

OPINION OF ADVOCATE GENERAL

YVES BOT

delivered on 9 February 2011¹

1. The Bayerischer Verwaltungsgerichtshof (Bavarian Higher Administrative Court, Germany) refers to this Court a number of questions for a preliminary ruling concerning the interpretation of the provisions of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.²

2. Those questions concern the legal status of food, such as honey and pollen-based food supplements, in which is detected, in very small amounts, the adventitious presence of pollen from genetically modified plants such as MON 810 maize, which is produced by Monsanto and contains genetically modified DNA and genetically modified proteins.

3. The questions seek, in essence, to establish whether such food is subject to the system of rules for the authorisation, labelling and supervision of genetically modified food instituted by Regulation No 1829/2003.

4. The answers to be given by this Court will determine whether or not, in the main proceedings, a right to financial compensation arises for certain beekeepers³ who operate beehives close to plots of land belonging to the Freistaat Bayern on which genetically modified MON 810 maize has in recent years been grown for research purposes.

5. The present case thus invites the Court to consider certain problems that arise from the coexistence of genetically modified crops and neighbouring traditional agricultural crops. In accordance with the principle of subsidiarity, the European Union legislature has chosen, for the moment, to leave it to the Member States to define the rules by which to ensure this coexistence. Such rules may, as is witnessed by the provisions of national law at the heart of the main proceedings, consist of the establishment of a system of liability that is specific to this situation. The implementation of such a system of liability and, in particular, any finding that losses have been sustained by farmers whose crops have been contaminated, may make it necessary to determine whether or not a given product is to be regarded as genetically modified food and, as such, subject to the requirement for authorisation for placing on the market and the supervision and labelling requirements

1 — Original language: French.

2 — OJ 2003 L 268, p. 1.

3 — Messrs Bablok, Egeter, Stegmeier and Müller, and Ms Klimesch ('Mr Bablok and Others').

imposed by Regulation No 1829/2003. That problem of classification is one of the central issues of the present case.

Article 3(1)(c) of that regulation is to be interpreted as meaning that honey containing pollen from a genetically modified plant and food supplements derived from such pollen are foods containing an ingredient produced from GMOs. I shall explain that it is irrelevant in that regard whether the genetically modified plant material incorporated into the food is incorporated intentionally or otherwise.

6. In this Opinion, I shall propose, first of all, that the Court hold that Article 2(1) of 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 organisms⁴ and repealing Council Directive 90/220/EEC⁵ and Article 2.4 of Regulation No 1829/2003 are to be interpreted as meaning that pollen from a genetically modified plant, which, when it is incorporated into honey or is used as a food supplement, is no longer capable of fulfilling its role in the plant reproduction process, is not an ‘organism’ within the meaning of those provisions.

7. I shall go on to suggest that the Court hold that Article 2.10 of Regulation No 1829/2003 is to be interpreted as meaning that it is sufficient, in order for food to be considered as being ‘produced from GMOs’, that it contain material from genetically modified plants. Moreover, I shall express the view that

8. Lastly, I shall propose that the Court hold that Articles 3(1) and 4(2) of Regulation No 1829/2003 are to be interpreted as meaning that the accidental presence in honey of pollen from a strain of maize, such as MON 810 maize, which has been authorised to be placed on the market pursuant to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms,⁶ and of which only certain derived products have been authorised as existing products pursuant to Article 8(1)(a) of the aforementioned regulation, has the consequence that the placing of that honey on the market requires an authorisation issued in accordance with the regulation. I will go on to say that the tolerance thresholds laid down in Articles 12(2) and 47(1) of Regulation No 1829/2003 do not apply by

4 — ‘GMOs’.

5 — OJ 2001 L 106, p. 1.

6 — OJ 1990 L 117, p. 15.

analogy to the requirement for a marketing authorisation arising under Article 4(2) of the regulation.

10. 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.’

I — Legal context

A — *European Union law*

1. Directive 2001/18

9. According to Article 1 thereof, read together, in particular, with recital 28 in the preamble thereto, Directive 2001/18, as amended by Regulation No 1829/2003 and Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003⁷ governs the deliberate release into the environment of GMOs for any other purposes than placing on the market within the European Community, and the placing on the market of GMOs as or in products where the intended use of the product involves the deliberate release of the organisms into the environment.

11. According to recital 5 in the preamble to the directive, ‘[t]he protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of [GMOs]’.

12. Moreover, recital 13 in the preamble to Directive 2001/18 states that ‘[t]he content of [the directive] duly takes into account international experience in this field and international trade commitments and should respect the requirements of the Cartagena Protocol on Biosafety⁸ annexed to the Convention on Biological Diversity’.⁹

13. Article 4(1) of the same directive provides that GMOs may only be deliberately released into the environment or placed on the

7 — OJ 2003 L 268, p. 24 (‘Directive 2001/18’).

8 — The Cartagena Protocol on Biosafety to the Convention on Biological Diversity, concluded in Montreal on 29 January 2000 (‘the Protocol’).

9 — The Convention was opened for signature at the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro on 5 June 1992. It entered into force on 29 December 1993.

market in conformity with part B or part C of the directive respectively, that is to say, principally, following notification of an application for authorisation, assessment of the risks to human health and the environment and authorisation by the competent authority.

14. Article 4(3) of Directive 2001/18 provides that this risk assessment, which must be carried out on a case-by-case basis, must 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.

2. Regulation No 1829/2003

15. Recital 1 in the preamble to Regulation No 1829/2003 states that '[t]he 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.'

16. Recital 2 in the preamble to that regulation states that '[a] high level of protection of human life and health should be ensured in the pursuit of Community policies.'

17. Recital 3 in the preamble to that regulation accordingly states that, '[i]n order to protect human and animal health, food and feed consisting of, containing or produced from [GMOs] (hereinafter referred to as genetically modified food and feed) should undergo a safety assessment through a Community procedure before being placed on the market within the Community'.

18. Recital 9 in the preamble to Regulation No 1829/2003 states that 'genetically modified food and feed should only be authorised for placing on the Community market after a scientific evaluation of the highest possible standard, to be undertaken under the responsibility of the European Food Safety Authority,¹⁰ of any risks which they present for human and animal health and, as the case may be, for the environment'.

19. According to recital 11 in the preamble to the regulation, 'where a GMO used in the production of food and/or feed has been authorised under this Regulation, foods and/or feed containing, consisting of or produced from that GMO will not need an authorisation

¹⁰ — "the Authority".

under this Regulation, but will be subject to the requirements referred to in the authorisation granted in respect of the GMO’.

22. That list includes the following definitions:

20. Recital 16 in the preamble thereto states that the regulation ‘should cover food and feed produced “from” a GMO but not food and feed produced “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’.

21. Article 2 of Regulation No 1829/2003 sets out a list of definitions of relevant terms for the purposes of that regulation’s application, where necessary by reference to the definitions given to those terms 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,¹¹ 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.¹²

— ‘food’: any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans;

— ‘organism’: any biological entity capable of replication or of transferring genetic material;

— ‘[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;

— ‘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;

— ‘environmental risk assessment’: the evaluation of risks to human health and the environment, whether direct or

¹¹ — OJ 2000 L 109, p. 29.

¹² — OJ 2002 L 31, p. 1.

indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose;

(b) food containing or consisting of GMOs;

— ‘genetically modified food’: food containing, consisting of or produced from GMOs;

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

— ‘[GMO] for food use’: a GMO that may be used as food or as a source material for the production of food;

24. Pursuant to Article 4(2) of the regulation:

— ‘produced from GMOs’: derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;

‘No person shall place on the market a GMO for food use or food referred to in Article 3(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied.’

