Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

12 September 2019*

(Appeal — Environment — Genetically modified products — Commission decision authorising the placing on the market of products containing genetically modified soybean MON 87701 x MON 89788 — Regulation (EC) No 1367/2006 — Article 10(1) — Request for internal review of the decision, submitted under the provisions relating to public participation in environmental decision-making — Rejection of the request)

In Case C-82/17 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 14 February 2017,

TestBioTech eV, established in Munich (Germany),

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

Sambucus eV, established in Vahlde (Germany),

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

appellants,

the other parties to the proceedings being:

European Commission, represented by L. Flynn, G. Gattinara and C. Valero, acting as Agents,

defendant at first instance,

Monsanto Europe, established in Antwerp (Belgium),

Monsanto Company, established in Wilmington (United States),

represented initially by M. Pittie, and subsequently by P. Honoré and A. Helfer, avocats,

United Kingdom of Great Britain and Northern Ireland,

European Food Safety Authority (EFSA),

interveners at first instance,

* Language of the case: English.

THE COURT (Third Chamber),

composed of M. Vilaras, President of the Fourth Chamber, acting as President of the Third Chamber, J. Malenovský, L. Bay Larsen (Rapporteur), M. Safjan and D. Šváby, Judges,

Advocate General: M. Szpunar,

Registrar: L. Hewlett, Principal Administrator,

having regard to the written procedure and further to the hearing on 27 June 2018,

after hearing the Opinion of the Advocate General at the sitting on 17 October 2018,

gives the following

Judgment

1 By their appeal, TestBioTech eV, European Network of Scientists for Social and Environmental Responsibility eV and Sambucus eV request the Court to set aside the judgment of the General Court of the European Union of 15 December 2016, *TestBioTech and Others* v *Commission* (T-177/13, not published, 'the judgment under appeal', EU:T:2016:736), by which the General Court dismissed their action for annulment of the Commission decision of 8 January 2013 concerning the internal 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 ('the decision at issue').

Legal context

Regulation (EC) No 1829/2003

2 Recital 6 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) states that, 'whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself'.

3 Article 5(8) and Article 17(8) of Regulation No 1829/2003 provide that, before the date of application of that regulation, the European Food Safety Authority (EFSA) is to publish detailed guidance to assist applicants in the preparation and the presentation of applications for authorisation to place a GMO on the market, in the case of, respectively, food and feed.

4 Under Article 5(3)(f) of Regulation No 1829/2003, the application for authorisation to place a GMO on the market is to 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 to the criteria specified in Article 13(2)(a), or a proposal for labelling the food in accordance with Article 13(2)(a) and (3)'.

5 Article 16(1)(a) of Regulation No 1829/2003 is worded as follows:

'Feed referred to in Article 15(1) must not:

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

Regulation (EC) No 1367/2006

6 Recitals 11, 18, 19 and 21 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) read as follows:

'(11) Administrative acts of individual scope should be open to possible internal review where they have legally binding and external effects. …

...

(18) Article 9(3) of the Aarhus Convention provides for access to judicial or other review procedures for challenging acts and omissions by private persons and public authorities which contravene provisions of law relating to the environment. Provisions on access to justice should be consistent with the Treaty. It is appropriate in this context that this Regulation address only acts and omissions by public authorities.

(19) To ensure adequate and effective remedies, including those available before the Court of Justice of the European [Union] under the relevant provisions of the Treaty, it is appropriate that the [EU] institution or body which issued the act to be challenged or which, in the case of an alleged administrative omission, omitted to act, be given the opportunity to reconsider its former decision, or, in the case of an omission, to act.

...

(21) Where previous requests for internal review have been unsuccessful, the non-governmental organisation concerned should be able to institute proceedings before the Court of Justice in accordance with the relevant provisions of the Treaty.'

7 Under Article 2(1)(g) of Regulation No 1367/2006, for the purposes of that regulation '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.

8 Article 10 of Regulation No 1367/2006, headed 'Request for internal review of administrative acts', states:

'1. 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 or, in case of an alleged administrative omission, should have adopted such an act.

Such a request must be made in writing and within a time limit not exceeding six weeks after the administrative act was adopted, notified or published, whichever is the latest, or, in the case of an alleged omission, six weeks after the date when the administrative act was required. The request shall state the grounds for the review.

