JUDGMENT OF THE COURT (Fourth Chamber)

6 September 2012 (*)

(Agriculture – Genetically modified organisms – Council Directive 2002/53/EC – Common catalogue of varieties of agricultural plant species – Genetically modified organisms accepted for inclusion in the common catalogue – Regulation (EC) No 1829/2003 – Article 20 – Existing products –Directive 2001/18/EC – Article 26a – Measures to avoid the unintended presence of genetically modified organisms – National measures prohibiting the cultivation of genetically modified organisms accepted for inclusion in the common catalogue and authorised as existing products pending measures based on Article 26a of Directive 2001/18/EC)

In Case C-36/11,

REFERENCE for a preliminary ruling under Article 267 TFEU from the Consiglio di Stato (Italy), made by decision of 14 January 2011, received at the Court on 24 January 2011, in the proceedings

Pioneer Hi Bred Italia Srl

v

Ministero delle Politiche agricole alimentari e forestali,

THE COURT (Fourth Chamber),

composed of J.-C. Bonichot, President of the Chamber, A. Prechal, L. Bay Larsen (Rapporteur), C. Toader and E. Jarašiūnas, Judges,

Advocate General: Y. Bot,

Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 21 March 2012,

after considering the observations submitted on behalf of:

– Pioneer Hi Bred Italia Srl, by A. Police and F. Degni, avvocati,

– the Italian Government, by G. Palmieri, acting as Agent, assisted by S. Varone and G. Aiello, avvocati dello Stato,

– the Spanish Government, by A. Rubio González, acting as Agent,

– the European Commission, by D. Bianchi and L. Pignataro-Nolin, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 26 April 2012,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Article 26a 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 (OJ 2001 L 106, p. 1), as amended by Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008 (OJ 2008 L 81, p. 45 ; 'Directive 2001/18'), read in conjunction with Commission Recommendation 2003/556/EC of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming (OJ 2003 L 189, p. 36; 'the Recommendation of 23 July 2003') and Commission Recommendation of 13 July 2010 on guidelines for the development of national measures to avoid the unintended presence of GMOs in conventional and organic crops (OJ 2010 C 200, p. 1; 'the Recommendation of 13 July 2010').

2 The reference has been made in a dispute between Pioneer Hi Bred Italia Srl ('Pioneer') and the Ministero delle Politiche agricole alimentari e forestali (Ministry of Agricultural, Food and Forestry Policies) concerning the legality of a note from the latter informing Pioneer that, pending the adoption by the regions of rules to ensure the coexistence of conventional, organic and genetically modified crops, it could not consider that company's application for authorisation to cultivate hybrids of genetically modified maize derived from MON 810 which were already listed in the common catalogue of varieties of agricultural plant species ('the common catalogue').

Legal context

European Union legislation

Directive 2001/18

3 Directive 2001/18 governs the deliberate release into the environment of genetically modified organisms (GMOs) and the placing on the market of GMOs as or in products.

4 Article 34 of Directive 2001/18 fixes its date of transposition as 17 October 2002 at the latest. Article 36 repeals, as from 17 October 2001, 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) and provides that references to that directive are to be understood as references to Directive 2001/18 pursuant to a correlation table annexed thereto.

5 In accordance with recitals 18 and 28 in the preamble to Directive 2001/18, and, previously, to Directive 90/220, the directive establishes harmonised procedures and criteria for the case-by-case evaluation of the potential risks arising from the deliberate release of GMOs into the environment and a Community authorisation procedure for

the placing on the market of GMOs, as or in products, where the intended use of the product involves the deliberate release of the organism(s) into the environment.

6 Recitals 50 to 52 in the preamble to that directive state:

‘(50) The existing consents granted under [Directive 90/220] have to be renewed in order to avoid disparities between consents granted under that Directive and those pursuant to this Directive and in order to take full account of the conditions of consent under [directive 90/220].

(51) Such renewal requires a transitional period during which existing consents granted under [Directive 90/220] remain unaffected.

(52) When consent is renewed, it should be possible to revise all the conditions of the original consent, including those related to monitoring and the time limitation of the consent.’

7 As regards GMOs placed on the market as or in products, Articles 13 to 24 of Directive 2001/18 govern, in essence, the assessment and consent procedure for new products, renewal of the consent for existing products, monitoring of authorised products, their labelling and a safeguard clause enabling the adoption by the Member States of restrictive measures where there is a risk to human health or the environment.