— ‘ingredient’: any substance including additives, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form.

25. Article 4(3) of Regulation No 1829/2003 makes authorisation conditional on it being shown, in particular, that the GMO or the genetically modified food has no adverse effects on human health, animal health or the environment.

23. The scope of Regulation No 1829/2003, in so far as concerns genetically modified food, is fixed in Article 3(1) of that regulation. That provision states that the section entitled ‘Authorisation and supervision’ applies to:

‘(a) GMOs for food use;

26. Under Article 7(5) of the same regulation, authorisations granted in accordance with the procedures referred to in the regulation are to be valid throughout the Community for 10 years and are renewable.

27. In so far as concerns existing products, Article 8 of the regulation provides as follows:

date of application of this Regulation, notify the Commission that the products were placed on the market in the Community before the date of application of this Regulation.

‘1. By way of derogation from Article 4(2), products falling within the scope of this Section which have been lawfully placed on the market in the Community before the date of application of this Regulation may continue to be placed on the market, used and processed provided that the following conditions are met:

(a) in the case of products placed on the market under Directive 90/220/EEC before the entry into force of Regulation (EC) No 258/97 [of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients]¹³ or in accordance with the provisions referred to in Regulation... No 258/97, operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission of the date on which they were first placed on the market in the Community;

(b) in the case of products which have been lawfully placed on the market in the Community but are not covered by point (a), operators responsible for placing on the market the products concerned shall, within six months after the

2. The notification referred to in paragraph 1 shall be accompanied by the particulars mentioned in Article 5(3) and (5), as appropriate, which the Commission shall forward to the Authority and the Member States. The Authority shall forward to the Community reference laboratory the particulars referred to in Article 5(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant.

3. Within one year from the date of application of this Regulation and after verification that all the information required has been submitted and examined, the products concerned shall be entered in the Register....

4. Within nine years from the date on which the products referred to in paragraph 1(a) were first placed on the market, but in no case earlier than three years after the date of application of this Regulation, operators responsible for placing them on the market shall submit an application in accordance with Article 11, which shall apply *mutatis mutandis*.

¹³ — OJ 1997 L 43, p. 1.

Within three years from the date of application of this Regulation, operators responsible for placing on the market products referred to in paragraph 1(b) shall submit an application in accordance with Article 11, which shall apply *mutatis mutandis*.

(b) are produced from or contain ingredients produced from GMOs.

...

2. This Section shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

28. Under Article 9(1) of Regulation No 1829/2003, after an authorisation has been issued in accordance with the regulation, the authorisation-holder and parties concerned must comply with any conditions or restrictions which have been imposed in the authorisation and must in particular make sure that products not covered by the authorisation are not placed on the market as food or feed.

...

29. Article 12 of the regulation, which falls in Section 2 of Chapter II thereof and is entitled 'Labelling', provides as follows:

30. Article 47 of the regulation, entitled 'Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation', provides as follows:

'1. This Section shall apply to foods which are to be delivered as such to the final consumer or mass caterers in the Community and which:

'1. 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% shall not be considered to be in breach of Article 4(2)...., provided that:

(a) contain or consist of GMOs; or

(a) this presence is adventitious or technically unavoidable;

(b) the genetically modified material has benefited from a favourable opinion from the Community Scientific Committee(s) or the Authority before the date of application of this Regulation;

(c) the application for its authorisation has not been rejected in accordance with the relevant Community legislation; and

(d) detection methods are publicly available.

...

5. This Article shall remain applicable for a period of three years after the date of application of this Regulation.’

3. Directive 2001/110/EC

31. Article 1 of Council Directive 2001/110 of 20 December 2001 relating to honey¹⁴ provides:

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

¹⁴ — OJ 2002 L 10, p. 47.

32. Point 1 of Annex I to the 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.’

33. The first to third paragraphs of Annex II to the 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), no pollen or constituent particular to honey may be removed except where this is unavoidable in the removal of foreign inorganic or organic matter.’

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

35. Paragraph 906(2) of the BGB, in the version published on 2 January 2002,¹⁶ provides as follows:

B — *National law*

34. Paragraph 36a of the Law on genetic technology (Gentechnikgesetz) (‘the GenTG’), introduced by the Law of 21 December 2004,¹⁵ is worded as follows:

- ‘(1) Any transmission of genetically engineered characteristics of an organism or other contamination by [GMOs] 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,

‘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.’

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

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

36. In 1998, pursuant to Commission Decision 98/294/EC of 22 April 1998 concerning

¹⁵ — BGBl. 2005 I, p. 186.

¹⁶ — BGBl. 2002 I, p. 42.

the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Council Directive 90/220/EEC,¹⁷ Monsanto obtained authorisation to place genetically modified MON 810 maize¹⁸ on the market.

Verbraucherschutz und Lebensmittelsicherheit (Federal Office for Consumer Protection and Food Safety), which ordered the provisional suspension of the marketing authorisation.

37. A number of products derived from the MON 810 strain were authorised under Regulation No 258/97 and were subsequently notified as existing products, in accordance with Article 8(1)(a) of Regulation No 1829/2003. They were maize flour, maize gluten, maize meal, maize starch, maize glucose and maize oil.

40. Genetically modified MON 810 maize contains a gene of the soil bacterium *Bacillus thuringiensis* (Bt) which causes the formation of Bt toxins in maize plants. Those Bt toxins help to combat corn borer caterpillars, a variety of butterfly that is a maize parasite and whose larvae, in the event of infestation, weaken the growth of maize plants. The Bt toxins destroy cells in the digestive tract of the larvae, resulting in their death.

38. In 2007, Monsanto applied for its authorisations to be renewed. That application is still under consideration. Under Article 11(4) of Regulation No 1829/2003, the duration of an authorisation is extended until such time as a decision is taken.

41. The Freistaat Bayern owns various plots of land on which, in recent years, MON 810 has been cultivated for research purposes. It does not rule out the possibility of resuming cultivation once the prohibition in force throughout the Federal Republic expires.

39. However, the cultivation of MON 810 maize was prohibited in Germany by a decision of 17 April 2009 of the Bundesamt für

42. Mr Bablok is an amateur beekeeper. In the vicinity of the plots of land owned by the Freistaat Bayern, he 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.

¹⁷ — OJ 1998 L 131, p. 32.

¹⁸ — In implementation of Article 1 of that decision and in accordance with Article 13(4) of the directive, the French Minister for Agriculture and Fisheries gave, by order of 3 August 1998, its written consent to the placing of this maize on the market (see the Order of 3 August 1998 giving written consent, pursuant to Article 13(4) of Directive 90/220/EEC of 23 April 1990 and Decisions 98/293/EC and 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. T 25 and MON 810 (JORF, 5 August 1998, p. 11985)).

43. 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 owned by Freistaat Bayern.

44. Pollen harvested by bees for feeding 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.

45. In 2005, MON 810-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 research farm belonging to the Freistaat Bayern.

46. Moreover, 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.

47. 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 Ms Klimesch.

48. In the main proceedings, brought by Mr Bablok and Others against Freistaat Bayern, supported by Monsanto Technology LLC, Monsanto Agrar Deutschland GmbH and Monsanto Europe SA, the referring court must decide, *inter alia*, whether, as a result of the presence of pollen from MON 810 maize, the apicultural products in question have been subject to 'material interference' within the meaning of Paragraph 36a of the GenTG and Paragraph 90600000(2) of the BGB and whether, as a result, they have been rendered unsuitable for marketing or consumption.¹⁹

49. At first instance, the Bayerisches Verwaltungsgericht Augsburg (Bavarian Administrative Court, Augsburg) held, in its judgment of 30 May 2008, that as a result of contamination by MON 810 maize pollen, the honey and pollen-based food supplements were foods which required authorisation, with the result that, under Article 4(2) of Regulation

¹⁹ — Mr Bablok and Others state that they seek an injunction against the Freistaat Bayern requiring it to take all appropriate measures to prevent the contamination of their apicultural products by MON 810 maize pollen and to remedy the resulting inability of the products concerned to be marketed and consumed.

