Reports of Cases

JUDGMENT OF THE GENERAL COURT (Seventh Chamber)

14 March 2018*

(Environment — Genetically modified products — Regulation (EC) No 1367/2006 — Regulation (EC) No 1829/2003 — Genetically modified soybeans MON 87769, MON 87705 and 305423 — Rejection of an application for internal review of market authorisation decisions — Concept of 'environmental law' — Article 10 of Regulation No 1367/2006)

In Case T-33/16,

TestBioTech eV, established in Munich (Germany), represented by R. Stein, Solicitor, K. Smith QC, and J. Stevenson, Barrister,

applicant,

v

European Commission, represented by J. Tomkin, L. Pignataro-Nolin and C. Valero, acting as Agents,

defendant,

supported by

Monsanto Europe, established in Antwerp (Belgium),

and

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

represented by M. Pittie, lawyer,

and by

Pioneer Overseas Corp., established in Johnston, Iowa (United States),

and

Pioneer Hi-Bred International, Inc., established in Johnston,

represented by G. Forwood, lawyer, J. Killick, Barrister, and S. Nordin, Solicitor,

interveners,

* Language of the case: English.

ACTION under Article 263 TFEU for annulment of the letter from the Commissioner for Health and Food Safety of 16 November 2015 rejecting an application for internal review, based on 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), of implementing decisions authorising the placing on the market of the genetically modified soybeans MON 87769, MON 87705 and 305423,

THE GENERAL COURT (Seventh Chamber),

composed of V. Tomljenović (Rapporteur), President, E. Bieliūnas and A. Kornezov, Judges,

Registrar: P. Cullen, Administrator,

having regard to the written part of the procedure and further to the hearing on 22 September 2017,

gives the following

Judgment

Background to the dispute

1 The applicant, TestBioTech eV, is a German-registered non-profit organisation for the promotion of independent research and public debate on the impact of biotechnology.

Market authorisation for the 305423 soybean

2 On 14 June 2007 Pioneer Overseas Corporation 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 genetically modified soybean 305423 ('the 305423 soybean'). The application for authorisation also covered the placing on the market of the 305423 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.

3 On 18 December 2013 the Scientific Panel on Genetically Modified Organisms ('the GMO Scientific Panel') of the European Food Safety Authority ('EFSA') issued a scientific opinion relating to the 305423 soybean, forming a report as provided for in Articles 6(6) and 18(6) of Regulation No 1829/2003 which, according to its wording, 'will be part of the EFSA overall opinion in accordance with Articles 6(5) and 18(5)' of that regulation. In essence, the GMO Scientific Panel considered that the 305423 soybean was as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment in the context of its intended uses.

4 On 24 April 2015 the European Commission adopted Implementing Decision (EU) No 2015/698 authorising the placing on the market of products containing, consisting of, or produced from the genetically modified 305423 soybean (DP-3Ø5423-1) pursuant to Regulation No 1829/2003 (OJ 2015 L 112, p. 71). In recitals 4 to 7 of that decision, the Commission explained — by reference to the scientific opinion mentioned in paragraph 3 above — that EFSA had given a 'favourable opinion' in accordance with Articles 6 and 18 of Regulation No 1829/2003; that it had concluded that the 305423 soybean was as safe as its non-genetically modified counterpart with respect to potential effects on

human and animal health or the environment in the context of its intended uses; and that it recommended the implementation of a post-market monitoring plan, focusing on the collection of consumption data for the European population.

5 Under Article 1 of Decision 2015/698, the Commission assigned a unique identifier to the 305423 soybean. By Article 2 of that decision, the Commission authorised, for the purposes of Articles 4(2) and 16(2) of Regulation No 1829/2003, foods and food ingredients containing, consisting of, or produced from the 305423 soybean; feed containing, consisting of, or produced from the 305423 soybean; and the 305423 soybean in products containing it or consisting of it for any use other than those mentioned above, with the exception of cultivation. In addition, Articles 3 to 5 of Decision 2015/698 concern the labelling and monitoring of the products concerned.

Market authorisation for the MON 87769 soybean

6 On 14 September 2009 Monsanto Europe SA submitted to the competent authority of the United Kingdom, in accordance with Articles 5 and 17 of Regulation No 1829/2003, an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from the genetically modified soybean MON 87769 ('the MON 87769 soybean'). The application also covered the placing on the market of the MON 87769 soybean present in products other than foods and feed containing or consisting of that soybean for the same uses as any other soybean, with the exception of cultivation.

7 On 16 May 2014 the GMO Scientific Panel issued a scientific opinion relating to the MON 87769 soybean, forming a report as provided for in Articles 6(6) and 18(6) of Regulation No 1829/2003 which, according to its wording, 'will be part of the EFSA overall opinion in accordance with Articles 6(5) and 18(5) [of that regulation]'. In essence, the GMO Scientific Panel concluded that the MON 87769 soybean, as described in the application, was as safe as its conventional counterpart and was unlikely to have adverse effects on human and animal health and the environment in the context of the scope of the application.

8 On 24 April 2015 the Commission adopted Implementing Decision (EU) 2015/686 authorising the placing on the market of products containing, consisting of, or produced from the genetically modified MON 87769 soybean (MON-87769-7) pursuant to Regulation (EC) No 1829/2003 (OJ 2015 L 112, p. 16). In recitals 4 to 8 of that decision, the Commission explained — by reference to the scientific opinion mentioned in paragraph 7 above — that EFSA had given a 'favourable opinion' in accordance with Articles 6 and 18 of Regulation No 1829/2003; that it had concluded that the MON 87769 soybean was as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment in the context of its intended uses; and that it recommended the implementation of a post-market monitoring plan, focusing on the collection of consumption data for the European population.

