JUDGMENT OF THE COURT (Grand Chamber)

6 September 2011 (*)

(Genetically modified food for human consumption – Regulation (EC) No 1829/2003 – Articles 2 to 4 and 12 – Directive 2001/18/EC – Article 2 – Directive 2000/13/EC – Article 6 – Regulation (EC) No 178/2002 – Article 2 – Apicultural products – Presence of pollen from genetically modified plants – Consequences – Placing on the market – Definition of 'organism' and 'food for human consumption containing ingredients produced from genetically modified organisms')

In Case C-442/09,

REFERENCE for a preliminary ruling under Article 234 EC from the Bayerischer Verwaltungsgerichtshof (Germany), made by decision of 26 October 2009, received at the Court on 13 November 2009, in the proceedings

Karl Heinz Bablok,

Stefan Egeter,

Josef Stegmeier,

Karlhans Müller,

Barbara Klimesch,

v

Freistaat Bayern,

intervening parties:

Monsanto Technology LLC,

Monsanto Agrar Deutschland GmbH,

Monsanto Europe SA/NV,

THE COURT (Grand Chamber),

composed of V. Skouris, President, A. Tizzano, J.N. Cunha Rodrigues, K. Lenaerts, J.-C. Bonichot and J.-J. Kasel, Presidents of Chambers, G. Arestis, A. Borg Barthet, M. Ilešič, J. Malenovský, L. Bay Larsen (Rapporteur), C. Toader and M. Safjan, Judges,

Advocate General: Y. Bot,

Registrar: B. Fülöp, Administrator,

having regard to the written procedure and further to the hearing on 7 December 2010,

after considering the observations submitted on behalf of:

– Messrs Bablok, Egeter, Stegmeier and Müller and Ms Klimesch, by A. Willand and G. Buchholz, Rechtsanwälte,

– Monsanto Technology LLC, Monsanto Agrar Deutschland GmbH and Monsanto Europe SA/NV, by M. Kaufmann, J. Dietrich and P. Brodbeck, Rechtsanwälte,

– the Greek Government, by I. Chalkias and K. Marinou, acting as Agents,

– the Polish Government, by M. Szpunar, acting as Agent,

– the European Commission, by L. Pignataro-Nolin and B. Schima, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 9 February 2011,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Article 2.5 and 2.10, Article 3(1), Article 4(2)

and Article 12(2) 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).

2 The reference has been made in the context of a dispute between Messrs Bablok, Egeter, Stegmeier and Müller and Ms Klimesch, beekeepers, on the one hand, and Freistaat Bayern (Free State of Bavaria), on the other, with Monsanto Technology LLC, Monsanto Agrar Deutschland GmbH and Monsanto Europe SA/NV ('Monsanto Technology', 'Monsanto Agrar Deutschland' and 'Monsanto Europe' respectively or, together, 'Monsanto') as intervening parties, concerning the presence, in apicultural products, of pollen from genetically modified maize.

Legal context

European Union law

Directive 2001/18/EC

3 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), as amended by Regulation No 1829/2003 and by Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 (OJ 2003 L 268, p. 24) ('Directive 2001/18'), governs, in addition to the deliberate release into the environment of genetically modified organisms ('GMOs'), the placing on the market of GMOs as products or product components, where the planned use of the products implies a deliberate release of organisms into the environment.

4 Recital 4 in the preamble to that directive states:

'Living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers, thereby affecting other Member States. The effects of such releases on the environment may be irreversible.'

5 Recital 5 in the preamble to that directive states that the

protection of human health requires that due attention be given to controlling risks from the deliberate release of GMOs into the environment.

6 Recital 8 in the preamble to the same directive states that the precautionary principle has been taken into account in the drafting of that directive and must be taken into account in its implementation.

7 Article 4(1) of Directive 2001/18 provides that GMOs may be deliberately released or placed on the market only in conformity with part B or part C respectively of that directive, that is to say, principally, after notification of an application to that effect, assessment of the risks to human health and the environment, followed by authorisation from the competent authority.

8 Article 4(3) provides that the assessment is to address the potential adverse effects on human health and the environment which may occur directly or indirectly through gene transfer from GMOs to other organisms.

Regulation No 1829/2003

9 Regulation No 1829/2003 lays down procedures for the authorisation and supervision of genetically modified food and feed, and also the labelling thereof.