No 1829/2003, they could not be placed on the market without such authorisation.²⁰

use as a foodstuff, in particular in the form of a food supplement, it no longer possesses any specific and individual capacity to reproduce and because the mere presence of transgenic DNA and/or transgenic proteins does not suffice to make it a GMO.

50. Mr Bablok, the Freistaat Bayern, Monsanto Technology LLC and Monsanto Agrar Deutschland GmbH appealed against the judgment of the Bayerisches Verwaltungsgericht Augsburg to the Bayerischer Verwaltungsgerichtshof.

51. Before that court, the Freistaat Bayern, Monsanto Technology LLC and Monsanto Agrar Deutschland GmbH 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, since the effects of low-level, natural contamination of foodstuffs were examined, and thus authorised, when the pollen was authorised for release into the environment pursuant to Directive 2001/18.

52. They further argue that 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

53. According to those same parties, Regulation No 1829/2003 is, in any event, not applicable to honey because it is a foodstuff of animal origin. If, however, the regulation is found to apply, the rules for authorisation contained within it must 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.

54. The Bayerischer Verwaltungsgerichtshof observes 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, pursuant to Paragraph 906(2) of the BGB, Mr Bablok and Others must, in consequence, tolerate it.

55. In the light of that provision, it explains that the question of material interference with the apicultural products, which is central to the outcome of the dispute in the main proceedings turns on the issue whether, in

20 — Mr Bablok and Others state that, on the basis of that ruling, they may only claim damages or an indemnity and that the Bayerisches Verwaltungsgericht Augsburg declined to recognise any right to protection or to have the disturbance brought to an end for the reason that, in this particular case, the interests worthy of protection (namely crop growing for research purposes) took precedence.

the event of contamination by pollen by 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.

56. 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.

57. The Bayerischer Verwaltungsgerichtshof observes that that question turns, first of all, on whether pollen from maize, such as that in issue in the main proceedings is an 'organism' within the meaning of Article 2.4 of that regulation and a 'GMO' within the meaning of Article 2.5 thereof, those two provisions referring to the definitions of those two terms given in Directive 2001/18.

58. In its view, maize pollen 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.

59. The Bayerischer Verwaltungsgerichtshof observes, however, 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 and 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.

60. According to the referring court, a number of factors suggest that the terms organism and GMO imply only a functional entity, that is to say a living biological entity. The fact that the dead maize pollen contains transgenic DNA or transgenic proteins does not suffice. The definitions of 'organism' and 'GMO' given by Directive 2001/18 necessarily imply that the genetic information contained in them may actually be transferred to a corresponding receptor for the purposes of recombination. That analysis is supported by recital 4 in the preamble to the directive. The directive thus seems to regard as decisive two criteria which go together, namely those of viability and fecundity, but not the mere transport of DNA that can no longer replicate itself independently by natural means.

61. The Bayerischer Verwaltungsgerichtshof nevertheless wonders whether such an interpretation may be contrary to the objective of protecting human and animal health pursued by Regulation No 1829/2003, which, according to recitals 1 to 3 and 9 in the preamble thereto, seeks to ensure that only safe and wholesome food and feed of the highest possible standard is placed on the market. To exclude from the scope of that regulation food containing unlimited amounts of genetically modified DNA or proteins might be incompatible with that objective. Therefore, within the framework of that regulation, and more particularly in the context of food safety, the specific reproductive ability of a GMO might be less relevant than the presence of genetically modified material.

62. In those circumstances, the Bayerischer Verwaltungsgerichtshof decided to stay the proceedings and to refer the following questions to the Court of Justice 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?

If that is answered in the affirmative:

(b) 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?

strain of maize finds its way into honey or is used as a food supplement is covered by Regulation No 1829/2003. The third question seeks to determine what the consequences are of including such products within the scope of that regulation.

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

A — Consideration of the first question

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*?

64. By its first question, the Bayerischer Verwaltungsgerichtshof seeks, in essence, to establish whether Article 2(1) of Directive 2001/18/EC and Article 2.4 of Regulation No 1829/2003 must be interpreted as meaning that pollen from a genetically modified plant which, when it is incorporated into honey or is used as a food supplement, is no longer capable of fulfilling its role in the plant reproduction process is an ‘organism’ within the meaning of those provisions.

III — Analysis

63. The first two questions asked by the Bayerischer Verwaltungsgerichtshof seek to establish whether a situation in which pollen from the genetically modified MON 810

65. I would recall that Article 2.4 of Regulation No 1829/2003 refers to the definition of the term ‘organism’ which appears in Directive 2001/18. Article 2(1) of that directive provides that an organism is ‘any biological entity capable of replication or of transferring genetic material’.

66. The express reference in Regulation No 1829/2003 implies that the term ‘organism’ is to have the same meaning in the context of both of the legislative acts.

67. The wording of Article 2(1) of Directive 2001/18 taken alone does not enable a categorical answer to be given to the question asked by the referring court. Having said that, since one of the characteristics that identify a living organism is its ability to replicate or to transfer genetic material, as is its ability to remain alive and to grow, depending on the environment in which it develops, I am already inclined to think, simply from a reading of Article 2(1) of Directive 2001/18, that the Community legislature chose a form of words that would define as an organism only biological entities that are actually able to replicate or to transfer genetic material at the time when the question of their classification as GMOs arises. Since biology may be defined as the science of life and, more especially, as the study of the reproductive cycle of living species, the juxtaposition of the expression ‘biological entity’ and the phrase ‘capable of replication or of transferring genetic material’ might appear somewhat redundant if the term were not meant to designate only active biological entities that are still capable of replication or of transferring their genetic material.

68. Other provisions of Directive 2001/18 encourage me to think that ‘organism’ within the meaning of Article 2(1) refers only to living organisms, that is to say, entities whose vital functions are still in place, first and foremost of which is the reproductive function.

69. To begin with, recital 4 in the preamble to that directive states that ‘*living organisms*,²¹ 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.’ Thus, if Article 2(1) of the directive is read in the light of that recital, it may be inferred that, when it refers to ‘biological entit[ies] capable of replication or of transferring genetic material’, the Community legislature is referring solely to entities which, at the time when they are released into the environment, still have their vital functions and, in particular, are still able to replicate and disseminate their genetic characteristics.

70. Next, it is clear from recital 13 in the preamble to Directive 2001/18 that the ‘content of [that directive] duly takes into account international experience in this field and

²¹ — Emphasis added.

international trade commitments and should respect the requirements of the ... Protocol to the Convention on Biological Diversity’.

refers to the definition of ‘organism’ given to that term in Article 2(1) of Directive 2001/18, which accredits the idea that the definitions of ‘organism’ within the meaning of that provision and of ‘living organism’ within the meaning of Article 3(h) of the Protocol, converge.

71. The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. The scope of the Protocol is expressly restricted to living organisms. Now, it is interesting to note that the definition of what constitutes a ‘living organism’ for the purposes of application of the Protocol, is very close to that given in Article 2(1) of Directive 2001/18. Thus, under Article 3(h) of the Protocol, a living organism is ‘any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids’.

