Reports of Cases

OPINION OF ADVOCATE GENERAL
BOT
delivered on 26 April 2012 [1]

Case C-36/11

Pioneer Hi Bred Italia Srl
v
Ministero delle Politiche agricole alimentari e forestali

(Reference for a preliminary ruling from the Consiglio di Stato (Italy))

(Agriculture — Genetically modified organisms — 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 in other products — 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)

1. At a time when the political and legal debate over whether or not there is a need to extend the discretion available to the Member States to restrict or prohibit the cultivation of genetically modified organisms [2] authorised in all or part of their territory is more intense than ever, [3] this reference for a preliminary ruling provides an opportunity to take stock of the current position in European Union law.

2. This reference relates principally to 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, [4] as amended by Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008. [5]

3. That article, 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.

1 — Original language: French.

2 — 'GMOs'.

3 — See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 13 July 2010 on the freedom for Member States to decide on the cultivation of genetically modified crops (COM(2010) 380 final), and the Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, presented by the European Commission on 13 July 2010 (COM(2010) 375 final). See also the European Parliament resolution of 5 July 2011 on that proposal. That proposal is intended to allow the Member States to rely on grounds other than those relating to the scientific evaluation of environmental and health risks to prohibit or restrict the cultivation of GMOs in their territory. Several Member States have expressed strong opposition to the Commission's proposal, as a result of which the Danish Presidency of the European Union is currently seeking a compromise that will secure the backing of the Member States.

4 — OJ 2001 L 106, p. 1.

5 — OJ 2008 L 81, p. 45, 'Directive 2001/18'.

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.'

4. The Commission has adopted two successive recommendations on this subject. These are, first, 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.[6] That recommendation was then repealed and replaced by the 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.[7]

5. Those recommendations contain general principles intended to serve as a guide to the Member States when deciding to adopt measures to ensure the coexistence of genetically modified, conventional and organic crops.

6. In both those texts, the Commission starts from the principle that no form of agriculture, be it conventional, organic or based on the use of GMOs, should be excluded within the European Union. To allow producers and consumers a choice between those three types of production, separate production systems should be maintained. With that in mind, the coexistence measures seek to avoid the unintended presence of GMOs in other products, in order to prevent potential economic damage[8] and the effects of admixtures of genetically modified and other crops.[9]

7. For example, coexistence measures might include the setting of isolation distances between fields in which GMOs are grown and those set aside for conventional or organic crops, the establishment of buffer zones, the laying of pollen traps or barriers, or the adaptation of suitable crop rotation systems.[10]

8. In the present case, the Consiglio di Stato (Council of State) (Italy) must assess the conformity with European Union law of national legislation which makes the issue of national permits for GMO cultivation subject to the adoption of coexistence measures by the regions. It seeks clarification as to the scope of Article 26a of Directive 2001/18, read in the light of the Recommendations of 23 July 2003 and 13 July 2010. With that in mind, the Consiglio di Stato has referred the following question to the Court for a preliminary ruling:

'Where a Member State has chosen to make authorisation to cultivate GMOs, even those listed in the [common catalogue of varieties of agricultural plant species provided for in Directive 2002/53/EC[11]], conditional upon compliance with appropriate general measures for ensuring coexistence with conventional and organic farming, must Article 26a of Directive 2001/18/EC, 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: authorisation must be issued where the application concerns GMOs listed in the … common catalogue; or consideration of the

6 — OJ 2003 L 189, p. 36, 'Recommendation of 23 July 2003'.

7 — OJ 2010 C 200, p. 1, 'Recommendation of 13 July 2010'.

8 — Such economic damage may, for example, be the result of an obligation to provide labelling indicating the presence of GMOs in a product where the regulatory threshold of 0.9% is exceeded.

9 — For an overview of the subject, see in particular Rosso Grossman M., 'Coexistence of Genetically Modified, Conventional, and Organic Crops in the European Union: The Community Framework', *The Regulation of Genetically Modified Organisms: Comparative Approaches*, Oxford University Press, 2010, p. 123.