2. The [EU] institution or body referred to in paragraph 1 shall consider any such request, unless it is clearly unsubstantiated. The [EU] institution or body shall state its reasons in a written reply as soon as possible, but no later than 12 weeks after receipt of the request.

3. Where the [EU] institution or body is unable, despite exercising due diligence, to act in accordance with paragraph 2, it shall inform the non-governmental organisation which made the request as soon as possible and at the latest within the period mentioned in that paragraph, of the reasons for its failure to act and when it intends to do so.

In any event, the [EU] institution or body shall act within 18 weeks from receipt of the request.'

9 Article 12 of Regulation No 1367/2006, headed 'Proceedings before the Court of Justice', provides:

'1. The non-governmental organisation which made the 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.

2. Where the [EU] institution or body fails to act in accordance with Article 10(2) or (3) the non-governmental organisation may institute proceedings before the Court of Justice in accordance with the relevant provisions of the Treaty.'

Background to the dispute

10 The first appellant, TestBioTech, is a German not-for-profit association whose object is to promote independent research and public debate on the impacts of biotechnology. The second appellant, the European Network of Scientists for Social and Environmental Responsibility, is a German not-for-profit organisation the object 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. The third appellant, Sambucus, is a German not-for-profit environmental organisation whose object relates to cultural activities.

11 On 14 August 2009, Monsanto Europe submitted to the competent authority of the Netherlands, in accordance with Regulation No 1829/2003, an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from MON 87701 x 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.

12 The modified soybean is a hybrid product. It is created by traditional breeding methods, used to combine the genetic material of two parent plants: soybean MON 87701 and soybean MON 89799 ('the parents'). The parents are themselves genetically modified. As the modified soybean combines the modified genes of both parents, it is called a 'stacked event'.

13 On 15 February 2012, EFSA issued an overall opinion under Regulation No 1829/2003 in which it concluded that the modified soybean fulfilled the requirements of that regulation for its placing on the market.

14 By Commission Implementing Decision 2012/347/EU of 28 June 2012 (OJ 2012 L 171, p. 13; 'the authorisation decision'), referred to in paragraph 1 of the present judgment, the European Commission authorised, subject to certain conditions:

– 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.

15 By letters of 6 August 2012, each of the appellants requested the Commission to carry out an internal review of the authorisation decision, pursuant to Article 10 of Regulation No 1367/2006. The appellants 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.

16 By the decision at issue, the Commission informed the first appellant 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.

17 On the same day, the Commission sent to the second and third appellants decisions that were substantially identical to the decision sent to the first appellant.

The action before the General Court and the judgment under appeal

18 By application lodged at the Registry of the General Court on 18 March 2013, the appellants brought an action for annulment of the decision at issue.

19 The Commission and EFSA, as well as Monsanto Europe and Monsanto Company ('Monsanto'), contended that the action was in part manifestly inadmissible and in part unfounded. The United Kingdom contended that the action should be dismissed in its entirety.

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

21 The General Court declared that certain complaints or arguments set out by the first appellant in the action for annulment were inadmissible, on the grounds, in particular, that they were not in the request for internal review which it had made or that they were not coherent or intelligible.

22 First of all, the General Court stated in paragraph 66 of the judgment under appeal that a request for internal review of an administrative act, within the meaning of Article 10(1) of Regulation No 1367/2006, must specify which act is being challenged and state the grounds for conducting the review. In order to state those grounds in the manner required, a party requesting internal review 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. Thus, 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.

23 So far as concerns the legal value of the guidance published by EFSA, the General Court concluded, in paragraph 118 of the judgment under appeal, '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'.

24 Next, the General Court held, in paragraphs 229 and 231 of the judgment under appeal, that, having regard to the assessments carried out by EFSA so far as concerns the toxicity of the product concerned, the first appellant's argument that the Commission cannot rely on the finding of substantial compositional equivalence in order to escape its obligation to conduct an 'appropriate toxicity assessment' did not show that the Commission made a manifest error of assessment in the decision at issue.

25 Finally, as regards the alleged failure to assess adequately the toxicity of the modified soybean in the light 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), the General Court held, in paragraph 233 of the judgment under appeal, that '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'.

26 The General Court dismissed the action in so far as it concerned the decision at issue as partly ineffective and partly inadmissible and, for the remainder, as unfounded. In so far as the action brought before it had to be regarded as also relating to the two decisions addressed, respectively, to the European Network of Scientists for Social and Environmental Responsibility and to Sambucus, the General Court held that, since those decisions were identical to the decision at issue, the pleas in law relied on had, in any event, to be rejected for the same reasons as those providing the basis for dismissal of the action in so far as it concerned the decision at issue.