73. I deduce from all those factors that the adjective ‘capable’ which appears both in Article 2(1) of Directive 2001/18 and in Article 3(h) of the Protocol, refers to biological entities that still actually possess the necessary qualities to replicate or to transfer genetic material. In that context, the adjective ‘capable’ should not be interpreted as implying any broader reference to any general, abstract ability to reproduce or to transfer genetic material typical of any given species.

72. I would also point out that Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms,²² whose purpose is to implement within the European Union the procedures contemplated by the Protocol,

74. Mr Bablok and Others do not agree with that conclusion. They take the contrasting view that the decisive factor for defining what constitutes an organism is the general, abstract ability of the organism to replicate. That, they say, is clear from Article 3(h) of the Protocol, which expressly includes sterile organisms within the class of ‘living organisms’. They argue that, if the decisive factor were to be the specific and individual ability to replicate, sterile genetically modified plants (which are incapable of reproduction) would, while still being plants, not be organisms.

22 — OJ 2003 L 287, p. 1.

The notion of ‘organism’ for the purposes of Directive 2001/18 would thus be narrower than the biological notion of organism, which would be contrary to the intention of the Community legislature.

Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms²⁴ and in Article 3(h) of the Protocol shows that the term organism does not include only living organisms.

75. I am not convinced by that argument. It fails to answer the point that, although sterile organisms cannot reproduce sexually, they can, despite all that, replicate their genetic material by non-sexual or vegetative processes. A sterile organism may therefore quite properly be regarded as having a specific and individual ability to transfer genetic material.²³

76. In support of their argument that the definition appearing in Article 2(1) of Directive 2001/18 refers to a general, abstract ability of the organism to replicate, Mr Bablok and Others refer to the case of viruses and viroids. Those micro-organisms are not living. Nor are they able to replicate autonomously. The mention of viruses and viroids in Article 2(a) of Directive 2009/41/EC of the European

77. I shall not try to answer here the question whether viruses and viroids are living beings, for this is a question that excites considerable scientific controversy. In so far as concerns their ability to transfer genetic material, it seems to me that the inclusion of the phrase ‘transferring genetic material’ in the above-mentioned provisions was meant precisely to include within the definition of what constitutes an organism entities such as viruses and viroids, despite the fact that they cannot by themselves actively replicate genetic material. Viruses are non-cellular micro-organisms composed of proteins and nucleic acids (DNA or RNA) containing genetic material that are incapable of autoreplication, but which can insert their genetic material into other cells (animal, vegetable or microbial) where it is replicated by the action of those cells. As regards viroids, they are infectious, pathogenic, vegetable agents containing small uncovered particles of RNA (uncovered by proteins). Viruses, like viroids, use the cells of the host

23 — See, to that effect, Mackenzie, R., and Others, An Explanatory Guide to the Cartagena Protocol on Biosafety, p. 58, paragraph 205. The text may be consulted at the following website: <http://www.unep.org/biosafety/files/IUCN-Guide%20on%20the%20CPB.pdf>.

24 — OJ 2009 L 125, p. 75. In Article 2(a) of the directive, ‘micro-organism’ is defined as ‘any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, and animal and plant cells in culture’.

organism in order to replicate their genetic material.²⁵ That dependency does not, however, mean, for our purposes, that viruses and viroids have no specific and individual capacity to 'transfer genetic material'.

78. In view of the foregoing, I remain unconvinced that the inclusion of sterile organisms, viruses and viroids, within definitions similar to that appearing in Article 2(1) of Directive 2001/18, means that the organisms to which Article 2(1) refers are solely active biological entities that can actually replicate or transfer genetic material.

79. Moreover, those examples to my mind illustrate the significance of the reference to the transfer of genetic material in addition to the mention of replication. The Community legislature meant, as did the States signatory to the international Protocol, by their reference both to replication and to the transfer of genetic material, to cover the various ways of transmitting genetic material, whether it be by replication or by the transfer of genetic material.

80. Mr Bablok and Others, joined on this point by the Greek Government, put forward other arguments in support of the view that Article 2(1) of Directive 2001/18 contains a broader definition of organisms that

goes beyond simple living beings that have a specific ability to reproduce or to transfer genetic material. They submit that both the precautionary principle and the objectives of protecting the environment and health militate in favour of such a construction. The fact that the Community legislature referred not only to replication but also to the transfer of genetic material means, instead, that even organisms that have lost their vital functions fall within the definition. The mainstay of their argument is the notion of the horizontal transfer of genetic material.

81. It is worth mentioning that, while the reality and extent of the phenomenon remain subject to scientific debate, the transfer of genetic material may occur in one of two ways: either vertically, that is to say within a single species, or horizontally, from species to species.

82. Among the suggested cases of genetic material being transferred horizontally is where the genetic material of a genetically modified plant is absorbed by micro-organisms such as bacteria. For example, parts of plants, such as their leaves, might, on decomposing in the soil, leave behind traces of their genetic material which might then be absorbed by bacteria present in that ecosystem. Or there could be the case where the genetic material of a genetically modified plant is incorporated by bacteria present in the digestive system of a

25 — See Mackenzie, R., and Others, p. 57, paragraph 204.

human being. Under certain circumstances, there might even be a recombining of the genetic material within the receptor organism following such transfer, although this too is the subject of scientific debate.

83. According to Mr Bablok and Others, the fact that, notwithstanding the death of a biological organism, there may continue to exist within its residues traces of the genetic material that characterise it, thus preserving the possibility of that genetic material being transferred, implies that the term 'organism' as defined in Article 2(1) of Directive 2001/18 also covers dead organisms. Thus, since the dead pollen found in honey or used as a food supplement has not systematically, after its transformation by, for example, drying, lost its genetic material, which can still therefore be spread to other organisms or micro-organisms, that pollen should still be regarded as an organism within the meaning of that provision. In summary, as long as a given material, even in inactive state, still contains genetic information (DNA or RNA) that is capable of being incorporated by other entities, it should be regarded as an 'organism' within the meaning of that provision.

84. I do not agree with that argument for the following reasons.

85. I would point out, first of all, that the content of the Protocol and of the preparatory and explanatory documents rather substantiates the view that the reference to both replication and to the transfer of genetic material was meant to cover the various ways in which a biologically active entity transmits its genetic material. Given the similarity between the definitions contained in Article 3(h) of the Protocol and in Article 2(1) of Directive 2001/18, I doubt that the reference to the transfer of genetic material could have any broader significance under the latter provision, so as to also include the possibility of the horizontal transfer of genetic material by biologically dead entities.

86. Next, once a biological entity has lost its vital functions, it can no longer actively participate in the transfer of genetic material. It ceases to play any role in its transfer. If its genetic material is released, if it is received by bacteria, that amounts to a purely passive transmission of the genetic material, which is entirely dependent on the environment in which it happens to be. In such a scenario, the biological entity cannot, I consider, be regarded as still 'capable' of transferring genetic material. In other words, the simple presence of DNA in biological material which no longer possess any vital functions and the possible incorporation of that DNA by other organisms is not the same thing, to my mind,

as a biological organism's ability to transfer genetic material within the meaning of Article 2(1) of Directive 2001/18.

a broader concept of organism, the risks associated with the horizontal transfer of genetic material will always undergo assessment. That legitimate concern, however, is not sufficient to bring within the definition of organism all biological entities, living or dead, belonging to a species capable of replication or of transferring genetic material.