9 Under Article 1 of Decision 2015/686, the Commission assigned a unique identifier to the MON 87769 soybean. By Article 2 of that decision, the Commission authorised for the purposes of Articles 4(2) and 16(2) of Regulation No 1829/2003 foods and food ingredients containing, consisting of, or produced from the MON 87769 soybean; feed containing, consisting of, or produced from the MON 87769 soybean; and the MON 87769 soybean in products containing it or consisting of it for any use other than those mentioned above, with the exception of cultivation. In addition, Articles 3 to 5 of Decision 2015/686 concern the labelling and monitoring of the products concerned.

Market authorisation for the MON 87705 soybean

10 On 18 February 2010 Monsanto Europe SA submitted to the competent authority of the Netherlands, in accordance with Articles 5 and 17 of Regulation No 1829/2003, an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from genetically modified soybean MON 87705 ('the MON 87705 soybean'). The application for authorisation also covered the placing on the market of the MON 87705 soybean present in products other than foods and feed containing or consisting of that soybean for the same uses as any other soybean, with the exception of cultivation.

11 On 30 October 2012, the GMO Scientific Panel issued a scientific opinion relating to the MON 87705 soybean, forming a report as provided for in Articles 6(6) and 18(6) of Regulation No 1829/2003 which, according to its wording, 'will be part of the EFSA overall opinion in accordance with Articles 6(5) and 18(5)' of that regulation. That opinion was supplemented by a statement from the GMO Scientific Panel dated 17 December 2013. In essence, the GMO Scientific Panel considered that the MON 87705 soybean was as safe, in the context of its intended uses as proposed by Monsanto Europe, as its conventional counterpart with respect to potential effects on human and animal health and the environment.

12 On 24 April 2015 the Commission adopted Commission Implementing Decision (EU) 2015/696 authorising the placing on the market of products containing, consisting of, or produced from the genetically modified MON 87705 soybean (MON-877Ø5-6) pursuant to Regulation (EC) No 1829/2003 (OJ 2015 L 112, p. 60). In recitals 4 to 10 of that decision, the Commission explained — by reference to the scientific opinion mentioned in paragraph 11 above, as supplemented — that EFSA had given a 'favourable opinion' in accordance with Articles 6 and 18 of Regulation No 1829/2003; that EFSA had concluded that the MON 87705 soybean was as safe as its conventional counterpart, in the context of its intended uses that covered the same uses as those of any conventional soybean intended for food and feed uses, except for the commercial frying uses of the oil, and that EFSA had recommended the implementation of a post-market monitoring plan, focusing on the collection of consumption data for the European population

13 Under Article 1 of Decision 2015/696, the Commission assigned a unique identifier to the MON 87705 soybean. By Article 2 of that decision, the Commission authorised, for the purposes of Articles 4(2) and 16(2) of Regulation No 1829/2003, foods and food ingredients containing, consisting of, or produced from the MON 87705 soybean; feed containing, consisting of, or produced from the MON 87705 soybean; and the MON 87705 soybean in products containing it or consisting of it for any other use, with the exception of cultivation. In addition, Articles 3 to 5 of Decision 2015/696 concern the labelling and monitoring of the products concerned.

The request for internal review

14 By letter of 29 May 2015, the applicant and another organisation asked the Commission to carry out an internal review of Decisions 2015/686, 2015/696 and 2015/698 ('the authorisation decisions'), 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). In their request for internal review, the applicant and the other organisation essentially claimed that (i) there was a lack of guidance from EFSA concerning the health impact of genetically modified crops with significantly altered nutritional content; (ii) the lack of guidance resulted in an inadequate and inconsistent assessment of nutritional risks which did not meet legal requirements; (iii) the lack of guidance resulted in infringement of the provisions on labelling; (iv) the lack of guidance resulted in inadequate and inconsistent post-marketing monitoring proposals; (v) there was a failure to consider herbicide

residues when examining the impact of the consumption of genetically modified food and feed on health as regards the MON 87705 and 305423 soybeans, and (vi) as regards the MON 87705 soybean, the assessment of the unintended effects of ribonucleic acid interference was inadequate.

15 By letter of 4 August 2015, the Commission informed the applicant that it would not be in a position to complete its review within 12 weeks and that, consequently, the applicant would receive a reply within 18 weeks, in accordance with Article 10(3) of Regulation No 1367/2006.

16 By email of 1 October 2015, an official in the Commission's Directorate-General for Health and Food Safety informed the applicant that the decision on its request for review had been 'prepared' but still had to go through the administrative procedure for signature.

17 By letter of 16 November 2015, bearing the reference Ares(2015) 5145741 ('the contested decision'), the Commissioner for Health and Food Safety refused the request for review on the ground that the first five complaints and part of the sixth complaint, described in paragraph 14 above, did not fall within the scope of Article 10 of Regulation No 1367/2006 and that the remainder of the sixth complaint concerning the environmental risk assessment did 'not justify the need to amend … Decision 2015/696'. In that regard, the Commissioner for Health and Food Safety found, in essence, that the aspects relating to the health assessment of genetically modified food and feed could not be examined within the framework of Article 10 of Regulation No 1367/2006 because those aspects were not concerned with environmental risk assessment. As regards the part of the sixth complaint relating to environmental protection, the Commissioner for Health and Food Safety considered that the argument was unfounded and did not warrant a review of the authorisation decisions. More specifically, the Commissioner for Health and Food Safety found, first, that the complaints concerning the guidance from EFSA on the health and nutritional assessment of genetically modified crops with altered nutritional content were clearly related to the impact on health of the consumption of food and feed. Second, he considered that a nutritional assessment should generally be carried out in the course of the examination of the health impact of the consumption of food and feed and not for the purposes of assessing the environmental risks associated with potential release into the environment. Third, he asserted that the labelling of the composition of genetically modified food is not related to environmental risk assessment. Fourth, he maintained that post-marketing monitoring is not related to environmental risk assessment. Fifth, he submitted that the failure to take account of the health effects of herbicide residues consumed together with genetically modified food and feed related to the impact on health and not on the environment. Sixth, he contended that a study on the unintended effects on human and animal health of the consumption of plants subject to ribonucleic acid interference, to which the applicant had referred, is not related to environmental risk assessment.