Forms of order sought by the parties to the appeal

27 The appellants claim that the Court should:

– set aside points 1 and 2 of the operative part of the judgment under appeal;

– deliver a judgment granting the annulment of the Commission's decisions in the manner sought before the General Court or, in the alternative, remit the case back to the General Court for a full rehearing;

– order the Commission to pay the costs; and

– order any other measure deemed appropriate.

28 The Commission contends that the Court should:

– dismiss the appeal; and

– order the appellants to pay the costs of both sets of proceedings.

29 Monsanto contends that the Court should:

– dismiss the appeal; and

– order the appellants to pay the costs.

The appeal

30 The appellants rely on five grounds of appeal, alleging errors of law committed by the General Court in declaring certain parts of the action for annulment inadmissible, ineffective or unfounded, in incorrectly applying an impossible burden of proof on them, in failing to recognise that the guidance published by EFSA in accordance with its legal obligations had given rise to a legitimate expectation that it would be complied with, in determining that the two-stage safety assessment required by Regulation No 1829/2003 did not need to be complied with and, finally, in relying upon Regulation No 396/2005 in dismissing certain elements of the appellants' complaint that the Commission wrongly failed to require a full examination of the potential toxicity of the soybean at issue and to monitor its impact after marketing authorisation.

The first ground of appeal

Arguments of the parties

31 By their first ground of appeal, the appellants contend that the General Court erred in holding that certain of their arguments, items of evidence or materials were inadmissible since they were not contained within or provided alongside the requests for review.

32 The appellants submit that a request for review made under Article 10 of Regulation No 1367/2006 is designed to allow the competent EU institution, here the Commission in conjunction with EFSA, to reconsider the decision previously adopted by it and to determine whether the decision-making process which resulted in that decision is in accordance with environmental law.

33 According to the appellants, although, under that provision, non-governmental organisations (NGOs) which make requests for review are required to state the grounds for review, they are not to step into the shoes of the institution involved in order to set out in detail the outcome of a review which that institution had to conduct. Therefore, when NGOs bring judicial proceedings against a decision relating to a request for review, they must be entitled to develop, or to add additional detail and evidence in support of, the grounds which they advanced in their requests for review, in order to show what the competent institution would have identified or would have had to take into account if it had granted the request for review. An overly restrictive interpretation of the requirement that the requesting party must state the grounds on which it seeks review would be contrary to the object and purpose of Regulation No 1367/2006, which is to enable access to justice in environmental matters.

34 The appellants submit that, as the General Court misinterpreted and misapplied Article 10(1) of Regulation No 1367/2006, its findings on inadmissibility in paragraphs 65 to 70, 125, 126, 136, 137, 199, 262 to 264, 266 and 267 of the judgment under appeal should be overturned.

35 Furthermore, the appellants put forward five complaints in the alternative. They contend that the General Court erred in law, first, by refusing, in paragraphs 140 to 142 and 201 of the judgment under appeal, to take into account the tables annexed to their application, which contained lists of evidence relied upon in support of clearly pleaded issues of law. It erred in law, second, by holding, in paragraphs 143 to 147 of the judgment under appeal, that the failure in respect of which the Commission was being criticised was not made clear coherently and intelligibly in their application. It erred in law, third, by holding, in paragraph 234 of the judgment under appeal, that the appellants challenged the failures of EFSA, as opposed to the Commission decisions, in relation to their three complaints alleging failure to assess adequately the toxicity of the soybean at issue. It erred in law, fourth, by not setting out clear reasoning for the findings in paragraphs 278 to 280 of the judgment under appeal dealing with the third part of the third plea, in particular when it rejected arguments as unfounded on the ground that the matters put forward in support of those arguments did not

concern the part of the decision at issue that was contested under the third part of the third plea and that the arguments were not numbered or grouped in the same way in the application at first instance and in the request for review. Fifth and finally, it erred in law in taking the view, in paragraphs 292 and 293 of the judgment under appeal, that the arguments put forward by the first appellant were insufficiently precise in the light of the complexity of the matter.

