Reports of Cases

JUDGMENT OF THE GENERAL COURT (First Chamber, Extended Composition)

13 December 2013 *

(Approximation of laws — Deliberate release of GMOs into the environment — Marketing authorisation procedure — Scientific opinions of EFSA — Comitology — Regulatory procedure — Infringement of essential procedural requirements — Finding of the Court of its own motion)

In Case T-240/10,

Hungary, represented by M. Fehér and K. Szíjjártó, acting as Agents,

applicant,

supported by

French Republic, represented by G. de Bergues and S. Menez, acting as Agents,

by

Grand Duchy of Luxembourg, represented initially by C. Schiltz, and subsequently by P. Frantzen and finally by L. Delvaux and D. Holderer, acting as Agents,

by

Republic of Austria, represented by C. Pesendorfer and E. Riedl, acting as Agents,

and by

Republic of Poland, represented initially by M. Szpunar, B. Majczyna and J. Sawicka, and subsequently by B. Majczyna and J. Sawicka, acting as Agents,

interveners,

v

European Commission, represented initially by A. Sipos and L. Pignataro-Nolin, and subsequently by A. Sipos and D. Bianchi, acting as Agents,

defendant,

APPLICATION for annulment of Commission Decision 2010/135/EU of 2 March 2010 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a potato product (*Solanum tuberosum L.* line EH92-527-1) genetically modified for

* Language of the case: Hungarian.

enhanced content of the amylopectin component of starch (OJ 2010 L 53, p. 11), and of Commission Decision 2010/136/EU of 2 March 2010 authorising the placing on the market of feed produced from the genetically modified potato EH92-527-1 (BPS-25271-9) and the adventitious or technically unavoidable presence of the potato in food and other feed products under Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ 2010 L 53, p. 15),

THE GENERAL COURT (First Chamber, Extended Composition),

composed of I. Labucka, acting as President of the First Chamber, S. Frimodt Nielsen and M. Kancheva (Rapporteur), Judges,

Registrar: J. Palacio González, Principal Administrator,

having regard to the written procedure and further to the hearing on 18 April 2013,

gives the following

Judgment

Legal context

Scheme for authorising the marketing of genetically modified organisms (GMOs)

1 The scheme for authorising the marketing (the 'marketing authorisation scheme') of genetically modified organisms ('GMOs') in EU law is based on the precautionary principle and, in particular, the principle that those organisms, or the products which contain them, may not be released into the environment or placed on the market unless consent has been given for specific purposes and subject to specified conditions, following a scientific assessment of the risks on a case by case basis.

2 The scheme consists of two principal legislative acts, the first relating to the deliberate release of GMOs into the environment in general and the second relating specifically to genetically modified food and feed.

3 The first legislative act is 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).

4 According to Article 4(2) of Directive 2001/18:

'Any person shall, before submitting a notification under part B [Deliberate release of GMOs for any other purpose than for placing on the market] or C [Placing on the market of GMOs as or in products], carry out an environmental risk assessment. The information which may be necessary to carry out the environmental risk assessment is laid down in Annex III. Member States and the Commission shall ensure that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment, with a view to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment. This phasing out shall take place by the 31 December 2004 in the case of GMOs placed on the market according to part C and by 31 December 2008 in the case of GMOs authorised under part B.'

5 Annex II to Directive 2001/18, as amended, describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to carry out the environmental risk assessment referred to in Article 4 of the directive. It must be read in conjunction with Commission Decision 2002/623/EC of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18 (OJ 2002 L 200, p. 22).

6 The principle underlying the harmonised procedure in Directive 2001/18, in particular Articles 13 to 19 thereof, is that the competent authority of a Member State, having received a notification from a company together with an environmental risk assessment, takes the initiative of issuing consent, in relation to which the competent authorities of the other Member States, or the European Commission, may make their observations or objections known.

7 The first subparagraph of Article 18(1) of Directive 2001/18, entitled 'Community procedure in case of objections', provides:

'In cases where an objection is raised and maintained by a competent authority or the Commission in accordance with Articles 15, 17 and 20, a decision shall be adopted and published within 120 days in accordance with the procedure laid down in Article 30(2). …'

8 Article 30(2) of Directive 2001/18 entitled 'Committee procedure', refers to the procedure provided for under Article 5 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23), (the 'Comitology Decision'), as amended by Council Decision 2006/512/EC, of 17 July 2006 (OJ 2006 L 200, p. 11).

9 The second principal legislative act in the marketing authorisation scheme for GMOs under EU law is 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). That regulation establishes a special single scheme, as opposed to the harmonised general scheme of Directive 2001/18, relating to the authorisation of genetically modified food (Chapter II) and genetically modified feed (Chapter III). Under that single scheme, the application for authorisation is directly assessed at EU level, following consultation with the Member States, and the final decision on the authorisation lies with the Commission, or, where applicable, the Council of the European Union.

10 The Commission and the Council base their decisions on the scientific opinions of the European Food Safety Authority (EFSA), which is governed by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1). That regulation lays down general principles for the assessment of risks in all matters having a direct or indirect impact on the safety of food and feed, including in relation to GMOs. EFSA is competent also to carry out the risk assessments under the Community procedure in the event of objections pursuant to Directive 2001/18.

11 Articles 7(1) and (3), and 19(1) and (3) of Regulation No 1829/2003, whose wording is identical and which are set out respectively in Chapters II and III of that regulation, provide:

'1. Within three months after receiving [EFSA's] opinion, the Commission shall submit to the Committee referred in Article 35 a draft of the decision to be taken in respect of the application, taking into account [EFSA's] opinion, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with [EFSA's] opinion, the Commission shall provide an explanation for the differences.

…

3. A final decision on the application shall be adopted in accordance with the procedure referred to in Article 35(2).'

12 Article 35(2) of Regulation No 1829/2003, entitled 'Committee procedure', like Directive 2001/18 (see paragraph 8 above), refers to the procedure provided for under Article 5 of Decision 1999/468.

Regulatory procedure

13 Article 5 of Decision 1999/468, entitled 'Regulatory procedure', as amended by Decision 2006/512, is worded as follows:

'1. The Commission shall be assisted by a regulatory committee composed of the representatives of the Member States and chaired by the representative of the Commission.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall express its Opinion on this draft within a period specified by the chairman in the light of the urgency of the matter in question. The opinion shall be delivered by the majority laid down in Article 205(2) and (4) of the Treaty, in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall, without prejudice to Article 8, adopt the measures envisaged if they are in accordance with the opinion of the committee.

4. If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal on the measures to be taken and shall inform the European Parliament thereof.

5. If the European Parliament considers that a proposal submitted by the Commission pursuant to a basic instrument adopted in accordance with the procedure laid down in Article 251 of the Treaty exceeds the implementing powers provided for in that basic instrument, it shall inform the Council of its position.

6. The Council may, where appropriate in view of any such position, act by qualified majority on the proposal, within a period to be laid down in each basic instrument but which shall in no case exceed three months from the date of referral to the Council.