Procedure and forms of order sought

18 By application lodged at the Court Registry on 26 January 2016, the applicant brought the present action and applied for the joinder of this case with Case T-177/13, *TestBioTech and Others* v *Commission*.

19 On 14 April 2016 the President of the Fifth Chamber of the General Court decided not to grant the application for joinder of this case with Case T-177/13, *TestBioTech and Others* v *Commission*.

20 By document lodged at the Court Registry on 31 May 2016, Monsanto Europe SA and Monsanto Company (together, 'Monsanto') sought leave to intervene in support of the form of order sought by the Commission.

21 By document lodged at the Court Registry on 9 June 2016, Pioneer Overseas and Pioneer Hi-Bred International, Inc. (together, 'Pioneer') sought leave to intervene in support of the form of order sought by the Commission.

22 By orders of 20 July 2016, the President of the Fifth Chamber of the General Court granted Monsanto and Pioneer leave to intervene.

23 Following a change in the composition of the Chambers of the General Court, pursuant to Article 27(5) of the Rules of Procedure of the General Court, the Judge Rapporteur was assigned to the Seventh Chamber, to which the present case was accordingly allocated.

24 On hearing the report of the Judge-Rapporteur, the Court decided to open the oral procedure and, by way of measures of organisation of procedure pursuant to Article 89 of the Rules of Procedure, asked the parties to answer a written question. The parties complied with that measure of organisation of procedure within the prescribed period.

25 By documents lodged at the Registry of the Court on 19 and 23 December 2016, the Commission and the applicant requested a hearing, in accordance with Article 106(2) of the Rules of Procedure. At the hearing on 22 September 2017, the Court found that the applicant, who had been duly given notice, was absent without excuse, and the hearing proceeded in the absence of the applicant, in accordance with Article 108(1) of the Rules of Procedure. The other parties presented oral argument and answered the questions put by the Court at that hearing.

26 By document lodged at the Registry of the Court on 22 September 2017, the applicant requested that the Court reopen the oral part of the procedure under Article 113(2) of the Rules of Procedure or, in the alternative, that it be allowed the opportunity to submit in writing the arguments that it had prepared for the hearing.

27 Since the conditions laid down in Article 113(2) of the Rules of Procedure were not satisfied, the Court decided not to reopen the oral part of the procedure.

28 The applicant claims that the Court should:

– give a ruling on the questions: (i) whether a request for internal review submitted under Article 10 of Regulation No 1367/2006 concerning an authorisation adopted pursuant to Regulation No 1829/2003 should be limited to the 'environmental risk assessment' under Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ 2001 L 106, p. 1); (ii) whether proceedings brought under Article 12 of Regulation No 1367/2006 should be limited to the EU institution's consideration of the 'environmental risk assessment' conducted in accordance with Directive 2001/18, and (iii) what standard of review to be carried out by the Court should apply in proceedings brought under Article 12 of Regulation No 1367/2006;

– declare the action admissible and well founded;

– annul the contested decision;

– order the Commission to pay the costs.

29 In response to a written question from the Court on the admissibility of the head of claim concerning the request for a ruling on the questions set out in the first indent of paragraph 28 above, the applicant stated, in its written reply, that there was no longer any need to give such a ruling. It must therefore be held that the applicant has withdrawn its first head of claim.

30 The Commission contends that the Court should:

– dismiss the action;

– order the applicant to pay the costs.

31 Monsanto contends that the Court should:

– dismiss the action;

– order the applicant to pay the costs.

32 Pioneer contends that the Court should:

– dismiss the action;

– order the applicant to pay the costs.

Law

33 Before examining the substance of the present case, it must be observed that, in the document lodged at the Registry of the Court on 22 September 2017, seeking the reopening of the oral part of the procedure (see paragraph 26 above), the applicant asked that it be allowed the opportunity to submit in writing the argument that it had prepared for the hearing. In that regard, suffice it to state that the Rules of Procedure make no provision for such a procedural document.

34 As regards the substance of this case, the applicant relies on two pleas in law in support of its action. By its first plea, the applicant claims that its request for internal review falls, in its entirety, within the scope of Regulation No 1367/2006. The applicant argues that the Commission infringed Article 10(1) of Regulation No 1367/2006, read in conjunction with Article 2(1)(f) and (g) and recitals 11 and 18 to 21 thereof, by finding that the greater part of the request for internal review related to matters falling outside the scope of that regulation. By its second plea, the applicant claims that the contested decision is unlawful in so far as the Commission failed to adopt it within the time limits laid down in Article 10(3) of Regulation No 1367/2006.