36 The Commission and Monsanto submit that the first ground of appeal should be rejected.

Findings of the Court

37 It should be recalled that, under Article 10(1) of Regulation No 1367/2006, any NGO which meets the criteria set out in Article 11 of that regulation is entitled to submit a reasoned request and trigger an internal review of an administrative act by the EU institution or body that has adopted it under environmental law. Where the administrative act at issue relates, as in the present instance, to a marketing authorisation for products — as specified in paragraph 14 of the present judgment — containing genetically modified soybean, a request for review relates, pursuant to that provision, to the reassessment of that authorisation.

38 A request for internal review of an administrative act is thus intended to establish that, as alleged, the act in question is unlawful or that it is not well founded. The party making the request may then, in accordance with Article 12 of Regulation No 1367/2006, read in conjunction with Article 10 thereof, bring the matter before the EU judicature by instituting proceedings — on grounds of lack of competence, infringement of an essential procedural requirement, infringement of the Treaties or of any rule of law relating to their application, or misuse of powers — against the decision rejecting the request for internal review as unfounded.

39 Such proceedings cannot be founded on new grounds or on evidence not appearing in the request for review, as otherwise the requirement, in Article 10(1) of Regulation No 1367/2006, relating to the statement of grounds for such a request would be made redundant and the object of the procedure initiated by the request would be altered.

40 It follows that the General Court did not err in law when, in paragraph 69 of the judgment under appeal, it held, first, that there had been nothing preventing the first appellant from asserting in the action at first instance any ground to the effect that the Commission was lacking in powers to adopt the decision at issue, 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 and, second, that the Commission was not required to examine grounds other than those put forward by the appellant in its request for internal review of the authorisation decision in order to determine whether that request gave rise to serious doubts as to the lawfulness of the grant of that authorisation.

41 As to the errors of law that are said to vitiate paragraphs 125, 126, 136, 137, 199, 262 to 264, 266 and 267 of the judgment under appeal, on the ground that the General Court refused to rule on grounds or evidence which had not been set out in the request for internal review, in the light of paragraphs 39 and 40 of the present judgment it is necessary to reject the ground of appeal in that regard.

42 So far as concerns the five alternative complaints summarised in paragraph 35 of the present judgment, by which the appellants contend that the General Court erred in law in declaring certain arguments inadmissible, ineffective or unfounded, it is to be borne in mind that it is apparent from Article 256 TFEU, the first paragraph of Article 58 of the Statute of the Court of Justice of the European Union and Article 169(2) of the Rules of Procedure of the Court of Justice that an appeal must indicate precisely the contested elements of the decision which the appellant seeks to have set aside and also

the legal arguments specifically advanced in support of the appeal. Accordingly, a ground of appeal supported by an argument that is not sufficiently clear and precise to enable the Court to exercise its powers of judicial review, in particular because essential elements on which the ground of appeal is based are not indicated sufficiently coherently and intelligibly in the text of the appeal, which is worded in a vague and ambiguous manner in that regard, does not satisfy those requirements and must be dismissed as inadmissible (see, inter alia, order of 3 December 2015, *Verband der Kölnisch-Wasser Hersteller* v *OHIM*, C-29/15 P, not published, EU:C:2015:799, paragraph 27 and the case-law cited).

43 The first alternative complaint concerns paragraphs 140 to 142 and 201 of the judgment under appeal, which are worded as follows:

'140 Firstly, inasmuch as the first applicant [(now the first appellant)] 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 the General Court] 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.

…

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.'

44 In that regard, the appellants, in breach of the requirements recalled in paragraph 42 of the present judgment, merely complain that the General Court refused to take into account evidence relied upon in support of their complaints, which were clearly set out in their application at first instance, without however identifying the error or errors of law supposedly committed by the General Court, in particular in the interpretation and application 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 the General Court, or pleading that the General Court distorted the facts.

45 That being so, the first alternative complaint is inadmissible.

46 The second alternative complaint concerns paragraphs 143 to 147 of the judgment under appeal, which read as follows:

'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 … decision [at issue] 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 … decision [at issue] 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 the General Court] 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.'

47 The appellants contend that the conclusions in paragraphs 143 to 147 of the judgment under appeal are wrong on the ground that the matters of fact and law were clearly set out in the application at first instance. Whilst the error of law relied upon in that regard consists in the complaint that the General Court did not rule on arguments set out in other parts of the first plea in the action for annulment, it must be held that the appellants provide no detail as to the relevance of those arguments in the light of the considerations set out by the General Court in paragraphs 143 to 147 of the judgment under appeal.