10 Recital 1 in the preamble to that regulation 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.

11 Recital 2 in the preamble to Regulation No 1829/2003 states that a high level of protection of human life and health should be ensured in the pursuit of Community policies.

12 Recital 3 states that genetically modified food and feed should therefore undergo a safety assessment through a Community procedure before being placed on the market within the Community.

13 Recital 16 states:

'This Regulation should cover food and feed produced "from" a GMO but not food and feed "with" a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore, are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation.'

14 Article 1 of Regulation No 1829/2003 sets out the objective of ensuring 'a high level of protection of human life and health'.

15 Article 2 of that regulation sets out a list of definitions of relevant concepts for the purposes of application of that regulation, where necessary by reference to the definitions of those concepts given in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ 2000 L 109, p. 29), Directive 2001/18 or 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).

16 That list includes the following definitions:

– 'food' (or 'foodstuff'): any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans (first paragraph of Article 2 of Regulation No 178/2002);

– 'organism': any biological entity capable of replication or of transferring genetic material (Article 2(1) of Directive 2001/18);

– ‘[GMO]’: an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination (Article 2(2) of Directive 2001/18);

– ‘deliberate release’: any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment (Article 2(3) of Directive 2001/18);

– ‘environmental risk assessment’: the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose (Article 2(8) of Directive 2001/18);

– ‘genetically modified food’: food containing, consisting of or produced from GMOs (Article 2.6 of Regulation No 1829/2003);

– ‘produced from GMOs’: derived, in whole or in part, from GMOs, but not containing or consisting of GMOs (Article 2.10 of Regulation No 1829/2003);

– ‘ingredient’: any substance, including additives, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in an altered form (Article 6(4) of Directive 2000/13).

17 Article 3 of Regulation No 1829/2003, entitled ‘Scope’ and contained in Section 1, entitled ‘Authorisation and supervision’, of Chapter II, which is entitled ‘Genetically modified food’, provides in paragraph (1):

‘This Section shall apply to:

(a) GMOs for food use;

(b) food containing or consisting of GMOs;

(c) food produced from or containing ingredients produced

from GMOs.'

18 Article 4(2) of that regulation prohibits the placing on the market of a GMO for food use or food containing or consisting of GMOs, or produced from or containing ingredients produced from GMOs, unless the product in question is covered by an authorisation granted in accordance with that regulation.

19 Article 4(3) provides that authorisation is not to be granted unless it can be demonstrated, in particular, that the GMO or the food does not have adverse effects on human health, animal health or the environment.

20 Article 13 sets out labelling requirements, which, under Article 12(1), apply to foods which:

– contain or consist of GMOs; or

– are produced from or contain ingredients produced from GMOs.

21 However, under Article 12(2), those requirements are not to apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9% of each ingredient, provided that this presence is adventitious or technically unavoidable.

22 Article 47 of Regulation No 1829/2003 provides, by way of a three-year transitional measure, that the presence in food or feed of material which contains, consists of or is produced from GMOs in a proportion no higher than 0.5% is not to be considered to be in breach of Article 4(2), provided, inter alia, that that presence is adventitious or technically unavoidable.

Directive 2001/110/EC

23 Article 1 of Council Directive 2001/110/EC of 20 December 2001 relating to honey (OJ 2002, L 10, p. 47) provides:

'This Directive shall apply to the products defined in Annex I. These products shall meet the requirements set out in Annex II.'

24 Point 1 of Annex I to that directive contains the following

definition:

'Honey is the natural sweet substance produced by *Apis mellifera* bees from the nectar of plants or from secretions of living parts of plants or excretions of plant-sucking insects on the living parts of plants, which the bees collect, transform by combining with specific substances of their own, deposit, dehydrate, store and leave in honeycombs to ripen and mature.'

25 The first to third paragraphs of Annex II to that same directive state:

'Honey consists essentially of different sugars, predominantly fructose and glucose as well as other substances such as organic acids, enzymes and solid particles derived from honey collection. …

When placed on the market as honey or used in any product intended for human consumption, honey shall not have added to it any food ingredient, including food additives, nor shall any other additions be made other than honey. Honey must, as far as possible, be free from organic or inorganic matters foreign to its composition. …

Without prejudice to Annex I, point 2(b)(viii) [defining filtered honey], no pollen or constituent particular to honey may be removed except where this is unavoidable in the removal of foreign inorganic or organic matter.'