35 First, the first plea in law should be examined. In that regard, the applicant claims, in essence, that the request for internal review relates to matters falling within the scope of Regulation No 1367/2006. The applicant considers that administrative acts adopted under Regulation No 1829/2003, such as the authorisation decisions, are acts adopted under environmental law within the meaning of Article 10(1) of Regulation No 1367/2006. Where a non-governmental organisation requests an internal review or brings an action for annulment, it is not, according to the applicant, required to limit the grounds relied on to the elements of the act that concern the 'environmental risk assessment'. The applicant claims that the impact of genetically modified organisms on the state of human health is a health issue linked to the state of the environment. In addition, the fact that Regulation No 1829/2003 was adopted on the basis of Article 168(4) TFEU, which relates to public health, is of no relevance to the question whether the authorisation decisions are acts adopted under environmental law within the meaning of Article 10(1) of Regulation No 1367/2006. Furthermore, the applicant submits that the elements of the overall assessment of the soybeans at issue in this case and evidence related to that assessment are not severable. Consequently, the Commission's decision to 'carve up' the different parts of the market authorisation for a genetically modified organism into environmental aspects and non-environmental aspects is, according to the applicant, misplaced.

36 The Commission, supported by Monsanto and Pioneer, contends, in essence, that the scope of the right of review provided for in Article 10 of Regulation No 1367/2006 is limited to questions of environmental law within the meaning of that regulation. According to the Commission, the mere fact that the authorisation decisions were made under Regulation No 1829/2003 does not automatically create a right to review of all aspects of those decisions under Article 10 of Regulation

No 1367/2006. On the contrary, the right to make a request for review exists solely with respect to those aspects that fall within the scope of environmental law, as defined in Article 2(1)(f) of Regulation No 1367/2006. Against that background, the Commission maintains that environmental concerns and public health concerns are conceptually and legally distinct and that the aspects of the applicant's request for review that relate to public health do not fall within the scope of Article 10 of Regulation No 1367/2006. More specifically, the Commission states: (i) most of the arguments raised in the request for review at issue relate to 'food safety'; (ii) the legal provisions on which the request for review is based clearly relate to public health aspects rather than environmental protection, and (iii) the arguments put forward by the applicant on the issues of nutritional value, labelling and the safety of genetically modified products present in food and feed relate to product safety rather than the state of the environment in general.

37 In this case, the dispute between the parties concerns whether the Commission could properly reject as inadmissible a large part of a request for internal review of the authorisation decisions, in particular that submitted by the applicant, on the basis of Article 10 of Regulation No 1367/2006, on the ground that most of the complaints raised in that request did not fall within the scope of environmental law.

The extent of internal review under Article 10 of Regulation No 1367/2006

38 Under Article 10(1) of Regulation No 1367/2006, any non-governmental organisation which meets the criteria set out in Article 11 of that regulation is entitled to make a request for internal review to the European Union institution which adopted an administrative act under environmental law.

39 Article 12(1) of Regulation No 1367/2006 provides that a non-governmental organisation that has 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 FEU Treaty.

40 Article 2(1)(g) of Regulation No 1367/2006 defines 'administrative act' for the purpose of that regulation as meaning any measure of individual scope under environmental law, taken by an EU institution or body, and having legally binding and external effects.

41 Article 2(1)(f) of Regulation No 1367/2006 states that 'environmental law' for the purpose of that regulation 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 FEU 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.

42 In that regard, first, it is clear that Article 2(1)(f) of Regulation No 1367/2006 states that the question whether an act was adopted under environmental law does not depend on the legal basis on which the legal provision at issue was adopted.

43 Second, Article 2(1)(f) of Regulation No 1367/2006 states that the concept of 'environmental law', for the purpose of that regulation, covers any EU legislation which contributes to the pursuit of the objectives of EU policy on the environment. In that context, that provision lists, in essence, the EU objectives with respect to the environment as they are set out in Article 191(1) TFEU: 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.

44 It follows from the wording of Article 2(1)(f) of Regulation No 1367/2006 that, by referring to the objectives listed in Article 191(1) TFEU, the EU legislature intended to give to the concept of 'environmental law', covered by Regulation No 1367/2006, a broad meaning, not limited to matters relating to the protection of the natural environment in the strict sense.

45 That finding is, it may be added, confirmed by Article 192(2) TFEU, according to which environmental law, in so far as it is the subject of Title XX of the FEU Treaty, may also include provisions that are primarily of a fiscal nature, measures that affect town and country planning, quantitative management of water resources (or affecting directly or indirectly the availability of those resources) and land use, and also measures significantly affecting a Member State's choice between different energy sources and the general structure of its energy supply. The effect of a restricted interpretation of the concept 'environmental law' would be that such provisions and measures would, to a great extent, fall outside its scope.

46 Further, it must be observed that Article 2(2) of Regulation No 1367/2006 provides that administrative acts and administrative omissions are not to include measures taken or omissions by an EU institution or body in its capacity as an administrative review body, under, for example, Articles 101, 102, 106, 107, 228, 258, 260 and 325 TFEU relating to the competition rules, infringement proceedings, European Ombudsman proceedings and anti-fraud proceedings. The fact that the legislature considered it necessary to include such exceptions again indicates that the concept of 'environmental law', covered by Regulation No 1367/2006, must be interpreted, in principle, very broadly.

47 As regards whether, as part of its internal review, the Commission was required to examine only matters within the scope of environmental law, it is clear that Article 10(1) of Regulation No 1367/2006 states that a non-governmental organisation which meets the criteria set out in Article 11 of that regulation is entitled to make a request for internal review of an administrative act adopted under environmental law. The wording of that provision does not restrict the extent of the internal review to matters concerning the environment.