48 Consequently, the second alternative complaint is inadmissible.

49 The third alternative complaint relates to paragraph 234 of the judgment under appeal, which states that, '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 … decision [at issue]; rather, it merely alleges failure on the part of EFSA. That argument must therefore be dismissed as inoperative'.

50 In that regard, whilst the appellants submit that the General Court did not take into consideration their arguments relating to other complaints in the third part of the second plea in the action for annulment and that it therefore wrongly considered that they were challenging a failure on the part of EFSA and not the unlawfulness of the decision at issue, it must be held that the appellants provide no detail as to the relevance of those arguments in the light of the considerations set out by the General Court in paragraph 234 of the judgment under appeal.

51 It follows that the third alternative complaint is inadmissible.

52 The fourth alternative complaint relates to paragraphs 278 to 280 of the judgment under appeal, which are worded as follows:

'278 It should be noted that the arguments put forward under the third part of the third plea do not concern the … decision [at issue] 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 … decision [at issue] 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 … decision [at issue] 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.'

53 In the appellants' submission, the General Court's reasoning for those paragraphs of the judgment under appeal is inadequate and, in any event, it erred in law by rejecting arguments as unfounded on the ground that they had been set out or numbered differently in the request for review and in the application at first instance.

54 As regards the allegedly inadequate reasoning, since the appellants have not in any way specified the nature of the lack of clarity said to vitiate the reasoning, their fourth alternative complaint is, in that regard, inadmissible.

55 As to the alleged error of law for which the General Court is criticised, this complaint results from a misreading of the judgment under appeal. In paragraphs 278 to 280 thereof, the General Court did not reject arguments on the ground that they had been numbered or grouped differently in the request for review and in the application at first instance. On the contrary, it rejected the third part of the third plea as unfounded on the ground that the first appellant did not produce anything demonstrating that the Commission had committed a manifest error in the reasoning at issue. In that regard, therefore, the fourth alternative complaint is unfounded.

56 Consequently, the fourth alternative complaint is in part inadmissible and in part unfounded.

57 The fifth alternative complaint concerns paragraphs 292 and 293 of the judgment under appeal, which read as follows:

'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 … decision [at issue].'

58 The appellants contest the General Court's findings by relying on the arguments that they set out in paragraphs 227 to 230 of the application at first instance, which are said to refer to the arguments already set out in paragraphs 80 and 97 to 119 thereof, from which it is said to be apparent that, on account of the statistically significant differences identified between the modified soybean and its conventional counterpart, a monitoring plan in respect of the consumption of the modified soybean by humans and animals ought to have been drawn up.

59 However, paragraphs 227 to 230 of the application at first instance make no reference at all to paragraphs 80 and 97 to 119 of that application. Accordingly, it does not appear that the General Court distorted the facts or committed an error of law in describing the application at first instance as vague in this respect and in holding it to be inadmissible in that regard.

60 Consequently, the fifth alternative complaint is unfounded.

61 It follows from all the foregoing that, as the first ground of appeal is in part inadmissible and in part unfounded, it must be rejected.

The second ground of appeal

Arguments of the parties

62 By their second ground of appeal, the appellants complain, first, that the General Court erred in law by imposing an impossible burden of proof on NGOs bringing challenges under Articles 10 and 12 of Regulation No 1367/2006. Thus, in paragraphs 67, 83 and 88 of the judgment under appeal, the General Court required a party requesting internal review of an administrative act to adduce substantial evidence liable to raise serious doubts as to the lawfulness of the act concerned and, in so doing, applied to that field a rule on the allocation of the burden of proof which is used in a different legal context. Whilst the present instance involves proceedings under Article 12 of Regulation No 1367/2006 brought against decisions adopted following requests for review, the rule on the allocation of the burden of proof which was applied by the General Court in the judgment under appeal is that used by the Court of Justice in proceedings concerning third-party challenges to marketing authorisations, where the third party is required to adduce substantial evidence liable to raise serious doubts as to the lawfulness of the grant of that authorisation. Ultimately, the purpose of requests for review is that the concerns raised by the parties making them be declared well founded.