87. Furthermore, the line of argument which Mr Bablok and Others develop, and which places emphasis on the continued existence, under certain conditions, of genetic material after the death of a biological entity, tends to treat the organism and its genetic material as one and the same thing, that is to say, in essence, its DNA, since that will always be amenable to incorporation by another organism, so long as it is not destroyed. The two must not be confused. The explanation given in the handbook for the implementation of Directive 90/220 prepared by the Commission²⁶ makes that clear:

'The definition of "organism" covers: micro-organisms, including viruses and viroids; plants and animals; including ova, seeds, pollen, cell cultures and tissue cultures from plants and animals. *This definition does not cover naked r DNA and naked r-plasmids.*'^{27 28}

88. I sympathise with the concern of Mr Bablok and Others, which is to ensure that, with

89. Indeed, if the Community legislature meant, as I think it did, to restrict the meaning of 'organism' under Article 2(1) of Directive 2001/18 to biologically active entities, that does not mean that, when granting authorisation for the release of a GMO, there is no assessment of the risks arising from the horizontal transfer of the genetic material belonging to that organism, either while it is alive or after its death. Proof of that is Commission Decision 2002/623/EC of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC²⁹ (which itself address 'Principles for the environmental risk assessment'). Among the characteristics which may have adverse effects, the Commission expressly identifies the transfer of genetic material, both vertical and horizontal.³⁰ That being so, the interpretation

26 — *Handbook for the implementation of Directive 90/220/EEC on the deliberate release of genetically modified organisms into the environment*, vol. I, May 1992, p. 17.

27 — Emphasis added.

28 — 'English original text.'

29 — OJ 2002 L 200, p. 22.

30 — *Idem*, pp. 28 and 29. The risk arising from the horizontal transfer of genes is thus one of the events to be taken into account in any GMO assessment. That does not, however, mean that it is something that defines a GMO.

which I propose the Court should give to Article 2(1) of Directive 2001/18 undermines neither the precautionary principle nor the objective of protecting the environment and health.

or consisting of GMOs' within the meaning of Article 3(1)(b) of that regulation.³²

90. It follows from all of the foregoing that pollen from MON 810 maize that is no longer viable, and which is thus no longer able to fulfil its function in the replication of that vegetable variety, cannot, in my opinion, be regarded as an 'organism' within the meaning of Article 2(1) of Directive 2001/18 and Article 2.4 of Regulation No 1829/2003. It follows that such pollen does not constitute a GMO within the meaning of Article 2(2) of that directive³¹ or Article 2.5 of that regulation. A situation such as the one which preoccupies the referring court, namely the presence in honey or food supplements of non-viable pollen from a genetically modified plant, is not therefore a case of a 'GMO for food use' within the meaning of Article 3(1)(a) of Regulation No 1829/2003, or of a 'food containing

91. In reaching that conclusion I adopt the same premiss as was suggested by the referring court, namely that pollen present in honey or used as a food supplement is no longer a living biological entity but is, by contrast, inanimate matter, different, for example, from a seed, which might still be able to germinate, even after incorporation within the food cycle. In the ultimate analysis, it is of course for the referring court to establish, on the basis of such scientific studies as may be presented to it, whether the pollen used as mentioned above is no longer a living biological entity.

92. As we shall now go on to see, the answer which I suggest the Court give to the first question does not mean that the presence in food of pollen from a genetically modified plant is a matter which falls outside the scope of Regulation No 1829/2003. Indeed, it is by way of the notion of food produced from a GMO that this type of situation may be

31 — See also, to that effect, recital 3 in the preamble to Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC (OJ 1998 L 159, p. 4), which states that Directive 90/220, which Directive 2001/18 replaced without altering its scope, 'does not cover non-viable products derived from [GMOs]'.

32 — I would also add, as a further argument in support of the view that GMOs are living organisms, that, in its draft recommendation for second reading of the Council common position for adopting a European Parliament and Council regulation on genetically modified food and feed, the European Parliament stated, when referring to the category of food and feed which contains or consists of GMOs, that this means 'living GMOs' (see paragraph (b) of the explanatory statement, p. 34).

caught by the regulation and that an assessment of the risks arising from the horizontal transfer of genetic material for that category of food may be carried out.³³

94. As is clear from recital 3 in the preamble thereto, Regulation No 1829/2003 is founded on the fundamental idea that, in order to protect human and animal health, genetically modified food and feed must undergo a safety assessment through a Community procedure before being placed on the market within the Community.

B — *Consideration of the second question*

93. The second question referred by the referring court falls into two parts. First, that court seeks a ruling from this Court, in essence, on whether Article 2.10 of Regulation No 1829/2003 is to be interpreted as meaning that it is sufficient, in order for food to be considered as being ‘produced from GMOs’ that it contain material from genetically modified plants which previously possessed a specific and individual capacity to reproduce. If that question is answered in the affirmative, the referring court then asks this Court to rule on whether the meaning of food ‘produced from GMOs’ requires that the GMO material is incorporated intentionally into the food or whether the expression also covers the involuntary contamination of food with GMO material.

95. By ‘genetically modified food,’ Article 2.6 of that regulation means ‘food containing, consisting of or produced from GMOs.’

96. The scope of Regulation No 1829/2003 is laid down in Article 3(1) thereof. It covers, firstly, GMOs for food use, secondly, food containing or consisting of GMOs and, thirdly, food produced from or containing ingredients produced from GMOs. The scope of the regulation is thus broad, excluding only food manufactured ‘with the help’ of a GMO.

97. Recital 16 in the preamble to Regulation 1829/2003 clarifies the distinction between food produced ‘from’ a GMO and food produced ‘with’ a GMO. According to that recital, the ‘determining criterion is *whether or not* material derived from the genetically

33 — In the same manner as other undesirable consequences such as allergies.

modified source material *is present*³⁴ in the food'.³⁵ In the light of that criterion, the recital gives as an example of products obtained 'with' a GMO, and thus excluded from the scope of Regulation No 1829/2003, 'products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products'. Indeed, at the present stage of scientific knowledge, it has not been proven that DNA present in genetically modified feed or, more broadly speaking, in material derived from such feed, or indeed in genetically modified medicinal products, can find its way into the meat of animals fed with such feed or treated with such medicine.

98. In view of that decisive criterion, that is to say, the presence in food of material derived from genetically modified source material, I take the view that both honey in which

pollen from MON 810 maize is detected and pollen-based food supplements containing pollen from that same strain of maize must be regarded as foods produced 'from' GMOs.

99. Contrary to the position defended by the Commission, I consider that any distinction between those two types of food or any distinction between what is a natural constituent of honey and what is an ingredient is irrelevant to the question of their classification as foods 'produced from GMOs'.

100. The Commission indeed takes the view that, while food supplements containing pollen derived from a GMO do fall within the scope of Regulation No 1829/2003 as foods produced from GMOs, that is not, however, the case for honey in which traces of pollen from a genetically modified plant are detected. Such pollen, it argues, should be regarded as a natural constituent of honey, not as an ingredient.

101. The Commission's argument leads me to consider the wording of Article 3(1)(c) of Regulation no 1829/2003, which brings within its scope, 'food produced from or containing

³⁴ — Emphasis added.

³⁵ — The explanatory memorandum for the proposal for a regulation of the European Parliament and of the Council on genetically modified food and feed (COM(2001) 425 final) explains that the proposal 'would cover products "produced from a GMO", but not products "produced with a GMO". The former implies that a proportion of the end product, whether it is the food or feed itself or one of its ingredients, has been derived from the original genetically modified material. The latter is produced with the assistance of a [GMO], but no material derived from the [GMO] is present in the end product'. The proposal gives as an example of the latter category cheese produced with a genetically modified enzyme that does not remain in the final product (p. 4).

ingredients produced from GMOs.' That provision thus develops, in so far as concerns food,³⁶ the definition contained in Article 2.10 of the regulation, referring as it does to 'ingredients'.

for honey.' According to the first paragraph of that annex, honey consists not only of different sugars, but also of 'other substances' such as 'solid particles derived from honey collection'.