If within that period the Council has indicated by qualified majority that it opposes the proposal, the Commission shall re-examine it. It may submit an amended proposal to the Council, re-submit its proposal or present a legislative proposal on the basis of the Treaty.

If the Council has not adopted the proposed implementing measures or has not indicated its opposition to the proposed implementing measures by the expiry of the time limit, they shall be adopted by the Commission.'

14 The regulatory committees competent to take part in the Commission's exercise of the implementing powers conferred upon it pursuant to Directive 2001/18 and Regulation No 1829/2003 are, respectively, the Regulatory Committee on the Release of Genetically Modified Organisms into the Environment, established in Article 30(1) of the directive, and the Standing Committee on the Food Chain and Animal Health, referred to in Article 35(1) of the regulation and established in accordance with Article 58 of Regulation No 178/2002.

Facts

Product covered by the authorisation

15 The genetically modified potato known as 'Amflora' (*Solanum tuberosum L.* line EH92-527-1) is a potato whose starch content has been modified. It is characterised by an increased amylopectin content, so that the starch is composed almost entirely of amylopectin. It differs from a non-genetically modified potato, whose starch consists of about 15-20% amylose and about 80-85% amylopectin. It allows for an optimized extraction of amylopectin for industrial applications, in particular the manufacture of pulp, fibres and adhesives.

16 The genetic modification involves introducing into the genome of the Amflora potato a gene known as 'nptII' (neomycin phosphotransferase II) (the 'nptII gene'). The nptII gene belongs to the category of antibiotic resistant marker genes ('ARM genes'). In genetic modification, the role of marker genes is to mark, in connection with the gene carrying the desired characteristic, the cells where the operation was successful. ARM genes carry out their role through resistance to the antibiotic issued. The nptII gene, in particular, expresses resistance to the antibiotics neomycin, kanamycin and geneticin, which belong to the family of aminoglycosides.

Applications for authorisation

17 On 5 August 1996, the Swedish competent authority received a notification under Directive 90/220, from a subsidiary of BASF Plant Science GmbH ('BASF') called Amylogene HB, which subsequently became known as Plant Science Sweden AB. That notification contained an application for a marketing authorisation for the Amflora potato for cultivation for industrial purposes (starch production) and for the preparation of potato products (potato dough), while mentioning the production of feed and the unintended presence of traces in food.

18 Following the entry into force of Directive 2001/18 on 17 April 2001 and of Regulation No 1829/2003 on 7 November 2003, BASF separated its notification to the Swedish competent authority into two parts, the first concerning the marketing authorisation relating to the Amflora potato's cultivation and use for industrial purposes, and the second concerning the marketing authorisation relating to the production of feed and the unintended presence of traces in food. BASF withdrew the second part of its notification to the authority in order to make the marketing authorisation subject to the single scheme provided for under Regulation No 1829/2003, but maintained the first part of its notification to the authority pursuant to Directive 2001/18. In December 2003, it attached an environmental risk assessment to the first part, in accordance with the rules set out in Annex II of Directive 2001/18.

19 On 8 April 2004, the competent Swedish authority adopted its assessment report and sent it to the Commission. In that assessment report, it stated that use of the product for industrial purposes was safe, but that it was important that the product be kept out of the food chain, as its use as food had not been subject to a full assessment. It concluded that the Amflora potato could be placed on the market on the basis of the conditions specified and in view of the uses envisaged by the notifier.

20 The Commission sent the competent Swedish authority's assessment report to the competent authorities of the other Member States. Several Member States, including Hungary, made observations. In its observations of 3 July 2004, Hungary submitted that the notifier had to, first, implement a quantitative detection method before the marketing authorisation might be granted and, secondly, conduct further research on the use of the Amflora potato in animal feed and its possible harmful effects on human health, given the risks of the food chain being contaminated.

21 On 9 February 2005, the Commission, in accordance with Article 28(1) of Directive 2001/18 and Articles 22 and 29(1) of Regulation No 178/2002, requested a risk assessment from EFSA.

22 At the same time, on 28 February 2005, BASF, in accordance with Articles 5 and 17 of Regulation No 1829/2003, sent an application for authorisation to the competent authority of the United Kingdom in relation to food and feed production. On 25 April 2005, the application was forwarded to the Commission under Article 6(4) and 18(4) of that regulation.

Risk assessments and comitology procedures

23 On 2 April 2004, the EFSA Scientific Panel on GMOs (the 'GMO Panel'), of its own initiative, issued an opinion on the use of ARM genes in genetically modified plants (Question No EFSA-Q-2003-109, *The EFSA Journal* (2004) 48, 1-18) (the '2004 opinion'). In that opinion, EFSA adopted a typology by which to classify ARM genes into three groups, based on various criteria. In particular, group I contained the least dangerous ARM genes, namely, those already widespread in soil and enteric bacteria and conferring resistance to antibiotics that have no therapeutic relevance or only minor therapeutic relevance in human and veterinary medicine. EFSA also, in accordance with the typological classification into three groups, made a classification of known ARM genes, which had important consequences for the authorisation of those genes for experimental purposes (recommended for groups I and II, excluding group III) or for marketing purposes (recommended for group I only, excluding groups II and III). The nptII gene, which, among ARM genes, is the most used in the selection of genetically modified plants, was classified under Group I.

24 On 7 December 2005, the GMO Panel issued two opinions with very similar content. In the first opinion, concerning the placing on the market of the Amflora potato for cultivation and industrial starch production purposes, published on 24 February 2006 (Question No EFSA-Q-2005-023, *The EFSA Journal* (2006) 323, 1-20) (the '2005 opinion'), EFSA concluded, in essence, that the placing on the market of that potato was unlikely to have an adverse effect on human and animal health or the environment in the context of the proposed uses. In the second opinion, concerning the placing on the market of that potato in food and feed, published on 10 November 2006 (Question No EFSA-Q-2005-070, *The EFSA Journal* (2006) 324, 1-20), EFSA also concluded that adverse effects were unlikely in the context of the proposed uses.

25 On 4 December 2006, the Regulatory Committee on the Release of Genetically Modified Organisms into the Environment, in accordance with Article 5(2) of Decision 1999/468, discussed a draft decision submitted by the Commission on the placing on the market, in accordance with Directive 2001/18, of a genetically modified potato (*Solanum tuberosum L.* line EH92-527-1) in order to obtain starch containing an increased amylopectin content. That committee failed to reach a qualified majority for or against the draft measure submitted by the Commission. The votes were divided as follows: 134 votes for, 109 against, 78 abstentions.

26 On 25 January 2007, the Commission asked the European Medicines Agency (EMA) to confirm that, in accordance with the World Health Organization (WHO)'s position on the classification of aminoglycosides (which include neomycin and kanamycin) as antibiotics of critical or high importance, current or potential uses for the future of those antibiotics were consistent with EFSA's 2004 opinion, which had classified them among those having no or only minor therapeutic relevance.

27 On 22 February 2007, the EMA adopted a declaration (the 'EMA declaration of 2007') in which it concluded that neomycin and kanamycin were important as a result of their use in human or veterinary medicine and that their current or potential future uses could not be classified among those with no or minor therapeutic relevance.

