ECLI:EU:T:2016:736

JUDGMENT OF THE GENERAL COURT (Fifth Chamber)

15 December 2016 (*)

(Environment – Genetically modified products – Genetically modified soybean MON 87701 x MON 89788 – Request for internal review of the decision on marketing authorisation dismissed as unfounded – Obligation to state reasons – Manifest error of assessment)

In Case T-177/13,

TestBioTech eV, established in Munich (Germany),

European Network of Scientists for Social and Environmental Responsibility eV, established in Braunschweig (Germany),

Sambucus eV, established in Vahlde (Germany),

represented by K. Smith, QC, and J. Stevenson, Barrister,

applicants,

v

European Commission, represented initially by C. Cattabriga and P. Oliver, and subsequently by P. Cattabriga and L. Flynn and, lastly, by C. Cattabriga, L. Flynn and C. Valero, acting as Agents,

defendant,

supported by

United Kingdom of Great Britain and Northern Ireland, represented initially by E. Jenkinson and L. Christie, and subsequently by L. Christie and, lastly, by S. Brandon, acting as Agents, and by J. Holmes, Barrister,

by

European Food Safety Authority (EFSA), represented by D. Detken and S. Gabbi, acting as Agents,

and by

Monsanto Europe, established in Antwerp (Belgium),

and

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

represented by M. Pittie, lawyer,

interveners,

APPLICATION pursuant to Article 263 TFEU for annulment of the decision of the European Commission of 8 January 2013, concerning the review of Commission Implementing Decision 2012/347/EU of 28 June 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87701 x MON 89788 (MON-877Ø1-2 x MON-89788-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ 2012 L 171, p. 13),

THE GENERAL COURT (Fifth Chamber),

composed of A. Dittrich, President, J. Schwarcz and V. Tomljenović (Rapporteur), Judges,

Registrar: S. Spyropoulos, Administrator,

having regard to the written part of the procedure and further to the hearing on 12 May 2016,

gives the following

Judgment

Background to the dispute

1 The first applicant is a not-for-profit association to promote independent research and public debate on the impacts of biotechnology, registered in Germany.

2 The second applicant, European Network of Scientists for Social and Environmental Responsibility eV, is a German not-for-profit organisation the purpose of

which is the advancement of science and research for the protection of the environment, biological diversity and human health against the negative impacts of new technologies and their products.

3 The third applicant, Sambucus eV, is a German not-for-profit environmental organisation which engages in cultural activities.

4 On 14 August 2009, Monsanto Europe SA submitted to the competent authority of the Netherlands, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ 2003 L 268, p. 1) an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from MON 87701 × MON 89788 soybean ('the modified soybean'). The application also covered the placing on the market of the modified soybean as present in products other than food and feed containing or consisting of that soybean for the same uses as any other soybean, with the exception of cultivation.

5 On 15 February 2012, the European Food Safety Authority (EFSA) issued an overall opinion in accordance with Articles 6 and 18 of Regulation No 1829/2003 ('the overall opinion'). In paragraph 3 of that opinion, EFSA explained that its Scientific Panel on Genetically Modified Organisms ('the Scientific Panel') had adopted a scientific opinion, on 25 January 2012, on the application (EFSA-GMO-NL-2009-73) concerning the placing on the market of the insect-resistant and herbicide-tolerant modified soybean, for food and feed uses, import and processing under Regulation No 1829/2003 by Monsanto (*The EFSA Journal* 2012;10(2):2560, 1-34) ('the scientific opinion of 25 January 2012'), finding that the modified soybean was, in the context of its intended uses, as safe as its non-genetically modified comparator with respect to potential effects on human or animal health or on the environment. Moreover, the Scientific Panel concluded that the crossing of modified soybean did not, in the context of its intended uses, result in interactions between the events that would affect the safety of the modified soybean with respect to potential effects on human and animal health and on the environment. In the overall opinion, EFSA concluded that it 'fulfil[led] the requirements of Articles 6 and 18 [of Regulation No 1829/2003] for the placing on the market of [the modified soybean]'.

6 By Implementing Decision 2012/347/EU of 28 June 2012 authorising the placing on the market of products containing, consisting of, or produced from the genetically modified soybean pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ 2012 L 171, p. 13) ('the authorisation decision'), the Commission authorised, subject to certain conditions, for the purposes of Article 4(2) and Article 16(2) of Regulation No 1829/2003:

– foods and food ingredients containing, consisting of, or produced from the modified soybean;

– feed containing, consisting of, or produced from the modified soybean;

– the modified soybean present in products other than food and feed ‘containing it’ or consisting of it, for the same uses as any other soybean, with the exception of cultivation.

7 In recitals 4, 6 and 7 of the authorisation decision, the Commission explained that, on 15 February 2012, EFSA had given a favourable opinion in accordance with Articles 6 and 18 of Regulation EC No 1829/2003, concluding that the modified soybean, as described in the application, was as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment. Furthermore, it is contended that EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant was in line with the intended use of the products. On that basis, the Commission considered it appropriate to authorise the modified soybean and all products containing it or consisting of it and for food and feed produced from it as described in the application.

8 By letters of 6 August 2012, each of the applicants requested the Commission to carry out an internal review of the authorisation decision, pursuant to Article 10 of Regulation (EC) No 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). The applicants considered, inter alia, that the assessment that the modified soybean was substantially equivalent to its counterpart was flawed, that the synergistic or combinatorial effects had not been taken into consideration, that the immunological risks had not been adequately assessed and that no monitoring of the effects on health had been required.

9 By letter of 8 January 2013, under reference Ares(2013)19605 (‘the first contested decision’), the Commissioner for Health informed the first applicant that it did not accept any of the legal and scientific allegations invoked to substantiate the request for internal review of the authorisation decision. The Commission considered, therefore, that the authorisation decision complied with Regulation No 1829/2003.That letter is in Annex PD/7 to the application.

10 More specifically, the Commission rejected the arguments put forward in the first applicant’s request for internal review, to the effect that the authorisation decision was unlawful on the grounds that EFSA’s finding that the modified soybean was ‘substantially equivalent’ was flawed, that the synergistic or combinatorial effects had not been taken into consideration, that the immunological risks had not been adequately assessed and that no monitoring of the effects on health had been required.

11 On the same date, the Commissioner for Health sent to the second and third applicants letters that are substantially identical to the letter sent to the first applicant (‘the second and third decisions’). Those letters are in Annexes PD/10 and PD/12 to the application.

12 In those three letters, the Commission acknowledged that each of the applicants satisfied the criteria set out in Article 11 of Regulation No 1367/2006 and were, therefore, as non-governmental organisations for the purposes of that article, entitled to make a request for internal review.

Procedure and forms of order sought by the parties

13 By application lodged at the General Court Registry on 18 March 2013, the applicants brought the present action.

14 As regards the measure contested by the present action, the applicants state, in the first paragraph of the application, that they 'challenge the European Commission's decision, dated 8 January 2012 and received on 9 January 2012, refusing to review its Decision [No] 2012/347 granting a market authorisation to Monsanto Europe SA for its genetically modified soybean "MON 87701 × MON 89788"' and refer to the application's Annex PD/7. The letter under reference Ares(2013) 19605 of 8 January 2013 from the Commissioner for Health, sent to the first applicant is set out in Annex PD/7 to the application.

15 The case was originally assigned to the Eighth Chamber. As the composition of the Chambers of the General Court was subsequently modified, the present case was assigned to the Fifth Chamber.

16 By document registered at the Court Registry on 29 July 2013, ESFA sought leave to intervene in support of the form of order sought by the Commission. By order of 4 November 2013, the President of the Fifth Chamber of the Court granted EFSA's application for leave to intervene.

17 By document lodged at the Court Registry on 31 July 2013, Monsanto Europe and Monsanto Company (hereinafter jointly referred to as 'Monsanto') sought leave to intervene in support of the form of order sought by the Commission. By order of 4 November 2013 the President of the Fifth Chamber of the Court granted Monsanto's application for leave to intervene.

18 By application lodged at the Registry of the General Court on 9 August 2013, the United Kingdom of Great Britain and Northern Ireland sought leave to intervene in support of the Commission. By order of 4 November 2013, the President of the Fifth Chamber of the Court granted the United Kingdom leave to intervene.

19 The interveners, the United Kingdom, EFSA and Monsanto lodged their statements in intervention within the period prescribed and the applicants submitted their observations on those statements, also within the period prescribed. The Commission stated that it had no observations to make on those statements.

20 By document lodged at the Registry of the General Court on 31 October 2013, the Commission informed the General Court that the first applicant had published the

statement of defence on its website and that it considered that such publication was prejudicial to the proper administration of justice. The applicants lodged their observations regarding that event within the period prescribed by the Court.

21 On a proposal from the Judge-Rapporteur, the General Court (Fifth Chamber) decided to open the oral part of the procedure and, by way of measures of organisation of procedure pursuant to Article 89 of its Rules of Procedure, put questions in writing to the applicants and the Commission. The parties all replied to the written questions within the period prescribed.

22 Furthermore, on a proposal from the Judge-Rapporteur, the General Court (Fifth Chamber) invited the applicants, by way of measures of organisation of procedure pursuant to Article 89 of its Rules of Procedure, to provide a complete copy of the requests for internal review, by which the second and third applicants had asked the Commission to withdraw the authorisation to place products containing the modified soybean on the market. The applicants did not provide the documents requested. In their written reply to the Court's questions, they indicated that all three requests for internal review, each one having been brought by one of the applicants, were identical. At the hearing, the Commission acknowledged that, for each of the requests for internal review, an identical file had been provided to it and that, consequently, a separate decision had been adopted for each of the requests for internal review on the basis of an identical underlying file, which was formally noted by the Court in the minutes of the hearing.

23 The parties presented oral argument and answered the questions put by the Court at the hearing on 12 May 2016.

24 At the hearing, the applicants, relying on Article 85(3) of the Rules of Procedure, produced inter alia two documents, being a letter from the Commission addressed to EFSA requesting a scientific opinion on the question whether glyphosate residues had a negative impact on animals and a scientific article, by way of additional evidence in support of their second plea in law. At the hearing, the President of the Fifth Chamber of the General Court decided to place those two documents in the case file for the present case, which was formally noted by the Court in the minutes of the hearing.

25 At the end of the hearing, the President of the Fifth Chamber of the General Court deferred the close of the oral part of the procedure to a later date.

26 By decision of 30 May 2016, the President of the Fifth Chamber of the General Court decided not to include in the case file of the present case a letter from the applicants dated 18 May 2016, by which they once again submitted a copy of the documents referred to in paragraph 24 above and additional explanations, not provided for in the Rules of Procedure, in relation thereto.

27 By letter of 7 June 2016, the Court served a copy of the documents referred to in paragraph 24 above on the Commission and the interveners, and gave them the opportunity to submit in writing any observations they might have on those documents.

The Commission and the interveners provided their observations within the period prescribed.

28 By decision of 28 June 2016, the President of the Fifth Chamber of the Court closed the oral part of the procedure.

29 The applicants claim that the Court should:

– declare the present action admissible;

– annul the ‘contested decision’;

– order the Commission to pay the costs.

30 The Commission contends that the Court should:

– dismiss the action as in part manifestly inadmissible and in part unfounded; and

– order the applicants to pay the costs.

31 The United Kingdom contends that the Court should dismiss the action in its entirety.

32 EFSA contends that the Court should:

– dismiss the action as in part inadmissible and in part unfounded, and

– order the applicants to pay the costs.

33 Monsanto contends that the Court should:

– dismiss the action as in part manifestly inadmissible and in part unfounded; and

– order the applicants to pay the costs.

Law

34 The applicants put forward four pleas in law in support of their action: (i) an alleged absence of substantial equivalence between the modified soybean and its conventional counterpart; (ii) an alleged failure to assess synergistic/combinatorial effects and toxicity; (iii) an alleged absence of exhaustive immunological assessment; and (iv) an alleged absence of post-market authorisation monitoring of consumption of products containing the modified soybean.

35 Without formally raising an objection of inadmissibility under Article 130 of the Rules of Procedure, the Commission, supported by the interveners, partly contests the admissibility of the present action.

36 Further to a written question put by the Court by way of measures of organisation of procedure provided for in Article 89 of the Rules of Procedure, disagreement arose between the main parties as to whether the subject matter of the present action concerned only the annulment of the first contested decision or whether it also concerned the second and third decisions addressed to the second and third applicants referred to in paragraph 11 above. It is therefore appropriate to begin by examining the action in so far as it concerns the decision addressed to the first applicant, which is common ground for the parties and, in a second stage, to examine it in so far as it concerns the second and third decisions.

Admissibility of the first applicant's application for annulment

37 Without formally raising an objection of inadmissibility under Article 130 of the Rules of Procedure, the Commission, supported by the United Kingdom and Monsanto, partly contests the admissibility of the present action, on two grounds. First, it takes the view that the first applicant's arguments, put forward in the present action, are inadmissible on the ground that they are not to be found in the request for internal review. More specifically, it refers to arguments put forward under the first three parts of the first plea and the first two parts of the third plea. Second, it submits that the present action is inadmissible in so far as it seeks, in essence, to call the authorisation decision into question. In its submission, Regulation No 1367/2006 did not create any rights for the applicants to contest the authorisation decision. To allow the applicants to bring an action against the authorisation decision outside of the framework of the fourth paragraph of Article 263 TFEU would be contrary to the provisions of the Treaty.

38 The first applicant submits that each of the arguments set out in the present action had been stated or clearly explained in its request for internal review. However, it could have added additional details or evidence in the present action in order to support the arguments upon which it requested the Commission to review the authorisation decision. It was not obliged to identify or explicitly define what the outcome of a properly conducted review would be, having regard to the asymmetry of the information available to it compared to that available to the institutions. The Commission, moreover, accepted that most of the arguments and evidence put forward in the action is admissible. The first applicant adds that it has an interest in bringing the present action under Article 12 of Regulation No 1367/2006, read in conjunction with recital 21 thereof, with a view to bringing an action against the refusal to grant its request for internal review. The Commission should have withdrawn the authorisation decision or asked EFSA to carry out a new assessment of the modified soybean.

39 EFSA submits that the Commission was required only to examine whether the first applicant's request for internal review had been dealt with in a comprehensive and appropriate manner and that an internal review of the authorisation decision ought to

have been carried out solely in the light of the reasons set out in the request. The assessment made by the Commission, in the context of that request, could not result, as such, in substitution of the scientific assessment and of the specific mechanisms and procedure provided for in Articles 10 and 34 of Regulation No 1829/2003.

40 The United Kingdom adds that, in the present case, as Monsanto did not seek authorisation for the modified soybean to be cultivated in the European Union, the environmental risk assessment is therefore limited to a consideration of the likely effects of accidental dissemination into the environment. That, it contends, greatly reduces the range of environmental risks that must be considered and the majority of the applicants' arguments fall outside the scope of Regulation No 1367/2006.

Partial inadmissibility of the present action due to the first applicant's inability to challenge the authorisation decision

41 The Commission submits that the present action is partly inadmissible on the ground that Regulation No 1367/2006 cannot, it contends, create any rights for the first applicant to contest the authorisation decision. In essence, the arguments put forward by the Commission, EFSA and Monsanto concern two aspects. Firstly, they consider that the present action is inadmissible on the ground that it is an attempt to bring an action for annulment of the authorisation decision 'through the back door'. A correct application of the provisions of Regulation No 1367/2006 does not allow for judicial review of the lawfulness of the authorisation decision itself, in consequence of which the present action should be limited to the question whether the applicants' request for internal review was dealt with in a comprehensive and appropriate manner. Secondly, they submit that many of the arguments put forward in the present action are aimed at establishing that the authorisation decision is unlawful and are therefore not directed at the first contested decision.