10 — See the indicative catalogue of coexistence measures in paragraph 3 of the Annex to the Recommendation of 23 July 2003.

11 — Council Directive of 13 June 2002 (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 on genetically modified food and feed (OJ 2003 L 268, p. 1, 'Directive 2002/53').

application for authorisation must be suspended until such time as the general measures have been adopted; or 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?'

9. The question has its origin 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.

10. In formulating its question, the Consiglio di Stato appears to proceed on the premiss that a Member State may lawfully introduce a procedure to authorise the cultivation of a GMO at national level, even though that GMO is already authorised by the European Union. In the first place, it will need to be established whether such a premiss is correct.

11. In the second place, I shall examine whether a Member State may legitimately rely on the fact that no coexistence plans have been introduced at regional level in order to refuse to authorise the cultivation in its territory of a GMO authorised under European Union law.

I – Factual and legal context of the reference for a preliminary ruling

A – *Legal status of MON 810 maize*

12. The placing on the market of MON 810 maize was authorised, on application by Monsanto Europe SA,[12] by Decision 98/294/EC.[13]

13. Pursuant to Article 34, Directive 2001/18 was to be transposed by 17 October 2002. It repealed and replaced Directive 90/220/EEC,[14] on the basis of which the placing on the market of MON 810 maize was authorised.

14. A product such as MON 810 maize was referred to in Article 17(1)(b) of Directive 2001/18 as a product benefiting from an authorisation granted under Directive 90/220 prior to 17 October 2002. However, Monsanto Europe did not submit a notification under Article 17(2) of Directive 2001/18 to the competent national authority before the deadline of 17 October 2006. That company did not therefore apply to have the authorisation to place MON 810 on the market renewed in accordance with the procedure laid down in Article 17 of that directive.

15. According to recitals 7 and 11 in its preamble, Regulation No 1829/2003 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.

12 — 'Monsanto Europe'.

13 — Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. line MON 810), pursuant to Council Directive 90/220/EEC (OJ 1990 L 131, p. 32).

14 — Council Directive of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ 1990 L 117, p. 15).

16. It was under the provisions of that regulation that Monsanto Europe wished the placing on the market of MON 810 to proceed. On 11 July 2004, Monsanto Europe notified the Commission, pursuant inter alia to Article 20(1)(a) of that regulation, of MON 810 maize as an 'existing product' covered by Section 1, Chapter III, of Regulation No 1829/2003.[15] On 4 May 2007, it applied for renewal of the authorisation to place MON 810 maize on the market pursuant to Article 20(4) of Regulation No 1829/2003. Under Article 23(4) of that regulation, the existing authorisation remains effective during the renewal procedure.

17. In its judgment in *Monsanto and Others*,[16] the Court held that Article 20(1) of Regulation No 1829/2003, which authorises the continued use of the products it governs, covers the use, as seeds, of products that have been notified.[17]

18. Article 20(5) of that regulation provides that '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*'.

19. It should also be pointed out that, on 8 September 2004, the Commission approved the listing of 17 varieties derived from MON 810 maize in the common catalogue governed by Directive 2002/53.

20. The link between the rules established by Regulation No 1829/2003 and those established by Directive 2002/53 is explained in Article 4(5) of the latter, which provides that, 'when material derived from a plant variety is intended to be used in food falling within the scope of Article 3 or in feed falling within the scope of Article 15 of Regulation No 1829/2003 …, the variety shall be accepted only if it has been approved in accordance with that Regulation'.

21. It follows from the foregoing that MON 810 maize is covered not only by the rules laid down in Regulation No 1829/2003 but also by those set out in Directive 2002/53.

