with Article 4(2), first indent, of Regulation No 1049/2001.

123 First, it is apparent from the contested decision that EFSA does not specify which parts of the requested studies were identified as coming under the list in Article 63(2) of Regulation No 1107/2009.

124 In that regard, it should be pointed out that, with regard to the information relating to the names and addresses of persons involved in testing on vertebrate animals, referred to in Article 63(2)(g) of Regulation No 1107/2009, EFSA expressly stated that they were protected by virtue of the exception provided for in Article 4(1)(b) of Regulation No 1049/2001. It should be recalled that that information is not the subject of the present action.

125 However, EFSA does not indicate which information in the requested studies comes under one of the other exceptions contained in the list in Article 63(2) of Regulation No 1107/2009. In that regard it should be pointed out that the table annexed to the contested decision, setting out which parts of the requested studies were or were not disclosed and for what reason, refers to Article 63(2) of Regulation No 1107/2009 only with regard to the parts of those studies which were disclosed, that is to say, the title, the table of contents and the tables, figures and annexes containing raw data from the studies.

126 Secondly, EFSA expressly states in the contested decision that it applied Article 63(2) of Regulation No 1107/2009 in the context of the exception provided for in Article 4(2), first indent, of Regulation No 1049/2001, that is to say, the protection of commercial interests.

127 It follows from the foregoing that the exception relating to the protection of commercial interests, provided for in Article 4(2), first indent, of Regulation No 1049/2001, cannot be relied upon in order to object to the disclosure of the requested studies which are regarded as information which 'relates to emissions into the environment' for the purposes of Article 6(1) of Regulation No 1367/2006.

128 Therefore, the view should be taken that EFSA has not justified the application of Article 63(2) of Regulation No 1107/2009.

129 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 it refused to disclose the whole of the requested studies, with the exception of the names and signatures of the persons mentioned therein.

Costs

130 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.

131 Since EFSA has been unsuccessful, it must be ordered to bear its own costs and to pay those incurred by the applicant, in accordance with the form of order sought by the applicant.

132 Under Article 138(1) of the Rules of Procedure, Member States which intervene in the proceedings are to bear their own costs. For that reason, the Kingdom of Sweden must bear its own costs.

On those grounds,

hereby:

1. **Annuls the decision of the European Food Safety Authority (EFSA) of 16 October 2017, annulling and replacing the decision of 30 July 2014 and granting partial access to two toxicity studies on the active substance glyphosate, conducted in connection with the procedure to renew approval of that active substance, in so far as EFSA refuses to disclose the whole of those studies, with the exception of the names and signatures of the persons mentioned therein;**

2. **Orders EFSA to bear its own costs and pay the costs incurred by Mr Anthony Tweedale;**

3. **Orders the Kingdom of Sweden to bear its 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.