42 In the present case, it is common ground that no action for annulment was brought against the authorisation decision, which has become definitive. It is also common ground that, under Article 10 of Regulation No 1367/2006, each of the applicants brought a substantively identical request for internal review aimed at having the Commission withdraw the decision. For the first applicant, the present action is directed against the first contested decision, by which the Commission held that the authorisation decision complied with Regulation No 1829/2003, thereby, in essence, rejecting the first applicant's request for internal review as unfounded.

43 In the first place, as regards the question whether a request for internal review made pursuant to Article 10 of Regulation No 1367/2006 may, where the arguments put forward in support of it turn out to be well founded, oblige the Commission to take any measures it deems appropriate in order to amend the authorisation decision, even if it is not or is no longer challengeable through an action for annulment under the fourth paragraph of Article 263 TFEU, it is clear that that provision covers three situations where any natural or legal person may bring an action for annulment. Under the first and second paragraphs, such persons may bring an action, firstly, against acts addressed to

them; secondly, against acts which are of direct and individual concern to them; and, thirdly, against regulatory acts which are of direct concern to them and do not entail implementing measures. That provision is therefore directed at those types of natural or legal persons, conferring on them the right to request the EU Courts to annul an act adopted by an EU institution or body.

44 Yet although it is true that the fourth paragraph of Article 263 TFEU determines the conditions under which a natural or legal person may prevent a legal act from becoming definitive in respect of them, it in no way restricts the possibility for EU institutions or bodies to amend, suspend, withdraw or repeal acts adopted by them, in so far as is legally permissible. The EU Courts have held that retrospective withdrawal of an unlawful administrative act which has created individual rights is permissible, subject to certain conditions (see, to that effect, judgments of 16 December 2010, *Athinaïki Techniki* v *Commission*, C-362/09 P, EU:C:2010:783, paragraph 59 and the case-law cited, and of 18 October 2011, *Reisenthel* v *OHIM – Dynamic Promotion (Hampers, crates and baskets)*, T-53/10, EU:T:2011:601, paragraph 40 and the case-law cited).

45 Moreover, as regards authorisation for genetically modified organisms, Articles 10, 22 and 34 of Regulation No 1829/2003 expressly permit the amendment, suspension and withdrawal of an authorisation or the adoption of emergency measures. The fact that that regulation allows for a review or reconsideration, in certain circumstances, of the issue of maintenance of an authorisation does not mean that the authorisation decision is not final (see, by analogy, judgment of 1 July 2010, *Povse*, C-211/10 PPU, EU:C:2010:400, paragraph 46).

46 Therefore, the fact that an EU institution or body effects an amendment, suspension, withdrawal or repeal of an act adopted previously by it cannot be regarded as broadening the scope of the conditions of admissibility of an action for annulment brought against that act under the fourth paragraph of Article 263 TFEU. Similarly, the fact that the amending measure in question was made of its own volition or following a request from a third party is irrelevant in that regard.

47 Regarding a request for internal review of administrative acts, Article 10(1) of Regulation No 1367/2006 states that any non-governmental organisation which meets the criteria set out in Article 11 is entitled to make a request for internal review to the EU institution or body that has adopted an administrative act under environmental law.

48 Under Article 2(1)(g) of Regulation No 1367/2006, ‘administrative act’ means any measure of individual scope under environmental law, taken by an EU institution or body, and having legally binding and external effects. Under Article 2(1)(f), ‘environmental law’ means EU legislation which, irrespective of its legal basis, contributes to the pursuit of the objectives of EU policy on the environment as set out in the Treaty: preserving, protecting and improving the quality of the environment, protecting human health, the prudent and rational utilisation of natural resources, and promoting measures at international level to deal with regional or worldwide environmental problems.

49 Article 12(1) of Regulation No 1367/2006 provides that a non-governmental organisation which made a request for internal review pursuant to Article 10 may institute proceedings before the Court of Justice in accordance with the relevant provisions of the Treaty.

50 It has been held, however, that Article 9(3) of the Convention on access to information, public participation in decision-making and access to justice in environmental matters, signed at Aarhus on 25 June 1998 and approved 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'), on which Article 10(1) of Regulation No 1367/2006 is based, cannot be relied on in order to assess the legality of the latter provision (judgment of 13 January 2015, *Council and Others* v *Vereniging Milieudefensie and Stichting Stop Luchtverontreiniging Utrecht*, C-401/12 P to C-403/12 P, EU:C:2015:4, paragraph 61).

51 It follows that Regulation No 1367/2006 allows any non-governmental organisation which meets the criteria set out in Article 11 to submit a reasoned request and trigger an internal review of an administrative act by the EU institution or body that adopted it under environmental law. The purpose of that review is not a re-evaluation of the marketing authorisation for the products in question (see, by analogy, judgment of 10 November 2005, *Stichting Zuid-Hollandse Milieufederatie*, C-316/04, EU:C:2005:678, paragraph 68). Consequently, in the first contested decision, the Commission concluded that the authorisation decision complied with Regulation No 1829/2003.

52 Unless the request for internal review in question is clearly unfounded, the institution or body that adopted the administrative act in question must consider the request and, once the internal review is concluded, may either reject the request for internal review as unfounded by reasoned decision or on the ground that the internal review did not lead to a different result than the one obtained by the authorisation decision or, as legally permitted, take any other measure it deems appropriate to amend the authorisation decision, including amendment, suspension or repeal of an authorisation.

53 Where there has been a decision to reject a request for internal review made pursuant to Regulation No 1367/2006 as unfounded, the non-governmental organisation to which that decision is addressed may bring an action for annulment against that decision, as provided for in the first situation covered by the fourth paragraph of Article 263 TFEU.

54 By contrast, if the institution or the body in question decides to adapt the authorisation covered by the request for internal review, the adapting measure may, where applicable, be the subject of a new request for internal review, provided that the conditions laid down in Article 10 of Regulation No 1367/2006 are met.

55 However, a non-governmental organisation that made the request for internal review of an administrative act under Article 10 of Regulation No 1367/2006 cannot require, at the end of the internal review, that a specific measure be taken by the institution or body concerned. The choice of measures to be adopted following an internal review is entirely discretionary.

56 It is of course inherent in a request for internal review of an administrative act that the party requesting the review is challenging the lawfulness or merits of the measure, in this case the authorisation decision. The purpose of the internal review procedure is therefore to obtain a finding that the authorisation decision is unlawful or unfounded. Pursuant to Article 12 of Regulation No 1367/2006, read in conjunction with Article 10 thereof, the party requesting the review may institute proceedings against the decision rejecting the request for internal review as unfounded before the EU Courts, and may allege lack of powers, infringement of essential procedural requirements, infringement of the Treaties or of any legal rule relating to their application, or misuse of powers. That does not mean that the party making the request is entitled, in the course of those proceedings, to put forward arguments directly challenging the lawfulness or merits of the authorisation decision. In the present case, therefore, the first applicant may only ask the Court to declare that the first contested decision referred to in the request for internal review is unlawful, even if it based on the authorisation decision being unlawful or unfounded.

57 It follows from the foregoing that the argument to the effect that the present action is inadmissible on the ground that Regulation No 1367/2006 cannot create rights for the applicants to request a finding of unlawfulness or unfoundedness of the authorisation decision must be dismissed as unfounded, in so far as the unlawfulness or unfoundedness was raised in the request for internal review made pursuant to Article 10 of that regulation and it is that request that is rejected, as in the first contested decision. Regarding the first applicant, moreover, the pleas put forward in the present action are admissible only in so far as they are directed at annulment of the first contested decision.

58 In the second place, as correctly pointed out by the Commission, many arguments put forward in the present action allege errors of assessment by EFSA in its overall opinion or concern directly only an alleged unlawfulness of the authorisation decision.

59 In that regard, in so far as the present action concerns the first applicant, it seeks annulment of the first contested decision. Therefore, the pleas put forward in that context may allege only the Commission's lack of powers to adopt that decision, unlawfulness of the decision, infringement of essential procedural requirements, misuse of powers or infringement of procedural rights in the adoption of the act in question.

60 It follows that the first applicant's pleas put forward in support of the present action must be rejected in so far as they do not allege any unlawfulness of the first contested decision, but merely affirm directly the unlawfulness of the authorisation decision or of EFSA's opinions, or that they are unfounded.

61 In the third place, the United Kingdom takes the view that, in the present case, as Monsanto has not sought authorisation to cultivate the modified soybean in the European Union, the environmental risk assessment is therefore restricted to an examination of the probable effects of accidental dissemination in the environment, which reduces considerably the scope of the environmental risks to be examined. Consequently, most of the first applicant's arguments do not come within the scope of Regulation No 1367/2006.

62 Suffice it to note in that regard that Article 10(1) of Regulation No 1367/2006 provides that certain non-governmental organisations are entitled to make a request for internal review with the EU institution or body that adopted an administrative act under environmental law. Article 2(1)(f) of that regulation contains a definition of the term 'environmental law' that includes EU legislative provisions covering the protection of human health and the preservation and protection of the quality of the environment. Moreover, recital 1 of that regulation states that EU legislation in the field of the environment aims to contribute inter alia to protecting human health.

63 Recital 1 of Regulation No 1829/2003 indicates that it aims to ensure the free movement of safe and wholesome food and feed, which is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests. Recitals 2 and 43 state that a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed should be ensured in the pursuit of EU policies, whilst recital 3 states that genetically modified food and feed should undergo a safety assessment before being placed on the market within the European Union.

64 It follows from those provisions that the scope of Regulation No 1829/2003 forms an integral part of the areas of environmental law covered by Article 10(1) of Regulation No 1367/2006. Consequently, the United Kingdom's argument on that point must be rejected.

Inadmissibility of the arguments that were not set out in the request for internal review

65 The first applicant submits that each of the arguments put forward in the present action had been announced or clearly explained in its request for internal review. It states, however, that further details or evidence may be added in the present action in order to substantiate the arguments by which it requested the Commission to conduct an internal review of the authorisation decision. It was not obliged to identify or explicitly define what the outcome of a properly conducted review would be, having regard to the asymmetry of the information available to them compared to that available to the institutions.

66 It is apparent from Article 10(1) of Regulation No 1367/2006 that a request for internal review of an administrative act made to the EU institution or body that adopted it

under environmental law must specify which act is being challenged and state the grounds for conducting the review.

67 In order to state the grounds for conducting the review in the manner required, a party requesting the internal review of an administrative act under environmental law is required to put forward any facts or legal arguments raising serious doubts about the assessment made in that act by the EU institution or body. As acknowledged by the Commission in its rejoinder and at the hearing, a third party challenging a marketing authorisation must adduce substantial evidence liable to raise serious doubts as to the lawfulness of the grant of that authorisation (see, to that effect, and by analogy, judgment of 21 May 2015, *Schräder* v *CPVO*, C-546/12 P, EU:C:2015:332, paragraph 57).

68 Furthermore, a party requesting internal review may only ask the Commission to state its position on the grounds set out in the request for review made pursuant to Article 10 of Regulation No 1367/2006 and, in particular, if the evidence adduced is substantial and liable to raise serious doubts as to the lawfulness of the grant of that authorisation. The party making the request may not ask the Commission to state its position on matters that were not referred to in a reasonably recognisable manner in the request or on matters that are not relevant for responding to the grounds of review set out in the request.

69 It follows from the foregoing that there was nothing preventing the first applicant from alleging in the present action that the Commission was entirely lacking in powers to adopt the first contested decision, any infringement of essential procedural requirements, any infringement of the Treaties or rule of law relating to their application or any misuse of powers at the time the act was adopted. It could not, however, argue that the Commission ought to have examined grounds other than those put forward by it in its request for internal review of the authorisation decision in order to determine whether that request raised serious doubts as to the lawfulness of the grant of that authorisation.

70 Therefore, in the light of all the foregoing, it is appropriate to examine, for each part of the pleas put forward in the present action and as part of the examination conducted in paragraphs 121 to 293 below, whether the present action is admissible in so far as it seeks a ruling that the first contested decision itself is unlawful or unfounded.

Examination of the merits of the first applicant's application for annulment

Preliminary observations

71 Before addressing the specific pleas put forward in the present action in so far as it concerns the first applicant, it is appropriate to begin by examining, firstly, the parties' arguments relating to the limited scope of the judicial review of a decision rejecting a request for internal review of an administrative act as unfounded, such as the first contested decision, brought pursuant to Article 10 of Regulation No 1367/2006; secondly, to specify the applicable evidentiary rules; thirdly, to rule on questions relating

to legal provisions relied on generally and as they overlap in application in relation to a number of pleas; and, fourthly, to examine the legal value of EFSA's guidance.

– The scope of the judicial review of the lawfulness of a decision rejecting a request for internal review made pursuant to Article 10 of Regulation No 1367/2006 as unfounded

72 The Commission, supported by United Kingdom, contends that it has a broad discretion as to the measures to be taken in the present case and considers that the standard of judicial review should be especially light on the ground that the first applicant is not entitled to seek annulment of the authorisation decision.

73 According to the first applicant, there is no justifiable basis for applying, in the present case, a lower standard of review. The application of a lower standard of review would be contrary to the object and purpose of the Aarhus Convention, which is to ensure access to justice in environmental matters.

74 According to EFSA, an action for annulment of the internal review decisions, introduced by the first applicant, should seek to demonstrate that there was a flaw in the way the Commission exercised its wide discretion when examining the grounds raised in its request for internal review. Judicial review should be limited to arguments regarding infringements of procedural requirements, errors in law or manifest errors of assessment in the administrative review decision, without giving rise to a review of the scientific basis of the authorisation decision.

75 Monsanto contends that judicial review must be limited to manifest errors of assessment that are 'so serious that even a non-scientist can easily detect and correctly identify them'.

76 Contrary to those arguments, it should be observed at the outset that the objective of the Aarhus Convention to give the public broad access to justice requires that the EU Courts do not conduct a more limited or less strict examination of a decision rejecting a request for internal review made pursuant to Article 10 of Regulation No 1367/2006 as unfounded than what it would do in a case in which a natural or legal person seeks annulment of an authorisation decision under Regulation No 1829/2003. Moreover, when a case has been brought before it concerning such a decision, the General Court is also bound by the precautionary principle.

77 According to the case-law, where an EU institution is called upon to make complex assessments it enjoys a wide measure of discretion, the exercise of which is subject to a judicial review restricted to verifying that the measure in question is not vitiated by a manifest error or a misuse of powers and that the competent authority did not clearly exceed the bounds of its discretion (see, by analogy, judgments of 21 January 1999, *Upjohn*, C-120/97, EU:C:1999:14, paragraph 34, and of 26 November 2002, *Artegodan and Others* v *Commission*, T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00, EU:T:2002:283, paragraph 201).

78 As regards the assessment by the Courts of the European Union as to whether an act of an institution is vitiated by a manifest error of assessment, it must be stated that, in order to establish that that institution committed a manifest error in assessing complex facts such as to justify the annulment of that act, the evidence adduced by the applicant must be sufficient to make the factual assessments used in the act implausible. Subject to that review of plausibility, it is not the Court's role to substitute its assessment of complex facts for that made by the institution which adopted the decision (see judgment of 9 September 2011, *France* v *Commission*, T-257/07, EU:T:2011:444, paragraph 86 and the case-law cited).

79 The abovementioned limits to the review by the Courts of the European Union do not, however, affect their duty to establish whether the evidence relied on is factually accurate, reliable and consistent, whether that evidence contains all the information which must be taken into account in order to assess a complex situation, and whether it is capable of substantiating the conclusions drawn from it (see judgment of 9 September 2011, *France* v *Commission*, T-257/07, EU:T:2011:444, paragraph 87 and the case-law cited).