8 With regard, in particular, to renewal, before 17 October 2006, of consents granted before 17 October 2002 under Directive 90/220, the procedure is governed by Article 17 of Directive 2001/18, entitled ‘Renewal of consent’. In accordance with Article 17(9), a notifier who has submitted before 17 October 2006 a notification for the renewal of a consent made may continue to place the GMOs on the market under the conditions specified in that consent until a final decision has been taken on the renewal requested.

9 Article 26a of Directive 2001/18, entitled ‘Measures to avoid the unintended presence of GMOs’, reads as follows

‘1. Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.

2. The Commission shall gather and coordinate information based on studies at Community and national level, observe the developments regarding coexistence in the Member States and, on the basis of the information and observations, develop guidelines on the coexistence of genetically modified, conventional and organic crops.’

The Recommendation of 23 July 2003

10 Recital 4 in the preamble to the Recommendation of 23 July 2003 is worded as follows:

‘Specific coexistence measures to protect the environment and the human health, if needed, are included in the final consent of the authorisation procedure in accordance with Directive 2001/18/EC of the European Parliament and of the Council, with a legal obligation for their implementation.’

11 Point 1.1 of the Guidelines annexed to the Recommendation of 23 July 2003, entitled 'The concept of coexistence', states:

'The cultivation of [GMOs)] in the EU is likely to have implications for the organisation of agricultural production. On the one hand, the possibility of the adventitious (unintended) presence of genetically modified (GM) crops in non-GM crops, and vice versa, raises the question as to how producer choice for the different production types can be ensured. In principle, farmers should be able to cultivate the types of agricultural crops they choose, be it GM crops, conventional or organic crops. None of these forms of agriculture should be excluded in the EU.

On the other hand, the issue is also linked to consumer choice. To provide European consumers with a real choice between GM food and non-GM food, there should not only be a traceability and labelling system that functions properly, but also an agricultural sector that can provide the different types of goods. The ability of the food industry to deliver a high degree of consumer choice goes hand in hand with the ability of the agricultural sector to maintain different production systems.

Coexistence refers to the ability of farmers to make a practical choice between conventional, organic and GM crop production, in compliance with the legal obligations for labelling and/or purity standards.

The adventitious presence of GMOs above the tolerance threshold set out in Community legislation triggers the need for a crop that was intended to be a non-GMO crop, to be labelled as containing GMOs. This could cause a loss of income, due to a lower market price of the crop or difficulties in selling it. Moreover, additional costs might incur to farmers if they have to adopt monitoring systems and measures to minimise the admixture of GM and non-GM crops. Coexistence is, therefore, concerned with the potential economic impact of the admixture of GM and non-GM crops, the identification of workable management measures to minimise admixture and the cost of these measures.

…'

The Recommendation of 13 July 2010

12 The Recommendation of 13 July 2010 repeals and replaces the Recommendation of 23 July 2003.

13 The Guidelines annexed to the Recommendation of 13 July 2010 repeat and amplify the indications in the Guidelines annexed to the Recommendation of 23 July 2003.

Directive 2002/53/EC

14 Recital 11 in the preamble to Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ 2002 L 193, p. 1), as amended by Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 (OJ 2003 L 268, p. 1; 'Directive 2002/53'), states:

'Seed covered by this Directive should be freely marketable within the Community once it has been published in the common catalogue.'

15 Article 1(1) and (2) of that directive provides:

‘1. This Directive concerns the acceptance for inclusion of varieties [inter alia, cereals, in the common catalogue].

2. The [common catalogue] shall be compiled on the basis of the national catalogues of the Member States.’

16 Article 4 of that directive states:

‘1. Member States shall ensure that a variety is accepted only if it is distinct, stable and sufficiently uniform. The variety must be of satisfactory value for cultivation and use.

…

4. In the case of a genetically modified variety …, the variety shall be accepted only if all appropriate measures have been taken to avoid adverse effects on human health and the environment.

5. Further, when material derived from a plant variety is intended to be used in [food or feed falling within the scope of Article 15 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)], the variety shall be accepted only if it has been approved in accordance with that Regulation.

…’

17 Article 7(1) and (4) provides:

‘1. Member States shall provide that the acceptance of varieties be based on the results of official examinations, particularly growing trials, covering a sufficient number of characteristics for the variety to be described. …

…

4. (a) In the case of a genetically modified variety referred to in Article 4(4), an environmental risk assessment equivalent to that laid down in [Directive 90/220] shall be carried out.