102. It thus becomes necessary to consider whether pollen present in honey or used as a food supplement may be regarded as an 'ingredient' within the meaning of the definition given to that term in Article 2.13 of Regulation No 1829/2003, by reference to Article 6(4) of Directive 2000/13. According to the latter provision, an 'ingredient' is 'any substance including additives, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form'.

105. According to the explanations furnished by Mr Bablok and Others, pollen, which is an important nutrient for young bees, is collected by bees from flowers with the help of their furry coat. They have on all their legs combs and brushes made of hair, which enable them to gather pollen and roll it into small balls. Inside the beehive, these pollen balls are released and deposited in special storage cells located on one surface of the honeycomb just next to the cells in which honey is stored.

103. While it is easy to show that pollen contained in pollen-based food supplements is indisputably an ingredient, certain explanations are necessary in order to show the same with respect to pollen present in honey.

106. In order to harvest the honey, the beekeeper takes the honeycombs from the beehive and centrifuges them, emptying the cells of their honey by centrifugal force. Inevitably, there will always be some pollen cells on the honeycombs and these too will empty along with the honey cells, thus mixing pollen into the honey.³⁷

104. Annex II to Directive 2001/110 relating to honey sets out the 'composition criteria

36 — By contrast, in the case of genetically modified feed, Article 15(1)(c) of the regulation makes no mention of 'ingredients'.

37 — In so far as concerns pollen intended for food use as a food supplement, Mr Bablok and Others explain that the pollen is obtained by means of 'pollen traps' placed at the entrance to the hives. These are, in essence, a grill through which the honey bees returning to the hive must force their way, leaving behind their pollen sacs which are rubbed off. The pollen balls fall into a receptacle and are then collected, cleaned and dried.

107. It is worth emphasising that, according to the third paragraph of Annex II to Directive 2001/110, '[w]ithout prejudice to Annex I, point 2(b)(viii),³⁸ no pollen or constituent particular to honey may be removed except where this is unavoidable in the removal of foreign inorganic or organic matter'.

108. It may be deduced from that provision that pollen is organic matter inherent in the composition of honey. It is not a foreign body or an impurity, but a normal constituent that may not, in principle, be removed.³⁹ The fact that it is a constituent of honey remains the case irrespective of when it is incorporated or what quantities of it are found in the honey, those factors being dependent upon certain variables during the honey's manufacture and harvesting.

109. If we turn now to the notion of 'ingredient' as it appears from Article 6(4) of Directive 2000/13, it seems relatively straightforward

to see that, at the same time as being a particular constituent of honey, pollen is also a substance 'used in the manufacture or preparation' of honey which is 'still present in the finished product'.

110. The distinction which the Commission draws between 'ingredients' and 'natural constituents', apart from being theoretical in nature, would lead to the presence in honey of pollen from a genetically modified plant being excluded, which goes against the clear intention of the Community legislature as expressed in recital 16 in the preamble to Regulation No 1829/2003, to use as a decisive criterion the fact of whether or not material derived from genetically modified source material is present in the food. Moreover, if I had to agree, as the Commission proposes, that in order to be an 'ingredient' a substance must be incorporated into food by means of human intervention, then clearly the harvesting of honey by centrifuging, which has the effect of mixing the pollen into the honey, is precisely an act of that nature.

38 — That provision concerns the particular case of filtered honey, that is to say, honey obtained by removing foreign inorganic or organic matter in such a way as to result in the significant removal of pollen. Recital 6 in the preamble to Directive 2001/110 states that the consumer must be correctly informed to that effect by means of an appropriate indication on the label.

39 — The presence of pollen in honey makes it possible to identify the honey's botanic origins. Melissopalynology, or the study of pollen presence in honey, is used to identify compositions and detect fakes and is also used in the labelling of certified content honey.

111. It can, in my opinion, also be easily acknowledged that pollen from MON 810 maize present in honey is an ingredient 'produced from GMOs' within the meaning of Article 3(1)(c) of Regulation No 1829/2003. Indeed, as prescribed by the definition given in Article 2.10 of the regulation, the pollen is 'derived' from a GMO and, in the light of the

points made in response to the first question, it cannot be regarded as consisting of or containing a GMO.

112. Lastly, once it is accepted that pollen is an ingredient of honey, and that it is an ingredient produced from a GMO, then the honey in issue in the main proceedings must, in my view, be regarded, for the purposes of Article 3(1)(c) of Regulation No 1829/2003, as a food 'containing' such an ingredient. By virtue of that provision, therefore, the honey undoubtedly falls within the scope of the regulation.

113. It is of little importance in that connection, turning to the second part of the second question referred for a preliminary ruling, whether or not a beekeeper intended to incorporate pollen from a genetically modified plant into his honey.

114. The explanations of how pollen finds its way into honey demonstrate that its incorporation, in random amounts, is not the fruit of any desire of the beekeeper but the result of something that happens during the honey production process.

115. The applicability of Regulation No 1829/2003, which is triggered by the presence (an objective criterion) in food either of a GMO or of material produced from

genetically modified source material, cannot be made conditional upon the subjective criterion of whether or not that presence was intended. Such a criterion would go against the objective of protecting human health pursued by the regulation, since the risk that a genetically modified food can pose to human health is not dependent on whether incorporation of the substance in question is intentional or unintentional.

116. Moreover, as Mr Bablok and Others rightly point out, a narrow interpretation of the expression 'produced from GMOs' that depended on a subjective criterion would have the result of limiting the scope of application of the provisions of Regulation No 1829/2003 relating to the labelling of genetically modified food in a manner contrary to their clear normative content. Indeed, under Article 12(1)(b) of that regulation, food produced from a GMO must be labelled as such. That labelling requirement only ceases to apply where the proportion of the material derived from a GMO is 0.9 % or less, provided that its presence is adventitious or technically unavoidable. The stipulation of that last condition would have no sense if the adventitious or technically unavoidable nature of the presence in food of GMO-derived material meant that the food was no longer 'produced from GMOs' and, as such, was excluded from the scope of Regulation No 1829/2003.

117. I deduce from all the foregoing considerations that Article 2.1 of Regulation No 1829/2003 must be interpreted as meaning that it is sufficient, in order for it to be considered that a food is ‘produced from GMOs’, that it contains material from genetically modified plants. Moreover, Article 3(1)(c) of that regulation must be interpreted as meaning that honey containing pollen from a genetically modified plant, and also food supplements derived from such pollen, are foods containing ingredients produced from GMOs. It is irrelevant, in that connection, whether the genetically modified plant material incorporated into the food is incorporated intentionally or otherwise.

118. Lastly, it is necessary to answer the argument that honey is a product of animal origin and as such does not fall within the scope of Regulation No 1829/2003. The referring court refers, in that regard, to an opinion expressed by the Standing Committee on the Food Chain and Animal Health at a meeting on 23 June 2004 to the effect that honey, being a product of animal origin, does not fall within the scope of the regulation unless it is produced by genetically modified bees. That is not, in my view, a decisive condition.