80 Moreover, where the EU institutions have a broad discretion, respect for the rights guaranteed by the EU legal order in administrative procedures is of even more fundamental importance. Those guarantees include, in particular, the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case, the right of the person concerned to make his views known and also his right to have an adequately reasoned decision (see, by analogy, judgments of 21 November 1991, *Technische Universität München*, C-269/90, EU:C:1991:438, paragraph 14, and of 13 July 2006, *Shandong Reipu Biochemicals* v *Council*, T-413/03, EU:T:2006:211, paragraph 63).

81 It should be noted that the case-law referred to in paragraphs 76 to 80 above applies irrespective of the judicial review conducted by the Courts of the European Union in their examination of an action for annulment brought pursuant to Article 12 of Regulation No 1367/2006 against a decision of the Commission rejecting as unfounded a request for internal review made pursuant to Article 10 of that same regulation.

– Evidentiary rules applicable to an internal review of an administrative act brought pursuant to Article 10 of Regulation No 1367/2006

82 The applicants claim that they were not required, when submitting their request for internal review, to prove that the modified soybean was not safe. In so far as their arguments give rise to legitimate and substantive doubts as to the safety of the modified soybean, the burden of proof falls on the Commission, which must ensure that EFSA requires the assessment or investigation necessary to either allay such concerns or find that the modified soybean is not safe.

83 As held in paragraph 67 above, in order to state the grounds for conducting the review in the manner required, a party requesting the internal review of an administrative

act under environmental law is required to put forward any facts or legal arguments raising serious doubts about the assessment made in that act by the EU institution or body. As acknowledged by the Commission in its rejoinder and at the hearing, a third party challenging a marketing authorisation must adduce substantial evidence liable to raise serious doubts as to the lawfulness of the grant of that authorisation.

84 However, it should be noted that, under Regulation No 1829/2003, in the area of marketing authorisations for genetically modified food and feed, non-governmental organisations' access to relevant information is usually restricted to information that is publicly available and to which the Commission also had access at the time of its in-depth assessment of the risks in terms of the conditions laid down in Article 4(1) and Article 16(1) of that regulation.

85 Where the Commission concludes that the evidence adduced by a party requesting an internal review is substantial and liable to raise serious doubts as to the lawfulness or well-foundedness of the grant of that authorisation, it is required to examine all relevant information of its own motion, since its role in an internal review under Article 10 of Regulation No 1367/2006 is not that of an arbitrator, whose remit is limited to making an award solely on the basis of the information and the evidence provided by the party requesting the review (see, by analogy, judgment of 22 March 2012, *GLS*, C-338/10, EU:C:2012:158, paragraph 32).

86 That remit also follows from the fact that the Commission is bound by the precautionary principle, which is a general principle of European Union law. That principle, as interpreted in the Court's case-law, means that where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent (judgment of 9 September 2003, *Monsanto Agricoltura Italia and Others*, C-236/01, EU:C:2003:431, paragraph 111).

87 It should also be borne in mind that Article 168(1) TFEU requires that a high level of human health protection be ensured in the definition and implementation of all EU policies and activities. The protection of human health takes precedence over economic considerations, with the result that it may justify adverse economic consequences, even those which are substantial, for certain traders (see judgment of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 143 and the case-law cited).

88 Therefore, and contrary to the Commission's assertions in the first contested decision, the first applicant cannot be required '[to] prove that the [authorisation] decision is in breach of Regulation (EC) No 1829/2003'; rather, it must provide a set of material raising serious doubts as to the lawfulness of the authorisation decision.

– The legal provisions relied on generally and as they overlap in application in relation to a number of pleas

89 It should be observed that in its first, second and third pleas, the first applicant criticises the Commission: (i) for having confirmed the authorisation of the modified soybean without ensuring that an appropriate risk assessment of the 'highest possible standard' had been carried out and that Monsanto had provided 'appropriate' data under Article 5(3)(f), Article 6(3)(a), Article 17(3)(f) and Article 18(3)(a) of Regulation No 1829/2003; (ii) for having infringed its obligation, under Article 4(1)(a) and Article 16(1)(a) of that regulation, to ensure that food and feed that would have an adverse effect on human health, animal health or the environment must not be placed on the European Union market; (iii) for not having fulfilled the obligation to take into account any relevant provisions of EU law, including the provisions that require the institutions to comply with 'their own guidance', in breach of Article 7(1) and Article 19(1) of Regulation No 1829/2003; (iv) for not having observed its obligation to ensure a high level of protection for human health, in breach of Article 168 TFEU; and (v) for having failed to meet the applicants' legitimate expectations.

90 Given that those arguments have been raised repeatedly, the following preliminary observations are apposite.

91 It must be remembered that, as stated in paragraph 63 above, recital 1 of Regulation No 1829/2003 indicates that it aims to ensure the free movement of safe and wholesome food and feed, which is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests. Recitals 2 and 43 state that a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed should be ensured in the pursuit of EU policies, whilst recital 3 states that genetically modified food and feed undergo a safety assessment before being placed on the market within the European Union.

92 Where a genetically modified product is liable to be used both as food and as feed, Article 27(1) of Regulation No 1829/2003 provides that a single application is to be submitted and give rise to a single opinion from EFSA and a single EU decision.

93 Article 4(2) of Regulation No 1829/2003 requires an authorisation in order for a genetically modified organism intended for food use or genetically modified food to be placed on the market. Under Article 4(3), no genetically modified organism for food use or food is to be authorised unless it can be adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of that article.

94 Article 4(1) of Regulation No 1829/2003 lists cumulatively the conditions to be met in that regard. In particular, the foods in question must not:

'(a) have adverse effects on human health, animal health or the environment;

(b) mislead the consumer;

(c) differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.'

95 Moreover, Article 16(2) of Regulation No 1829/2003 requires an authorisation in order to place on the market, use or process a genetically modified organism for feed use, whilst under Article 16(3), authorisation is not to be granted if it cannot be adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of that article.

96 Article 16(1) of Regulation No 1829/2003 lists cumulatively the conditions to be met in that regard. In particular, the feed in question must not:

'(a) have adverse effects on human health, animal health or the environment;

(b) mislead the user;

(c) harm or mislead the consumer by impairing the distinctive features of the animal products;

(d) differ from feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans.'

97 As regards the assessment of adverse effects on human health, animal health and the environment, at issue in the present action, suffice it to observe that, in referring as it does to 'adverse effects' and not 'danger', it is readily apparent from the wording of Article 4(1)(a) and Article 16(1)(a) of Regulation No 1829/2003 that they require, for the purposes of an authorisation procedure under that regulation, that an assessment of the relevant risks for human health, animal health and the environment be carried out.

98 Moreover, recital 9 of Regulation No 1829/2003 states that authorisation procedures for genetically modified food and feed should make use of the framework for risk assessment in matters of food safety set up by 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), and that the placing on the market of genetically modified food and feed should be authorised only after a scientific evaluation of the highest possible standard of any risks which they present for human and animal health and, as the case may be, for the environment.

99 As regards the respective roles of EFSA and the Commission in the context of authorisation procedures under Regulation No 1829/2003, first of all, it should be remembered that Article 6(1) and (3)(a) and Article 18(1) and (3)(a) of that regulation provide that, following an application for authorisation, EFSA gives an opinion in which it determines whether the genetically modified food complies with the criteria laid down in Article 4(1) of that regulation and whether the genetically modified feed complies with the criteria laid down in Article 16(1). Under Article 5(3)(f) of that regulation, the

application must be accompanied by either an analysis, supported by appropriate information and data, showing that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics and the composition, nutritional value or nutritional effects, intended use of the food and implications for the health of certain sections of the population, or a proposal for labelling the food. Article 17(3)(f) of that same regulation contains an analogous provision for feed.

100 Following receipt of EFSA's opinion, the Commission adopts, in accordance with Articles 7 and 19 of Regulation No 1829/2003, a final decision on the application for authorisation. In so doing, it is obliged to take account of EFSA's opinion, any relevant provisions of EU law and other legitimate factors relevant to the matter under consideration.

101 Recital 9 of Regulation No 1829/2003 also reiterates that the scientific evaluation undertaken under the responsibility of EFSA must be followed by a risk management decision by the Commission, under a regulatory procedure ensuring close cooperation between the Commission and the Member States.

102 Moreover, Article 22(6) of Regulation No 178/2002 provides that EFSA is to provide opinions which will serve as the scientific basis for the drafting and adoption of EU measures in the fields falling within its mission. Furthermore, under Article 23(c) of that regulation, it is the task of EFSA to provide scientific and technical support to the Commission in the areas within its mission and, when so requested by the Commission, in the interpretation and consideration of risk assessment opinions (judgment of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 82).

103 The conclusion is, therefore, that under Articles 4 and 16 of Regulation No 1829/2003, the Commission is not bound by EFSA's opinion in adopting its decision. Although, admittedly, the Commission adopts its decision to authorise the placing on the market of a genetically modified organism after obtaining the opinion of EFSA, note must be taken of the fact that there is nothing in that regulation to suggest that the Commission is obliged to comply with EFSA's opinions in substantive terms and therefore has no discretion (see, by analogy, judgment of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 87 and the case-law cited).

104 It has been held that the risk assessment consists, for the EU institution faced with potentially negative effects stemming from a phenomenon, in assessing, on the basis of a scientific assessment of the risks, whether they exceed the level of risk deemed unacceptable for society. Thus, in order for the EU institutions to be able to carry out a risk assessment, it is important for them, first, to have a scientific assessment of the risks and, secondly, to determine what level of risk is deemed unacceptable for society (see judgment of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 145 and the case-law cited).

105 The responsibility for determining the level of risk which is deemed unacceptable lies, provided that the applicable rules are observed, with the EU institutions responsible for the political choice of determining an appropriate level of protection for society. It is for those institutions to determine the critical probability threshold for adverse effects on human health and for the seriousness of those possible effects which, in their judgment, is no longer acceptable for society and above which it is necessary, in the interests of protecting human health, to take preventive measures in spite of any existing scientific uncertainty (see, to that effect, judgment of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 148).

106 In determining that level of risk, the EU institutions are bound by their obligation, under the first subparagraph of Article 168(1) TFEU, to ensure a high level of human health protection. That high level does not necessarily, in order to be compatible with that provision, have to be the highest that is technically possible (judgments of 14 July 1998, *Safety Hi-Tech*, C-284/95, EU:C:1998:352, paragraph 49, and of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 149).

107 Next, recital 32 of Regulation No 1829/2003 recognises that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision of the Commission should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account by it. Recital 43allows, for example, account to be taken ‘of the international trade commitments of the European [Union] and of the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity as regards importer obligations and notification’.

108 Lastly, it should be borne in mind, as set out in paragraph 86 above, that the Commission is bound by the precautionary principle, which is a general principle of EU law. It requires the authorities concerned, in the particular context of the exercise of the powers conferred on them by the relevant rules, to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests (see judgment of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 144 and the case-law cited).

109 It follows from the findings set out in paragraphs 99 to 108 above that it is for the Commission to make use of its broad discretion to identify what it considers relevant to its risk assessment so as to be able to find, once that assessment has been completed, that the conditions laid down in Article 4(1) and Article 16(1) of Regulation No 1829/2003, as applicable, have been met in the case under examination before granting a marketing authorisation.

– The legal value of EFSA’s guidance

110 The Scientific Panel adopted a number of guidance documents which were relied on by the parties in the present proceedings, in particular the Guidance document on genetically modified organisms for the risk assessment of genetically modified plants and

derived food and feed (question EFSA-Q-2003-005, *The EFSA Journal* (2006) 99, 1-100) ('the 2006 guidance document'), the guidance document for the risk assessment of genetically modified plants containing stacked transformation events of 16 May 2007 (question EFSA-Q-2003-005D, *The EFSA Journal* (2007) 512, 1-5) ('the 2007 guidance document'), and the Scientific Opinion: Guidance for risk assessment of food and feed from genetically modified plants (*The EFSA Journal* (2011); 9(5):2150, 1-37) ('the 2011 guidance document'), which provide, in essence, for molecular characterisation, comparative assessment of the organism for which authorisation was sought with appropriate comparators and toxicology, allergenicity and nutritional risk studies.

111 The first applicant submits that the Commission did not comply with either 'the provisions of Union law that require Union institutions to comply with their own guidance' or its legitimate expectation that 'EFSA would act in accordance with its own guidance' issued pursuant to Regulation No 1829/2003. In its submission, the Commission ought to have ensured compliance before taking its decision on authorisation. However, the Commission failed to ensure that EFSA applied the 2006 guidance document and the 2007 guidance document on comparative assessment and risk assessment of the soybean. EFSA did, however, partly apply the 'draft 2011 guidance'.

112 It is therefore appropriate to consider whether the first applicant may rely in the present case on infringement of the guidance documents referred to in paragraph 110 above or on its legitimate expectations so that EFSA will act 'in accordance with its own guidance' issued pursuant to Regulation No 1829/2003.

113 In the first place, Article 5(8) and Article 17(8) of Regulation No 1829/2003 provide that EFSA is to publish detailed guidance to assist the applicant in the preparation and the presentation of the application. EFSA's guidance documents are thus aimed at structuring the pieces of information an applicant is required to provide in submitting an application and are not intended to confer on a third party, such as the first applicant, a right to require that certain information be provided at that time.

114 Moreover, as explained by EFSA, the guidance documents in question are in the form of non-binding scientific opinions from one of its scientific groups or its scientific committee. Those documents are thus in no way binding on the Commission in its decision whether to grant or refuse authorisation under Regulation No 1829/2003 or, a fortiori, in its internal review process.

115 In the second place, according to case-law, the principle of the protection of legitimate expectations extends to any individual in a situation where it is clear that the EU administration has, by giving him precise, unconditional and concordant assurances, emanating from authorised and reliable sources, led him to entertain justified hopes. However, such assurances must comply with the applicable provisions and rules, since promises which do not take account of those provisions cannot give rise to a legitimate expectation on the part of the person concerned (see judgment of 17 December 2010, *EWRIA and Others* v *Commission*, T-369/08, EU:T:2010:549, paragraph 139 and the case-law cited).

116 Moreover, the guidance in question contains no precise, unconditional and concordant assurances given to the first applicant on which it may rely in a request for internal review of an administrative act brought pursuant to Article 10 of Regulation No 1367/2006.

117 In the third place, the first applicant relies on the case-law according to which guidance documents issued by the institutions may satisfy that criterion, thereby giving rise to a legitimate expectation (judgment of 28 June 2005, *Dansk Rørindustri and Others* v *Commission*, C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P, EU:C:2005:408, paragraphs 209 to 211). It should be noted in that regard that the guidance documents in question were not adopted by the Commission, which is responsible for adopting the authorisation decision and the decision on the request for internal review of an administrative act brought pursuant to Article 10 of Regulation No 1367/2006. It should further be noted that that case-law concerns cases where an institution, in adopting such guidance documents, restricts itself in the exercise of its broad discretion and cannot depart from those rules on pain of being sanctioned. The guidance documents at issue here, however, in no way limit the Commission's discretion, but are addressed to authorisation applicants, on whom they confer no such obligation.

118 For those reasons, the conclusion is thus that EFSA's guidance documents do not bind the Commission in its assessment or review, although it is certainly possible that it may opt to apply them as an assessment framework in the cases brought before it.

119 It follows that the first applicant may not rely on an infringement of the guidance documents referred to in paragraph 110 above, or rely on its legitimate expectations so that EFSA will act 'in accordance with its own guidance' issued pursuant to Regulation No 1829/2003.