22. Furthermore, Article 26a of Directive 2001/18, which was inserted into the latter by Article 43(2) of Regulation No 1829/2003, has general scope and is therefore applicable to a GMO such as MON 810 maize.[18]

B – *Facts of the dispute in the main proceedings and relevant national law*

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

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

15 — Since MON 810 maize is a variety of genetically modified maize that appears to be used mainly for animal feed, in the submissions that follow, I shall refer only to Section 1, Chapter III, of Regulation No 1829/2003, which concerns the authorisation and supervision of genetically modified feed. It should be pointed out, however, that Monsanto Europe also notified MON 810 maize to the Commission as an 'existing product' under Article 8(1)(a) and (b) of that regulation, which forms part of Section 1, Chapter II, of that regulation, devoted to the authorisation and supervision of genetically modified food. In so far as the provisions contained in Section 1, Chapter II, of Regulation No 1829/2003 and those contained in Section 1, Chapter III, of that regulation are similar, the fact that reference is made only to the provisions set out in the latter section has no bearing on the line of argument itself.

16 — Joined Cases C-58/10 to C-68/10 [2011] ECR I-7763.

17 — Paragraph 55.

18 — The priority given to sectoral legislation, in accordance with Article 12(1) of Directive 2001/18, does not affect Article 26(a) of that directive.

25. On 18 October 2006, it applied to the Ministry of Agricultural, Food and Forestry Policies for authorisation to place those varieties on the market in accordance with Article 1(2) of Legislative Decree No 212 (Decreto Legislativo n. 212) of 24 April 2001,[19] which provides:

'… 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.'[20]

26. By Note No 3734 of 12 May 2008, the Ministero delle Politiche agricole alimentari e forestali – Dipartimento delle Politiche di sviluppo economico e rural della Repubblica Italiana (Department of Economic and Rural Development Policies of the Italian Republic) 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 [No 269] from the [Ministero delle Politiche agricole alimentari e forestali] of 31 March 2006'.

27. It is important to set out the national legislative context which led to the adoption of such a decision.

28. Legislative Decree No 279 (Decreto-Legge n. 279) of 22 November 2004,[21] as amended and converted into law by Law No 5 (Legge n. 5) of 28 January 2005,[22] concerns the adoption of coexistence measures in the light of the Recommendation of 23 July 2003.

29. Article 3 of Legislative Decree No 279 provides for the adoption of such coexistence measures by a non-regulatory decree of the Ministero delle Politiche agricole alimentari e forestali, 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.

30. Pursuant to that article and Article 4 of Legislative Decree No 279, 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.

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

32. 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.

19 — GURI No 131 of 8 June 2001, 'Legislative Decree No 212/2001'.

20 — Article 1(5) of Legislative Decree No 212/2001 also states that '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'.

21 — GURI No 280, 29 November 2004.

22 — GURI No 22, 28 January 2005, 'Legislative Decree No 279'.

33. By judgment 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 in particular to be unconstitutional.

34. More specifically, it held that Article 4 of that Legislative Decree 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.

35. 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.

36. Consequently, Articles 1 and 2 of Legislative Decree No 279 remained in force, which explains the national legislature's wish to rely on the possibility of adopting the measures necessary to avoid the unintended presence of GMOs in other crops such as conventional and organic crops.

37. 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 considers 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 must be understood as meaning that, if the prohibition on cultivating GMOs remains in place, provision must be made for the regional or provincial authority to exercise its competence in that field.

38. In paragraph 4 of that circular, it points out that, after the regions and autonomous provinces have adopted their own provisions on coexistence, the 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.

39. In paragraph 5 of that circular, the Ministero delle Politiche agricole alimentari e forestali 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;

— 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.

40. The aforementioned Note No 3734 of 12 May 2008 is in keeping with the provisions of Circular No 269 of 31 March 2006.

41. Pioneer submitted an extraordinary petition to the President of the Italian Republic for the annulment of that note. It was in those circumstances that the Consiglio di Stato decided to stay the proceedings and to refer to the Court for a preliminary ruling the question reproduced in point 8 of this Opinion.

42. In the course of this reference for a preliminary ruling, written observations have been lodged by Pioneer, the Spanish and Italian Governments and the Commission. At a hearing held on 21 March 2012, oral argument was presented by Pioneer, the Italian Government and the Commission.