48 However, in recital 18 of Regulation No 1367/2006, the legislature stated that, like Article 9(3) of the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, signed in Aarhus on 25 June 1998 (OJ 2005 L 124, p. 1) and consistently with the provisions of the FEU Treaty, the objective of that regulation is to make provision for access to procedures for challenging acts which contravene provisions of law relating to the environment. Further, it is apparent from the title of Regulation No 1367/2006 and from recital 5 of that regulation that Regulation No 1367/2006 concerns only access to information, public participation in decision-making and access to justice in environmental matters.

49 The Court must therefore interpret the extent of the obligation to carry out an internal review pursuant to Article 10 of Regulation No 1367/2006 in such a way that the Commission is required to examine a request for internal review only in so far as the applicant for review has claimed that the administrative act in question contravened environmental law within the meaning of Regulation No 1367/2006.

50 Those are the considerations that must guide the Court in examining, first, whether the authorisation decisions were acts adopted under environmental law within the meaning of Regulation No 1367/2006 and, second, whether the arguments submitted by the applicant in its request for internal review fell within the scope of environmental law within that meaning.

Regulation No 1829/2003

51 The request for internal review made by the applicant concerned the internal review of the authorisation decisions, which were adopted by the Commission under Article 7(3) and Article 19(3) of Regulation No 1829/2003.

52 Regulation No 1829/2003 refers, for its legal basis, in particular, to Articles 37 and 95 EC and to Article 152(4)(b) EC, provisions which correspond, for the purposes of the present case, to Articles 43 and 114 TFEU and to Article 168(4)(b) TFEU, which concern the areas of agriculture, approximation of laws, and public health.

53 According to Article 1(a) of Regulation No 1829/2003, the objective of that regulation is, in accordance with the general principles laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1), to provide the basis for ensuring 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, whilst ensuring the effective functioning of the internal market.

54 Further, recital 1 of Regulation No 1829/2003 states that the free movement of safe and wholesome food and feed 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 of Regulation No 1829/2003 state that a high level of protection of human life and health, of animal health and welfare, of the environment and consumer interests in relation to genetically modified food and feed should be ensured in the pursuit of EU policies. According to recital 3 of Regulation No 1829/2003, genetically modified food and feed should undergo a safety assessment, in order to protect human and animal health, before being placed on the market within the European Union.

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

56 Article 4(1) of Regulation No 1829/2003 lists the conditions which must be cumulatively satisfied in that regard. In particular, the food 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.’

57 Further, Article 16(2) of Regulation No 1829/2003 requires an authorisation in order to place on the market, use or process genetically modified feed. Under Article 16(3) of Regulation No 1829/2003, such authorisation will not be granted unless it is adequately and sufficiently demonstrated that the feed in question satisfies the requirements of Article 16(1) of that regulation.

58 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.'

59 In addition, recital 9 of Regulation No 1829/2003 states that authorisation procedures for genetically modified food and feed must make use of the framework for risk assessment in matters of food safety set up by Regulation No 178/2002 and that genetically modified food and feed should be authorised for placing on the market only after a scientific evaluation, of the highest possible standard, of risks which they present for human and animal health and, as the case may be, for the environment.

60 Following receipt of an opinion from the EFSA, the Commission is to adopt, in accordance with Articles 7 and 19 of Regulation No 1829/2003, a final decision on an application for authorisation. In that context, 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.

The question to what extent authorisation decisions may be the subject of internal review under Article 10 of Regulation No 1367/2006

61 First, as regards whether the authorisation decisions were acts adopted under environmental law within the meaning of Regulation No 1367/2006, it is clear, in the first place, that it follows from the recitals and provisions referred to in paragraphs 53, 54, 56, 58 and 59 above that an authorisation decision, such as those that are the object of the applicant's request for internal review, is an act which falls within the scope of, inter alia, the area of environmental protection. In the second place, the objective of Articles 4, 7, 16 and 19 of Regulation No 1829/2003 is to regulate human interventions that affect the environment by reason of the presence of genetically modified organisms liable to have effects on human and animal health. It is therefore clear that the authorisation decisions constitute, without any possible doubt, acts adopted under environmental law within the meaning of Article 2(1)(f) of Regulation No 1367/2006.

62 Second, as regards whether the arguments submitted by the applicant in its request for internal review fell within the scope of environmental law within the meaning of Regulation No 1367/2006, it follows from the finding made in paragraph 49 above that, in this case, the Commission was indeed required to examine the applicant's request for review only in so far as the applicant had claimed that the authorisation decisions contravened the provisions of environmental law within the meaning of Regulation No 1367/2006.

63 However, it is clear that the scope of the concept of 'environmental law' is not as restricted as claimed by Commission in the contested decision. The mere fact that Regulation No 1829/2003 makes, according to the Commission, a distinction between the safety assessment of the food and feed concerned and the environmental risk assessment, including health risks linked to their presence in the environment, cannot call into question the finding that the complaints made in the request for review which the Commission rejected in the contested decision, on the ground that they did not fall within the scope of environmental law, do in fact fall within the scope of Article 10 of Regulation No 1367/2006.

64 In that regard, the Commission maintains, correctly, that Regulation No 1829/2003 is concerned with public health from a food product safety perspective, but that it also encompasses the possible environmental impacts of genetically modified products for food and feed use. In addition, the Commission accepts that decisions that concern the right to cultivate genetically modified organisms in the Member States are, by definition, liable to have a greater connection with the environment and

that authorisations that concern the right to use genetically modified products imported as food and feed or in food and feed, may also have an impact on the environment, according to how, for example, they are handled or whether they are released into the environment during their handling. However, according to the Commission, the arguments submitted by the applicant on the nutritional value, labelling and safety of genetically modified products, present in food and feed, which the Commission held in the contested decision to be inadmissible, are related to product safety and not to the state of the environment.