28 On 23 March 2007, the GMO Panel, following consultation by the Commission, adopted a declaration (the 'EFSA declaration of 2007') in which it agreed at the outset with the EMA on the importance of preserving the therapeutic potential of aminoglycosides, including neomycin and kanamycin. Next,

relying in particular on the extremely low probability of horizontal transfer of the nptII gene from plants to bacteria, it reiterated its conclusion that the use of the nptII gene in GMOs and GMO products did not present any risks to human or animal health or to the environment.

29 On 13 June 2007, there being no qualified majority in the committee for or against the draft measures submitted by the Commission (see paragraph 25 above), the Commission submitted to the Council a proposal for a Council decision concerning the placing on the market, in accordance with Directive 2001/18, of a genetically modified potato (*Solanum tuberosum L.* line EH92-527-1) in order to obtain starch containing an increased amylopectin content. On 16 July 2007, during the Council meeting, the qualified majority required to adopt or reject the proposal submitted by the Commission could not be reached.

30 On 10 October 2007, the Standing Committee on the Food Chain and Animal Health, in accordance with Article 5(2) of Decision 1999/468, debated a draft marketing authorisation decision submitted by the Commission in relation to the Amflora potato's use in food and feed, pursuant to Regulation 1829/2003. The committee did not manage to reach a qualified majority for or against the draft measure submitted by the Commission. The votes were divided as follows: 123 votes for, 133 against, 89 abstentions. On 18 December 2007, following the committee's failure to reach a qualified majority, the Commission submitted a draft decision on the same issue to the Council.

31 On 13 February 2008, in preparation for the Council's meeting, a non-governmental organisation (NGO) sent a letter to the Commissioner for Health and Food Safety citing inconsistencies affecting the Commission proposal. According to that NGO, the proposal failed to mention, first, that, in its 2004 opinion, EFSA had incorrectly classified the antibiotics affected by the genetically modified potato as unimportant in human and veterinary medicine, while the EMA and the WHO considered them to be of critical importance, and, secondly, that, in its declaration of 2007, EFSA had recognised its error in that respect, but had failed to draw the logical and necessary conclusions regarding the exclusion of the nptII gene in group I and its reclassification in group II or III, in accordance with the classification used in EFSA's 2004 opinion.

32 On 18 February 2008, at the Council's meeting, it proved impossible to reach the qualified majority required to adopt or oppose the proposal submitted by the Commission.

33 On 14 March 2008, the Danish Ministers of Food, Agriculture and Fisheries, on the one hand, and of the Environment, on the other, sent a letter to the Commissioners for Health and the Environment explaining, in essence, that the Danish experts, while agreeing with EFSA that the nptII gene posed no risk, had noted an inconsistency between EFSA's 2004 opinion and the EFSA declaration of 2007 in relation to the classification of the nptII gene according to the criteria of the 2004 opinion, and asking the Commission and EFSA to clarify the point.

34 On 14 May 2008, the Commission, on the basis of Article 29 of Regulation No 178/2002, sent EFSA a 'mandate for a consolidated opinion on the use of antibiotic resistant genes as marker genes in genetically modified plants'. According to that mandate, the Commission intended to 'avoid any doubt' on the issue of the use of ARM genes in genetically modified plants, which use was the subject of two EFSA safety assessments, namely, the 2004 opinion and the declaration of March 2007, following the EMA declaration of 2007. According to the terms of reference of that mandate, the Commission then asked EFSA, first, to prepare a consolidated scientific opinion taking account of the previous opinions and declarations on the use of ARM genes while explaining the reasoning leading to its conclusions and, secondly, to state the possible consequences of the new opinion on EFSA's previous assessments of genetically modified plants containing ARM genes. The Commission expressly required EFSA to work in close collaboration with the EMA and attached, in the annex to the new mandate, the letters from an NGO and from the Danish Government.

35 By application lodged at the Court Registry on 24 July 2008, BASF, Plant Science Sweden AB, Amylogene HB and BASF Plant Science Holding GmbH brought an action against the Commission for failure to act, seeking a declaration that, by failing to adopt a decision in respect of the notification concerning the placing on the market of the genetically modified Amflora potato, the Commission had failed to fulfil its obligations under Article 18(1) of Directive 2001/18 and Article 5 of Decision 1999/468.

36 On 11 and 26 March 2009, respectively, the GMO Panel and the EFSA Scientific Panel on Biological Hazards (the 'Biohaz panel') adopted, in response to the Commission's first request, a joint opinion entitled 'Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants' (Questions No EFSA-Q-2008-411 and EFSA-Q-2008-706, *The EFSA Journal* (2009) 1034, 1-82) (the 'joint opinion of 2009'). EFSA, while recognising that the antibiotics kanamycin and neomycin were of high, even critical, therapeutic importance, relied on, inter alia, the lack of proof of the horizontal transfer of ARM genes of genetically modified plants to the bacteria of the environment. It concluded that, despite the uncertainties relating to, inter alia, sampling, detection, difficulties in evaluating levels of exposure and the difficulties in pinpointing the transferable resistance genes to a specific source, the current state of knowledge indicated that it was unlikely that there would be adverse effects on human health and the environment, as a result of the use of genetically modified plants, from the transfer of the MRA gene nptII from those plants to bacteria.

37 However, two members of the BIOHAZ panel submitted dissenting opinions, mainly concerning scientific uncertainty relating to the probability of horizontal transfer of the nptII gene to bacteria. The authors of those opinions suggested concluding, in essence, that it would be unwise to consider antibiotic resistance as unimportant or of minimal importance or that, overall, it was not possible to assess the adverse effects on human health and the environment of a possible transfer.

38 On 25 March 2009, the GMO Panel adopted, in response to the Commission's second request, an opinion entitled 'Consequences of the opinion on the use of antibiotic resistant genes as marker genes in genetically modified plants on previous EFSA evaluations of individual [genetically modified] plants' (Question No EFSA-Q-2008-04977, *The EFSA Journal* (2009) 1035, p. 1-9) in which it reached the conclusion that no new scientific evidence which was capable of leading it to alter its previous assessments had been found.

39 On 28 April 2009, the Director of EFSA asked the chairmen of the GMO and BIOHAZ panels and the chairman of the joint working group whether the two dissenting opinions required further work of a scientific nature. On 25 May 2009, those chairmen replied that, during the preparation of the joint opinion of 2009, the content of the two dissenting opinions had largely been taken into account, so that, from a scientific point of view, the joint opinion of 2009 did not require further clarification or additional work of a scientific nature.

40 On 11 June 2009, EFSA adopted the consolidated scientific opinion containing the joint opinion of 2009, the opinion of 25 March 2009, the letter of 28 April 2009 and the letter of 25 May 2009 (Questions No EFSA-Q-2009-00589 and EFSA-Q-2009-00593, *The EFSA Journal* (2009) 1108, pp. 1-8) (the 'consolidated opinion of 2009').

41 The Commission did not refer new draft authorisation decisions to the competent regulatory committees following the adoption of the consolidated scientific opinion.