II – Analysis

43. Before I examine the scope to be given to Article 26a of Directive 2001/18, it must be ascertained whether a Member State is entitled to superimpose national rules for the authorisation of GMO cultivation onto those laid down by European Union law. As the Italian Government itself conceded at the hearing, the answer is, in my opinion, negative.

44. As we have seen, the use and marketing of seeds of varieties of genetically modified MON 810 maize may be regarded as being authorised in the European Union on two counts.

45. First, they are so authorised under Regulation No 1829/2003, in so far as those varieties constitute 'existing products' within the meaning of Article 20 of that regulation. A product which has been through that authorisation procedure may be used and marketed within the European Union. In the case of genetically modified feed, this follows from Article 16(2) of that regulation, which provides that '[n]o person shall place on the market, use or process a product referred to in Article 15(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation'. Furthermore, Article 19(5) of Regulation No 1829/2003 provides that 'the authorisation granted in accordance with the procedure referred to in this Regulation shall be valid throughout the Community'.

46. Also, the statement in recital 1 in the preamble to that regulation to the effect 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' implies that, once products have, in accordance with the procedures laid down by that regulation, formed the subject of a scientific evaluation concluding that there is no risk of any adverse impact on the environment or on health, and have therefore been authorised to be placed on the market, such authorisation has the effect of allowing the food or feed concerned to move freely between the Member States.

47. Secondly, the use and marketing of seeds of genetically modified MON 810 maize varieties are permitted within the European Union in so far as those varieties have been accepted for inclusion in the common catalogue governed by Directive 2002/53.

48. According to recital 11 in the preamble to that directive, '[s]eed covered by this Directive should be freely marketable within the Community once it has been published in the common catalogue'. Article 16(1) of that directive thus requires Member States to 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 the principles corresponding to those of this Directive is not subject to any marketing restrictions relating to the variety'.

49. Neither Regulation No 1829/2003 nor Directive 2002/53 permits the Member States to add at national level an additional mechanism for monitoring the risks to the environment or to health potentially posed by a GMO that results in the issue or the refusal by the competent authority of a Member State of an authorisation to cultivate that GMO in its territory. As European Union law currently stands, the system governing the placing of GMOs on the market within the European Union is thus based on an authorisation issued by the European Union which allows the GMOs concerned to be used and marketed freely in the Member States. Article 1(2) of Legislative Decree No 212/2001 is therefore contrary to the system established by the European Union rules in so far as it systematically makes the cultivation of GMOs subject to national authorisation.

50. As a first stage in its reasoning, the Court should therefore state in reply to the referring court that GMOs such as genetically modified maize hybrids derived from MON 810 maize which were authorised in particular as seeds for cultivation, pursuant to Directive 90/220, and which, in accordance with the conditions laid down in Article 20 of Regulation No 1829/2003, were notified as

existing products, were then the subject of an application for the renewal of that authorisation which is currently under consideration, and were accepted for inclusion in the common catalogue of species of agricultural plants governed by Directive 2002/53, cannot be subjected to a national authorisation procedure.

51. If, after the issue of an authorisation for a GMO at European Union level, a Member State identifies a risk to the environment or to health and wishes that risk to be taken into account, it must use one of the procedures which the European Union rules provide for that purpose. If we confine our examination, in the light of the circumstances of the dispute in the main proceedings, to Directive 2002/53 and Regulation No 1829/2003, those procedures are as follows.

52. Article 16(2) of Directive 2002/53 provides:

'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.'

53. In addition, Article 18 of the same directive provides that, '[i]f it is established that the cultivation of a variety included in the common catalogue … 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 …'.

54. As regards the procedures put in place by Regulation No 1829/2003, reference should be made to Article 22 of that regulation, which, in the case of genetically modified feed,[23] permits the modification, suspension and revocation of authorisations on the initiative of the European Food Safety Authority or at the request of a Member State or the Commission.