65 If the reasoning of the Commission were to be followed, the impact of genetically modified organisms on public health and on animal protection, such as the potential impact on nutritional value, would fall within the scope of environmental law in the event that the cultivation took place within the European Union. Conversely, if the cultivation took place outside the European Union, those effects would not fall within the scope of environmental law. Such a distinction is artificial, and would be liable to deprive Article 10 of Regulation No 1367/2006 of its effectiveness.

66 First, Article 4(1)(a) and Article 16(1)(a) of Regulation No 1829/2003 provide that the food and feed in question must not be placed on the EU market if they have negative effects, including on the environment. In that regard, it must be observed that those provisions are not restricted, according to their wording, exclusively to the protection of the natural environment within the European Union. Consequently, an assessment of risks arising from the possible release of genetically modified organisms into the natural environment within the European Union is only one specific aspect of the environmental risk assessment within the framework of the authorisation procedure under Regulation No 1829/2003.

67 Further, it is plain that, before it is possible to process genetically modified organisms into food or feed, it is necessary to cultivate them. It must be observed that, when being so cultivated, the genetically modified organisms are part, as a general rule, of the natural environment and therefore properly constitute an element of the environment. That finding is, it may be added, also confirmed by Article 2(1)(d)(i) of Regulation No 1367/2006, which defines the expression 'environmental information' within the meaning of that regulation and which includes genetically modified organisms as one of the elements of the environment. Accordingly, given that genetically modified organisms properly constitute an element of the environment, it follows from Article 2(1)(f) of Regulation No 1367/2006 that the provisions whose objective is to regulate the effect on human or animal health of genetically modified organisms also fall within the area of the environment (see paragraph 43 above).

68 Last, it follows from the provisions set out in paragraphs 53, 54, 56, 58 and 59 above that an authorisation decision, such as those that are the object of the applicant's request for internal review, is an act which falls within the area of protection of animal health and welfare. It is, however, clear that the animals which consume feed covered by the authorisation decisions must themselves, in normal or realistic conditions of use of the feed concerned, corresponding to the conditions with respect to which the authorisation decisions were granted (see, by analogy, judgment of 23 November 2016, Commission v *Stichting Greenpeace Nederland and PAN Europe*, C-673/13 P, EU:C:2016:889, paragraph 79), be considered to constitute an element of the environment, since it cannot be ruled out that they will interact with the environment or will form part of the environment. The legislation designed to achieve the protection of those animals, such as Chapters I, III and IV of Regulation No 1829/2003, is therefore entirely within the scope of environmental law, which is the subject of Article 10(1) of Regulation No 1367/2006. Any other conclusion would be possible only if it could in fact be ruled out that an animal nourished with the feed in question would have any contact with the population and with the environment, either through its presence, its secretions and waste, or its remains, by reason of being completely isolated, something the Commission has failed to demonstrate in this case.

69 It follows that environmental law, within the meaning of Regulation No 1367/2006, covers, in this case, any provision of EU legislation, concerning the regulation of genetically modified organisms, that has the objective of dealing with a risk, to human or animal health, that originates in those genetically modified organisms or in environmental factors that may have effects on those organisms when they are cultivated or bred in the natural environment. That finding is no less applicable in situations where the genetically modified organisms have not been cultivated within the European Union.

70 In this case, in the contested decision, the Commission explains that the complaints submitted in the request for review, set out in paragraph 14 above, refer to the health effects of the consumption of genetically modified organisms. Therefore, according to the Commission, those complaints could not be examined within the framework of Article 10 of Regulation No 1367/2006. More specifically, the Commission maintains, in the first place, that the authorisation decisions permit the importation of the soybeans at issue for use in food and in feed, but exclude their being used for cultivation. According to the Commission, a distinction should be made between the safety assessment, which relates to, inter alia, toxicity, allergenicity and nutrition, and the environmental risk assessment. In the second place, the Commission explains that the arguments submitted by the applicant in the request for review on the absence of EFSA guidance concerning the safety and nutritional assessment of genetically modified crops is related to the impact on health of the consumption of genetically modified food and feed. The Commission adds that the nutritional assessment is one of the 'areas of risks' that is taken into consideration when assessing the impact on health of the consumption of genetically modified food and feed, but is not part of the environmental risk assessment related to potential release into the environment. Further, the Commission considers that the labelling of the food at issue concerns the characteristics of that food as delivered to final consumers for consumption and that that labelling has no connection with the environmental risk assessment. Last, the Commission maintains that the other three arguments of the applicant, namely the absence of post-market monitoring, the failure to examine herbicide residues in the food and feed in question and the relevance of a study on the unintended effects on human or animal health of the consumption of plants affected by ribonucleic acid interference, have no connection with the environmental risk assessment. Consequently, those arguments cannot be examined within the framework of Article 10 of Regulation No 1367/2006 (see paragraph 17 above).

71 As regard the considerations set out in the contested decision to the effect that, first, the applicant's arguments on the lack of EFSA guidance with respect to the safety and health impacts of genetically modified crops with significantly altered nutritional content related to the health impact of the consumption genetically modified food and feed and, second, the nutritional assessment was not part of the environmental risk assessment with respect to potential release into the environment, it is clear that the authorisation decisions implemented provisions of Regulation No 1829/2003 which contributed to the pursuit of, inter alia, the objective of protecting human and animal health within the European Union and that the identified risk to human or animal health, namely possible alterations of nutritional content, originated in the genetically modified organisms at issue. In accordance with the finding in paragraph 69 above, it follows that the complaints which the Commission rejected by means of the abovementioned arguments fall wholly within the scope of the area of environmental law within the meaning of Regulation No 1367/2006.