120 It is in the light of those considerations that the Court must examine the various pleas in law put forward by the first applicant.

The first plea: EFSA's finding that the modified soybean is 'substantially equivalent' to its conventional counterpart

121 The first applicant considers: (i) that the Commission confirmed the authorisation of the modified soybean without ensuring that an appropriate risk assessment of the 'highest possible standard' had been carried out and that Monsanto had provided 'appropriate' data under Article 5(3)(f), Article 6(3)(a), Article 17(3)(f) and Article 18(3)(a) of Regulation No 1829/2003; (ii) that it infringed its obligation, under Article 4(1)(a) and Article 16(1)(a) of that regulation, to ensure that food and feed that would have an adverse effect on human health, animal health or the environment must not be placed on the European Union market; (iii) that it failed to fulfil the obligation to take into account any relevant provisions of EU law, including the provisions that require the institutions to comply with 'their own guidance', in breach of Article 7(1) and Article 19(1) of Regulation No 1829/2003; (iv) that it failed to observe its obligation to ensure a high level of protection for human health, in breach of Article 168 TFEU; and (v) that it failed

to meet the applicants' legitimate expectations. In particular, the Commission confirmed that authorisation, even though: (i) EFSA did not require Monsanto to include the parents or single events in the field trials conducted for the purpose of the application, contrary to the requirements stipulated by its own guidance; (ii) even though EFSA had identified a certain number of statistically significant differences between the modified soybean and its conventional counterparts, it concluded that there was 'substantial equivalence' between them; (iii) EFSA failed to take into account the fact that there is a substantial amount of scientific literature which documents the fact that spraying genetically modified plants with glyphosate-based herbicides affects the composition of such plants; (iv) EFSA failed to properly assess the data obtained from the field trials conducted by Monsanto in relation to agronomic and phenotypic differences; and (v) EFSA failed to require Monsanto to properly investigate the potential effect of specific biotic and abiotic stressors on the modified soybean.

122 The Commission disputes those arguments.

– The first part of the first plea

123 Under the first part of the first plea, the first applicant submits that under its guidance, EFSA did not require Monsanto to include 'the parents or single events', that is to say, the two genetically modified parent plants MON 87701 and MON 89799, in field trials as comparators.

124 The Commission considers that this part is inadmissible on the ground that it was not raised in the first applicant's request for internal review.

125 It should be noted in that regard that, in its request for internal review, the first applicant, in essence, submits that the genetically modified parent plants had not been properly assessed and that the investigation of the differences between the stacked soy and its comparators should include 'the isogenic and non transgenic parental plants', namely the non-genetically modified parent plants; however, only one comparator, Asgrown A5547, which was the non-genetically modified isogenic comparator, was provided.

126 It follows that the first applicant's request for internal review did not concern the inclusion of the 'the parents or single events', that is to say, the two genetically modified parent plants MON 87701 and MON 89799, in field trials as comparators and that, in the light of the considerations set out in paragraph 69 above, this part must be dismissed as inadmissible.

– The second part of the first plea

127 As regards the second part of the first plea, to the effect that EFSA allowed Monsanto to base itself on the alleged 'slightness' of the statistically significant differences across a broad cross-section of 'reference substances' and on the 'ILSI' database to mask the high number of statistical differences between the composition of

the modified soybean and the composition of its conventional counterpart, the first applicant takes the view that, in the first contested decision, the Commission failed to address its specific complaints about the fact that, in the present case, EFSA had relied on data obtained using a large number of different reference substances and the 'ILSI' database. Moreover, the Commission's statement that the correct comparator was used was vitiated, for the reasons set out in the first part of this plea.

128 The Commission states that it provided a detailed answer to the arguments put forward in the first applicant's request for internal review in Annex II to the first contested decision.

129 In so far as the first applicant submits that the first contested decision was vitiated by a failure to state reasons, it should be borne in mind that, according to the case-law, the plea alleging infringement of the second paragraph of Article 296 TFEU is a separate plea from the one alleging a manifest error of assessment. While the former, which alleges absence of reasons or inadequacy of the reasons stated, goes to an issue of infringement of essential procedural requirements within the meaning of Article 263 TFEU and, involving a matter of public policy, must be raised by the European Union judicature of its own motion, the latter, which goes to the substantive legality of a decision, is concerned with the infringement of a rule of law relating to the application of the Treaty, again within the meaning of Article 263 TFEU, and can be examined by the European Union judicature only if it is raised by the applicant. The obligation to state reasons is therefore a separate question from that of the merits of those reasons (see, to that effect, judgment of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 245 and the case-law cited).

130 It is settled case-law that the statement of reasons required by the second paragraph of Article 296 TFEU must be appropriate to the act at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the competent court to exercise its power of review. The requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations. It is not necessary for the reasoning to go into all the relevant facts and points of law, since the question whether the statement of reasons meets the requirements of the second paragraph of Article 296 TFEU must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question. In particular, the Commission is not obliged to adopt a position on all the arguments relied on by the parties concerned and it is sufficient if it sets out the facts and the legal considerations having decisive importance in the context of the decision (see judgments of 4 March 2009, *Associazione italiana del risparmio gestito and Fineco Asset Management* v *Commission*, T-445/05, EU:T:2009:50, paragraph 67 and the case-law cited, and of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 246).

131 In its request for internal review, the first applicant submits that, instead of using appropriate comparator lines, many soybean varieties were grown as 'reference substances'. Consequently, Monsanto generated a broad range of data that are not related to the genomic background of the modified soybean and are liable to produce scientific 'noise' that masks the differences between the soybean and its comparator. Moreover, in its submission, the 'ILSI' database was used as an additional reference for historical data. EFSA ought to have conducted a more in-depth analysis of those differences.

132 In the first contested decision, the Commission rejected the arguments put forward in the first applicant's request for review, finding that it had used an appropriate comparator in accordance with the 2006 guidance document and internationally-agreed standards for risk assessment. In its view, the use of non-genetically modified commercial reference varieties was a fundamental component of that comparative approach and served to estimate under the same environmental conditions the range of natural variation to which consumers would be exposed by consuming a specific crop. Every statistically significant difference identified when comparing the genetically modified plant with its comparator is then evaluated against the values derived from the set of non-genetically modified commercial reference varieties planted in the same field trial to assess its biological relevance. The Commission took the view that, in the case of the modified soybean, the only statistically significant differences detected between that genetically modified crop and its comparator were changes in the level of some fatty acids and increased levels of daidzein and genistein. Those differences fell within the range estimated from the non-genetically modified commercial soybean varieties grown in the same field trials. According to the Commission, this means that, if the genetically modified plant displays a statistically significant higher or lower content of a specific compound with respect to its comparator, such content is not higher or lower than that of commercial varieties grown under the same conditions. Therefore, consumers will not be over- or under-exposed to any component when consuming the modified soybean as compared to the consumption of 'conventional soybean'. The Commission also stated that the conclusions on safety were based on those data and not on the 'ILSI' database.

133 In the light of those findings, it should be noted that the reasons given in the first contested decision enable the first applicant to understand the reasons why the Commission, in the exercise of its broad discretion, rejected the applicants' arguments. The first applicant is therefore incorrect in asserting that the Commission failed to comply with its obligation to state reasons in not addressing the specific complaints raised in the first applicant's request for internal review. In addition, that statement of reasons is also sufficient to enable the Court to exercise its power of review.

134 In any event, in so far as the first applicant's argument is aimed at calling into question the merits of the Commission's findings in the first contested decision, it should be observed that, by its arguments, the applicant has not demonstrated any manifest error in the Commission's assessment since, as the Commission explains in its statement in defence, once differences have been observed, those reference varieties with a history of safe use are used to estimate, under the same environmental conditions, the range of natural variation to which consumers would be exposed by consuming a specific crop. In

its submission, they are not used to detect possible differences between the genetically modified plant and its conventional counterpart, as the applicants seem to imply. The statistical comparison between the genetically modified crop and its conventional counterpart is independent of the non-genetically modified reference varieties, so that no statistical 'noise' exists, contrary to what the first applicant states. The Commission further states, correctly, that Article 5(3)(f) and Article 17(3)(f) of Regulation No 1829/2003 explicitly mention the fact that 'natural variations' must be taken into account when determining whether a genetically modified organism is different from its conventional counterpart.

135 Therefore, the argument that in the first contested decision the Commission failed to address the first applicant's specific complaints to the effect that, in the present case, EFSA had relied on data obtained using a high number of different reference substances and the 'ILSI' database, must be rejected.

136 As regards the argument that the Commission's statement to the effect that the appropriate comparator was used was vitiated for the reasons set out in the first part of this plea, it should be observed that, as held in paragraphs 123 to 126 above, the arguments put forward under that first part were not included in the request for review and were therefore inadmissible. Inter alia they were not put forward by way of argument included in the first applicant's request for internal review directed at the incorrect references called into question under the present plea.

137 Therefore, the second part of the first plea must be rejected, without its being necessary to consider the Commission's argument that most (without further particulars) of the present part is clearly inadmissible on the ground that the arguments put forward in this part were not in the first applicant's request for internal review.

– The third part of the first plea

138 By the third part of the first plea, the first applicant submits that EFSA failed to take into account the fact that there is a substantial amount of scientific literature documenting the fact that spraying genetically modified plants with certain herbicides affects their composition, which is also likely to influence agronomic and phenotypic effects. Firstly, in the first contested decision, the Commission based itself on 'a' manifest failure in EFSA's approach to the comparative analysis to justify its failure to investigate in greater depth differences that could reveal unintended effects caused by the stacking of the proteins in question, given that the divergences identified between daidzein and genistein levels present in the modified soybean and those present in its conventional counterpart remained within the range shown by the reference substances. Secondly, the Commission disregarded not only differences that had been identified between that soybean, its comparator and the reference substances, but also the scientific literature relied on which, in its submission, was 'not applicable' in the present case and was of the utmost importance inasmuch as it indicates that an appropriate study of the effects of spraying would have led to the identification of further, significant differences.

139 The Commission considers, in essence, that it provided detailed answers to the first applicant's arguments in the first contested decision. In its submission, even if information from the scientific literature and publicly-available databases were taken into account by EFSA in its conclusions on the safety of stacking, the primary method for determining whether unintended effects (compositional or agronomic and phenotypic) have occurred is the comparative analysis, taking into account different herbicide treatment regimes; hence EFSA's conclusion that the consumers would not be over-exposed or under-exposed to any of those compounds when consuming the modified soybean as compared to the 'conventional soybean'.

140 Firstly, inasmuch as the first applicant refers in that context to the literature listed in Annex I to the application, entitled 'Table on the impact of spraying genetically modified plants with a glyphosate-based herbicide', it should be remembered that, in the present case, the first applicant merely makes a general allegation that differences between the modified soybean, its comparator and the reference substances had been identified and that the scientific literature relied on is of the utmost importance in so far as it indicates that an appropriate study of the effects of spraying would likely have led to further, significant differences.

141 In that regard, it should be remembered that under Article 21 of the Statute of the Court of Justice of the European Union and Article 44(1)(c) of the Rules of Procedure of the General Court of 2 May 1991, each application is required to state the subject matter of the proceedings and a summary of the pleas in law on which the application is based. That statement must be sufficiently clear and precise to enable the defendant to prepare its defence and the Court to rule on the action, if necessary, without any further information. It is necessary, for an action to be admissible, that the basic matters of law and fact relied on be indicated, at least in summary form, coherently and intelligibly in the application itself. Whilst the body of the application may be supported and supplemented on specific points by references to extracts from documents annexed thereto, a general reference to other documents, even those annexed to the application, cannot make up for the absence of the essential arguments in law which, in accordance with the abovementioned provisions, must appear in the application. The annexes may be taken into consideration only in so far as they support or supplement pleas or arguments expressly set out by applicants in the body of their pleadings and in so far as it is possible to determine precisely what are the matters they contain that support or supplement those pleas or arguments. Furthermore, it is not for the Court to seek and identify in the annexes the pleas and arguments on which it may consider the action to be based, since the annexes have a purely evidential and instrumental function. That interpretation of Article 21 of the Statute of the Court of Justice of the European Union and Article 44(1)(c) of the Rules of Procedure of 2 May 1991 also applies to the reply (see judgment of 14 March 2013, *Fresh Del Monte Produce* v *Commission*, T-587/08, EU:T:2013:129, paragraphs 268 to 271 and the case-law cited).

142 In accordance with that case-law, the formulation of this complaint does not enable the Court to give a ruling, if appropriate, without other information in support, and to allow the annexes to provide the detail of an argument which is not presented in a

sufficiently clear and precise manner in the application would be contrary to their purely evidential and instrumental function. Therefore, the argument, referring to Annex I to the application, that abundant scientific literature supporting the fact that spraying of certain herbicides on genetically modified plants affects their composition was not taken into consideration, must be rejected as inadmissible.

143 Secondly, as regards the argument that the Commission based itself on 'a' manifest failure in EFSA's approach to the comparative analysis to justify its failure to investigate in greater depth differences that could reveal unintended effects caused by the stacking of the proteins in question, it should be noted that the first applicant does not explain exactly which 'failure' on the part of the Commission contained in the first contested decision it means. It does not indicate in this part why it believes that the Commission's argument to the effect that the variations identified between daidzein and genistein levels present in the modified soybean, and those present in its conventional counterpart remained within the range shown by the reference substances is vitiated by a manifest error of assessment.

144 Nor is it clear from the first applicant's arguments directed against the first contested decision specifically which statistically significant differences the Commission ought to have taken into account and which, in the first applicant's view, are relevant to substantiate its assertion that there is 'a' manifest failure vitiating the comparative analysis approach.

145 It should be borne in mind that Article 44(1)(c) of the Rules of Procedure of 2 May 1991 provides that the application must state the subject matter of the proceedings and a summary of the pleas in law on which the application is based. According to settled case-law, those particulars must be sufficiently clear and precise to enable the defendant to prepare its defence and the Court to rule on the action, if necessary, without any further information. In order to guarantee legal certainty and the sound administration of justice it is necessary, in order for an action to be admissible, that the basic legal and factual particulars relied on be indicated, at least in summary form, coherently and intelligibly in the application itself (see, to that effect, order of 11 January 2013, *Charron Inox and Almet* v *Commission and Council*, T-445/11 and T-88/12, not published, EU:T:2013:4, paragraph 57).

146 Moreover, given that the arguments put forward in the present case concern highly technical facts and given the complexity of the field at issue, the use of general and imprecise references to other parts of the application or other documents does not satisfy the requirements of the case-law cited in paragraph 145 above. Although it is possible, where there is a general reference to points made in other pleas, that the basic legal and factual particulars relied on by the applicant are set out in the application, it is nevertheless important for the applicant to present them coherently and intelligibly. In particular, it is not the task of the Court to search through all the matters relied on in support of a first plea in order to ascertain whether those matters could also be used in support of a second plea and, in this instance, which matters could be used (see, to that effect, judgment of 27 September 2006, *Roquette Frères* v *Commission*, T-322/01, EU:T:2006:267, paragraph 209).

147 Therefore, since it is not stated coherently and intelligibly in the application in respect of which ‘failure’ the first applicant is criticising the Commission, its argument on this point must be rejected as inadmissible.

148 Thirdly, as regards the argument about there being differences between the modified soybean, its comparator and the reference substances and the relevance of the scientific literature relied on by the first applicant, the Commission acknowledged in the first contested decision that increased daidzein and genistein levels had been identified in the comparison between the modified soybean sprayed with glyphosate and its comparator. According to the Commission, those differences had been assessed and found to be included in the range of natural variation defined by the commercial varieties of non-genetically modified soybean used in the study. The Commission adds that the references on which the first applicant based itself were not applicable to the modified soybean as no difference in composition had been identified between that soybean, its comparator and the reference substances treated with glyphosate.