The authorisation decisions

42 On 2 March 2010, the Commission adopted, on the basis of the first subparagraph of Article 18(1) of Directive 2001/18, Commission Decision 2010/135/EU of 2 March 2010 concerning the placing on the market, in accordance with Directive 2001/18, of a potato product (*Solanum tuberosum L.* line

EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch (OJ 2010 L 53, p. 11). This decision authorises, in essence, the marketing of the Amflora potato for cultivation and for the production of starch for industrial purposes.

43 Recitals 11 and 12 in the preamble to Decision 2010/135 are worded as follows:

'(11) On 14 May 2008, the Commission sent a mandate to EFSA, with a request: (i) to prepare a consolidated scientific opinion taking into account the previous opinion and the statement on the use of ARM genes in GM plants intended or already authorised to be placed on the market and their possible uses for import and processing and for cultivation; (ii) to indicate the possible consequences of this consolidated opinion on the previous EFSA assessments on individual GMOs containing ARM genes. The mandate brought to EFSA's attention, inter alia, letters by the Commission from Denmark and [an NGO].

(12) On 11 June 2009, EFSA published a statement on the use of ARM genes in GM plants which concludes that the previous assessment of EFSA on genetically modified potato *Solanum tuberosum L.* line EH92-527-1 is in line with the risk assessment strategy described in the statement, and that no new evidence has become available that would prompt EFSA to change its previous opinion.'

44 Article 1 of Decision 2010/135, entitled 'Consent', provides:

'Without prejudice to other [European Union] legislation, in particular Regulation … No 1829/2003, written consent shall be granted by the competent authority of Sweden to the placing on the market, in accordance with this Decision, of the product identified in Article 2, as notified (Reference C/SE/96/3501) by BASF Plant Science.

The consent shall, in accordance with Article 19(3) of Directive 2001/18/EC, explicitly specify the conditions to which the consent is subject, which are set out in Articles 3 and 4.'

45 Article 2(1) of Decision 2001/135, entitled 'Product', provides:

'The [GMO] to be placed on the market as or in products, hereinafter 'the product', is potato (*Solanum tuberosum L.*) modified for enhanced content of the amylopectin component of starch, which has been transformed with *Agrobacterium tumefaciens*, using the vector pHoxwG, resulting in line EH92-527-1. The product contains the following DNA in two cassettes:

(a) … an nptII-type kanamycin resistance gene originating from Tn5 …;

(b) … a segment of the potato gbss gene encoding for granule bound starch synthase protein …'

46 Article 3 of Decision 2010/135 indicates, in particular, among the conditions for consent, that the period of validity of the consent is 10 years starting from the date the consent is issued and that the consent holder is to ensure that the Amflora potato tubers are physically separated from potatoes for food and feed uses during planting, cultivation, harvest, transport, storage and handling in the environment and are delivered exclusively to designated processing plants, notified to the relevant competent national authority, for processing into industrial starch within a closed system.

47 Article 4 of Decision 2010/135 provides, inter alia, that, throughout the period of validity of the consent, the consent holder is to ensure that a monitoring plan, to monitor for any adverse effects on human and animal health or the environment arising from handling or use of the product, is put in place and implemented; the plan is to include case-specific monitoring, general surveillance and an Identity Preservation System (IPS).

48 Pursuant to Article 5 of Decision 2010/135, that decision is addressed to the Kingdom of Sweden.

49 On 2 March 2010, the Commission also adopted, on the basis of Articles 7(3) and 19(3) of Regulation No 1829/2003, Commission Decision 2010/136/EU of 2 March 2010 authorising the placing on the market of feed produced from the genetically modified potato EH92-527-1 (BPS-25271-9) and the adventitious or technically unavoidable presence of the potato in food and other feed products under [Regulation No 1829/2003] (OJ 2010 L 53, p. 15). That decision authorises, in essence, the placing on the market of animal feed products made from the Amflora potato, and the unintended presence of traces thereof in food or feed.

50 Recitals 7 and 8 of the preamble to Decision 2010/136 are worded in terms identical to those of recitals 11 and 12 of Decision 2010/135, cited in paragraph 43 above.

51 Article 2 of Decision 2010/136, entitled 'Authorisation', provides:

'The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) feed produced from the [Amflora] potato;

(b) foods containing, consisting of, or produced from the [Amflora] potato resulting from the adventitious or technically unavoidable presence of this GMO in a proportion no higher than 0,9% of the food ingredients considered individually or food consisting of a single ingredient;

(c) feed containing or consisting of the [Amflora] potato resulting from the adventitious or technically unavoidable presence of this GMO in a proportion no higher than 0,9% of the feed and of each feed of which it is composed.'

52 Pursuant to Article 6 of Decision 2010/136, the authorisation holder is BASF Plant Science GmbH, Germany.

53 In view of the Commission's adoption of Decisions 2010/135 and 2010/136, on 9 June 2010, the First Chamber of the General Court, with a composition different from that in the present case, dismissed the application relating to the action against the Commission for failure to act (Order of the General Court of 9 June 2010 in Case T-293/08 *BASF Plant Science and Others* v *Commission*, not published in the ECR).

Procedure and forms of order sought

54 By application lodged at the Registry of the General Court on 27 May 2010, Hungary brought the present action.

55 By documents lodged at the Registry of the General Court on 21, 14, 3 and 21 September 2010, respectively, the French Republic, the Grand Duchy of Luxembourg, the Republic of Austria and the Republic of Poland applied for leave to intervene in the present proceedings in support of the form of order sought by Hungary.

56 By order of 8 November 2010, the President of the Seventh Chamber of the General Court granted the applications of the French Republic, the Grand Duchy of Luxembourg, the Republic of Austria and the Republic of Poland.

57 On 24 January 2011, the French Republic, the Grand Duchy of Luxembourg, the Republic of Austria and the Republic of Poland lodged their statements in intervention.

58 On 2 May 2011, the Commission lodged its observations on those statements in intervention.

59 On 24 May 2012, the Registry of the General Court informed the parties that the case had been reassigned to the First Chamber of the Court, following a change in the composition of the chambers.

60 On 7 December 2012, the Registry of the General Court informed the parties of the Court's decision to assign the present case to the First Chamber (Extended Composition) of the General Court. The same day, the Registry of the General Court notified the parties, by way of measures of organisation of procedure provided for under Article 64(3) of the Rules of Procedure of the General Court, of a list of requests for the production of documents and of written questions. The parties complied with those requests and responded to the questions within the time allowed.

61 On 4 March 2013, upon hearing the report of the Judge-Rapporteur, the General Court (First Chamber, Extended Composition) decided to open the oral procedure.

62 At the public hearing on 18 April 2013, the parties submitted argument and answered oral questions from the General Court. In particular, the parties were questioned by the General Court on the conduct of the procedure leading to the adoption of Decisions 2010/135 and 2010/136 (the 'contested decisions') following EFSA's adoption of the consolidated opinion of 2009, and on the Commission's observance of essential procedural requirements during that procedure. On that occasion, the General Court also made an additional request for the Commission to produce documents relating to written submissions made by the Commission to the General Court in the case which gave rise to the order in *BASF Plant Science and Others* v *Commission*, paragraph 53 above. The Commission subsequently complied with that request; the other parties did not submit any observations on the documents produced.