72 As regards the argument, made in the contested decision, that the applicant's complaints concerning the failure to consider herbicide residues in the food and feed in question and on the relevance of a study concerning human or animal health have no connection with the environmental risk assessment, it is clear that those complaints allege an infringement of the provisions of Regulation No 1829/2003, the objective of which is the protection of human and animal health within the European Union against risks that originate in the genetically modified organisms concerned. In accordance with the finding made in paragraph 69 above, it follows that the complaints which the Commission rejected by means of those arguments also fall within the area of environmental law within the meaning of Regulation No 1367/2006.

73 As regards the assertions, in the contested decision, that the arguments made in the request for review concerning labelling have no connection with the environmental risk assessment, it is clear that, in accordance with recitals 20 and 22 of Regulation No 1829/2003, the objective of the labelling requirements for genetically modified feed is to provide final users, in particular livestock farmers, with accurate information on the composition and properties of feed, thereby enabling the user to make an informed choice. Accordingly, the labelling should give information about any characteristic or property which renders a food or feed different from its conventional counterpart with respect to composition, nutritional value or nutritional effects, intended use of the food or feed and health implications for certain sections of the population. It follows that, in this case, the appropriate labelling of genetically modified food and feed constitutes an ancillary factor that is essential to the proper application of the results of the assessment with respect to, inter alia, human and animal health. It was therefore for the Commission to examine, pursuant to Article 10 of Regulation No 1367/2006, the applicant's complaint as to labelling in relation to the composition of the food and feed concerned.

74 Concerning the declaration made by the Commission, in the contested decision, that the alleged lack of post-market monitoring has no connection with the environmental risk assessment, suffice it to recall that the first sentence of recital 35 of Regulation No 1829/2003 explains that it is necessary to introduce, where appropriate and on the basis of the conclusions of the risk assessment, post-market monitoring requirements for the use of genetically modified foods for human consumption and for the use of genetically modified feed for animal consumption. It must also be held that one of the aims of a monitoring plan is to ensure that no risk to human or animal health derived from the food and feed concerned materialises after their placing on the market has been authorised or that any detrimental effects that arise remain limited. The post-market monitoring of authorised products is therefore a measure that complements market authorisation.

75 In that regard, the Commission was correct to state, in the contested decision, that the objective of the post-market monitoring requirements is the collection of data on the consumption of genetically modified food. Further, it must be added that that monitoring also concerns the consumption of feed for animals that are themselves part of the environment.

76 It follows that concerns with respect to human and animal health, expressed in relation to the lack of appropriate monitoring in this case, also fall within the scope of Article 10 of Regulation No 1367/2006.

77 Consequently, the Commission was wrong to conclude, in the contested decision, that the arguments set out in paragraph 70 above could not be examined within the framework of Article 10 of Regulation No 1367/2006. That finding is not called into question by the other arguments submitted by the Commission and by the interveners.

78 First, as regards the Commission's argument that the essential focus of the request for review, with respect to the aspects of that request that the Commission held to be inadmissible, was the safety of the genetically modified organisms at issue for food and feed use, suffice it to state that there is no provision in Regulation No 1367/2006 that the essential focus of a request for review should be a matter falling within the scope of environmental law (see, to that effect and by analogy, judgment of 23 November 2016, *Commission* v *Stichting Greenpeace Nederland and PAN Europe*, C-673/13 P, EU:C:2016:889, paragraphs 77 and 78). As has been held in paragraphs 49 and 62 above, within the framework of an internal review, the Commission is bound to examine any argument whereby the applicant for review has claimed that the administrative act in question contravened provisions of environmental law within the meaning of Regulation No 1367/2006, and there is no need for a matter within the scope of environmental law to constitute the principal legal objective of the argument to be examined.

79 Second, as stated in paragraphs 63 to 69 above, the Court must reject the Commission's argument that the fact that Regulation No 1829/2003 makes a distinction between the safety assessment of the food and feed concerned and the environmental risk assessment is of relevance to the question of whether a request for review falls within the scope of Regulation No 1367/2006.

80 In so far as the Commission relies in this context on the fact that recital 33 of Regulation No 1829/2003 makes a distinction between the environmental risk assessment and the safety assessment, it must be observed that that recital states that, where an application for authorisation under Regulation No 1829/2003 concerns products containing or consisting of genetically modified organisms, the applicant may choose either to supply an authorisation for deliberate release into the environment, already obtained under Part C of Directive 2001/18, or to apply, within the authorisation procedure under Regulation No 1829/2003, for the environmental risk assessment to be carried out at the same time as the safety assessment. It follows from that statement that an assessment of the effects of a deliberate release into the environment may be carried out as part of a procedure based on Directive 2001/18 or, alternatively, within the framework of a procedure under Regulation No 1829/2003. However, while recital 33 of Regulation No 1829/2003 concerns the question, under which conditions may an assessment of the effects of a deliberate release into the environment take place within the framework of a procedure under Regulation No 1829/2003, it has no relevance to the question whether the complaints submitted within a request for internal review under Regulation No 1367/2006 fall within the scope of environmental law for the purposes of the latter regulation.