63 Second, the appellants complain that the General Court applied that rule on the allocation of the burden of proof in a way that fell foul of its conclusion that NGOs are not required to prove that GMOs are unsafe. Thus, the General Court wrongly held, in paragraphs 134, 135, 148 to 150, 157, 163 to 168, 170, 205 to 209, 217 to 224, 230, 231, 238 to 243, 246, 247, 256, 282, 287 and 289 of the judgment under appeal, that the evidence put forward by the appellants did not show that the modified soybean was unsafe.

64 The Commission and Monsanto submit that the second ground of appeal should be rejected.

Findings of the Court

65 The first part of the second ground of appeal relates to paragraphs 67, 83 and 88 of the judgment under appeal, which are worded as follows:

> ‘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).
>
> ...
>
> 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.

...

88 Therefore, and contrary to the Commission's assertions in the … decision [at issue], 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.'

66 As is apparent from recital 11, Article 2(1)(g) and Article 10(1) of Regulation No 1367/2006, any NGO which meets the criteria set out in Article 11 of that regulation is entitled to make a request for internal review of administrative acts of individual scope having legally binding and external effects, and the request must state the grounds for the review.

67 Thus, concerns as to the legality of the grant of an authorisation decision expressed by a party requesting review which are not based on matters of fact or law do not satisfy the requirement recalled in the preceding paragraph of the present judgment that the request is to state the grounds for the review.

68 As the Advocate General has maintained, in essence, in point 68 of his Opinion, it is inherent in the system of review that the party requesting the review provides concrete and precise grounds which might be able to call into question the assessments on which the authorisation decision is based.

69 Accordingly, the General Court was correct in holding, in essence, in paragraphs 67, 83 and 88 of the judgment under appeal, that, in order to state in the manner required the grounds for conducting the review, a party requesting the internal review of an administrative act under environmental law is required to put forward the facts or legal arguments of sufficient substance to give rise to serious doubts as to the assessment made in that act by the EU institution or body.

70 Consequently, the first part of this ground of appeal is unfounded.

71 So far as concerns the complaints relating to paragraphs 134, 135, 148 to 150, 157, 163 to 168, 170, 205 to 209, 217 to 224, 230, 231, 238 to 243, 246, 247, 256, 282, 287 and 289 of the judgment under appeal, it must be stated, in any event, that it is not apparent that, in those paragraphs, the General Court held that the evidence put forward by the appellants did not show that the modified soybean was unsafe.

72 As those complaints are unfounded, the second part of this ground of appeal must be rejected.

73 It follows from all the foregoing that the second ground of appeal must be rejected as unfounded.

The third ground of appeal

Arguments of the parties

74 By their third ground of appeal, the appellants submit that the General Court incorrectly held, in paragraphs 116 to 118, 268 to 270 and 281 of the judgment under appeal, that guidance published by EFSA did not give rise to a legitimate expectation that it would be complied with on the ground that it

was not binding on the Commission, it did not contain any precise, unconditional and concordant assurances and that it was not issued by the Commission which had the task of adopting the final decision in the exercise of its discretion.

75 The Commission cannot simply ignore, without good cause, the guidance published by EFSA, which is expressly intended to make sure that the legal obligations imposed, inter alia by Regulation No 1829/2003, are complied with. The General Court allowed the Commission to rely on the guidance, using it as a 'shield to challenge', but it took the view that the Commission was not required to justify failure to comply with it.

76 The Commission and Monsanto submit that the third ground of appeal should be rejected.

Findings of the Court

77 The paragraphs of the judgment under appeal criticised by the appellants are worded as follows:

'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.

...

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.

...

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.'

78 In paragraph 113 of the judgment under appeal, the General Court, in the first place, held that (i) 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 and (ii) EFSA's guidance documents are thus aimed at structuring the pieces of information that an applicant is required to provide in submitting an application for authorisation and are not intended to confer on a third party, such as TestBioTech, a right to require that certain information be provided at that time. In paragraph 115 of the judgment under appeal, it is stated, in the second place, that, 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.

79 Paragraphs 113 and 115 of the judgment under appeal have not been challenged by the appellants.

80 In stating, in paragraph 116 of the judgment under appeal, that the guidance in question contained no precise, unconditional and concordant assurances given to the first appellant on which it might rely in a request for internal review of an administrative act submitted pursuant to Article 10 of Regulation No 1367/2006, the General Court merely drew the appropriate conclusions from the uncontested findings set out in paragraphs 113 and 115 of that judgment.