63 Pursuant to Article 32 of the Rules of Procedure, as the President of the Chamber was prevented from attending the deliberations following the expiry of his term of office on 16 September 2013, the most junior Judge within the meaning of Article 6 accordingly abstained from taking part in the deliberations. The General Court's deliberations were continued by the three judges whose signature is affixed to the present judgment, the most senior judge within the meaning of that article acting as President.

64 Hungary, supported by the Grand Duchy of Luxembourg, the Republic of Austria and the Republic of Poland with regard to the principal and alternative claims, and by the French Republic with regard to the alternative claims, claims that the General Court should:

— principally, annul the contested decisions;

— in the alternative, if the claim for annulment of Decision 2010/136/EU is dismissed, annul Article 2(b) and (c) thereof;

— order the Commission to pay the costs.

65 The Commission contends that the General Court should:

— dismiss the action;

— order Hungary to pay the costs.

Law

66 Hungary submits two pleas in law in support of its action.

67 The first plea, raised by way of principal claim, rests on a manifest error of assessment and on an infringement of the precautionary principle and also on breach of Article 4(2) and Annex II to Directive 2001/18, in that the GMO marketing authorisation decisions are based on a risk assessment that is deficient, inconsistent and incomplete.

68 The second plea, raised in the alternative, rests on a breach of Regulation 1829/2003, in particular the requirements of Articles 4(2) and 16(2) of that regulation, by Article 2(b) and (c) of Decision 2010/136, as the latter article establishes a tolerance threshold of 0.9%, which is neither provided for under nor even authorised by the regulation, for the adventitious or technically unavoidable presence of the traces of GMO in food or feed.

69 The Commission disputes Hungary's arguments.

70 It should however, as a preliminary point, be noted that, according to settled case-law, infringement of essential procedural requirements within the meaning of Article 263 TFEU constitutes a ground said to be of 'public policy', which must be raised by the judicature of the European Union of its own motion (see, to that effect, Case C-367/95 P *Commission* v *Sytraval and Brink's France* [1998] ECR I-1719, paragraph 67; Case C-265/97 P *VBA* v *Florimex and Others* [2000] ECR I-2061, paragraph 114; Joined Cases T-228/99 and T-233/99 *Westdeutsche Landesbank Girozentrale and Land Nordrhein-Westfalen* v *Commission* [2003] ECR II-435, paragraph 143 and the case-law cited). The same goes for lack of competence, within the meaning of that article (see, to that effect, Case 19/58 *Germany* v *High Authority* [1960] ECR 225, 233; Case C-210/98 P *Salzgitter* v *Commission* [2000] ECR I-5843, paragraph 56; Case T-147/00 *Laboratoires Servier* v *Commission* [2003] II-85, paragraph 45).

71 In addition, the requirement that the European Union judicature should raise of its own motion a ground involving a question of public policy must be complied with in the light of the rule that the parties should be heard (see, to that effect, Case C-89/08 P *Commission* v *Ireland and Others*, [2009] ECR I-11245, paragraphs 59 and 60).

72 In the present case, the parties were requested, both during the written and oral proceedings, to submit their comments as to whether, on the one hand, the Commission had complied with the essential procedural requirements of the procedure applicable to the adoption of the contested decisions and, on the other, whether the Commission was competent to adopt those decisions. In particular, the Court sent the parties two written questions by way of measures of organisation of procedure which read as follows:

— 'The Commission is asked to clarify why it has not adopted, in accordance with the third subparagraph of Article 5(6) of Decision 1999/468/EC the implementing measures it had suggested to the Council immediately following the Council's failure to reach a qualified majority for the adoption of the two proposals the Commission had submitted to it (see recital 22 of Decision [2010/135] and recital 17 of decision [2010/136]). The Commission is invited to clarify, in that regard, the reasons why it considered it appropriate to consult EFSA once more following the Council's failure to reach a qualified majority, which is, in essence, the subject of the debate in the action for failure to act in Case T-293/08 *BASF Plant Science GmbH and Others* v *Commission*.'

— 'It is not apparent from the file whether, following EFSA's consolidated opinion of 11 June 2009 mentioned in recital 12 of Decision 2010/135/EU and in recital 8 of Decision 2010/136/EU, the Commission (a) again consulted, on the one hand, the committee established by Article 30(1) of Directive 2001/18/EC and, on the other, the committee established by Article 58(1) of Regulation (EC) No 178/2002 (referred to in Article 35(1) of Regulation (EC) No 1829/2003), and (b) submitted amended proposals to the Council incorporating the wording, on the one hand, of recitals 11 and 12 of Decision 2010/135/EU, and on the other, of recitals 7 and 8 of Decision 2010/136/EU. If that is not actually the case, the parties are invited to indicate whether (1) failure to submit an amended proposal to the competent committee and to the Council constitutes a

breach of an essential procedural requirement and (2) whether the Commission, after obtaining new scientific findings from EFSA which it did not submit to the Council, was competent to adopt the contested decisions on 2 March 2010, in the light, in particular, of the provisions of Article 5(6) of Decision 1999/468/EC.'

73 The Commission complied with the Court's request, answering both questions. Hungary did the same in relation to the second question, whereas the interveners made no comment in that regard.

Compliance with the essential procedural requirements of the regulatory procedure

74 The Commission submits that it did not infringe any of the essential procedural requirements during the procedures for the drawing up and adoption of the contested decisions. It submits that, both for Decision 2010/135 and for Decision 2010/136, it followed the regulatory procedure laid down in Article 5 of Decision 1999/468, by submitting the initial draft authorisation decisions to the committees, and where those committees did not deliver an opinion, to the Council. In that regard, the Commission considers that it was not required to resubmit the amended draft authorisation decisions to those committees, because, first, the enacting terms of the initial and amended drafts were identical; secondly, the amended drafts contained no substantive changes; and, thirdly, the Commission was quick to adopt the two authorisation decisions following the Council's failure to take a position on the proposed measures.

75 Hungary disputes the Commission's arguments.

Facts

76 First, it should be noted that the Commission, following the receipt of EFSA's 2005 opinions (see paragraph 24 above), submitted the initial draft authorisation decisions to the competent regulatory committees (see paragraphs 25 and 30 above). As those committees did not deliver an opinion, the Commission submitted the initial draft authorisation decisions to the Council (see paragraphs 29 and 30 above).

77 Secondly, it is important to note that, despite the Council's failure to reach a qualified majority for or against the proposed measures, the Commission did not adopt those measures. Having meanwhile received letters from an NGO and from the Danish Government putting forward certain inconsistencies between the scientific opinions of EFSA on which those measures were based (see paragraphs 31 and 33 above), the Commission decided instead to consult EFSA again by mandate of 14 May 2008 (see paragraph 34 above). On 11 June 2009, EFSA submitted its consolidated opinion, which contained the joint opinion of the GMO and BIOHAZ panels of 11 and 26 March 2009, including the findings relating to the improbability of adverse effects of the nptII gene, coupled with dissenting opinions of two members of the BIOHAZ panel (see paragraphs 36 to 40 above). It is not disputed that the consolidated opinion was not sent to the regulatory committees before which the initial drafts had been brought and that no new draft marketing authorisation decision in relation to the Amflora potato was submitted to those committees.