National law

26 Paragraph 36a of the Gentechnikgesetz (Law on genetic technology) ('GenTG'), introduced by the Law of 21 December 2004 (BGBl. 2005 I, p. 186), is worded as follows:

'Any transmission of genetically engineered characteristics of an organism or other contamination by genetically modified organisms shall constitute a material interference within the meaning of Paragraph 906 of the Bürgerliches Gesetzbuch [German Civil Code ('BGB')], if, as a result of the transmission or other contamination, products, contrary to the intention of the persons entitled to such, in particular,

1. are not permitted to be placed on the market, or

2. under the provisions of the present or other legislation may be marketed only on condition that the genetic modification is labelled as such …'.

27 Paragraph 906(2) of the BGB, in the version published on 2 January 2002 (BGBl. 2002 I, p. 42), provides:

'The same applies to the extent that a material interference is caused by a use of the other plot of land that is customary in the location and cannot be prevented by measures that are economically reasonable for users of that kind. Where, pursuant to these provisions, an owner is obliged to tolerate a disturbance, he may require from the party in possession of the other plot of land reasonable monetary compensation if the disturbance impairs a use of his plot of land that is customary in the location or if it reduces the income produced from it to a greater degree than he may reasonably be expected to tolerate.'

The dispute in the main proceedings and the questions referred for a preliminary ruling

28 In 1998, pursuant to Commission Decision 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L line MON 810), taken under Council Directive 90/220/EEC (OJ 1998 L 131, p. 32), Monsanto Europe obtained authorisation to place genetically modified MON 810 maize ('MON 810 maize') on the market.

29 The cultivation of MON 810 maize was prohibited in Germany by a decision of 17 April 2009 of the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (German Federal Office for Consumer Protection and Food Safety), which ordered the provisional suspension of the marketing authorisation.

30 Monsanto Technology is the holder of the seed variety registrations effected under the legislation governing seeds. Monsanto Agrar Deutschland is responsible for placing seeds based on the MON 810 strain of maize on the German market.

31 MON 810 maize contains a gene of the soil bacterium *Bacillus thuringiensis* (Bt), which excretes Bt toxins in maize plants.

These toxins help to combat corn borer caterpillars, a variety of butterfly that is a harmful maize parasite and the larvae of which, in the event of infestation, weaken the growth of maize plants. The Bt toxins destroy cells in the digestive tract of the insect larvae, resulting in their death.

32 Freistaat Bayern owns various plots of land on which MON 810 maize has been cultivated for research purposes in recent years. It does not rule out the possibility of resuming cultivation of that crop once the prohibition in force throughout Germany expires.

33 Mr Bablok is an amateur beekeeper. In the vicinity of the plots of land owned by Freistaat Bayern, Mr Bablok produces honey both for sale and for his own personal consumption. Up to 2005, he also produced pollen for sale as a foodstuff in the form of a food supplement. He intends to resume pollen production as soon as the risk of contamination by genetically modified pollen has been removed.

34 Messrs Egeter, Stegmeier and Müller and Ms Klimesch joined in the national proceedings at the appellate stage. They too are amateur beekeepers, in some cases solely for the purpose of their own personal consumption. Their beehives are situated at a distance of between one and three kilometres from the plots of land owned by Freistaat Bayern.

35 Pollen, gathered by bees and stored in certain parts of the beehive for food purposes, may find its way into honey either accidentally, through the action of bees during honey production, or as a result of a technical process, when honeycombs are centrifuged in the harvesting of the honey, which may result in the extraction of the content not only of cells filled with honey, but also of neighbouring cells intended for the storage of pollen.

36 In 2005, MON 810 maize DNA (4.1% as a proportion of the total maize DNA) and transgenic proteins (Bt toxins) were detected in the maize pollen harvested by Mr Bablok in beehives situated 500 metres from the plots of land belonging to Freistaat Bayern.

37 Very small amounts of MON 810 maize DNA, derived from contamination by pollen from that strain of maize, were also

detected in a number of samples of Mr Bablok's honey.

38 As at the date of the order for reference, the presence of MON 810 maize DNA had not been detected in the apicultural products of Messrs Egeter, Stegmeier and Müller or of Ms Klimesch.