81 That being so, no error of law can be identified in paragraph 116 of the judgment under appeal.

82 Since it is apparent from paragraph 116 of the judgment under appeal that the appellants cannot rely on EFSA's guidance in a request for internal review of an administrative act submitted pursuant to Article 10 of Regulation No 1367/2006, the complaints alleging errors of law committed by the General Court in paragraphs 117 and 118 of the judgment under appeal, when it held that that guidance had not been adopted by and did not bind the Commission, are ineffective.

83 It follows that, in so far as the third ground of appeal alleges errors of law affecting paragraphs 116 to 118 of the judgment under appeal, it is in part unfounded and in part ineffective.

84 As no independent complaint is relied upon to challenge paragraphs 268 to 270 and 281 of the judgment under appeal, which refer to paragraphs 110 to 118 thereof, the third ground of appeal must be rejected in that regard.

85 It follows from the foregoing that the third ground of appeal must be rejected in its entirety.

The fourth ground of appeal

Arguments of the parties

86 By their fourth ground of appeal, the appellants contend that the General Court erred in law in holding, in paragraphs 176 to 192, 213, 214, 216, 217, 222 to 224, 229 to 231 and 271 to 277 of the judgment under appeal, that the Commission was not obliged to comply with the two-stage safety assessment required by Regulation No 1829/2003 and by the guidance published by EFSA and that the first stage, that is to say, the comparison of the genetically modified crop and its comparators, could by itself be sufficient to satisfy the obligations set out in that regulation.

87 The appellants submit that the Commission maintained before the General Court that further investigation had not been necessary because of the findings in respect of the substantial equivalence of the soybean at issue and the assessments carried out of the individual parents. The General Court accepted that argument in paragraphs 176 to 192 of the judgment under appeal, when it held that the guidance did not require an assessment of the toxicity, allergenicity and the effects of processing on the GMO where there was no evidence of interactions between the stacked events. The General Court stated that the guidance established a case-by-case approach which did not rule out as a matter of principle a limited toxicity assessment.

88 In the appellants' submission, such reasoning is flawed and contrary to the obligations imposed by Regulation No 1829/2003. First, no mention is made of recital 6 of Regulation No 1829/2003, in accordance with which, whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself. The General Court did not set out the reasons why its assessment is compatible with that recital and its clear indication that Regulation No 1829/2003 is intended to require a thorough safety assessment of each GMO, going beyond the assessment of substantial equivalence. Second, the guidance published by EFSA makes clear that a safety assessment for each GMO is required, even if it is limited. Third, in paragraph 191 of the judgment under appeal, the General Court essentially accepted the argument that only a comparative analysis was required. It took the view that the carrying out of an assessment of the data on comparative analysis removed the need for any second-stage safety assessment. The error committed by the General Court in this regard is also the basis for the grounds set out in paragraphs 213, 214, 216, 217, 222 to 224, 230 and 231 of the judgment under appeal, according to which comparative trials accepted by EFSA constituted an investigation for the purposes of the second-stage safety assessment, and in paragraphs 271 to 275 and 277 thereof in respect of the inadequate allergenicity assessment.

89 The Commission and Monsanto submit that the fourth ground of appeal should be rejected.

Findings of the Court

90 Paragraphs 176 to 185 of the judgment under appeal are essentially descriptive in nature and, by their fourth ground of appeal, the appellants do not rely on any error of law vitiating those paragraphs. In paragraphs 186 and 187 of the judgment under appeal, the General Court found that, contrary to TestBioTech's contentions, the reasons stated for the decision at issue were sufficient in the light of the second paragraph of Article 296 TFEU, as interpreted by settled case-law. The appellants do not plead any error of law in that regard.

91 Therefore, in the light of the complaints relied on by the appellants in their fourth ground of appeal, it is to be regarded as concerning only paragraphs 188 to 192 of the judgment under appeal.

92 Those paragraphs are worded as follows:

'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 … decision [at issue]. The first part of the second plea must therefore be rejected as unfounded.'

93 It is apparent from paragraph 191 of the judgment under appeal that, contrary to the appellants' contentions, the General Court did not consider that just a comparative analysis of the modified soybean and its comparator was sufficient in order not to conduct a toxicity assessment and in order to conclude that the GMO was safe. The General Court took account, first, of the fact that such a comparative analysis was supplemented, in particular, by a toxicity study in the context of an assessment of the potential synergistic or antagonistic effects between the two genetically modified parents of the modified soybean and, second, of the fact that the assessment of the risks associated with stacking was not restricted to a comparative analysis but related to the potential for increased toxicity.