149 EFSA accordingly did examine the publications annexed to the first applicant’s request for internal review and found that those publications were not relevant in the present case. In any event, the first applicant has not produced anything showing that the Commission had made a manifest error of assessment in that regard.

150 Although it is true that the Commission’s finding in the first contested decision, that ‘no difference’ had been identified in the compositional analysis, is exaggerated, it should nevertheless be observed that, in response to a written question from the Court, the Commission explained that, in the present case, an assessment had been made and the daidzein and genistein levels identified were within the range of natural variation defined on the basis of the commercial varieties of non-genetically modified soybean used in the study and that, consequently, the comparative compositional analysis had thus revealed no significant difference. It is also apparent from paragraphs 67 to 69 of the statement in defence that no ‘statistically or biologically relevant’ difference had been identified by the Commission.

151 Therefore, the third part of the first plea must be rejected as partly inadmissible and partly unfounded.

– The fourth part of the first plea

152 As regards the fourth part of the first plea, to the effect that EFSA did not assess properly the data collected in the field studies led by Monsanto concerning agronomic and phenotypic differences, the first applicant submits that the Commission merely summarised EFSA’s approach for interpreting the agronomic and phenotypic data and failed to address the specific complaints set out in the first applicant’s request for internal review.

153 In that regard, it should be noted that the first applicant, in essence, considered in its request for internal review that EFSA had not assessed properly the data collected in

the field studies led by Monsanto concerning agronomic and phenotypic differences, which showed significant differences such as an increase in final stand count. In its view, such changes in phenotype were an indication of unintended effects in the plant's genome and a change in its components, which can affect food safety.

154 The Commission considers that it did provide a detailed answer in the first contested decision to the specific complaints set out in the first applicant's request for internal review.

155 The first applicant submits that the first contested decision is vitiated by a failure to state reasons. In Annex II to that decision, the Commission inter alia explained that EFSA had assessed and interpreted the agronomic and phenotypic data in the light of the scope of the application for authorisation submitted by Monsanto, which did not include cultivation. According to the Commission, the data from the field trials enabled EFSA to conclude that no consistent changes in phenotypic and agronomic characteristics had been observed between the modified soybean and its comparator, with the exception of a small increase in final stand count, which was not considered biologically relevant. The Commission accordingly considered that the agronomic and phenotypic characteristics had not revealed the presence of unintended effects, which is also supported by the outcome of the compositional analysis.

156 In the light of the conditions set out in the case-law as referred to in paragraphs 129 and 130 above, it should be noted that the reasons given in the first contested decision enable the first applicant to understand properly the reasons why, in the exercise of its broad discretion, the Commission rejected the applicants' arguments. The applicants are incorrect in their conviction that the Commission failed to comply with its obligation to state reasons in not addressing the specific complaints set out in the first applicant's request for internal review. In addition, that statement of reasons is also sufficient to enable the Court to exercise its power of review.

157 In any event, as regards the argument that EFSA did not assess properly the data collected in the field studies led by Monsanto concerning agronomic and phenotypic differences, it should be observed that the first applicant has not demonstrated any manifest error of assessment by the Commission. The Commission stated in the first contested decision that it considered that EFSA had conducted the assessment in question in accordance with its own 2006 guidance document. In that regard, the Commission stated in its statement in defence that EFSA had made its own assessment of the phenotypic data provided by Monsanto, so that it did not simply rely on Monsanto's analysis, contrary to the applicants' allegation. Moreover, given that EFSA's assessment was conducted in the light of the scope of application for authorisation, which did not include cultivation, the Commission considered that EFSA had assessed the differences identified in the phenotypic comparative analysis for their relevance for food and feed safety, which was examined primarily in the light of the scope of the application. The Commission further explained that, even though the stack was intended for food and feed uses, EFSA had assessed potential enhanced fitness taking account of possible accidental release into the environment of viable grains during transport and processing.

158 The fourth part of the first plea must therefore be rejected as unfounded.

– The fifth part of the first plea

159 As regards the fifth part of the first plea, to the effect that EFSA failed to require Monsanto to properly investigate the potential effect of specific biotic and abiotic stressors on the modified soybean, the first applicant considers that in the first contested decision the Commission does not address the specific complaints set out in its request for internal review but merely suggests that the scientific literature presented to it was not relevant on the ground that that literature referred to other cultivations. It was for EFSA to ensure that appropriate checks of the soybean were made, which was not done. According to the first applicant, certain studies concerning other cultivations provide scientifically relevant data for analysing the soybean.

160 It should be noted in that regard that the applicants explained at the hearing that, by those arguments, they were alleging a manifest error of assessment by the Commission, but not a failure to state reasons, which was formally noted by the Court in the minutes of the hearing.

161 The Commission considers that it provided a detailed answer in the first contested decision to the specific complaints set out in the first applicant's request for internal review. It adds in the statement in defence that the risk assessment of genetically modified organisms must be done on a case-by-case basis and that, in the present case, EFSA assessed the stack in the light of the scope of the application for authorisation, which did not include cultivation. Thus, the environmental risk assessment of the stack was carried out in the light of the limited exposure to the environment through accidental release. EFSA also examined the publications relied on in the requests for internal review, but found them not to be relevant.

162 Biotic stressors are factors of biological origin, such as insects or viruses, which might influence some plant parameters and have consequences on its food safety. Abiotic stressors are factors of non-biological origin, such as temperature and soil salinity, which might influence some plant parameters and have consequences on food safety.

163 In the present case, in the first contested decision, the Commission rejected the arguments set out in the first applicant's request for internal review, finding firstly that the assessment of the modified soybean had been carried out in the context of its intended uses, namely for import and processing. Considering those intended uses, which exclude cultivation, and the low level of exposure to the environment, potential interactions with the biotic and abiotic environmental cycles were not considered an issue by EFSA. However, the Commission added that EFSA had nevertheless assessed the data provided by Monsanto in its file on biotic and abiotic stressors. As regards abiotic stressors, the evaluation of 96 observations did not reveal any differences between that soybean and its comparator. Therefore, there was no evidence that the possible effects of abiotic stressors would be different between the two plants. As regards biotic stressors, the Commission observed that, out of 334 comparisons made of the effects of different biotic agents, 9

comparisons had shown statistically significant differences not related to the intended effects of the genetic modification. However, according to the Commission, those differences had not been consistently observed in the analysis across sites; they were small and did not indicate that the modified soybean was either more or less affected than other 'commercial soybeans'. According to the Commission, the references provided by the applicants concerning abiotic and biotic stress for genetically modified plants concerned varieties other than the modified soybean and were therefore not relevant in the present case.

164 In response to a written question put by the Court, the Commission explained that the reply set out in the first contested decision meant that potential interactions with biotic and abiotic environmental cycles had not been viewed as problematic by EFSA and that, in other words, no problem had been detected on the basis of the data provided in the application, including in relation to the compositional analyses, and that it had not been deemed necessary to obtain further data. It added that the biotic and abiotic interactions to which the modified soybean and its conventional counterpart had been exposed during the field trials had been taken into account in the compositional analysis. In its view, given that the application did not cover cultivation in Europe, the field trials for the purposes of the agronomic and phenotypic compositional analyses, conducted on a number of sites in North and South America, had been found to be insufficiently representative of the possible receiving environments for the cultivation of that soybean. No further tests of specific abiotic and biotic stressors other than those already present at the time of the field trials had been deemed necessary in the present case. It is noteworthy that the first applicant has not disputed those assertions.

165 In fact the first applicant merely states that the Commission made a manifest error of assessment in finding that the references provided by the first applicant about abiotic and biotic stress on genetically modified plants concerned varieties other than the modified soybean and are not relevant to the present case. According to the first applicant, the scientific research indicating that spraying may have unintended effects on plants cannot simply be dismissed on the ground that it relates to cultivations other than soybean and findings made about other cultivations provide scientifically relevant data for analysing the modified soybean. Moreover, scientists regularly extrapolate from other findings.

166 It should be observed, firstly, that there is nothing in the first applicant's arguments indicating which scientific studies show that spraying may have unintended effects on the plants in question and for which reasons it considers that such studies provide scientifically relevant data in the present case.

167 Secondly, nor does the first applicant's general assertion that scientists regularly extrapolate from other findings establish any relevance whatsoever for those studies in the present case.

168 In the light of those considerations, the conclusion is that the first applicant has failed to produce sufficient material to establish that the Commission's explanations, set out in in paragraphs 163 and 164 above, are vitiated by a manifest error of assessment.

169 The fifth part of the first plea must therefore be rejected.

170 Therefore, the first plea must be rejected as partly inadmissible. The remainder of the plea must be rejected as unfounded on the ground, firstly, that the first applicant did not demonstrate through its arguments, put forward under the present plea, that the Commission had confirmed the authorisation of the modified soybean without ensuring that an appropriate risk assessment of the 'highest possible standard' had been carried out and that Monsanto had provided 'appropriate' data under Article 5(3)(f), Article 6(3)(a), Article 17(3)(f) and Article 18(3)(a) of Regulation No 1829/2003. Secondly, nor has it shown through its arguments: that the Commission had infringed its obligation, under Article 4(1)(a) and Article 16(1)(a) of that regulation, to ensure that food and feed that would have an adverse effect on human health, animal health or the environment must not be placed on the European Union market; that it had not fulfilled the obligation to take into account any relevant provisions of EU law, including the provisions that require the institutions to comply with 'their own guidance', in breach of Article 7(1) and Article 19(1) of Regulation No 1829/2003; that it had not observed its obligation to ensure a high level of protection for human health, in breach of Article 168 TFEU; and that it had failed to meet the first applicant's legitimate expectations.

The second plea: the synergistic or combinatorial effects were not taken into consideration or no appropriate toxicity assessment was required

171 The first applicant submits that the Commission confirmed the authorisation of the modified soybean despite the fact that EFSA's toxicity assessment was 'manifestly in error, unlawful and/or contrary to its own … guidance'. The Commission, therefore (i) committed a manifest error of assessment by maintaining the authorisation of the modified soybean and failing to require an appropriate risk assessment that was of the 'highest possible standard'; (ii) was in breach of its duty, under Article 4(1)(a) and Article l6(1)(a) of Regulation No 1829/2003, to ensure that food and feed that would have an adverse effect on human health, animal health, or the environment must not be placed on the European Union market; (iii) did not, in breach of Articles 7(1) and 19(1) of Regulation No 1829/2003, take into account any relevant provisions of EU law, including the provisions of Union law that require Union institutions to comply with 'their own guidance'; (iv) did not, in breach of Article 168 TFEU, comply with its duty to ensure a high level of protection for human health; and (v) failed to meet the applicants' legitimate expectations.

172 More specifically, it argues, firstly, that EFSA did not carry out an appropriate safety assessment of the modified soybean.

173 Secondly, in the applicant's submission, the EFSA finding, relating to the interactions between certain proteins in the stacked event and the other plant constituents

together with other factors, is ‘flawed’ on the grounds: (i) that the selectivity of the newly expressed Cry proteins has not been sufficiently investigated to date; (ii) that there has been insufficient assessment of the expression of the Bt toxins generally, in different climatic conditions and of the ‘emerging genomic effects’; (iii) that there are a number of external factors which may have combinatorial or synergistic effects with Bt toxins/Cry proteins, without EFSA requiring any further investigation in that regard; (iv) that there has been no proper analysis of the degradation of protease inhibitors and of any potential synergies; and (v) that EFSA failed to require Monsanto to investigate the emerging genomic effects between the parents and the modified soybean.

174 Thirdly, it considers that EFSA failed to require Monsanto to carry out an adequate toxicity assessment, even though: (i) scientific evidence shows that the application of glyphosate-based sprays to genetically modified food increases their toxicity; (ii) EFSA failed to require [assessment of] the potential effect of the modified soybean on the reproductive system and the transfer of biologically active compounds from the modified soybean to animal tissue or humans through consumption; and (iii) evidence shows that Bt toxins potentially have detrimental health effects in animals.

175 The Commission disputes those arguments.

– Preliminary observations

176 By this plea, the first applicant submits, in essence, that the first contested decision is unlawful owing to the fact that the Commission maintained the marketing authorisation of products containing the modified soybean despite the fact that EFSA had carried out an inadequate toxicity assessment. Reference must therefore be had, as a preliminary point, to the provisions of the 2006, 2007 and 2011 guidance documents concerning toxicity assessment and the findings of the Scientific Panel in that regard, which form the basis of EFSA’s overall opinion and the authorisation decision.

177 As regards the toxicity assessment, the 2006 guidance document states that the requirements of toxicological testing in the safety assessment must be considered on a case-by-case basis and will be determined by the outcome of the assessment of the differences identified between the genetically modified product and its conventional counterpart. In principle, the safety assessment must consider the presence of new proteins expressed as a result of the genetic modification, the potential presence of other new constituents and/or possible changes in the level of natural constituents beyond normal variation.

178 Further in relation to the toxicity assessment, the 2007 guidance document states that an assessment of any potential for increased toxicity to humans and animals should be provided. Those potential effects may be particularly relevant where the combined expression of the newly-introduced genes has unexpected effects.

179 According to the 2011 guidance document, the toxicological impact of any biologically relevant change in the genetically modified plant, food or feed resulting from

the genetic modification should be assessed. Toxicological assessment must consider: the presence and levels of newly-expressed proteins; the potential presence of other new constituents; possible changes in the levels of endogenous constituents beyond normal variation; and the impact of other changes in composition due to the genetic modification. In the case of genetically modified plants containing stacked events, toxicological testing of the food or feed derived from the genetically modified plant should be considered when there are indications of possible interactions between the events stacked.

180 The scientific opinion of 25 January 2012 indicates that EFSA conducted a review of all the data available for newly-expressed proteins in the modified soybean, a review of new constituents other than the proteins and an assessment of food and feed overall. The findings of the Scientific Panel were confirmed by EFSA's overall opinion of the modified soybean.

181 As regards the assessment of newly-expressed proteins in the modified soybean, the Scientific Panel found that the parental soybean varieties had been evaluated for safety and no safety concerns had been identified. The modified soybean and the parental soybean varieties showed comparable expression levels of newly-expressed proteins, with 'at most a twofold' difference. Furthermore, the Scientific Panel considered that interactions between single events that might have an impact on foods and feed were 'unlikely'.

182 As regards the assessment of new constituents other than proteins, the Scientific Panel considered that, apart from the two newly-expressed proteins, no relevant change in the composition of the modified soybean had been detected in the compositional analysis.

183 In an overall assessment of food and feed, the Scientific Panel found that a molecular characterisation undertaken on the modified soybean had not identified an altered stability of the single events when they were brought together by crossing and that the expression analysis of the newly-expressed proteins had not revealed any relevant change in expression levels in the modified soybean as compared with the single events of the parental soybean varieties. According to the Scientific Panel, given that no biologically relevant differences were identified in the compositional characteristics of the modified soybean as compared to non-genetically modified soybean varieties, except that it expresses the newly-expressed proteins, and an assessment found no indication for interaction between the single events that could influence the safety of the modified soybean for humans and animals, no additional animal safety studies were required.

– The first part of the second plea

184 By the first part of the second plea, the first applicant submits that EFSA based itself on the finding that there was a substantial equivalence between the modified soybean and its comparator to justify its not requiring a toxicity assessment. In its submission, the Commission failed to address their key concern, namely that whilst the assessment of substantial equivalence was a key part of the procedure of conducting a safety assessment, it is not a safety assessment in itself.