39 In the main proceedings, the referring court must rule on an application for a declaration that, as a result of the presence of pollen from MON 810 maize in the apicultural products in question, those products are no longer marketable or fit for consumption and, accordingly, that they have been subjected to a 'material interference' within the meaning of Paragraph 36a of the GenTG and Paragraph 906(2) of the BGB.

40 That application was upheld at first instance by the Bayerisches Verwaltungsgericht Augsburg (Bavarian Administrative Court, Augsburg) by judgment of 30 May 2008. That court held that, due to the contamination through pollen from MON 810 maize, the honey and pollen-based food supplements were foods which required authorisation, with the result that, under Article 4(2) of Regulation No 1829/2003, those products could not be placed on the market without such authorisation.

41 According to the Bayerisches Verwaltungsgericht Augsburg, the honey and pollen-based food supplements produced by Mr Bablok have been subjected to material interference by reason of the presence of pollen from the MON 810 strain of maize.

42 Monsanto Technology, Monsanto Agrar Deutschland and Freistaat Bayern disagreed with that analysis and appealed against that judgment to the Bayerischer Verwaltungsgerichtshof (Bavarian Higher Administrative Court).

43 Before that latter court, they have argued that Regulation No 1829/2003 is not applicable to pollen from the MON 810 strain of maize found in honey or used as a food supplement. The consequences of natural contamination in foods have, they submit, been examined and, accordingly, authorised by Decision 98/294.

44 Moreover, they contend, pollen found in honey or used as a

food supplement is not a GMO for the purposes of Regulation No 1829/2003 because, at the time when it finds its way into honey or is designated for use as a foodstuff, in particular in the form of a food supplement, it no longer possesses any specific and individual capability to reproduce and because the mere presence of transgenic DNA and/or transgenic proteins does not suffice to make it a GMO.

45 If Regulation No 1829/2003 is found to apply, the rules for authorisation contained within it must, they submit, be interpreted restrictively. In the event of adventitious contamination by pollen from the MON 810 strain of maize lawfully present in the environment, authorisation for placing the honey on the market is required only where a threshold of 0.9%, such as that laid down in respect of labelling in Article 12(2) of that regulation, is exceeded.

46 The Bayerischer Verwaltungsgerichtshof points out that the cultivation of the MON 810 strain of maize, which has taken place in the past and may be resumed in future, is lawful, subject to renewal of the marketing authorisation, and that the applicants at first instance must accordingly tolerate it under Paragraph 906(2) of the BGB.

47 In the light of that latter provision, it explains that the question of material interference with the products, which is central to the outcome of the dispute in the main proceedings, turns on the issue whether, in the event of contamination by pollen from the MON 810 strain of maize, those products may no longer, as genetically modified foods, be placed on the market without authorisation as required by Article 4(2) of Regulation No 1829/2003 or whether, at any rate, they may be so placed only on condition that they are labelled as having been genetically modified, as required by Paragraph 36a of the GenTG.

48 The referring court emphasises that the presence of pollen from the MON 810 strain of maize can have such consequences only if the apicultural products containing that pollen come within the scope of Regulation No 1829/2003.

49 It finds that that question turns, first, on whether maize pollen such as that at issue in the main proceedings is an ‘organism’ within the meaning of Article 2.4 of Regulation No 1829/2003

and a ‘GMO’ within the meaning of Article 2.5, those two provisions referring to the definitions of those two terms given by Directive 2001/18.

50 In the view of the referring court, pollen from maize is an ‘organism’, since, notwithstanding its inability to replicate itself, it can, as a male gamete, under natural conditions, transfer genetic material to female gametes.

51 The Bayerischer Verwaltungsgerichtshof nevertheless observes that, as a result of desiccation, maize pollen very rapidly loses its capacity to fertilise a female maize blossom, with the result that it no longer constitutes a functional living organism throughout the honey’s ripening period, from the moment at which the honey in which it is deposited is sealed in the combs. It adds that the same holds true for pollen contained in pollen-based products, once those products are intended for use as food, including in the form of food supplements.

52 accordingly seeks to determine, principally, what consequences follow from the loss by the pollen in question of its ability to reproduce.

53 In that context, the Bayerischer Verwaltungsgerichtshof decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

‘1. Must the term [GMO] defined in Article 2.5 of [Regulation No 1829/2003] be interpreted as meaning that it includes also material from genetically modified plants (in this case, pollen from the genetically modified MON 810 strain of maize) which, although containing genetically modified DNA and genetically modified proteins (in this case, Bt toxin) at the time of entering a food (in this case, honey) or designation for use as a food/food supplement, does not possess (or no longer possesses) a specific and individual capacity to reproduce?