119. It is clear from point 1 of Annex I to Directive 2001/110 that, while honey is indeed a substance produced by bees, the source material is both vegetable (the nectar of plants and secretions of the living parts of plants) and animal (excretions of plant-sucking insects on plants). Moreover, it has been seen that, according to the first paragraph of Annex II to that directive, ‘honey consists [inter alia] of solid particles derived from honey collection’, and I have already had occasion to say that the decisive criterion which will bring honey within the scope of Regulation No 1829/2003 is whether or not it contains material derived from a genetically modified plant, in this case pollen.⁴⁰

120. Moreover, I do not share the Commission’s view that recital 16 in the preamble to Regulation No 1829/2003 should be read as meaning that all products of animal origin are excluded from its scope. The sole purpose of the examples given in that recital by the Community legislature, such as products obtained from animals fed with genetically modified feed, is to illustrate what falls into the category of food produced ‘with’ a GMO in which no material derived from genetically modified source material may be detected. They

40 — The question could equally be addressed from the point of view of the presence in honey of nectar from a genetically modified plant. That question does not, however, arise in the present case, since MON 810 maize produces no nectar.

cannot, in my opinion, serve to express the desire of the Community legislature to exclude from the scope of Regulation No 1829/2003 products of animal origin which, like honey, may contain material produced from genetically modified source material.

by virtue of Article 3(1)(c) thereof. It must also, in accordance with Article 2.10 of the regulation, be regarded as 'derived, in whole or in part, from GMOs, but not containing or consisting of GMOs'.

121. Having completed my analysis of the first two questions referred for a preliminary ruling, I think it useful to summarise my reading of the subdivisions of Article 3(1) of Regulation No 1829/2003, whose purpose is to define the scope of the regulation.

122. As I stated in the context of my analysis of the first question, only living organisms or, if one prefers, biologically active organisms, can be GMOs. Thus, the categories described in Article 3(1)(a) ('GMOs for food use') and in Article 3(1)(b) ('food containing or consisting of GMOs') of the regulation require the presence of living organisms, that is to say, organisms still able to replicate or transfer genetic material.

124. It is important in this context to emphasise the fact that, in accordance with recital 16 in the preamble to Regulation No 1829/2003, the deciding characteristic which will bring a food within that category is the presence within it of material derived from genetically modified source material. That last expression goes beyond the mere presence of genetic material in the strict sense, which specifically means nucleic acids that contain functional heredity units (DNA). It covers, more broadly, material of vegetable, animal or other origin, which is derived from a GMO and which may or may not still contain genetically modified DNA or genetically modified proteins. The continued presence of genetic material in food is difficult to predict and varies for each type of food, depending on whether or not the process by which the genetically modified source material is transformed results in the destruction of the genetic material.⁴¹

123. As soon as a food contains inanimate or dead fragments derived from a GMO, it falls within the scope of Regulation No 1829/2003

⁴¹ — By way of example, a highly refined product such as oil obtained from genetically modified maize will most likely no longer contain any trace of DNA. However, such a product continues to be governed by Article 3(1)(c) of Regulation No 1829/2003.

125. The division which can thus be made into the three categories of food preserves the utility of the last of those categories. Indeed, if one had to accept that the first and second categories also included GMOs or parts of biologically inactive GMOs, the category 'food produced from or containing ingredients produced from GMOs' would be limited to food in which no DNA could be detected. However, as recital 21 in the preamble to Regulation No 1829/2003 in particular suggests, in relation to labelling, the Community legislature seems not to have wanted account to be taken of whether or not genetically modified DNA or genetically modified protein can be detected in the final product.

126. By departing from the criteria of the presence of DNA or proteins derived from genetic modification in the final product, which formerly applied (as Regulation No 1139/98, for example, bears witness), the Community legislature thus sought to broaden the scope of Regulation No 1829/2003 so as to include, by means of Article 3(1)(c), all products derived from GMOs, irrespective of whether or not DNA or proteins derived from genetic modification are present in the final product.

C — Consideration of the third question

127. In its order for reference, the Bayerischer Verwaltungsgerichtshof poses the question whether the combined provisions of Article 3(1) and 4(2) of Regulation No 1829/2003 may, contrary to their wording, be interpreted restrictively as meaning that the requirement for a marketing authorisation does not apply to foodstuffs such as honey which contain very small amounts, hardly above the threshold of detection, of material from genetically modified plants, in this case, pollen from the genetically modified MON 810 strain of maize.

128. It states that the principle of proportionality, as expressed in recital 24 in the preamble to the regulation in relation to labelling, may justify a restrictive interpretation of the authorisation provisions of the regulation. It observes that contamination, at very low levels, through transgenic maize pollen only arises inadvertently and is in practice unavoidable where genetically modified maize is planted across a large area.

129. The referring court also states that since, when authorisation to be placed on the market was granted pursuant to Directive 90/220, the MON 810 strain of maize underwent a risk assessment that took into account all potentially adverse effects on the environment, it might be compatible with the protective purpose of the regulation to allow the placing on the market of honey containing MON 810

pollen below a certain threshold to fall outside the prohibition of Article 4(2) of Regulation (EC) No 1829/2003. In addition, various foodstuffs produced from MON 810 maize or containing ingredients produced from MON 810 maize, such as maize flour and maize gluten, have already been granted Community authorisation.

before it is placed on the market. The referring court asks this Court to state whether it is possible, in connection with the requirement for marketing authorisation arising under Article 4(2) of the regulation, to apply, by analogy, the tolerance thresholds laid down in Articles 12(2) and 47(1) thereof.

130. The Bayerischer Verwaltungsgesichtshof nevertheless acknowledges that the wording and general structure of Regulation No 1829/2003, as well as the objective of protecting health pursued by that regulation, might preclude such a restrictive interpretation of the authorisation requirement laid down in Article 4(2) therein.

132. In order to answer that question, which concerns the particular case of honey containing pollen from MON 810 maize,⁴² it is necessary first of all to ascertain the legal status of that plant variety and its food derivatives in the light of the Community rules both on the voluntary release of GMOs into the environment and on genetically modified food.

131. In short, by its third question, the referring court seeks, in essence, a ruling from the Court as to whether or not Articles 3(1) and 4(2) of Regulation No 1829/2003 must be interpreted as meaning that the adventitious presence in honey of pollen from a variety of maize such as MON 810 maize, which has been authorised for placing on the market pursuant to Directive 90/220 and of which only certain derived products have been authorised as existing products pursuant to Article 8(1)(a) of Regulation No 1829/2003, means that that honey must be authorised

133. In so far as concerns the deliberate release of GMOs into the environment, that is to say, principally, the cultivation of GMOs, MON 810 maize was the subject of Decision 98/294/EC, adopted on the basis of Directive 90/220, which, it should be remembered, was repealed and replaced by Directive 2001/18.

⁴² — However, the points which follow apply equally to pollen-based food supplements.

134. In so far as concerns foodstuffs, a number of products derived from the MON 810 strain were authorised pursuant to Regulation No 258/97 and were subsequently notified as existing products in accordance with Article 8(1)(a) of Regulation No 1829/2003.⁴³ Those derived products are maize flour, maize gluten, maize meal, maize starch, maize glucose and maize oil.

135. Under Article 11 of Regulation No 1829/2003, Monsanto applied for renewal of the authorisation relating to those products. That application is still pending.⁴⁴ In accordance with Article 11(4) of the regulation, the period of authorisation is automatically extended until a decision is taken.

136. Monsanto and the Polish Government maintain that, where a GMO is authorised under Directive 2001/18, or under the preceding legislation, namely Directive 90/220, this means that all the potential effects which cultivation of that GMO may have on the

environment have been assessed, including the consequences of the dissemination of pollen from genetically modified plants and the contamination of foodstuffs, such as honey, by such pollen. The situation does not, therefore, require a new marketing authorisation under Article 4(2) of Regulation No 1829/2003.

137. I do not share that view. Indeed, I do not think that an authorisation issued under Directive 2001/18 addresses all the repercussions of the release or placing on the market of a GMO. If that were the case, the utility of Regulation No 1829/2003 would be called into question and GMOs could, without any restriction or any specific food safety assessment, constitute foods or be incorporated into food.