185 The Commission replies that, in Annex II to the first contested decision, it set out in detail its position on the comparative approach. In particular, it confirmed that the principle of substantial equivalence or comparative approach is only the starting point of the safety assessment and explained the strategy followed for the risk assessment.

186 Since the first applicant alleges a failure to state reasons in the first contested decision, it should be noted that in that decision the Commission explained that the principle of substantial equivalence was a key step in the safety assessment of food and feed derived from biotechnology and that the strategy was considered the point of departure for safety assessment. All differences arising from the genetic modification would then be the subject of an in-depth examination with respect to possible toxicological, allergenic or nutritional aspects. As regards the modified soybean, according to the Commission the experimental data provided in the file enabled EFSA to conclude that that genetically modified variety was as safe as its comparator for its intended uses. The Commission further submits that the applicants had not produced anything proving that the risk assessment had not been carried out in a reliable manner.

187 Therefore, the Commission was able, without infringing its obligations following from the case-law referred to paragraphs 129 and 130 above, to base its analysis in the first contested decision on the finding that EFSA had not restricted its assessment of the risks associated with stacking to a comparative analysis, but had assessed the potential for increased toxicity completed by an allergenicity and nutritional evaluation due to the stacked events.

188 In so far as the first applicant submits that, as a matter of principle, the Commission cannot rely on the finding of substantial compositional equivalence in order to escape its obligation to conduct an 'appropriate toxicity assessment', it should be noted first of all that each of the guidance documents referred to in paragraphs 177 to 179 above state that the scope of the toxicity assessment must be determined on a case-by-case basis and that a limited toxicity assessment is possible and therefore not ruled out as a matter of principle.

189 Furthermore, the first applicant has not specified any passage from the guidance documents referred to in paragraphs 177 to 179 above which, in its submission, infringes any provision whatsoever of Regulation No 1829/2003.

190 Next, it should be noted that the first applicant has not explained in its written pleadings what, in its view, would be an 'appropriate' toxicity assessment in the present case.

191 Lastly, as observed by the Commission in its statement in defence and as is apparent from the content of the scientific opinion of 25 January 2012 referred to in paragraphs 180 to 183 above, in the present case, the evaluation of the stack was preceded by an assessment of the two genetically modified parents of the modified soybean, including a comparative approach completed by a molecular characterisation and toxicology, allergenicity and nutritional risk studies. That assessment of the risks

associated with the two parents was completed by a comparative analysis of the stack and a molecular characterisation in order to assess potential synergistic or antagonistic effects between the two genetically modified parents. According to the Commission, EFSA assessed the need for further toxicological assessment of the stack on the basis of all the information gathered on the genetically modified parents and on the stack. The Commission is therefore also correct in finding that EFSA did not restrict its assessment of the risks associated with stacking to a comparative analysis, but assessed the potential for increased toxicity due to the stacked transformation events.

192 It follows that the argument that, as a matter of principle, the Commission cannot rely on the finding of substantial compositional equivalence in order to escape its obligation to conduct an 'appropriate toxicity assessment' does not prove that there has been a manifest error of assessment by the Commission in the first contested decision. The first part of the second plea must therefore be rejected as unfounded.

– The second part of the second plea

193 By the second part of the second plea, the first applicant puts forward five complaints directed at EFSA's finding that the assessment had not identified any indications of interaction between the single events liable to influence the safety of the modified soybean for humans and animals.

194 By the first complaint, to the effect that the mode of action of the Cry proteins is not yet understood with a minimum of certainty and EFSA had no sound basis for assuming that those proteins would not interact or produce synergistic effects, the first applicant considers that in the first contested decision the Commission ignored the abundant scientific literature submitted by it in its request for internal review.

195 The Commission explains that in the first contested decision it provided a detailed answer about the allegedly insufficient investigation of the newly-expressed proteins.

196 In the first contested decision the Commission considered, in essence, in that regard that, in the request for internal review, the first applicant had failed to provide any new scientific information that might change EFSA's conclusions on the toxicity assessment of the modified soybean, that the reference to the mode of action and selectivity of Cry proteins in target organisms was not relevant in the context of food and feed safety assessment, and that the safety of Cry1Ac had been appropriately addressed in previous EFSA scientific opinions, including on the basis of experimental evidence.

197 Consequently, the first applicant is incorrect in arguing that the Commission 'ignored' the scientific literature submitted in the request for internal review. It should be noted in that context that the mere fact that the first applicant's request for internal review was not fully upheld does not mean that its observations were not considered by the Commission.

198 In any event, the first applicant refers, in paragraph 161 of the application, to studies by Zhang et al. (2006), Soberon et al. (2009), Broderick et al. (2009), Johnston & Crickmore (2009) and Mason et al. (2011), in which it points out that they all reach different conclusions as to the mode of action in target organisms. However, the first applicant does not dispute the Commission's finding in the first contested decision that the reference to the mode of action and the selectivity of Cry proteins in target organisms was not relevant in the present case, where it was a matter of assessing food and feed safety.

199 As regards the studies by Broderick et al. (2006), Jiminez-Juares (2007), referred to in paragraph 161 of the application, and the studies referred to in paragraphs 162 and 164 of the application, they were not relied on as part of the relevant argument put forward in the request for review, namely the 'B2' argument. Therefore, the first applicant cannot validly argue that the Commission ought to have taken those studies into account in the first contested decision.

200 Therefore, the argument that the Commission failed to take account of the studies referred to in paragraph 199 above must be rejected as unfounded.

201 Moreover, it must be noted that although as part of this complaint the first applicant refers to the literature listed in Annex II to the application, headed 'Table B: Summary of scientific literature showing the numerous plant constituents and chemicals which can have synergistic or combinatorial effects with the inserted Cry proteins/Bt toxins', it merely alleges generally that that literature was ignored by the Commission. In accordance with the case-law referred to in paragraph 141 above, such a formulation of the complaint does not enable the Court to give a ruling, if appropriate, without other information in support, and to allow the annexes to provide the detail of an argument which is not presented in a sufficiently clear and precise manner in the application would be contrary to their purely evidential and instrumental function. It is therefore appropriate to reject as inadmissible the argument that the Commission ignored the literature listed in Annex II to the application.

202 Therefore, the first complaint must be rejected.

203 By the second complaint, concerning the synergistic effects of Bt toxins, the first applicant 'rejects' the Commission's finding in the first contested decision that the scientific publications provided by the first applicant had been taken out of context and had not provided any new scientific information that might change the conclusions on the toxicity assessment of the modified soybean, on the ground that that finding was not 'explained'.

204 The Commission states that it gave a detailed answer to the allegation concerning the interaction of Bt toxins, adding that all the publications referred to in the first applicant's request for internal review were examined by EFSA, which enabled it to confirm that no new scientific data demonstrating the toxicity of 'Bt proteins' had been provided.

205 It is true that the reasons relating to the scientific publications given by the Commission in the first contested decision are very succinct and are limited to the finding that the scientific publications in question were taken out of context and provided no new information that might change the conclusions on the toxicity assessment of the modified soybean. The Commission also explained that it considered that no new scientific information had been provided that could have demonstrated the toxicity of the proteins in question, a point not disputed by the applicants.

206 However, the Commission also explained in the first contested decision that the interactions between the newly-expressed proteins had been examined and that, on the basis of the known functions and modes of action of the newly-expressed proteins, including the Cry1Ac protein, EFSA had considered it unlikely that interactions raising any safety concerns between those proteins would occur. Furthermore, according to the Commission, the compositional analyses provided by Monsanto included data from plants sprayed with glyphosate and maintenance pesticides. Thus, the Commission considered that a potential combined effect of the newly-expressed proteins and the herbicide treatment had been taken into account.

207 In that regard, the Commission explained, in response to a written question from the Court, that it considered that either most of the publications did not make any reference to the effects of the *Bacillus thuringiensis* or Cry proteins (Ab, Ac) on humans or mammals, or the publications referred to another type of proteins, not relevant for the modified soybean. Most of the publications referred to in the first applicant's request for internal review concerned the effects of Bt toxins on insects. In the Commission's submission, those effects could be of relevance for a cultivation application where the Cry protein is active on the insects, but for an import and processing application, such as the one lodged for the modified soybean, they are completely irrelevant. Furthermore, the Commission did address those allegations in the first place in the first contested decision, before providing comments on the references provided by the first applicant in support of its allegations.

208 In the light of the requirements established by the case-law relating to the obligation to state reasons and set out in paragraphs 129 and 130 above, the conclusion is that the reasons given in the first contested decision enable the first applicant to understand properly why the Commission, in the exercise of its broad discretion, rejected the first applicant's argument, and enable the Court to exercise its power of review. The first applicant has not explained in its written pleadings why it considers that statement of reasons to be inadequate.

209 In any event, in the light of the Commission's explanations set out in paragraphs 205 to 207 above, the conclusion is that the first applicant has not demonstrated through its arguments any manifest error of assessment by the Commission.

210 The present complaint must therefore be rejected as unfounded.

211 By the third and fifth complaints, which are dealt with together in the application and which concern, on the one hand, the potential synergistic or combinatorial effects of environmental conditions and glyphosate treatment with Bt toxins or Cry proteins and, on the other, their displaying emerging genomic effects, the first applicant submits, firstly, that the finding that the proteins in question are 'non- toxic', without investigation is untenable and, secondly, that the Commission failed to deal with the specific criticisms levelled in the request for internal review against EFSA's failure both to ensure that proper field trials were carried out and to recognise genomic effects and differences which were in fact found in the inadequate field trials.

212 The Commission considers that it gave detailed answers in the first contested decision to the arguments put forward in the first applicant's request for internal review.

213 In the first place, the argument that the finding that the proteins in question are 'non-toxic' is merely an assertion which, in the first applicant's submission, is not the product of any investigation, must be rejected. As correctly explained by the Commission in the first contested decision, the methodology applied to study protein expression was considered adequate by EFSA and the data relating to that expression were obtained from five field trials, under conditions similar to cultivation for commercial purposes and covering different environmental conditions. It follows that there was an investigation.

214 In the second place, in so far as the first applicant submits that the first contested decision was vitiated by a failure to state reasons, it should be noted that it maintained, in essence, in its request for internal review that the expression of newly-expressed proteins in different environmental conditions had been insufficiently assessed and that the 'stacked soybean' had a substantially higher content of newly-expressed proteins than the parental plants. The Commission rejected those arguments in the first contested decision on the ground that the methodology applied to study protein expression was described in detail in the application for authorisation and was considered adequate by EFSA; that the data were obtained from five field trials, under conditions similar to cultivation for commercial purposes and covering different environmental conditions; and that, given the scope of the application, which excluded cultivation and the non-toxic nature of the newly-expressed proteins for humans and animals, the data were considered adequate. According to the Commission, differences between the levels of expression of the modified soybean and its parental lines were either not consistent throughout the growing season or very small, and in no way show emerging genomic effects in the stack.

215 In the light of the conditions established by the case-law relating to the obligation to state reasons and set out in paragraphs 129 and 130 above, the conclusion is that the reasons given in the first contested decision enable the first applicant to understand properly why the Commission, in the exercise of its broad discretion, rejected the first applicant's argument, and enable the Court to exercise its power of review.

216 In any event, with regards to the merits of the arguments set out herein, it should be noted that the Commission explained in the statement in defence that, in the comparison of seven tissue types, only those corresponding to the more mature leaf and seed showed

statistically significantly higher levels of CrylAc protein in the stack than in the genetically modified parental line. For the rest, there were, in its view, no significant differences. Moreover, in case of a hypothetical interaction between the two transformation events leading to an increased level of CrylAc in the stack, it would have expected to find a statistically significant increase along the different stages of maturity of the plant, because the stack expresses both events throughout the growing season. This not being the case, it considered that different environmental conditions were indeed tested and the data did not show emerging genomic effects in the stack.

217 Nor does the first applicant substantiate the reasons why it considers in the application that the field studies conducted in two countries over one year/harvesting season were insufficient to determine the potential impact of different environmental conditions on the modified soybean.

218 It follows that nor has the first applicant demonstrated a manifest error of assessment by the Commission.

219 Therefore, it is correct to reject the argument that the Commission failed to deal with the specific criticisms levelled in the request for internal review against EFSA's failure both to ensure that proper field trials were carried out and to recognise genomic effects and differences which were in fact found in the inadequate field trials.

220 Therefore, the third and fifth complaints must be rejected as unfounded.

221 By the fourth complaint, relating to the need to evaluate the different processing levels for the modified soybean in order to identify potential synergies, the first applicant submits that the Commission's response in the first contested decision missed the point. In its submission, EFSA took no account of the fact that the modified soybean could be used as sprouts or for producing soy milk. Thus, contrary to 'EFSA's guidance', no analysis was made of the possible implications of processing the modified soybean for those uses.

222 The Commission states that it explained in the first contested decision that, since no biologically relevant differences had been identified in the comparative analysis, it was not expected that any effects of processing and cooking would be different, and that consequently no additional data were needed.

223 In that regard, in the first contested decision the Commission rejected the arguments put forward in the first applicant's request for internal review on the grounds that, as no biologically relevant difference had been identified in the compositional, agronomic and phenotypic characteristics of the modified soybean with respect to its comparator (except that it expresses the Cry1Ac and CP4EPSPS proteins), it was not expected that any effects of processing and cooking would be different among those two soybeans, which had been corroborated by the data provided by Monsanto on the cooking treatment of the soybean. Nor had the first applicant adduced any evidence in support of

its arguments. It therefore concluded that EFSA had carried out a comprehensive scientific assessment of the relevant risks.

224 It is clear that the first applicant does not dispute the Commission's finding that in its request for review it had not provided any evidence in support of the arguments put forward and that it had simply stated that there were no data on the effects of other technical treatments used to process soybeans and that, therefore, no conclusions could be drawn as to the effects on consumers and animals. It should be borne in mind in that context that, as stated in paragraph 67 above, a third party challenging a marketing authorisation for products must adduce substantial evidence liable to raise serious doubts as to the lawfulness of the grant of that authorisation. Since the first applicant has not demonstrated that there were serious doubts surrounding the lawfulness of the grant of the marketing authorisation for products containing the modified soybean, the fourth complaint must be rejected as unfounded.

225 Consequently, the second part of the second plea must be rejected in its entirety.

– The third part of the second plea

226 The third part of the second plea comprises three complaints alleging failure to assess adequately the toxicity of the modified soybean.

227 By the first complaint, the first applicant submits that EFSA ought to have required an assessment of potential synergistic and combinatorial effects of spraying the modified soybean with glyphosate and maintenance pesticides. Firstly, the Commission merely made a finding of substantial equivalence of the modified soybean to justify its refusal to conduct an appropriate safety assessment. Secondly, the first applicant argues that no tests were conducted and no adjustments made to establish maximum residue levels for the modified soybean, in accordance with the provisions 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/EEC (OJ 2005 L 70, p. 1), in order to take account of glyphosate- or herbicide-tolerant soybeans. Without that adjustment, EFSA cannot ignore the potential effect of the residues on the basis of an application of a maximum residue level that does not take account of the insertion of the proteins in question. In any event, even if the maximum residue level had been adjusted, EFSA would have been required to examine the risk of interactions and synergies liable to occur in connection with the specific genetically modified plant in question, which obligation arises under Regulation No 1829/2003.

228 The Commission states that the interactivity of the modified soybean with herbicides had been tested in the comparative analysis and no biologically relevant differences had been identified. Moreover, the assessment of the effects of pesticide residues on health is not covered by the scope of Regulation No 1829/2003, but falls under Regulation No 396/2005.