2. If Question 1 is answered in the negative:

(a) Does it suffice, at any rate for foods which, within the meaning of Article 2.10 of [Regulation No 1829/2003], are deemed to be “produced from

GMOs", that the food contains material from genetically modified plants which previously possessed a specific and individual capacity to reproduce?

(b) If that is answered in the affirmative:

Must the term "produced from GMOs" within the meaning of Article 2.10 and Article 3(1)(c) of [Regulation No 1829/2003] be interpreted as meaning that, in relation to GMOs, no deliberate and targeted production process is required and the unintentional and adventitious contamination of food (in this case, honey or pollen as a food supplement) by (former) GMOs is also covered?

3. If either Question 1 or Question 2 is answered in the affirmative:

Must Article 3(1) and Article 4(2) of [Regulation No 1829/2003] be interpreted as meaning that any contamination of food of animal origin, such as honey, through genetically modified material lawfully present in the environment triggers the obligation for such to be authorised and supervised or can thresholds applicable elsewhere (for example, under Article 12(2) of the Regulation) apply *mutatis mutandis*?'

Consideration of the questions referred for a preliminary ruling

The first question

54 By its first question, the referring court asks, in essence, whether the concept of GMO within the meaning of Article 2.5 of Regulation No 1829/2003 must be interpreted as meaning that a substance such as pollen derived from a genetically modified variety of maize is not, or is no longer, a GMO because it has lost all specific and individual capability to reproduce, even though it still contains genetically modified material.

55 The order for reference indicates that, according to one possible interpretation of the concept of GMO, that concept refers only to

an entity which is capable of functioning, that is, a living biological entity. It is therefore not sufficient that dead maize pollen contains transgenic DNA or transgenic proteins. The definitions of organism and GMO given by Directive 2001/18 necessarily imply that the genetic information included is capable of being transferred specifically to a suitable recipient for the purposes of recombination. Recital 4 in the preamble to Directive 2001/18 supports such an analysis. That directive thus seems to endorse conclusively two criteria which go together, namely viability and fertility, and not merely a transfer of DNA which is no longer capable of playing a role in reproduction.

56 The referring court is unsure, however, whether such an interpretation is not contrary to the objective of protection pursued by Regulation No 1829/2003. Exclusion from the scope of that regulation of foodstuffs containing unlimited quantities of genetically modified DNA or genetically modified proteins may be incompatible with that objective. The relevant factor for food safety may therefore lie less in the reproductive ability of the GMO than in the presence of genetically modified material.

57 Article 2.5 of Regulation No 1829/2003 defines a GMO by referring to the definition of that concept given in Article 2(2) of Directive 2001/18, that is, 'an organism … in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'.

58 It is not disputed that the genetic material of the pollen at issue in the main proceedings was modified in conditions covered by the definition of a GMO.

59 The referring court may therefore classify that pollen as a GMO only if that substance still constitutes an 'organism' within the meaning of Article 2.4 of Regulation No 1829/2003, which, by reference to Article 2(1) of Directive 2001/18, defines 'organism' as 'any biological entity capable' either of 'replication' or of 'transferring genetic material'.

60 Since the debate is focused on the second part of that definition, based on ability to replicate or transfer genetic material, and as it is common ground that the pollen at issue in the main proceedings has lost all specific and individual ability to reproduce, it is for the referring court to ascertain whether that

pollen is also capable of 'transferring genetic material', taking due account of the scientific data available and considering all forms of scientifically-established transfer of genetic material.

61 If, at the conclusion of that assessment, the referring court finds that the pollen at issue in the main proceedings is not, or is no longer, capable of transferring genetic material, with the result that it cannot be categorised as an organism and therefore as a GMO within the terms of Regulation No 1829/2003, that will not necessarily mean that that pollen does not come within the scope of that regulation. If, in that case, the pollen does not come within the scope of Article 3(1)(a) and (b) of Regulation No 1829/2003, it may nevertheless come within the scope of Article 3(1)(c) thereof, a possibility which the referring court itself considers in the second question which it has referred.