(b) The procedures ensuring that the environmental risk assessment and other relevant elements shall be equivalent to those laid down in [Directive 90/220] shall be introduced on a proposal from the Commission, in a Council Regulation based on the appropriate legal basis in the Treaty. Until this Regulation enters into force genetically modified varieties shall only be accepted for inclusion in a national catalogue after having been accepted for marketing in accordance with [Directive 90/220].

…’

18 Article 16 provides:

‘1. Member States shall ensure that, with effect from the publication referred to in Article 17, seed of varieties accepted in accordance with this Directive or in accordance with principles corresponding to those of this Directive is not subject to any marketing restrictions relating to variety.

2. A Member State may, upon application … be authorised to prohibit the use of the variety in all or in part of its territory or to lay down appropriate conditions for cultivating the variety in accordance, in cases provided for in subparagraph (c), with the conditions for using the products resulting from such cultivation:

(a) where it is established that the cultivation of the variety could be harmful from the point of view of plant health to the cultivation of other varieties or species; or

…

(c) where it has valid reasons other than those already mentioned or which may have been mentioned during the procedure [for acceptance for inclusion in the national catalogue of varieties] for considering that the variety presents a risk for human health or the environment.’

19 Article 17 provides:

‘The Commission shall, on the basis of the information supplied by the Member States and as this is received, publish in the [common catalogue] a list of all varieties of which the seed and propagating material, under Article 16, are not subject to any marketing restrictions as regards variety … The published notice shall indicate the Member States which have received an authorisation under Article 16(2) or Article 18.

…

The published notice shall clearly indicate those varieties which have been genetically modified.’

20 Article 18 provides:

‘If it is established that the cultivation of a variety included in the common catalogue of varieties could in any Member State be harmful from the point of view of plant health to the cultivation of other varieties or species, or present a risk for the environment or for human health, that Member State may upon application, be authorised … to prohibit the marketing of the seed or propagating material of that variety in all or part of its territory. Where there is imminent danger of the spread of harmful organisms or imminent danger for human health or for the environment, that prohibition may be imposed by the Member State concerned as soon as its application has been lodged until such time as a final decision has been taken. That decision shall be taken within a period of three months …’

Regulation No 1829/2003

21 According to recitals 7 and 11 in the preamble thereto, Regulation No 1829/2003, applicable as from 18 April 2004 pursuant to Article 49 thereof, establishes a single Community authorisation procedure applying, inter alia, to feed consisting of,

containing or produced from GMOs and to GMOs to be used as a source material for the production of feed.

22 Article 16(1), (2) and (7) of Regulation No 1829/2003 provides:

‘1. Feed [covered by Regulation No 1829/2003] must not:

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

…

2. No person shall place on the market, use or process a [genetically modified feed covered by Regulation No 1829/2003] unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied.

…

7. Authorisation under this Regulation shall be without prejudice [inter alia, to Directive 2002/53].’

23 Article 20 of that regulation, entitled ‘Status of existing products’, provides:

‘1. By way of derogation from Article 16(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 which have been authorised under [Directive 90/220] or [Directive 2001/18] …, 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;

…

2. The notification referred to in paragraph 1 shall be accompanied by the particulars [required under Regulation No 1829/2003 for an initial application for consent based thereon] …

…

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 23, which shall apply *mutatis mutandis*.

…

5. Products referred to in paragraph 1 and feed containing them or produced from them shall be subject to the provisions of this Regulation, in particular Articles 21, 22 and 34, which shall apply *mutatis mutandis*.

…'

24 Article 23, entitled 'Renewal of authorisations', provides, in particular, for the application *mutatis mutandis* of Article 17(2), concerning the manner in which an initial application for authorisation based on Regulation No 1829/2003 is to be handled by the competent national authority and by the European Food Safety Authority ('the Authority'), and of Articles 18 and 19, which set out the circumstances in which, firstly, an opinion is issued on the application by the Authority and, secondly, a decision is adopted at Community level respectively. Article 18(3) provides, inter alia, that, in order to prepare its opinion, the Authority is to examine whether the feed complies with the criteria laid down in Article 16(1), namely, in particular, whether it has adverse effects on human health, animal health or the environment.