229 As regards the argument that the Commission merely made a finding of substantial equivalence of the modified soybean to justify its refusal to conduct an appropriate safety assessment, first of all, it was held in paragraph 188 above that, in so far as the first applicant submits that, as a matter of principle, the Commission cannot rely on the finding of substantial compositional equivalence in order to escape its obligation to conduct an 'appropriate toxicity assessment', the scope of the toxicity assessment must be determined on a case-by-case basis and a limited toxicity assessment is possible and therefore not ruled out as a matter of principle.

230 In that regard, the Commission found in the first contested decision that the compositional analyses provided by Monsanto included data expressed for genetically modified plants sprayed with glyphosate and maintenance pesticides. Therefore, according to the Commission, the unintended effects of a hypothetical interaction of the newly-expressed proteins with those herbicides on the composition of the modified soybean were taken into consideration. It also stated in the defence that the interaction between the modified soybean and herbicides had been studied in the comparative analysis and that no biologically relevant differences had been identified. It further explained that the compositional analyses provided by Monsanto included data taken from plants treated using glyphosate and a conventional herbicide and that no indication of unintended effects had been found.

231 In those circumstances, the first applicant has not demonstrated to the requisite legal standard that the Commission made a manifest error of assessment in examining its request for internal review.

232 In any event, the first applicant has not explained in its written pleadings what an 'appropriate' toxicity assessment ought to have comprised.

233 Next, as regards the argument about the application of Regulation No 396/2005 in the present case, as rightly pointed out by the Commission, tests and adjustments made to establish maximum residue levels for the modified soybean, in accordance with the provisions of Regulation No 396/2005, in order to take account of glyphosate- or herbicide-tolerant soybeans, should be done as part of an examination under that regulation and not under Regulation No 1829/2003.

234 Lastly, in so far as the first applicant considers that EFSA was required under Regulation No 1829/2003 to examine the risk of interactions and synergies liable to occur in connection with the modified soybean, it should be noted that it has not put forward any argument establishing any unlawfulness whatsoever of the first contested decision; rather, it merely alleges failure on the part of EFSA. That argument must therefore be dismissed as inoperative.

235 Therefore, the first complaint must be dismissed.

236 By the second complaint, the first applicant argues that the arguments put forward in the request for internal review, relating to the failure to examine the effects of the

modified soybean on the reproductive system and the transfer of biologically active compounds of the modified soybean to animal tissue or humans through consumption, were not even addressed by the Commission in the first contested decision. Rather, the Commission merely noted that, for one of the studies relied on by the first applicant, it acknowledged that EFSA considered that it raised interesting issues requiring further investigation.

237 The Commission considers that it replied to the arguments put forward in the first applicant's request for internal review in the first contested decision.

238 The first applicant criticises the Commission, in essence, for having failed, in the first contested decision, to address specific complaints put forward in the request for internal review. In so far as the first applicant submits that the first contested decision was vitiated by a failure to state reasons, it should be noted that it stated, as part of the 'B9' and 'B10' arguments put forward in support of its request for internal review, that EFSA had failed to investigate the potential effects of the modified soybean on the reproductive system and the transfer of biologically active compounds of the modified soybean to animal tissue or humans through consumption. In that regard, referring to a few scientific studies, it based its request for internal review on the fact that 'soybeans [were] known to produce several hormonally active substances' and that 'DNA and RNA [were] known to be transferred from genetically engineered soybeans to animal tissue … and [that] biological activity of the transferred plant RNA in animals [had been] shown'.

239 In Annex II to the first contested decision, the Commission rejected the argument about potential effects of the modified soybean on the reproductive system, finding, in essence, that no biologically relevant difference had been identified in the compositional, agronomic and phenotypic characteristics of the modified soybean with respect to its comparator, except that, for the newly-expressed proteins, in the light of those data and toxicology, allergenicity and nutritional risk studies, EFSA had considered that no specific endocrinological studies were necessary and had followed the principle set out in its 2006 guidance document concerning inter alia the request for toxicology studies.

240 Furthermore, in rejecting the argument about the transfer of biologically active compounds, the Commission considered that the study relied on by the first applicant did not include any scientific evidence showing effects impacting on the safety of the modified soybean, opting to base its decision on the fact that EFSA had demonstrated that the transgenic construct of the modified soybean had been fully characterised at the molecular level, including sequence information, and that that construct did not raise any safety concerns.

241 It is clear that in its request for internal review the first applicant referred to certain studies, referring generally to 'soybeans' or 'genetically modified soybeans'. The Commission replied to those arguments, referring to the results of the assessment carried out by EFSA in the present case. It found inter alia that one of the studies replied on by the first applicant has not, at the present juncture, been corroborated.

242 It follows that the Commission, albeit succinctly, replied correctly to the first applicant's arguments. It cannot therefore be criticised for having infringed its obligation to state reasons, since the Commission's reply complies with the requirements of the case-law referred to in paragraphs 129 and 130 above. Accordingly, the conclusion is that the reasons given in the first contested decision enables the first applicant to understand properly why the Commission, in the exercise of its broad discretion, rejected the first applicant's argument, and enable the Court to exercise its power of review.

243 In so far as the first applicant's argument is directed at calling into question the merits of the Commission's considerations in the first contested decision, it should be observed that, as stated in paragraph 241 above, the first applicant referred to certain studies, referring generally to 'soybeans' or 'genetically modified soybeans'. The Commission replied to those arguments, referring to the results of the assessment carried out by EFSA in the present case. It found inter alia that one of the studies relied on by the first applicant has not, at the present juncture, been corroborated. The first applicant has not produced anything calling that finding into question and has therefore failed to demonstrate a manifest error of assessment by the Commission.

244 The second complaint must therefore be rejected as unfounded.

245 By the third complaint, the first applicant submits that the first contested decision in no way addresses its argument that EFSA failed to take into consideration the existence of evidence showing that Bt toxins are liable to have adverse effects on the health of animals (mammals).

246 It should be observed that the first applicant put forward this argument as part of the 'B2' argument in its request for internal review of the authorisation decision. The Commission rejected that argument, finding, in essence, in the first contested decision that the first applicant had not submitted any new scientific information that might change EFSA's conclusions on the toxicity assessment of the modified soybean and that the safety of the Cry1Ac protein had been addressed in earlier scientific opinions.

247 Given that the Commission therefore did reply to the first applicant's argument, the third complaint must also be rejected.

248 The third part of the second plea must therefore be rejected.

– The relevance of the documents submitted at the hearing

249 At the hearing, the applicants provided the Court with two documents in support of the second plea, pursuant to Article 85(3) of the Rules of Procedure. The first document is a letter of 25 February 2016 from the Commission to EFSA, requesting it to provide a scientific opinion on the effects on animal health of glyphosate residues in feed. The second document is a scientific article, published online on 16 March 2016 and which, according to the applicants, confirms that the insect *daphnia magna* is adversely affected

by chronic exposure to purified Cry toxins. Both documents were generated in 2016 and are subsequent to the closure of the written part of the present proceedings.

250 Article 85(3) of the Rules of Procedure provides that the main parties may, exceptionally, produce or offer further evidence before the oral part of the procedure is closed, provided that the delay in the submission of such evidence is justified.

251 The submission of evidence before the oral part of the procedure is closed is subject to the two-fold requirement that the delay in the submission of the evidence is justified and that the late submission of the evidence is justified by exceptional circumstances. As to the second condition of admissibility, being the affirmation of exceptional circumstances justifying the submission at the hearing, it should be noted that, in any event, the exceptional nature of such a submission implies that it was impossible for the applicant to produce the documents in question before the Court prior to the hearing or that earlier submission could not reasonably be required of the applicant. It is for the party wishing to submit the documents before the Court to prove that that condition is met at the time when the new evidence is submitted.

252 In the present case, the applicants have not pleaded or produced anything establishing that it was impossible for them to produce the documents in question before the Court prior to the hearing or that it would have been unreasonable to require submission at an earlier time. Therefore, the two documents referred to in paragraph 249 above must be rejected as inadmissible.

253 In any event, by the letter of 25 February 2016, referred to in paragraph 249 above, the Commission entrusted EFSA with the task of providing a scientific opinion on the effects on animal health of glyphosate residues in feed. As stated by the Commission in its observations, that task did not concern the assessment of risks associated with the modified soybean, but rather the review of the existing maximum limits for glyphosate-related residues, in accordance with Regulation No 396/2005.

254 As stated by the Commission in its observations, the scientific article referred to in paragraph 249 above concerns other Cry proteins than the one present in the modified soybean. Furthermore, the first contested decision concerns a marketing authorisation for products ‘containing the soybean’ for the purposes of import as food or feed but does not include cultivation, whereas the scientific article referred to concerns the insect *daphnia magna,* which is an organism to which the modified soybean will have negligible exposure.

255 Therefore, the conclusion is that the applicants have not put forward any arguments relating to the two documents referred to in paragraph 249 above which are liable to call into question the first contested decision.

256 It follows from the findings set out in paragraphs 176 to 255 above that the second plea must be partly rejected as inadmissible. For the remainder, it is clear that the first applicant, through its arguments put forward under this plea, has not established: (i) that

the Commission made a manifest error of assessment in maintaining the marketing authorisation of products containing the modified soybean and in failing to require an appropriate risk assessment of the 'highest possible standard'; (ii) that it infringed its obligation, under Article 4(1)(a) and Article 16(1)(a) of Regulation No 1829/2003, to ensure that food and feed that would have an adverse effect on human health, animal health or the environment must not be placed on the European Union market; (iii) that it failed to fulfil the obligation to take into account any relevant provisions of EU law, including the provisions that require the institutions to comply with 'their own guidance', in breach of Article 7(1) and Article 19(1) of Regulation No 1829/2003; (iv) that it failed to observe its obligation to ensure a high level of protection for human health, in breach of Article 168 TFEU; and (v) that it failed to meet the first applicant's legitimate expectations.

257 The second plea must therefore be dismissed in its entirety.

The third plea: the absence of exhaustive immunological assessment

258 The first applicant argues: (i) that the Commission made a manifest error of assessment in maintaining the marketing authorisation of products containing the modified soybean and in failing to require an appropriate risk assessment of the 'highest possible standard'; (ii) that it infringed its obligation, under Article 4(1)(a) and Article 16(1)(a) of Regulation No 1829/2003, to ensure that food and feed that would have an adverse effect on human health, animal health or the environment must not be placed on the European Union market; (iii) that it failed to fulfil the obligation to take into account any relevant provisions of EU law, including the provisions that require the institutions to comply with 'their own guidance', in breach of Article 7(1) and Article 19(1) of Regulation No 1829/2003; (iv) that it failed to observe its obligation to ensure a high level of protection for human health, in breach of Article 168 TFEU; and (v) that it failed to meet the first applicant's legitimate expectations. More specifically, the Commission confirmed that authorisation, even though (i) EFSA's immunological assessment is flawed insofar as, contrary to its own guidance, it did not consider at all the possible adjuvant effects, given that soybean is one of the most potent allergenic foods; (ii) EFSA's assessment of the allergenicity of the modified soybean is flawed in that, contrary to its own guidance, it failed to conduct any assessment of the specific allergenic risk posed by the modified soybean to infants and other vulnerable subpopulations; and (iii) EFSA failed to require further investigation into the allergenicity of the modified soybean.

259 The Commission disputes those arguments.

– The first part of the third plea

260 By the first part of the third plea, the first applicant submits, in essence, that the first contested decision in no way addresses the question of EFSA's failure to conduct an immunological assessment of the adjuvanticity of the modified soybean.

261 The Commission submits that this part is inadmissible on the ground that it was not included in the first applicant's request for internal review.

262 In that regard, pages 48 and 49 of the request for internal review, referred to by the first applicant in the application, concern an introduction to the plea alleging 'insufficient assessment of immunological risks' and its first part relating to 'insufficient testing of allergic reactions'. More specifically, it requests further testing in that context, on three grounds: (i) there remain uncertainties surrounding the risk assessment of the plants; (ii) the Cry1Ac content is higher in the modified soybean and (iii) combinatorial effects of the modified soybean can cause unpredictable reactions in the immune system. The introduction does include two citations, drawn from comments from representatives of the Kingdom of Belgium and the Kingdom of Norway concerning allergenicity, in which the question of adjuvant effects was discussed. However, the first applicant fails to develop any specific argument in relation to which the Commission ought to have acknowledged that it was obliged to respond in the first contested decision.

263 It follows that the first applicant's request for internal review does not contain any specific indication that the internal review to be conducted ought to focus explicitly on the potential adjuvant effects of the modified soybean. A generic reference about the lack of sufficient immunological assessment in the request for internal review does not invalidate this finding.

264 Therefore, and as explained in paragraph 68 above, the Commission was not required to state its position on this point in the first contested decision and this part must accordingly be dismissed as inadmissible.

– The second part of the third plea

265 By the second part of the third plea, the first applicant submits, in essence, that EFSA failed to conduct any assessment of the specific allergenic risk posed by the modified soybean to infants and other vulnerable subpopulations and to request risk assessments. In its submission, the Commission found in the first contested decision that EFSA had complied with guidance adopted in the Codex Alimentarius (2009), but ignored the points made in the scientific opinion of 30 June 2010 of EFSA's Panel on GMOs: Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed (*EFSA Journal* 2010; 8(7):1700) ('the Scientific Opinion on allergenicity'), which binds EFSA and requires such assessments.

266 The Commission submits that this part is inadmissible in so far as it concerns subpopulations other than infants, whereas the request for internal review raised specific concerns about only them. Furthermore, it considers that it did address in detail the point in the first contested decision relating to potential allergenic risk for infants, adding that investigations on potential allergenicity risk are based on a weight-of-evidence approach, which was duly followed by EFSA, and that the Scientific Opinion on allergenicity is not applicable in the present case, as it had not yet been published when Monsanto filed its application for authorisation.

267 In the first place, regarding the admissibility of this part in so far as it concerns subpopulations other than infants, it should be observed that, in its request for internal review, the first applicant explicitly referred only to the argument that no assessment had been made of specific risks linked to potential allergenicity for infants. Moreover, the first applicant has not developed any sufficiently specific argument indicating to the Commission that it was required to address that point in the first contested decision. In the light of the considerations set out in paragraph 70 above, this part must be dismissed as inadmissible in so far as it concerns vulnerable subpopulations other than infants.

268 In the second place, as regards the relevance to the present case of the Scientific Opinion on allergenicity, it should be noted that it states in its preamble that it addresses some aspects of food allergies and food allergens and that it reviews the methods for assessing the potential for allergenicity of newly-expressed proteins and of whole genetically modified food and feed.

269 The Scientific Opinion on allergenicity acknowledges that the specific risk of allergenicity of genetically modified foods for infants and therefore differences in the digestive physiology of those subpopulations must be taken into consideration. Primary sensitisation in the gut of young infants might be favoured by the immaturity of the local immunity and incomplete barrier function of the intestinal gut mucosa as well as incomplete protein degradation by pepsin in the stomach due to a gastric pH above values seen in adults.

270 On its wording alone, the Scientific Opinion on allergenicity does not purport to contain guidelines to be applied by EFSA in the assessment of each file. Moreover, as explained in paragraphs 110 to 118 above, a scientific opinion from EFSA does not bind the Commission in its assessment of an application for authorisation or a request for internal review. Accordingly, the first applicant's argument must be rejected as unfounded in so far as it alleges that the Commission was bound in its assessment of requests for internal review by the Scientific Opinion on allergenicity.