62 The answer to the first question is therefore that the concept of a GMO within the meaning of Article 2.5 of Regulation No 1829/2003 is to be interpreted as meaning that a substance such as pollen derived from a variety of genetically modified maize, which has lost its ability to reproduce and is totally incapable of transferring the genetic material which it contains, no longer comes within the scope of that concept.

The second question

63 In its second question, the referring court, which seeks clarification as to the scope of Regulation No 1829/2003, refers to Article 2.10 thereof, which defines the term 'produced from GMOs'.

64 As regards food, the parameters of the scope of Regulation No 1829/2003 are set out in Article 3(1) thereof, which covers:

'(a) GMOs for food use;

(b) food containing or consisting of GMOs;

(c) food produced from or containing ingredients produced from GMOs.'

65 The scope of Article 3(1)(a) and (b) depends, in essence, on

the concept of 'GMO'.

66 If, in the dispute in the main proceedings, the referring court finds that the pollen in question is not, or is no longer, capable of transferring genetic material, with the result that it cannot be regarded as a GMO, that dispute will be capable of coming within the scope of Regulation No 1829/2003 only if the conditions laid down in Article 3(1)(c) thereof are satisfied.

67 In circumstances such as those of the dispute in the main proceedings, which concern products 'containing' the disputed pollen, the scope of Article 3(1)(c) of Regulation No 1829/2003 depends on the concept of 'food' as defined in Article 2.1 thereof, by reference to Article 2 of Regulation No 178/2002, and also on the concept of 'ingredient', as defined in Article 2.13 of Regulation No 1829/2003 by reference to Article 6(4) of Directive 2000/13, and that of 'produced from GMOs', as defined in Article 2.10 of Regulation No 1829/2003.

68 By its second question, the referring court is thus asking, in essence, whether:

– Article 2.1, 2.10 and 2.13 and Article 3(1)(c) of Regulation No 1829/2003, Article 2 of Regulation No 178/2002 and Article 6(4)(a) of Directive 2000/13 must be interpreted as meaning that, when a substance such as pollen containing genetically modified DNA and genetically modified proteins is not liable to be considered as a GMO, products such as honey and food supplements containing such a substance constitute 'food … containing ingredients produced from GMOs' within the meaning of Article 3(1)(c) of Regulation No 1829/2003;

– that classification may be made irrespective of whether contamination by the substance in question was intentional or adventitious.

69 Products such as the honey and pollen-based food supplements at issue in the main proceedings are intended to be ingested by humans. They are therefore 'food' within the meaning of Article 2.1 of Regulation No 1829/2003 and Article 2 of Regulation No 178/2002.

70 The pollen at issue in the main proceedings is derived from MON 810 maize, that is to say, from a GMO.

71 That pollen must be regarded as being 'produced from GMOs' within the meaning of Article 2.10 of Regulation No 1829/2003 when it can no longer be classified as a GMO since, in that case, it no longer consists of a GMO and no longer contains a GMO.

72 In order to answer the second question, it is thus necessary to consider principally whether that pollen can be classified as an 'ingredient'.

73 Under Article 2.13 of Regulation No 1829/2003 and Article 6(4)(a) of Directive 2000/13, an ingredient is 'any substance … used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form'.

74 Pollen contained in pollen-based food supplements must be classified as an 'ingredient', since it is introduced into those products in the course of their manufacture or production.

75 As regards pollen contained in honey, it should be observed that, according to the first paragraph of Annex II to Directive 2001/110, honey consists not only of different sugars but also of other substances, including 'solid particles derived from honey collection'.

76 Pollens are solid particles actually derived from honey collection, partly due to bees but mainly due to the centrifugation carried out by the beekeeper. Furthermore, in accordance with the third paragraph of Annex II to Directive 2001/110, 'no pollen … may be removed except where this is unavoidable in the removal of foreign inorganic or organic matter'.

77 Pollen is therefore not a foreign substance or impurity in honey, but rather a normal component of it which, according to the intention of the European Union legislature, cannot in principle be removed from it, even if the frequency with which it is incorporated and the quantities in which it is present in honey are attributable to certain random factors arising during production.

78 In that context, under Article 6(4)(a) of Directive 2000/13, pollen, which comes within the very definition of honey as laid down in Directive 2001/110, must be regarded as a substance which is 'used in the manufacture or preparation of a foodstuff and still present in the finished product'.