78 Thirdly, it must be observed that the Commission, on 2 March 2010, adopted the contested decisions (see paragraphs 42 and 49 above). In that regard, it should admittedly be noted that the respective operative parts of those decisions reproduce in their entirety, and without addition, the articles of the drafts and proposals of the authorisation decisions initially submitted to the regulatory committees and to the Council (the 'earlier drafts and proposals'), and that the statements of reasons on which they are respectively based reproduce in their entirety the recitals of the earlier drafts and proposals. However, it must be stated that those decisions are different from the earlier drafts and proposals in that their preambles contain new recitals which refer respectively to the mandate sent by the

Commission to EFSA on 14 May 2008 and to the findings of EFSA's consolidated opinion of 11 June 2009. At issue are recitals 11 and 12 of Decision 2010/135 and recitals 7 and 8 of Decision 2010/136, whose wording is identical (see paragraphs 43 and 50 above) (the 'additional recitals').

79 In the light of this evidence, it is appropriate to examine whether the Commission observed the procedural rules governing the adoption of the contested decisions.

Fulfilment of the obligation to submit the amended drafts of the contested decisions to the competent regulatory committees

80 It is not disputed that the measures put forward by the Commission were to be adopted in accordance with the regulatory procedure, as it is set out in Article 5 of Decision 1999/468. That procedure lays down an obligation, for the Commission, to submit a draft of the measures to the competent regulatory committee. If there is no opinion of the committee adopted by qualified majority, the Commission is required without delay to submit to the Council a proposal on the measures to be taken.

81 It should be noted that the Commission did not submit to the competent regulatory committees, before adopting Decisions 2010/135 and 2010/136, the amended drafts of those decisions, together with the consolidated opinion of 2009 and the dissenting opinions.

82 It must be observed that, whilst the enacting terms of the contested decisions are identical to those of the draft decisions initially submitted to the competent committees and to the Council, that is not the case of the scientific basis relied on by the Commission to adopt those decisions, which is part of the reasoning on which those decisions are based.

83 It must, therefore, be noted that the Commission, in deciding to seek a consolidated opinion from EFSA as a result of the observations of an NGO and of the Danish Government, and in using that opinion in particular as a basis for the contested decisions without allowing the competent committees to take a position either on the opinion or on the statement of reasons on which the amended draft decisions were based, disregarded the regulatory procedure laid down in Article 5 of Decision 1999/468, in particular the second paragraph thereof.

84 In that regard, it must be observed that, according to the case-law, non-compliance with a procedural rule constitutes, inter alia, a breach of essential procedural requirements where, if the rule had not been breached, the outcome of the procedure or the content of the adopted act could have been substantially different (see, to that effect, Case 30/78 *Distillers Company* v *Commission* [1980] ECR 2229, paragraph 26; Joined Cases 209/78 to 215/78 and 218/78 *van Landewyck and Others* v *Commission* [1980] ECR 3125, paragraph 47; and Case 150/84 *Bernardi* v *Parliament* [1986] ECR 1375, paragraph 28).

85 In the present case, the committee votes on the earlier drafts were divided (see paragraphs 25 and 30 above), and the findings of EFSA's consolidated opinion of 2009 expressed more uncertainties than EFSA's earlier opinions, in particular the EFSA declaration of 2007, and were coupled with dissenting opinions (see paragraphs 28, 36 and 37 above). In view of those elements, it was therefore not inconceivable that the members of the committees could amend their position and reach a qualified majority for or against the draft measures. In addition, if the opinion were unfavourable or if no opinion were given, the Commission, pursuant to Article 5(4) of Decision 1999/468, would have been required to submit without delay the proposed measures to the Council, which could formally adopt or reject those measures, by qualified majority, within a period of three months. It was only at the outcome of that procedure, if the Council had failed to obtain a qualified majority, that the Commission was entitled to adopt the draft measures which are in dispute. Consequently, it must be

held that the outcome of the procedure or the content of the contested decisions could have been substantially different if the Commission had followed the procedure laid down in Article 5 of Decision 1999/468.

86 Furthermore, it must be stated that the regulatory procedure governs an implementing power conferred on the Commission by the Council in the basic instrument which the Council draws up, in accordance with the third indent of Article 202 EC. That procedure thus forms part of the institutional balance within the European Union, in particular between the powers of Council and the Parliament, on the one hand, and of the Commission, on the other. The Commission's failure to follow that procedure is capable of affecting the institutional balance of the Union.

87 It must, therefore, be held that the Commission, when it adopted the contested decisions, while omitting to submit the amended drafts of the authorisation decisions to the competent regulatory committees, failed to fulfil its procedural obligations under Article 5 of Decision 1999/468 and the provisions of Directive 2001/18 and of Regulation No 1829/2003 which refer thereto, and, thereby, in relation to each of those decisions, infringed the essential procedural requirements within the meaning of the second paragraph of Article 263 TFEU, which infringement the Court is required to raise of its own motion. Accordingly, those decisions are, in accordance with the first paragraph of Article 264 TFEU, null and void in their entirety.

Whether the contested decision and the earlier drafts are identical, or whether there were any substantive amendments.

88 The above findings cannot be rebutted by the Commission's arguments.

89 First, the Commission submits that the contested decisions are identical to the earlier drafts and proposals, having regard to their identical normative parts. On the other hand, the preambles to those decisions are not part of the 'measures' laid down in those decisions within the meaning of Article 5 of Decision 1999/468.

90 In that regard, it is sufficient to note that the Commission's argument is inadmissible as it runs counter to the settled case-law that the enacting terms of a measure must be read in the light of the grounds which led to its adoption, and with which it is inextricably linked, the measure forming a whole (see, to that effect, Joined Cases 97/86, 99/86, 193/86 and 215/86 *Asteris and Others* v *Commission* [1988] ECR 2181, paragraph 27; Case C-355/95 P *TWD* v *Commission* [1997] ECR I-2549, paragraph 21; Case T-228/97 *Irish Sugar* v *Commission* [1999] ECR II-2969, paragraph 17 and the case-law cited).

91 In addition, contrary to the Commission's related argument that EFSA's scientific opinions, in particular that of 11 June 2009, did not form part of the statement of reasons on which the contested decisions are based, it must be held that the Commission, in relying in its decisions on the opinions of a scientific authority, incorporates the wording of those opinions in the assessment that underlies the adoption of those decisions and in the statement of reasons on which those decisions were based. Thus, inasmuch as, in those decisions, the Commission purports to use as a basis the scientific assessment set out in EFSA's 2005 and 2009 opinions (whilst refraining from mentioning EFSA's 2004 opinion) and refers thereto in certain recitals, the content of those opinions is an integral part of the statement of reasons on which those decisions were based (see, to that effect and by analogy, Case T-326/99 *Fern Olivieri* v *Commission and EMEA* [2003] ECR II-6053, paragraph 55).