25 Article 24, which forms part of Section 2 entitled 'Labelling', itself entitled 'Scope', provides:

'1. This Section shall apply to feed [covered by Regulation No 1829/2003].

2. This Section shall not apply to feed containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9 per cent of the feed and of each feed of which it is composed, provided that this presence is adventitious or technically unavoidable.

…'

26 Article 34, entitled 'Emergency measures', provides:

'Where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment …, measures shall be taken under the procedures provided for in Articles 53 and 54 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 (OJ 2002 L 31, p. 1)].'

Regulation No 178/2002

27 Article 53 of Regulation No 178/2002, entitled 'Emergency measures for food and feed of Community origin or imported from a third country', is worded as follows:

'1. Where it is evident that food or feed originating in the Community or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, acting … on its own initiative or at the request of a Member State, shall immediately adopt one or more of the following measures, depending on the gravity of the situation:

[suspension of the placing on the market or use of food or feed of Community origin; suspension of imports of food or feed from third countries; laying down special conditions or other appropriate interim measure for food or feed of Community origin or from third countries].

2. However, in emergencies, the Commission may provisionally adopt the measures referred to in paragraph 1 after consulting the Member State(s) concerned and informing the other Member States.

As soon as possible, and at most within 10 working days, the measures taken shall be confirmed, amended, revoked or extended … and the reasons for the Commission's decision shall be made public without delay.'

28 Article 54 of that regulation, entitled 'Other emergency measures', is worded as follows:

'1. Where a Member State officially informs the Commission of the need to take emergency measures, and where the Commission has not acted in accordance with Article 53, the Member State may adopt interim protective measures. In this event, it shall immediately inform the other Member States and the Commission.

2. Within 10 working days, the Commission shall put the matter before the [Standing Committee on the Food Chain and Animal Health] with a view to the extension, amendment or abrogation of the national interim protective measures.

3. The Member State may maintain its national interim protective measures until the Community measures have been adopted.'

Regulation (EC) No 641/2004

29 Article 11 of Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation (OJ 2004 L 102, p. 14), which forms part of Section 2 thereof, entitled 'Additional requirements for notifications of certain products placed on the market before 18 April 2004', provides:

'1. … notifications of GMOs which have been placed on the market in accordance with part C of [Directive 90/220] or part C of Directive [2001/18] shall include a copy of the relevant consent granted under those directives.

2. The date of publication in the *Official Journal of the European Union* of the Decision to grant consent under Directive [90/220] or Directive [2001/18] shall be considered to be the date on which the product was first placed on the market, unless the notifier provides verifiable proof that it was first placed on the market at a later date.'

National legislation

30 Article 1 of Legislative Decree No 212 of 24 April 2001 (*GURI* No 131 of 8 June 2001; 'Legislative Decree No 212/2001') provides:

'…

2. … The cultivation of seed products … shall be subject to authorisation by act of the Minister for Agricultural and Forestry Policies, by agreement with the Minister for the Environment and the Minister for Health, adopted on an opinion by the [committee for seed products of genetically modified varieties], which lays down appropriate measures to ensure that crops from seed products of genetically modified species do not come into contact with crops from conventional seed products and do not cause biological damage to the immediate environment, having regard to specific agroecological, environmental and pedoclimatic factors.

…

5. Anyone cultivating seed products of genetically modified varieties without the authorisation referred to in paragraph 2 shall be liable to a prison sentence of between six months and three years or a fine of up to ITL 100 million. The same penalty shall apply in the event of revocation or suspension of the authorisation.

…'

31 Legislative Decree No 279 of 22 November 2004 (*GURI* No 280 of 29 November 2004), as amended and converted into law by Law No 5 of 28 January 2005 (GURI No 22 of 28 January 2005; 'Legislative Decree No 279/2004'), concerns the adoption of coexistence measures in the light of the Recommendation of 23 July 2003.

32 Article 3 of Legislative Decree No 279/2004 provides for the adoption of such coexistence measures by a non-regulatory decree of the Ministero delle Politiche agricole alimentari e forestali (Ministry of Agricultural, Food and Forestry Policies), adopted in consultation with the standing conference on relations between the State, the regions and the autonomous provinces of Trento and Bolzano, which is to be published after the competent parliamentary committees have delivered their opinions.