79 It must therefore also be classified as an 'ingredient' within the meaning of Article 2.13 of Regulation No 1829/2003 and Article 6(4)(a) of Directive 2000/13.

80 The European Commission submits, by way of rebuttal of such a conclusion, that a distinction must be drawn between the concept of 'ingredient' and that of 'natural component'. In its submission, pollen is a natural component of honey, not an ingredient, with the result that honey containing pollen does not come within the scope of Article 3(1)(c) of Regulation No 1829/2003. That conclusion, it argues, is, moreover, consistent with recital 16 in the preamble to that regulation, from which it must be inferred that foods of animal origin may be considered to be produced from a GMO only if the animal itself has been genetically modified.

81 That distinction as put forward, however, does not take account of the particular conditions under which pollen is incorporated into honey or of the voluntary maintenance of that pollen in the composition of the end product.

82 The interpretation proposed would undermine the objective of protecting human health, since a foodstuff such as honey would escape any safety checks, even though it might contain significant quantities of genetically modified material.

83 It would disregard the determining criterion for the application of Regulation No 1829/2003, as set out in recital 16 in the preamble thereto, namely that as to 'whether or not material derived from the genetically modified source material is present in the food …'.

84 It should be observed in this regard that the analysis put forward by the Commission is not supported by recital 16, which states that food produced not 'from' a GMO but 'with the help of' a genetically modified processing aid is not included in the scope of that regulation.

85 The examples given in that recital of food products obtained from animals fed with genetically modified feed are merely intended to illustrate the category of foods produced 'with' a GMO in which the presence of material produced from materials of genetically modified origin cannot be detected.

86 Those examples cannot therefore serve as a basis for excluding from the scope of Regulation No 1829/2003 a food such as the honey at issue in the main proceedings, which does in fact contain such material.

87 Lastly, Monsanto's suggestion, put forward in order also to exclude honey from the scope of that regulation, to the effect that the presence of pollen is not the result of an intentional production process, cannot be accepted.

88 On the contrary, that presence is the very consequence of a conscious and deliberate production process by the beekeeper, who wishes to produce the foodstuff classified as honey by the European Union legislation. Moreover, it results, essentially, from the action of the beekeeper himself, by virtue of the centrifugation operation which he carries out for the purposes of collection.

89 In any event, the intentional introduction, into a foodstuff, of a substance such as the pollen at issue in the main proceedings cannot be made into a condition for application of the authorisation scheme provided for by Regulation No 1829/2003, since the risk to human health which that regulation is intended to prevent is independent of whether the substance in question is introduced intentionally or adventitiously.

90 Furthermore, an interpretation such as that proposed by Monsanto would render meaningless Article 12(2) of Regulation No 1829/2003, which departs from the labelling obligation laid down in Article 13 of that same regulation when the presence of the material concerned does not exceed 0.9% of each ingredient, 'provided that this presence is adventitious or technically unavoidable'.

91 The fact of taking into account the adventitious or technically unavoidable nature of that presence would, of itself, place the foodstuff outside the scope of Regulation No 1829/2003 and

would therefore exempt it from any labelling requirement.

92 The answer to the second question is therefore that:

– Article 2.1, 2.10 and 2.13 and Article 3(1)(c) of Regulation No 1829/2003, Article 2 of Regulation No 178/2002 and Article 6(4)(a) of Directive 2000/13 must be interpreted as meaning that, when a substance such as pollen containing genetically modified DNA and genetically modified proteins is not liable to be considered as a GMO, products such as honey and food supplements containing such a substance constitute 'food … containing ingredients produced from GMOs' within the meaning of Article 3(1)(c) of Regulation No 1829/2003;

– that classification may be made irrespective of whether contamination by the substance in question was intentional or adventitious.

The third question

93 By its third question, the referring court asks, in essence, whether Articles 3(1) and 4(2) of Regulation No 1829/2003 must be interpreted as meaning that, when they imply an obligation of authorisation and supervision of a foodstuff, a tolerance threshold such as that provided for in Article 12(2) of that regulation may be applied by analogy to that obligation.

94 Monsanto and the Polish Government take the view that, in a case where a GMO has been authorised under Directive 2001/18 or, as in the dispute in the main proceedings, under Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ 1990 L 117, p. 15), which was repealed and replaced by Directive 2001/18, the authorisation issued covers adventitious contamination, in other products, through weak traces of genetically modified material, which is merely a consequence of the implementation of that authorisation, a consequence which, in their view, would have been taken into consideration in the assessment of the GMO.