271 However, if the first applicant's intention is to argue that the Commission ought to have assessed the specific allergenic risk posed by the modified soybean for infants, it should be observed that, according to the first contested decision, allergenicity assessment is based on a weight-of-evidence approach, in accordance with the Codex Alimentarius (2009). Based on all the available information, and adopting a weight-of-evidence approach, EFSA concluded that it was unlikely that the newly-expressed proteins in the modified soybean were allergenic. The Commission thus implicitly endorses EFSA's opinion to the effect that further studies were not necessary. Moreover, referring to its answer to the 'C1' complaint in Annex II to the first contested decision, the Commission found that the data available to EFSA had shown that the overall allergenicity of the parental soybean varieties of the modified soybean was probably not different from that of their corresponding conventional counterparts and commercial soybean varieties and that EFSA had found it unlikely that potential interactions that might change the allergenicity of the crop would occur in the modified soybean.

272 Moreover, as regards the allergenicity assessment of the whole plant, EFSA concluded, in section 5.1.5.2 of its scientific opinion of 25 January 2012, after explaining the particulars of its assessment, that the Scientific Panel believed it unlikely that interactions that might change the allergenicity of the cultivation as a whole would occur in the modified soybean.

273 In that regard, as clarified by the Commission in its reply to a written question from the Court, EFSA's allergenicity assessment, on which the Commission based its assessment, encompasses potential risks for all segments of the population, including infants. Accordingly, the first applicant's argument that no reference was made in the first contested decision to the risks of vulnerable subgroups must be rejected.

274 Consequently, the conclusion is that, in the first contested decision, the Commission assessed the allergenic risk posed by the modified soybean for infants, and the first applicant has failed to produce anything specific establishing that that assessment was inappropriate. Therefore, the first applicant has failed to prove that there was any manifest error of assessment by the Commission in that regard.

275 Consequently, the second part of the third plea must be rejected as unfounded.

– The third part of the third plea

276 By the third part of the third plea, the first applicant submits that EFSA did not request further studies on the potential allergenicity of the modified soybean. In its submission, the Commission's reply does not meet their legitimate expectation that EFSA will comply with its own guidance. The Commission merely finds that EFSA had allegedly complied with the weight-of-evidence approach applied under the Codex Alimentarius and that the scientific publications relied on by it concerning immunological effects do not contain any new information that might have changed EFSA's conclusions.

277 It is apparent from paragraphs 220 and 224 of the application that this part refers to the 'C1' argument put forward in the first applicant's request for internal review concerning further allergenicity studies. With respect to that argument, the Commission explains, in essence, in the first contested decision that the available data showed that it was unlikely that overall allergenicity of the parental soybean varieties would be different from that of their corresponding conventional counterparts and commercial soybean varieties. Based on all the information provided, EFSA considered it unlikely that potential interactions that might change the allergenicity of the crop would occur in the modified soybean Moreover, all experimental methodologies presented in the file were, in the Commission's view, described correctly and the scientific standard were assessed by EFSA and found to be appropriate. The Commission therefore considered that the applicants had not in any way substantiated their claim and that EFSA had conducted an exhaustive scientific assessment of the risks.

278 It should be noted that the arguments put forward under the third part of the third plea do not concern the first contested decision in so far as it addresses the ‘C1’ argument of the first applicant’s request for internal review. Regarding the point of inter alia further allergenicity studies, the Commission makes no reference in the first contested decision to the weight-of-evidence approach applied or to scientific publications relied on by the applicants.

279 Furthermore, the arguments put forward by the first applicant under this part are in reality directed at that part of the first contested decision relating to the ‘C4’ argument put forward in the first applicant’s request for internal review concerning the absence of assessment of further immunological effects.

280 Given that the arguments put forward by the first applicant concern the Commission’s reply to the arguments about the absence of assessment of further immunological effects and not the one about complementary allergenicity studies, the third part of the third plea must be rejected as unfounded, as the first applicant has not produced anything demonstrating a manifest error in the Commission’s reasoning on this point.

281 In any event, so too must the first applicant’s argument concerning its legitimate expectation that EFSA would comply with its own guidance be rejected, for the reasons set out in paragraphs 110 to 118 above.

282 It follows from the findings set out in paragraphs 260 to 281 above that the third plea must be partly rejected as inadmissible. For the remainder, it is apparent therefrom that the first applicant has not demonstrated through its arguments put forward under this plea: (i) that the Commission had made a manifest error of assessment in maintaining the marketing authorisation of products containing the modified soybean and in failing to require an appropriate risk assessment of the ‘highest possible standard’; (ii) that it had infringed its obligation, under Article 4(1)(a) and Article 16(1)(a) of Regulation No 1829/2003, to ensure that food and feed that would have an adverse effect on human health, animal health or the environment must not be placed on the European Union market; (iii) that it had not, in breach of Article 7(1) and Article 19(1) of Regulation No 1829/2003, fulfilled the obligation to take into account any relevant provisions of EU law, including the provisions that require the institutions to comply with ‘their own guidance’; (iv) that it had not, in breach of Article 168 TFEU, observed its obligation to ensure a high level of protection for human health and (v), that it had failed to meet the first applicant’s legitimate expectations. This plea must therefore be dismissed in its entirety.

The fourth plea: alleged absence of post-market authorisation monitoring of consumption of products containing the modified soybean

283 The first applicant considers that the Commission did not examine the merits of its argument that it ought to have required a plan for post-market authorisation monitoring of consumption of products containing the modified soybean concerning, in general, the

statistically significant differences identified between the modified soybean and its conventional counterpart and, in particular, concerning whether the modified soybean is likely to contain residues of glyphosate-based spray treatments. Thus, under Article 5(3) of Regulation No 1829/2003, it ought to have ensured that EFSA required Monsanto to carry out a post-marketing monitoring plan of the consumption of the modified soybean by humans and animals in the light of the statistically significant differences identified between the modified soybean and its conventional counterpart. In view of the unlawfulness of the authorisation decision, as alleged in the first three pleas, the Commission could not conclude that such monitoring was not necessary.

284 The Commission contends that it gave a very detailed response, in the first contested decision, as to when monitoring is required.

285 It should be noted that, under Article 5(3)(k) of Regulation No 1829/2003, an applicant for authorisation is required, where appropriate, to provide a proposal for post-market monitoring regarding use of the food for human consumption. Under Article 6(5)(e) of that regulation, EFSA's opinion includes, 'where applicable', post-market monitoring requirements based on the outcome of the risk assessment, whilst Article 9(1) thereof provides that such conditions or restrictions must be imposed in the authorisation.

286 In the first place, as regards the argument that the Commission failed to examine the merits of the argument put forward in the first applicant's request for internal review to the effect that it ought to have required a post-marketing monitoring plan focusing on whether the modified soybean was liable to contain residues of glyphosate-based spray treatments, it should be noted that the first applicant submits, in essence, that the first contested decision does not contain an adequate statement of reasons.

287 However, the Commission explained inter alia in Annex I to the first contested decision, that it considered that, in the light of the product and the uses covered by the application for authorisation, and taking into account the outcome of the EFSA opinion, in which it was found that no monitoring of the use of food and feed was deemed appropriate, the monitoring obligations provided for in the monitoring plan for the modified soybean required by Article 4 of the authorisation decision complied with the provisions of Regulation No 1829/2003. It further found that EFSA had correctly conducted the scientific assessment in accordance with its 2006 guidance document. It also found that the monitoring of pesticide residues in foods and feed imported from outside the EU, including food and feed derived from genetically modified plants, was determined in accordance with the provisions of Regulation No 396/2005 and that that regulation provided for the assessment of risks associated with pesticide residues in foods and feed and fixed maximum limits for the residues applicable to all foods and feed placed on the market.

288 Firstly, in the light of the conditions established by the case-law relating to the obligation to state reasons and set out in paragraphs 129 and 130 above, the conclusion is that the reasons given in the first contested decision enable the first applicant to understand properly why the Commission, in the exercise of its broad discretion, rejected

the first applicant's argument, and enable the Court to exercise its power of review. Secondly, the first applicant does not explain why it considers those explanations to be inadequate.

289 In any event, in so far as the first applicant's argument is aimed at calling into question the merits of the Commission's considerations, it should be noted that, in the light of the considerations set out in paragraph 287 above, the first applicant has not demonstrated any manifest error of assessment in the first contested decision. Furthermore, as explained in paragraph 233 above, tests and adjustments for establishing a maximum residue level for the modified soybean under the provisions of Regulation No 396/2005, in order to take account of glyphosate- or herbicide-tolerant soybeans, must be made as part of an assessment under that regulation and not under Regulation No 1829/2003.

290 Therefore, the first applicant's argument that the Commission failed to consider the merits of the argument put forward in its request for internal review, to the effect that it ought to have required a post-marketing monitoring plan focusing on whether the modified soybean was liable to contain residues of glyphosate-based spray treatments, must be rejected.

291 In the second place, regarding the argument that the Commission's maintaining the authorisation of the modified soybean means that no appropriate assessment was made of the need to introduce post-marketing monitoring of human consumption, suffice it to note that, under the case-law referred to in paragraph 145 above, it is necessary, in order for an action to be admissible, that the basic legal and factual particulars relied on be indicated, at least in summary form, coherently and intelligibly in the application itself.

292 In that regard, the first applicant does not explain which are 'the statistically significant differences identified between the modified soybean and its conventional counterpart' in relation to which a monitoring plan of the consumption of the modified soybean by humans and animals ought to have been drawn up, which arguments put forward under the first three pleas in law in the present action, in its submission, led to the authorisation being maintained and how 'no appropriate assessment was made of the need to introduce post-marketing monitoring of human consumption', or which conditions would have made a monitoring plan 'appropriate'. In view of the complexity of the material at issue, such a vague claim does not meet the conditions laid down in Article 44(1)(c) of the Rules of Procedure of 2 May 1991, which requires that the basic legal and factual particulars relied on be indicated, at least in summary form, coherently and intelligibly in the application itself.

293 Consequently, the fourth plea must be dismissed in its entirety in so far as it concerns the first contested decision.

294 Therefore, in so far as it concerns the first contested decision, the present action must be rejected as partly ineffective and partly inadmissible and, for the remainder, as unfounded.

The second and third applicants' applications for annulment

295 Further to a written question put by the Court by way of measures of organisation of procedure provided for in Article 89 of the Rules of Procedure, the main parties to the case disagreed as to whether the subject matter of the present proceedings concerned only annulment of the first contested decision, addressed to the first applicant, referred to in paragraph 9 above, or whether it also concerned the second and third decisions addressed to the second and third applicants, referred to in paragraph 11 above.

296 The Commission submits that the action is inadmissible in so far as the second and third applicants are concerned, as they lack locus standi to bring the present action, which seeks solely annulment of the first contested decision.

297 The applicants submit, in essence, that the action is directed at 'three identical decisions (barring the name of the addressee)' and that in the application they referred solely to the letter in Annex PD/7 to the application as the contested decision for ease of reference and avoidance of duplication.

298 Without its being necessary to rule on the question whether the present action is also directed at the second and third decisions addressed to the second and third applicants and is, consequently, admissible in so far as it was brought by the second and third applicants, suffice it to observe that the content of the first contested decision and the second and third decisions is, in essence, identical and that the pleas in law relied on by the applicants are the same. They must therefore, in any event, be rejected, for the same reasons as set out in paragraphs 37 to 294 above, in their entirety on the ground that the pleas put forward are partly inadmissible and, for the remainder, unfounded.

Costs

299 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.

300 Under Article 135(1) and (2), exceptionally, if equity so requires, the General Court may decide that an unsuccessful party is to pay only a proportion of the costs of the other party in addition to bearing his own costs, or even that he is not to be ordered to pay any costs. Furthermore, the General Court may order a party, even if successful, to pay some or all of the costs, if this appears justified by the conduct of that party, including before the proceedings were brought, especially if he has made the opposite party incur costs which the General Court holds to be unreasonable or vexatious.

301 The applicants submit that the Commission's requests for its costs, or at least its costs in full, is contrary to the obligation imposed by 'Aarhus' to prevent access to justice in environmental matters being prohibitively expensive. At the hearing, they stated that, should the present action be dismissed, each party should be ordered to bear its own costs, which was formally noted by the Court in the minutes of the hearing.

302 With respect to the relevant criteria for determining whether the costs of the present proceedings would be prohibitively expensive within the meaning of Article 9(4) of the Aarhus Convention, it has been held that the assessment carried out by the Court cannot be carried out solely on the basis of the financial situation of the person concerned but must also be based on an objective analysis of the amount of the costs. The cost of proceedings must not appear, in certain cases, to be objectively unreasonable. Thus, the cost of proceedings must neither exceed the financial resources of the person concerned nor appear, in any event, to be objectively unreasonable. As regards the analysis of the financial situation of the person concerned, the assessment cannot be based exclusively on the estimated financial resources of an 'average' applicant, since such information may have little connection with the situation of the person concerned. The Court may also take into account the situation of the parties concerned, whether the claimant has a reasonable prospect of success, the importance of what is at stake for the claimant and for the protection of the environment, the complexity of the relevant law and procedure and the potentially frivolous nature of the claim at its various stages (see, by analogy, judgment of 11 April 2013, *Edwards and Pallikaropoulos*, C-260/11, EU:C:2013:221, paragraphs 40 to 42).

303 It should be noted, however, that under Article 170 of the Rules of Procedure, the Court carries out an objective analysis of the amount of recoverable costs only by way of order, where they are in dispute. It follows that the analysis of the financial situation of the person concerned and the objective analysis of the amount of recoverable costs may be carried out only under the procedure provided for in Article 170 and only if the parties do not reach a mutual agreement on the amount of recoverable costs.

304 In any event, at the present juncture the applicants have not explained how, in the present case, the costs incurred by the Commission are too burdensome for them and how, specifically, being ordered to pay the costs would deprive them of access to justice in environmental cases.

305 In the light of all the foregoing considerations, the conclusion is that it is not inappropriate under Article 135(1) of the Rules of Procedure not to apply, in the present case, the general provisions laid down in Article 134 thereof. As the applicants have been unsuccessful, they must be ordered to pay their own costs and those incurred by the Commission, in accordance with the form of order sought by the Commission.

306 In accordance with Article 138(1) and (3) of the Rules of Procedure, the United Kingdom, EFSA and Monsanto must bear their own costs.

307 As the Commission alleges that there has been abuse of procedure due to the fact, set out in paragraph 20 above, that the first applicant had published the Commission's statement in defence on its website, should an abuse of procedure be found to have taken place (judgment of 17 June 1998, *Svenska Journalistförbundet* v *Council*, T-174/95, EU:T:1998:127, paragraphs 135 to 137, and order of 16 March 2016, *One of Us and Others* v *Commission*, T-561/14, EU:T:2016:173, paragraphs 49 to 51), the only

consequence will be that the first applicant will be ordered to pay an additional share of the costs. There is therefore no need to make such a determination in the present case.

308 However, as the first applicant confirmed in its letter of 27 November 2013 that it does not intend to publish the statement in defence ‘as long as the judicial proceedings are not completed’, it should be remembered that the obligation not to make procedural documents public does not end upon completion of the proceedings before the courts of the European Union.

On those grounds,

THE GENERAL COURT (Fifth Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders TestBioTech eV, European Network of Scientists for Social and Environmental Responsibility eV and Sambucus eV to bear their own costs and to pay those incurred by the European Commission;**

3. **Orders the United Kingdom of Great Britain and Northern Ireland, the European Food Safety Authority (EFSA) and Monsanto Europe and Monsanto Company to bear their own costs.**

Dittrich Schwarcz Tomljenović

Delivered in open court in Luxembourg on 15 December 2016.

E. Coulon

Registrar President

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* Language of the case: English.