33 Pursuant to Article 3 and Article 4 of Legislative Decree No 279/2004, the non-regulatory decree to be adopted must set out the framework provisions for coexistence in accordance with which the regions will approve their own coexistence plans by adopting acts for that purpose.

34 Under Article 4(1) of Legislative Decree No 279/2004, the coexistence plan is to be adopted by each region and autonomous province and is to contain technical rules for the implementation of coexistence, while also providing for instruments which guarantee the cooperation of local territorial bodies, on the basis of the principles of subsidiarity, differentiation and proportionality.

35 Article 8 of the same legislative decree provides that, until such time as the various coexistence plans have been adopted, genetically modified crops are not to be authorised, with the exception of those intended for research and experimentation.

36 By judgment No 116 of 17 March 2006, given following an appeal brought by the Marche region, the Corte costituzionale (Constitutional Court) declared Articles 3, 4 and 8 of Legislative Decree No 279/2004 in particular to be unconstitutional.

37 More specifically, it held that Article 4 thereof infringed the competence of the regions to enact legislation in agricultural matters, in so far as those regions have the power to lay down the detailed rules for applying the principle of coexistence in the various regions, which are known to differ in terms of their morphology and production.

38 The Corte costituzionale declared Article 8 of that Legislative Decree to be unconstitutional inasmuch as it appeared to be indissociable from the other provisions considered to be unlawful.

39 Consequently, Articles 1 and 2 of Legislative Decree No 279/2004 remained in force, from which it is apparent that the national legislature intends to use the possibility of adopting the measures necessary to avoid the unintended presence of GMOs in other crops such as conventional and organic crops.

40 Following the judgment of 17 March 2006, the Ministero delle Politiche agricole alimentari e forestali adopted Circular No 269 of 31 March 2006, in which it states that that judgment does not call in question the lawfulness of the prohibition on cultivating GMOs pending the adoption of coexistence plans and that the declaration as to unconstitutionality of Article 8 of Legislative Decree No 279/2004 must be understood as meaning that the prohibition on cultivating GMOs remains in place, but provision must be made for the regional or provincial authorities to exercise their competence in that field.

41 In paragraph 4 of that circular, it points out that, after the regions and autonomous provinces have adopted their own provisions on coexistence, the complex procedure for authorising the cultivation of GMOs still has to be brought to a positive conclusion, in accordance with the provisions of Legislative Decree No 212/2001, which requires the issue of a ministerial authorisation.

42 In paragraph 5 thereof, it concludes that GMO cultivation remains prohibited until regional regulations have been adopted to ensure the coexistence of conventional, organic and transgenic crops and until appropriate solutions have been identified between neighbouring regions, and that in the event of failure to comply with that prohibition, the penalties provided for in Article 1(5) of Legislative Decree No 212/2001 will be applicable.

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

43 By 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), pursuant to Directive 90/220 (OJ 1998 L 131, p. 32), the Commission authorised the placing on the market of inbred lines and hybrids derived from maize line MON 810, on application by Monsanto Europe SA (‘Monsanto Europe’), on the basis of Directive 90/220.

44 On 11 July 2004, Monsanto Europe notified the MON 810 maize varieties, in particular under Article 20(1)(a) of Regulation No 1829/2003, to the Commission as 'existing products'.

45 On 8 September 2004, the Commission approved the inclusion of 17 varieties derived from MON 810 maize in the common catalogue.

46 Monsanto Europe did not effect a notification under Article 17(2) of Directive 2001/18 to the competent national authority before 17 October 2006.

47 On 4 May 2007, Monsanto Europe applied for renewal of the authorisation to place MON 810 maize on the market pursuant to Article 20(4) of Regulation No 1829/2003.

48 Pioneer is a company whose business is the global production and distribution of conventional and genetically modified seeds.

49 It is planning to cultivate the MON 810 maize varieties listed in the common catalogue.

50 On 18 October 2006, it applied to the Ministero delle Politiche agricole alimentari e forestali for authorisation to place those varieties on the market in accordance with Article 1(2) of Legislative Decree No 212/ 2001.

51 By Note No 3734 of 12 May 2008, the Ministero delle Politiche agricole alimentari e forestali – Dipartimento delle Politiche di sviluppo economico e rurale (Ministry of Agricultural, Food and Forestry Policies – Department of Economic and Rural Development Policies) informed Pioneer that it could not consider the company's application for authorisation to cultivate hybrids of genetically modified maize already listed in the common catalogue 'pending the adoption by the regions of rules to ensure the coexistence of conventional, organic and genetically modified crops, as provided for in the circular from Mipaaf [Ministero delle Politiche agricole alimentari e forestali] of 31 March 2006'.