92 It must accordingly be held that the addition, in the drafts of the contested decisions, of recitals referring to a new EFSA opinion as a scientific basis, constitutes an amendment that rebuts any claim that those decisions and the earlier drafts and proposals are identical.

93 Secondly, the Commission submits that the addition of additional recitals in the amended drafts did not constitute a substantive amendment; rather, its purpose was simply to consolidate the statement of reasons on which the contested decisions were based by referring to EFSA's consolidated opinion of 2009. That opinion confirms the earlier EFSA opinions, in as much as it also found, in essence, that the nptII gene was safe for use.

94 In that regard, it must be held that, according to the Commission's own words, the new process of consulting EFSA started in May 2008 was 'due in part to the doubts expressed in the letter [from an NGO] of February 2008 and to the letter of the Danish Minister[s] for [Food and] Agriculture and the Environment of March 2008', and to the scientific uncertainty which flowed therefrom. Those doubts related to the inconsistency between the EFSA opinions specific to the Amflora potato and the general EFSA 2004 opinion on the ARM genes read in conjunction with the EMA declaration of 2007 on the therapeutic relevance of the antibiotics to which the nptII gene is resistant.

95 It follows that the purpose of the addition of additional recitals was not simply to consolidate the statement of reasons on which the contested decisions were based, but also, in accordance with the new mandate sent to EFSA by the Commission on 14 May 2008, to clarify certain inconsistencies between the earlier opinions and to reduce the pervading scientific uncertainty, by attempting to respond to the substantive objections expressed in the letters from an NGO and from the Danish Ministers. It must be held that the EFSA response, whether well-founded or not, to such substantive objections is an essential element in the statement of reasons on which those decisions were based, which carries with it an amendment of the substance of the measure and of the decision.

96 In addition, as to the Commission's argument that EFSA's consolidated opinion of 11 June 2009 did no more than confirm the risk assessments emanating from EFSA's earlier opinions (and mentioned in the Commission's earlier drafts and proposals of authorisation decisions at the time they were submitted to the committees and to the Council), it must be held that, in finding also that the nptII gene was safe for use, that opinion constitutes a fresh assessment of the merits, and not merely a purely formal confirmation, in relation to the risk assessments set out in EFSA's 2004 and 2005 opinions and in the EFSA declaration of 2007. That finding is based on both the wording of the new mandate sent to EFSA and on major differences between EFSA's new opinion and earlier opinions.

97 On the one hand, it is apparent from the actual wording of the terms of reference of the new mandate sent by the Commission to EFSA on 14 May 2008, mentioned in recital 11 of Decision 2010/135 and in recital 7 in the preamble to Decision 2010/136, that the new opinion which EFSA had been asked to provide could not be a mere confirmation. First, it was incumbent upon EFSA, while 'taking account' of the previous opinions and declarations, to 'explain the reasons' and 'set out the reasoning' which led to those conclusions. That wording shows that the Commission was seeking a new scientific reasoning from EFSA, which, while taking account of the previous opinion and declarations, was to clarify and complete the statement of reasons on which they were based, even amend their findings. That it was necessary for EFSA to revisit its previous scientific analyses was further confirmed by the subsequent six month extension of the time allowed for the submission of the consolidated opinion, requested by EFSA and granted by the Commission, in relation to the initial mandate. Secondly, it was for EFSA to indicate the possible consequences of this new opinion on its own previous assessments of genetically modified plants containing ARM genes. This clearly shows that the Commission expected EFSA, working in close collaboration with the EMA, to provide a revised scientific analysis, capable of having new consequences for the evaluation of other GMOs. Thirdly, the Commission annexed letters from an NGO and from the Danish Government. This suggests that it was for EFSA to remedy the inconsistencies put forward in those letters.

98 On the other hand, three major differences between EFSA's consolidated opinion of 2009, referred to in recitals 12 in the preamble to Decision 2010/135 and 8 in the preamble to decision 2010/136, and EFSA's earlier opinions must be observed, without its being necessary to rule on whether the risk assessments carried out in each of those opinions were well-founded. In the present case, those

differences relate to the author of the scientific opinions on which the amended and earlier drafts of the authorisation decisions are respectively based, to the content of the findings of those opinions, and to the presence of dissenting opinions in those opinions. First, EFSA's consolidated opinion of 2009 is the work of additional authors, in contrast to the opinions and declarations of 2004, 2005 and 2007 which were issued by the GMO panel only, in that the consolidated opinion of 2009 was also issued by the BIOHAZ panel, and was, according to the Commission's new mandate, drafted in close collaboration with the EMA. Secondly, the findings of EFSA's consolidated opinion of 2009, on which the amended proposals are based, place greater emphasis on scientific uncertainty ('not fully understood', 'limitations', 'uncertainties', 'unlikely') and dangers ('cause for global concern') than the findings of EFSA's 2005 opinion ('no reason to assume', 'would not pose any additional risk', 'no significant risk', 'no adverse environmental effects were observed or would be likely') and the EFSA declaration of 2007 ('will not be compromised', 'extremely low probability', 'very unlikely', 'does not pose a risk'), on which the earlier drafts are based. Thirdly, EFSA's consolidated opinion of 2009 contains dissenting opinions from two members of the BIOHAZ panel emphasising scientific uncertainty, whereas EFSA's 2005 opinion and the EFSA declaration of 2007 did not include any dissenting opinion.

99 In view of those elements, it must be held that the Commission's submission that EFSA's consolidated opinion of 2009 merely confirms EFSA's earlier opinions has no factual basis.

100 Moreover, it must be observed that the argument contradicts the Commission's other submissions, made in its written submissions as part of the present proceedings and in the course of the proceedings in the case having given rise to the order in *BASF Plant Science and Others* v *Commission*, paragraph 53 supra.

101 First, that argument contradicts paragraph 25 of the defence, from which it emerges that EFSA's opinions which predate 2009 were not, by the Commission's own admission, totally clear and devoid of 'ambiguity', and were 'contradictory'. In various paragraphs of its defence and of the rejoinder, the Commission emphasises the 'complete[ness]' of EFSA's consolidated opinion of 2009 and the 'exhaustive' nature of the risk analysis set out in that opinion. The Commission thus suggests that, according to its assessment, EFSA's 2009 opinion did much more than confirm the earlier risk assessments, since such an opinion is, in its eyes, complete and exhaustive, whereas the earlier opinions were ambiguous and contradictory.

102 Secondly, the Commission's submission contradicts its defence in the case giving rise to the order in Case T-293/08 *BASF Plant Science and Others* v *Commission* (paragraph 53 supra), which was added to the file in the present case. The Commission first noted therein 'the very essence' of that case, namely its 'obligations in the presence of information setting out … inconsistencies between scientific opinions'. The Commission then noted that 'EFSA ha[d] not envisaged, in its declaration of 2007, the criterion of therapeutic relevance, [as it did not take into] account either the opinion of the [EMA], or the opinion of the WHO', thus disregarding the criteria used in EFSA's 2004 opinion. The Commission accordingly submitted that 'the whole of the problem [was] to determine whether there [was] any consistency between the reasoning and the grounds which served as a basis for the findings of the 2004 opinion on the one hand, and of the declaration of 2007 on the other'. Finally, the Commission cited its 'duty, having regard to the precautionary principle, to clarify those inconsistencies and ha[d] thus, to that end, consulted [EFSA]', so that no failure could be attributed to it.