94 Furthermore, the General Court noted, in paragraph 188 of the judgment under appeal, that each of the guidance documents referred to in paragraphs 177 to 179 thereof states 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.

95 In particular, it is underlined in paragraph 177 of the judgment under appeal that 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) states, as

regards the toxicity assessment, 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.

96 That approach is not, in any event, incompatible with recital 6 of Regulation No 1829/2003, according to which, whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself, since that recital does not preclude the scope of the toxicity assessment from being determined on a case-by-case basis.

97 Nor is such an approach contrary to Article 5(3)(f) of Regulation No 1829/2003, referred to by the appellants in support of their ground of appeal, which provides that the application for authorisation to place a GMO on the market is to 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 to the criteria specified in Article 13(2)(a), or a proposal for labelling the food in accordance with Article 13(2)(a) and (3)'.

98 It follows from the foregoing that the appellants have not shown that paragraphs 188 to 192 of the judgment under appeal are vitiated by an error of law.

99 As no independent complaint is relied upon to challenge paragraphs 213, 214, 216, 217, 222 to 224, 229 to 231 and 271 to 277 of the judgment under appeal, the fourth ground of appeal must, in the light of the determination in the preceding paragraph of the present judgment, be held to be unfounded in that regard.

100 It follows from the foregoing that the fourth ground of appeal must be rejected in its entirety.

The fifth ground of appeal

Arguments of the parties

101 By their fifth ground of appeal, the appellants contend that the General Court erred in law, in paragraphs 233 and 289 of the judgment under appeal, in relying upon Regulation No 396/2005 when rejecting certain elements of their complaint that the Commission wrongly failed to require a sufficiently complete investigation of the potential toxicity of the soybean at issue and to monitor its impact after marketing authorisation.

102 In the appellants' submission, Regulation No 396/2005 does not curtail the obligations imposed, in particular, by Articles 14 and 16 of Regulation No 1829/2003 or the obligations in respect of monitoring after marketing authorisation. If the spraying of a particular GMO, due to the stacking or genetic changes made, has adverse effects on the environment, human health or animal health, this must be investigated and determined through the application of Regulation No 1829/2003.

103 The Commission and Monsanto submit that the fifth ground of appeal should be rejected.

Findings of the Court

104 Paragraphs 233 and 289 of the judgment under appeal are worded as follows:

'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.

...

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 … decision [at issue]. 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.'

105 As the Commission has observed, the appellants have not put forward any arguments capable of demonstrating that the finding set out in paragraphs 233 and 289 of the judgment under appeal is wrong.

106 Thus, whilst it is true that Article 16 of Regulation No 1829/2003, cited by the appellants, provides, in paragraph 1(a), that genetically modified feed must not have adverse effects on human health, animal health or the environment, the fact remains that neither that provision nor any other provision of that regulation, even as amended, requires the effects connected with any pesticide use to be examined in the course of the procedure for authorising a GMO.

107 Furthermore, Regulation No 396/2005 refers neither to Regulation No 1829/2003 nor to the procedure for authorising GMOs falling under that regulation.

108 Accordingly, it must be held that the error of law pleaded by the appellants has not been established.

109 The fifth ground of appeal must consequently be rejected as unfounded.

110 As none of the grounds of appeal has been upheld, the appeal must be dismissed in its entirety.

Costs

111 In accordance with Article 184(2) of the Rules of Procedure of the Court of Justice, where the appeal is unfounded, the Court is to make a decision as to the costs. Under Article 138(1) of the Rules of Procedure, which is applicable to appeal proceedings by virtue of Article 184(1) thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

112 Under Article 184(4) of the Rules of Procedure, the Court may decide that an intervener at first instance is to bear its own costs.

113 As the appellants have been unsuccessful, they must be ordered, in accordance with the form of order sought by the Commission, to bear their own costs and to pay those incurred by the Commission.

114 Monsanto, which intervened at first instance, is to bear its own costs.

On those grounds, the Court (Third Chamber) hereby:

1. Dismisses the appeal;

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 Monsanto Europe and Monsanto Company to bear their own costs.

Vilaras Malenovský Bay Larsen

Safjan Šváby

Delivered in open court in Luxembourg on 12 September 2019.

A. Calot Escobar
Registrar

K. Lenaerts
President