95 Such an analysis cannot be accepted.

96 Directives 90/220 and 2001/18 were adopted successively in order to govern the deliberate release of GMOs into the environment and the placing on the market of GMOs as products, since the objective pursued is to avoid the adverse effects which those GMOs might have on human health and the environment.

97 Regulation No 1829/2003 applies to the specific field of food and feed. As regards food, its first objective, referred to in Article 4(1), is also to avoid adverse effects on human health and the environment.

98 However, Directives 90/220 and 2001/18 were drafted primarily from the angle of the concept of 'deliberate release', which is defined in Article 2(3) of each of those directives as an intentional introduction of a GMO into the environment without specific containment measures designed to limit their 'contact' with 'the general population and the environment'.

99 That approach thus appears to be more general, including with regard to the placing on the market of a GMO as a product. In this respect, the twelfth, thirteenth and fourteenth recitals in the preamble to Directive 90/220 and recitals 25, 28 and 32 in the preamble to Directive 2001/18 link the need to introduce an assessment and authorisation procedure to the situation in which the placing on the market involves a deliberate release into the environment.

100 Although Regulation No 1829/2003 also includes, in particular in Articles 5(5) and 6(4), aspects of environmental risk assessment of food, it is, as regards food, based overwhelmingly on an approach emphasising protection of human health which is linked to the specific fact that that food is, by definition, intended for human consumption. Thus, in accordance with recital 3 in the preamble, in order to protect human health, foods containing, consisting or produced from GMOs must undergo a 'safety' assessment.

101 Regulation No 1829/2003 thus introduces an additional level of control.

102 That regulation would be rendered nugatory if the view were to be taken that an assessment carried out and an authorisation

issued pursuant to Directives 90/220 or 2001/18 covered all subsequent potential risks to human health and the environment.

103 When the conditions set out in Article 3(1) of Regulation No 1829/2003 are fulfilled, the authorisation and supervision obligation exists irrespective of the proportion of genetically modified material contained in the product in question.

104 With regard to that obligation, a tolerance threshold of 0.5% was laid down only in Article 47 of Regulation No 1829/2003. That threshold, however, ceased to be applicable three years after the date of application of that regulation, in accordance with Article 47(5) thereof.

105 With regard to the tolerance threshold of 0.9% per ingredient laid down in Article 12(2) of Regulation No 1829/2003, this relates to the labelling obligation and not to the authorisation and supervision obligation.

106 An application by analogy of that threshold to the latter obligation would deprive Article 12(2) of any utility, as it would exclude the foodstuff in question from the scope of Regulation No 1829/2003.

107 It would, in any event, run counter to the objective of ensuring 'a high level of protection of human life and health' set out in Article 1 of that regulation.

108 The answer to the third question is therefore that Articles 3(1) and 4(2) of Regulation No 1829/2003 must be interpreted as meaning that, when they imply an obligation to authorise and supervise a foodstuff, a tolerance threshold such as that provided for in respect of labelling in Article 12(2) of that regulation may not be applied to that obligation by analogy.

Costs

109 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Grand Chamber) hereby rules:

1. **The concept of a genetically modified organism within the meaning of Article 2.5 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed must be interpreted as meaning that a substance such as pollen derived from a variety of genetically modified maize, which has lost its ability to reproduce and is totally incapable of transferring the genetic material which it contains, no longer comes within the scope of that concept.**

2. **Article 2.1, 2.10 and 2.13 and Article 3(1)(c) of Regulation No 1829/2003, Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, and Article 6(4)(a) of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs must be interpreted as meaning that, when a substance such as pollen containing genetically modified DNA and genetically modified proteins is not liable to be considered as a genetically modified organism, products such as honey and food supplements containing such a substance constitute 'food ... containing ingredients produced from [genetically modified organisms]' within the meaning of Article 3(1)(c) of Regulation No 1829/2003. That classification may be made irrespective of whether contamination by the substance in question was intentional or adventitious.**

3. **Articles 3(1) and 4(2) of Regulation No 1829/2003 must be interpreted as meaning that, when they imply an obligation to authorise and supervise a foodstuff, a tolerance threshold such as that provided for in respect of labelling in Article 12(2)**

of that regulation may not be applied to that obligation by analogy.

[Signatures]