103 It is apparent from those assertions that the Commission, at the very least after receiving the letters from an NGO and the Danish Government, considered that the EFSA declaration of 2007, which was inconsistent with EFSA's 2004 opinion read in conjunction with the EMA declaration of 2007, constituted a scientific basis too uncertain for the adoption of the proposed decisions already submitted to the regulatory committees and to the Council and that, having regard to the pervading

scientific uncertainty, it was incumbent upon the Commission, pursuant to the precautionary principle, to consult EFSA once more in order to obtain clarification on the scientific assessment of the risks linked to the Amflora potato, in particular to the nptII gene.

104 Accordingly, the Commission's arguments that the contested decisions and the earlier drafts and proposals are identical, or that there were no substantive amendments to them, must be dismissed as unfounded.

105 In addition, it is appropriate to consider that the facts at issue in the Court's judgment of 13 September 2006 in Joined Cases T-217/99, T-321/00 and T-222/01 *Sinaga* v *Commission* (not published in the ECR, paragraphs 90 to 96), relied on by the Commission for the purpose of asserting that the statement of reasons added to the additional recitals did not contain 'any amendment to the substance of the act' (*Sinaga* v *Commission*, paragraph 95), must be distinguished from the present case. First of all, the case giving rise to the judgment in *Sinaga* v *Commission* concerned the management procedure within the meaning of Article 4 of Decision 1999/468 and not the regulatory procedure within the meaning of Article 5 of that decision. In the context of the management procedure, the Commission adopts measures which are immediately applicable and, where those measures are not in accordance with the committee's opinion, the Commission communicates the measures it has already adopted to the Council, which has three months to adopt another decision. The same is not true in the regulatory procedure, where, if the measures envisaged are not in accordance with the opinion of the committee or, as in the present case, where no opinion is delivered, the Commission is not to adopt any measures, but rather to submit a proposal to the Council. Next, what was at issue in the case giving rise to the judgment in *Sinaga* v *Commission* was the stage of the procedure following the referral to the committee (the management committee for sugar), not the stage following referral to the Council, as in the present case. Finally, in the case giving rise to the judgment in *Sinaga* v *Commission*, the committee had, before the addition of the additional statement of reasons which did not amend the substance of the act, provided a 'positive opinion' and thus 'approved' (judgment in *Sinaga* v *Commission* paragraphs 91 to 95) the measures proposed by the Commission, in contrast to the present case where the committee could not issue a positive opinion.

106 Thirdly, the Commission submits that it did not delay in adopting the two authorisation decisions after the Council failed to take a position on the proposed measures. It submits that it was subject to a deadline for seeking a supplementary scientific opinion and that Article 5(6) of Decision 1999/468, in contrast to Article 5(4) of that decision, does not include the term 'without delay'.

107 In that regard, it should be noted, from the outset, that the defect rendering the contested decisions unlawful is not linked to the time taken in adopting those decisions after the submission to the Council of the initial proposals during the sessions of 16 July 2007 and 18 February 2008, but to the omission to submit the amended drafts of the authorisation decisions to the competent regulatory committees and, where applicable, to the Council.

108 Accordingly, the Commission's argument that there was no delay in adopting the contested decisions must be dismissed as ineffective.

109 In addition, it must be held that the Commission's reference to the Court's judgment of 18 November 1999 in Case C-151/98 P *Pharos* v *Commission* ([1999] ECR I-8157), relied on in support of that argument, is irrelevant in the present case. The case that gave rise to the judgment in *Pharos* v *Commission* related to the stage of the procedure between the referral to the committee and the referral to the Council, during which the Court accepted that the Commission had a certain amount of time in which to seek a new scientific opinion before submitting a proposal to the Council, with a view to finding an early compromise and thus avoiding a subsequent dismissal of the proposal by the Council (judgment in *Pharos* v *Commission*, paragraphs 22 to 27). By contrast, the Commission's

submission in the present dispute concerns the stage of the procedure following the Council's failure to reach a decision, when, pursuant to the third paragraph of Article 5(6) of Decision 1999/468, it is for the Commission to adopt the measures as proposed, but no longer to amend them.

110 Finally, whilst the 'great political sensitivity' and the 'complexity of the subject-matter' of the marketing authorisation of GMOs must be noted, as the Commission has done, the fact remains that such elements argue exactly in favour of the Commission's obligation to submit the amended drafts of the authorisation decisions in relation to the Amflora potato to the competent regulatory committees and, where applicable, to the Council.

111 It follows from those considerations that the Commission's arguments, being either unfounded or ineffective, cannot prevent the Court from raising of its motion and finding an infringement of the essential procedural requirements that renders the contested decisions unlawful. Furthermore, it is appropriate to note that, because, on the one hand, the Commission's competence to adopt those decisions is subject to its compliance with the regulatory procedure and because, on the other, it does not submit the amended drafts of the measures which give rise to those decisions to the regulatory committees, those decisions have not been adopted in accordance with Article 5(3) and (6) of Decision 1999/468. Thus, the Commission's lack of competence for the purposes of adopting the decisions at issue flows from the very breach of the essential procedural requirements noted in paragraph 87 above.

The application for annulment

112 In the light of all the foregoing, and without any need to consider the merits of the pleas put forward by Hungary, the application for annulment set out in the submissions made by way of principal claim must be granted.

113 Consequently, in accordance with the first paragraph of Article 264 TFEU, the contested decisions must be declared void.

Costs

114 Under Article 87(2) 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 Commission has been unsuccessful, it must be ordered to pay the costs, in accordance with the form of order sought by Hungary.

115 The first subparagraph of Article 87(4) of the Rules of Procedure provides that the Member States which intervened in the proceedings are to bear their own costs. The French Republic, the Grand Duchy of Luxembourg, the Republic of Austria and the Republic of Poland shall therefore bear their own costs.

On those grounds,

THE GENERAL COURT (First Chamber, Extended Composition)

hereby:

1. **Annuls Commission Decision 2010/135/EU of 2 March 2010 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a potato product (*Solanum tuberosum L.* line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch, and Commission Decision**

2010/136/EU of 2 March 2010 authorising the placing on the market of feed produced from the genetically modified potato EH92-527-1 (BPS-25271-9) and the adventitious or technically unavoidable presence of the potato in food and other feed products under Regulation (EC) No 1829/2003 of the European Parliament and of the Council;

2. **Orders the European Commission to bear its own costs and to pay the costs incurred by Hungary;**

3. **Orders the French Republic, the Grand Duchy of Luxembourg, the Republic of Austria and the Republic of Poland to bear their own costs.**

Labucka Frimodt Nielsen Kancheva

Delivered in open court in Luxembourg on 13 December 2013.

[Signatures]

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