52 In its action seeking annulment of that note, Pioneer disputes the requirement for national authorisation for the cultivation of products such as GMOs listed in the common catalogue.

53 Furthermore, it disputes the interpretation of Article 26a of Directive 2001/18 according to which the cultivation of GMOs in Italy will not be authorised until the regions have adopted rules to implement measures ensuring the coexistence of conventional, organic and genetically modified crops.

54 In those circumstances the Consiglio di Stato decided to stay proceedings and refer the following question to the Court of Justice for a preliminary ruling:

'Where a Member State has chosen to make authorisation to cultivate GMOs, even those listed in the [common catalogue], conditional upon compliance with appropriate general measures for ensuring coexistence with conventional and organic farming, must Article 26a of [Directive 2001/18], read in the light of the [Recommendation of 23 July 2003] and the [Recommendation of 13 July 2010], be interpreted as meaning that, in the period preceding adoption of the general measures:

(a) authorisation must be issued where the application concerns GMOs listed in the [common catalogue]; or

(b) consideration of the application for authorisation must be suspended until such time as the general measures have been adopted; or

(c) authorisation must be issued, but coupled with appropriate requirements for preventing, in the specific case, contact – including unintended contact – between authorised GM crops and surrounding conventional or organic crops?'

Consideration of the question referred

Preliminary observations

55 In order to ascertain the scope of the question referred, it is appropriate, as an initial step, to define the legal context of the dispute in the main proceedings.

56 First, it must be noted that no notification of renewal of the authorisation for the MON 810 maize varieties was made before 17 October 2006 on the basis of Article 17(2) of Directive 2001/18.

57 Next, it must be noted that the use and marketing of seed of the MON 810 maize varieties have dual authorisation.

58 They are authorised in so far as the varieties in question are 'existing products' within the meaning of Article 20 of Regulation No 1829/2003 since, in accordance with Article 20(1)(a) and (4), they were notified as such to the Commission on 11 July 2004, thus before 18 October 2006, and an application was made for renewal of their authorisation on 4 May 2007, which is within the time-limit of nine years laid down for that purpose, which began to run on 5 May 1998, the date of publication in the Official Journal of Decision 98/294, and expired on 5 May 2007, in accordance with Article 11(2) of Regulation No 641/2004.

59 The use and marketing of seed of MON 810 maize varieties are also authorised in so far as those varieties were accepted for inclusion in the common catalogue governed by Directive 2002/53.

60 Furthermore, it must be borne in mind that, although the MON 810 maize varieties are authorised under Article 20 of Regulation No 1829/2003 and listed in the common catalogue pursuant to Directive 2002/53, Article 26a thereof applies.

61 Finally, it must be pointed out that only the Recommendation of 23 July 2003 is relevant *ratione temporis* to the dispute in the main proceedings.

62 The legal context having been thus defined, it must be understood that by its question the national court asks, in essence, whether the cultivation of GMOs such as the MON 810 maize varieties can be made subject to a national authorisation procedure when the use and marketing of those varieties are authorised pursuant to Article 20 of Regulation No 1829/2003 and those varieties have been accepted for inclusion in the common catalogue provided for in Directive 2002/53. It also asks whether Article 26a of

Directive 2001/18 entitles a Member State to prohibit the cultivation on its territory of such GMOs pending the adoption of coexistence measures to avoid the unintended presence of GMOs in other crops.

The obligation to seek national authorisation

63 Regulation No 1829/2003 states, in recital 1 in the preamble thereto, that the free movement of safe and wholesome food and feed is an essential aspect of the internal market. In accordance with Article 19(5) of that regulation, the authorisation granted in accordance with the procedure referred to therein is valid throughout the European Union.

64 Recital 11 in the preamble to Directive 2002/53 states that seed and seedlings covered by this Directive should be freely marketable within the European Union once they have been published in the common catalogue. Article 16(1) of the directive therefore provides that the Member States are to ensure that, with effect from publication in the common catalogue, seed of varieties accepted in accordance with that directive is not subject to any marketing restrictions relating to variety.