81 In addition, the Court must also reject the Commission's argument that it follows from Articles 5 and 17 of Regulation No 1829/2003 that, while all products falling within the scope of that regulation must be the object of a safety assessment, only genetically modified organisms or food and feed containing or consisting of genetically modified organisms are subject to an environmental risk assessment, while food and feed produced from genetically modified organisms are not subject to that requirement. It must be recalled that it is necessary that the conditions laid down in Article 4(1) of Regulation No 1829/2003 and in Article 16(1) of that regulation (see paragraphs 56 and 58 above) are satisfied before placing on the market can be authorised. However, it is apparent from the wording of Articles 5 and 17 of Regulation No 1829/2003 that those provisions concern only the procedure for the submission of an application for authorisation and the formal requirements to do so. Those articles therefore do not concern either the conditions for or the extent of the examination of the substance of an application for authorisation.

82 In so far as the Commission contends that, within the framework of Article 2(1)(d)(i) of Regulation No 1367/2006 on the definition of the expression 'environmental information', the reference to genetically modified organisms is made in the context of biological diversity, which, precisely, concerns a situation in which public health issues may be regarded as indicative of the state of certain elements of the environment, it is clear that that provision refers to genetically modified organisms as elements of the environment. That confirms the finding, made in paragraph 67 above, that genetically modified organisms constitute elements of the environment. In any event, even if the Commission's interpretation were confirmed, it must be stated that Article 2(1)(d)(i) of Regulation No 1367/2006 contains only an illustrative list of some typical elements of the environment, but does not preclude genetically modified organisms from constituting elements of the environment.

83 Third, the Commission, supported by Monsanto, argues that public health considerations may be the effect and the consequence of the protection of the environment, but that it is not the purpose of references to public health within provisions relating to the environment to cause the area of public health to be entirely subsumed within the area of environmental law. According to the Commission, the aspects of the request for review at issue are not indicative of or connected to the state of the elements of the environment and therefore do not fall within the scope of Article 10 of Regulation No 1367/2006.

84 In that regard, as was stated in paragraph 43 above, the protection of the health of individuals is one of the objectives of EU policy in the area of the environment (see judgment of 22 December 2010, *Gowan Comércio Internacional e Serviços*, C-77/09, EU:C:2010:803, paragraph 71 and the case-law cited). However, it is clear that, as correctly stated by the Commission, it is not the purpose of Article 10 of Regulation No 1367/2006 to cause the area of public health to be entirely subsumed within the area of environmental law.

85 It is plain, as was stated in paragraphs 49 and 62 above, that the request for internal review is admissible, in this case, only to the extent that it claims that the authorisation decisions contravened provisions of environmental law within the meaning of Regulation No 1367/2006. Article 4(1)(a) and Article 16(1)(a) of Regulation No 1829/2003 provide that the food and feed concerned must not be placed on the market if they cause adverse effects on human health, animal health or the environment. The 305423, MON 87769 and MON 87705 soybeans constituted, when being cultivated, elements modified by human intervention that were in interaction with the natural environment. Accordingly, genetic modifications of those elements of the environment were liable to have consequences for their nutritional value or to represent a risk for food safety and constituted therefore matters within the scope of environmental law within the meaning of Regulation No 1367/2006.

86 In any event, it must be recalled (see paragraph 68 above) that the feed, that is also part of the subject matter of the authorisation decisions, is liable to be consumed by animals that will interact with the environment or will be part of the environment. Consequently, those animals themselves constitute elements of the environment and the effects on their nutritional value as a result of the feed concerned or the fact that they may contravene food safety requirements are therefore matters that fall within the scope of environmental law within the meaning of Regulation No 1367/2006.

87 Fourth, as regards the Commission's argument that the mere fact that the food or feed concerned may have undergone biological or technical processing in their country of origin does not mean that the safety of the products in question has any bearing on the state of the environment, suffice it to recall that environmental law within the meaning of Regulation No 1367/2006, at issue in the present case, is not confined exclusively to the state of the natural environment within the European Union, and that that argument also disregards the fact that the animals which consume the feed concerned are affected by that feed.

88 Fifth, in so far as the Commission relies, in this case, on the relevance of Article 9(3) of the Aarhus Convention, it must be recalled that, in accordance with the case-law, that provision, on which Article 10(1) of Regulation No 1367/2006 is based, cannot be relied on for the purposes of assessing 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).

89 In the light of all the foregoing, it must be concluded that the Commission, in finding that the greater part of the complaints raised by the applicant in its request for internal review did not fall within the scope of environmental law, erred in law. Consequently, the first plea in law must be upheld and the contested decision must be annulled in its entirety, there being no need to examine the applicant's second plea in law.

Costs

90 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. Since the applicant has applied for costs and the Commission has been unsuccessful, the latter must be ordered to bear its own costs and to pay those incurred by the applicant.

91 In accordance with Article 138(3) of the Rules of Procedure, Monsanto and Pioneer are each to bear their own costs.

On those grounds,

THE GENERAL COURT (Seventh Chamber)

hereby:

1. **Annuls the letter of the Commissioner for Health and Food Safety of 16 November 2015, bearing the reference Ares(2015) 5145741, concerning a request for internal review, based on 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, of the implementing decisions authorising the placing on the market of the genetically modified soybeans MON 87769, MON 87705 and 305423.**

2. **Orders the Commission to bear its own costs and to pay those incurred by TestBioTech eV.**

3. **Orders Monsanto Europe, Monsanto Company, Pioneer Overseas Corp. and Pioneer Hi-Bred International, Inc. each to bear their own costs.**

Tomljenović Bieliūnas Kornezov

Delivered in open court in Luxembourg on 14 March 2018.

E. Coulon
Registrar

V. Tomljenović
President