138. Directive 2001/18 is a legislative act that has horizontal effect. It applies wherever there is no specific legislation to govern the use of GMOs in a given sector. Its primary purpose is, as its title suggests, the assessment of the potential effects of GMOs on the environment prior to their authorisation for release into the environment.

139. Regulation No 1829/2003, for its part, is sectoral legislation that specifically addresses genetically modified food. In accordance with

⁴³ — I shall limit myself to referring to the notifications of foodstuffs and omit notifications of feed produced from MON 810 maize. For a more complete picture, reference should be had to the Community register of genetically modified foods and feed available at the following website: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

⁴⁴ — See, in that regard, the scientific opinion of the Authority on that application (EFSA Journal [2009] 1149, p. 1), available at the following website: <http://www.efsa.europa.eu/en/efsajournal/pub/1192.htm>.

its objective, the regulation provides, first and foremost, for scientific assessment of the risks that such food may pose to human and animal health. Assessment of the risks posed to the environment is not ruled out, but will not routinely take place.⁴⁵

141. It is clear from Article 4(2) of that regulation that whenever a GMO for food use or food referred to in Article 3(1) thereof is placed on the market, an authorisation issued in accordance with section 1 of Chapter II of Regulation No 1829/2003 must be obtained and the relevant conditions of the authorisation must be satisfied.

142. This may be a new authorisation granted under Article 7 of the regulation, or the extension of a product authorisation granted earlier, under the rules which apply to existing products in accordance with Article 8 of the regulation.

140. Directive 2001/18 and Regulation No 1829/2003 thus appear to be complementary legislative acts, the first focusing upon the risks arising from the voluntary release of GMOs into the environment, the second being more concerned with the risks posed by genetically modified food to human and animal health. Given how specific the analytical framework laid down by Regulation No 1829/2003 is, it cannot be considered that an authorisation to place a GMO on the market issued pursuant to Directive 2001/18 can cover all foods containing, consisting of, or produced from that GMO. In other words, authorisation granted under Directive 2001/18 has no effect upon the ‘safety assessment’ of genetically modified food that must, in accordance with the wording of recital 3 in the preamble thereto, be carried out under Regulation No 1829/2003.

143. Moreover, according to recital 11 in the preamble to Regulation No 1829/2003, ‘where a GMO used in the production of food and/or feed has been authorised under [the regulation], foods and/or feed containing, consisting of or produced from that GMO will not need an authorisation under [the regulation], but will be subject to the requirements referred to in the authorisation granted in respect of the GMO’.

45 — There will be such an assessment in the case of GMOs and foods containing or consisting of GMOs (see, *inter alia*, Articles 5(5) and 6(4) of Regulation No 1829/2003).

144. Can one, therefore, take the view that honey containing traces of pollen from MON

810 maize is a genetically modified food that may be regarded as having been duly authorised under Regulation No 1829/2003?

145. I would be inclined the answer that question in the affirmative if there were a decision of the Commission authorising, without stipulating any particular list or restrictions, food produced from a genetically modified plant such as MON 810 maize, along the lines, for example, of Commission Decision 2009/866/EC of 30 November 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR604 (SYN-IR604-5) pursuant to Regulation (EC) No 1829/2003.⁴⁶

146. That, however, is not the case with MON 810 maize. The only derivatives that may be regarded as authorised under the regulation are maize flour, maize gluten, maize meal, maize starch, maize glucose and maize oil. I cannot rule out the possibility that the restriction of the authorisation to those particular products is significant in terms of food safety and I therefore prefer to regard it as not being comparable to a general authorisation to place on the market food produced from MON 810 maize.

147. Given the present state of the authorisations relating to MON 810 maize and its derivatives, I take the view that any food, other than the types mentioned above, that may be regarded as being produced from that plant variety should be authorised before they are placed on the market pursuant to Regulation No 1829/2003. If that requirement seems excessive in comparison with the risks which products derived from MON 810 maize pose to human health, it is a matter for the competent authorities to grant a general authorisation for the placing on the market of foods produced from that variety of genetically modified maize.

148. In any event, the inconveniences and practical difficulties to which that requirement for a marketing authorisation may give rise cannot be remedied by interpreting Regulation No 1829/2003 in such a way as to introduce a tolerance threshold which would enable an operator to dispense with such an authorisation.

149. Tolerance thresholds are nevertheless not totally absent from the regulation. They do, however, apply to certain well-defined cases.

150. First of all, Article 12(2) of Regulation No 1829/2003 provides that the labelling

⁴⁶ — OJ 2009 L 314, p. 102.

requirement does 'not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable'. That tolerance threshold applies solely to the obligation to label genetically modified food. It cannot, therefore, in the absence of any indication to that effect on the part of the Community legislature, be applied by analogy to the obligation to obtain a marketing authorisation which arises under Article 4(2) of the regulation.

151. Secondly, Article 47(1) of the same regulation introduces a threshold of 0.5 % in respect of the adventitious or technically unavoidable presence in food of genetically modified material that has not been authorised in accordance with Community legislation, but which has undergone a risk assessment and has the benefit of a favourable opinion from the competent authorities. The provision states in relation to food that, if this presence does not exceed a proportion of 0.5 %, there is no infringement of Article 4(2) of the regulation.

152. This is, indeed, an exception to the requirement to obtain a marketing authorisation, but it is merely a transitional measure⁴⁷ that applies, as is stated in Article 47(5) of Regulation No 1829/2003, for a period of three years following the date of application of the regulation. It cannot, therefore, be applied by analogy to a situation such as that in issue in the present case.

153. Given the current state of European Union rules relating to GMOs, it falls, by virtue of the principle of subsidiarity, to the national authorities to lay down rules and to prescribe procedural mechanisms to lessen the inconvenience that may arise from the coexistence of genetically modified crops and traditional agriculture where the solution to such problems does not flow directly from European Union law. Compensation for the financial losses sustained by a beekeeper who finds himself prevented from placing his products on the market is one such solution.

⁴⁷ — See recital 26 in the preamble to Regulation No 1829/2003.

IV — Conclusion

154. In the light of the foregoing considerations, I propose that the Court reply as follows to the questions referred for a preliminary ruling by the Bayerischer Verwaltungsgerichtshof:

- (1) Article 2(1) of 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, and Article 2.4 of Regulation 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 pollen from a genetically modified plant, which, when it is incorporated into honey or is used as a food supplement, is no longer capable of fulfilling its role in the plant reproduction process, is not an ‘organism’ within the meaning of those provisions.
- (2) Article 2.10 of Regulation No 1829/2003 must be interpreted as meaning that it is sufficient, in order for food to be considered as being ‘produced from [genetically modified organisms]’, that it contain material from genetically modified plants. Moreover, Article 3(1)(c) of that regulation is to be interpreted as meaning that honey containing pollen from a genetically modified plant, and also food supplements derived from such pollen, are foods containing ingredients produced from genetically modified organisms. It is irrelevant in that regard whether the genetically modified plant material is incorporated intentionally or otherwise.
- (3) Articles 3(1) and 4(2) of Regulation No 1829/2003 must be interpreted as meaning that the accidental presence in honey of pollen from a strain of maize, such as MON 810 maize, which has been authorised to be placed on the market

pursuant to Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, and of which only certain derived products have been authorised as existing products pursuant to Article 8(1)(a) of that regulation, has the consequence that the placing of that honey on the market requires an authorisation issued in accordance with that regulation. The tolerance thresholds laid down in Articles 12(2) and 47(1) of Regulation No 1829/2003 may not be applied by analogy to the requirement for a marketing authorisation arising under Article 4(2) of that regulation.