65 It is thus apparent that Regulation No 1829/2993 and Directive 2002/53 both seek to enable the free use and marketing of GMOs throughout the European Union, provided they are authorised in accordance with that regulation and accepted for inclusion in the common catalogue pursuant to that directive.

66 Furthermore, it is apparent, having regard to recitals 9, 33 and 34 in the preamble to Regulation No 1829/2003 and Articles 4(4) and (5) and 7(4) of Directive 2002/53, that the conditions imposed by those two acts, for authorisation or inclusion in the common catalogue respectively, cover the requirements for the protection of health and the environment.

67 As regards existing products the use and marketing of which are authorised pursuant to Article 20 of Regulation No 1829/2003, the European Union legislature took the view, in essence, that those requirements were provisionally met when those products were notified, since an assessment was carried out when consent was previously granted under Directive 90/220 or Directive 2001/18.

68 Furthermore, by means of the reference from Article 20(4) of Regulation No 1829/2003 to Article 23 and from that article to Article 18 and 19 of that regulation, the legislature treated existing products like products authorised initially on the basis of Regulation No 1829/2003 so far as concerns the assessment of risks to health and the environment at the stage of applications for renewal of the authorisations.

69 It follows from those findings that, as European Union law presently stands, a Member State is not entitled to make the cultivation of GMOs authorised under Regulation No 1829/2003 and listed in the common catalogue pursuant to Directive 2002/53 conditional on national authorisation based on considerations of protection of health or the environment.

70 However, a prohibition or restriction on the cultivation of those products may be adopted by a Member State in the situations expressly provided for in European Union law.

71 Those exceptions include, firstly, the measures adopted under Article 34 of Regulation No 1829/2003 and those adopted under Articles 16(2) or 18 of Directive 2002/53, which provisions are not at issue in the main proceedings, and, secondly, the coexistence measures adopted under Article 26a of Directive 2001/18.

The prohibition of cultivation of GMOs pending the adoption of coexistence measures

72 First of all, it must be borne in mind, as the Spanish Government and the Commission point out, that Article 26a of Directive 2001/18 provides only that the Member States may institute coexistence measures.

73 Accordingly, if a Member State refrains from any action in that field, a prohibition on cultivating GMOs could continue indefinitely and constitute a means of avoiding the procedures laid down in Article 34 of Regulation No 1829/2003 and Articles 16(2) and 18 of Directive 2002/53.

74 An interpretation of Article 26a of Directive 2001/18 which would enable the Member States to establish such a prohibition would therefore run counter to the system implemented by Regulation No 1829/2003 and Directive 2002/53, which consists in ensuring the immediate free movement of products authorised at a Community level and accepted for inclusion in the common catalogue, once the requirements of protection of health and the environment have been taken into consideration during the authorisation and acceptance procedures.

75 In conclusion, Article 26a of Directive 2001/18 can give rise to restrictions, or even to geographically restricted prohibitions, only through the effect of coexistence measures actually adopted in compliance with the objective of that directive. Accordingly, that provision does not permit the Member States to adopt a measure such as that at issue in the main proceedings which, pending adoption of coexistence measures, lays down a general prohibition on cultivation of GMOs authorised under European Union law and listed in the common catalogue.

76 In the light of all the foregoing considerations, the answer to the question referred is:

– the cultivation of GMOs such as the MON 810 maize varieties cannot be made subject to a national authorisation procedure when the use and marketing of those varieties are authorised pursuant to Article 20 of Regulation No 1829/2003 and those varieties have been accepted for inclusion in the common catalogue provided for in Directive 2002/53;

– Article 26a of Directive 2001/18 does not entitle a Member State to prohibit in a general manner the cultivation on its territory of such GMOs pending the adoption of coexistence measures to avoid the unintended presence of GMOs in other crops.

Costs

77 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 (Fourth Chamber) hereby rules:

1. **The cultivation of genetically modified organisms such as the MON 810 maize varieties cannot be made subject to a national authorisation procedure when the use and marketing of those varieties are authorised pursuant to Article 20 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed and those varieties have been accepted for inclusion in the common catalogue provided for in Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, as amended by Regulation No 1829/2003.**

2. **Article 26a 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, as amended by Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008, does not entitle a Member State to prohibit in a general manner the cultivation on its territory of such genetically modified organisms pending the adoption of coexistence measures to avoid the unintended presence of genetically modified organisms in other crops.**

[Signatures]

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* Language of the case: Italian.