55. Furthermore, the Member States may adopt emergency measures in accordance with Article 34 of that regulation, which states '[w]here it is evident that products authorised by or in accordance with this Regulation are likely to constitute a clear and 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'.[24] In its judgment in *Monsanto and Others*, the Court held that 'with a view to the adoption of emergency measures, Article 34 of Regulation No 1829/2003 requires the Member States to establish, in addition to urgency, the existence of a situation which is likely to constitute a clear and serious risk to human health, animal health or the environment'.[25]

23 — For genetically modified food, the relevant provisions are contained in Article 10 of Regulation No 1829/2003.

24 — Regulation 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).

25 — Paragraph 81.

56. Member States may not, on the other hand, rely on Article 26a of Directive 2001/18, which, it should be recalled, confers on them the power to take appropriate measures to avoid the unintended presence of GMOs in other products, in order to prevent generally the cultivation in their territory of a GMO authorised under Regulation No 1829/2003 and accepted for inclusion in the common catalogue in accordance with Directive 2002/53. In this regard, the purpose of measures to ensure the coexistence of different types of crop must be clearly distinguished from the objective pursued by the procedures which I have just described.

57. As the Recommendations of 23 July 2003 and 13 July 2010 indicate, coexistence measures seek to maintain the diversity of forms of agriculture in order to allow producers to choose which types of cultivation they prefer and to allow consumers to choose which types of food, genetically modified or otherwise, they wish to consume. The actual exercise of those choices is subject to the adoption of measures ensuring the existence of segregated agricultural production.

58. Furthermore, in seeking to avoid the unintended presence of GMOs in other products, coexistence measures make it possible to prevent the potential economic damage which this might inflict on producers of conventional and organic crops, particularly where the regulatory labelling threshold above which the presence of GMOs must be indicated is exceeded.

59. With that in mind, the main purpose of the coexistence measures provided for in Article 26a of Directive 2001/18 is to allow different types of agriculture to coexist. As I pointed out earlier, those measures may involve the setting of isolation distances between fields in which GMOs are grown and those set aside for conventional or organic crops, the establishment of buffer zones, the laying of pollen traps or barriers, or the adaptation of rotation systems.

60. Prompted by the concern to ensure optimum conditions for the coexistence of different types of crop rather than to exclude a particular type of crop generally for reasons relating to the protection of health or the environment, Article 26a of Directive 2001/18 is thus clearly distinguishable from the procedures which allow the Member States to oppose the cultivation of a GMO in their territory on such grounds.

61. Admittedly, it is not inconceivable that, on account of characteristics specific to a geographical area, such as climatic conditions, topography, cropping patterns and crop rotation systems or farm structures, the adoption of technical measures may not in itself be sufficient to avoid the unintended presence of GMOs in conventional or organic crops. In such a situation, Article 26a of Directive 2001/18 might be interpreted as allowing a Member State to prohibit the cultivation of GMOs in a specific area of its territory.[26] However, in accordance with the principle of proportionality, such a possibility would be subject to the provision of strict proof that other measures would not be sufficient to control the presence of GMOs in neighbouring conventional or organic crops in that location.

62. Other than in those particular circumstances and in the absence of such proof, a Member State cannot rely on Article 26a of Directive 2001/18 in order to prohibit the cultivation in its territory of a GMO authorised under Regulation No 1829/2003 and accepted for inclusion in the common catalogue in accordance with Directive 2002/53.

63. In the light of the foregoing observations relating to the scope which, in my opinion, should be given to Article 26a of Directive 2001/18, I consider that that article likewise does not allow a Member State to oppose the cultivation of such a GMO in its territory pending the adoption of coexistence measures at national, regional or local level.

26 — See to that effect the Recommendation of 23 July 2003 (paragraph 2.1.5) and, more explicitly, the Recommendation of 13 July 2010 (paragraph 2.4).

64. Apart from the fact that the adoption of coexistence measures by the Member States under Article 26a of Directive 2001/18 is merely optional, it is also important to point out that to accept the contrary proposition would be to impose a further condition on the placing on the market of a GMO authorised by the European Union, which would be dependent on the responsiveness, or otherwise, demonstrated by the Member States in adopting coexistence measures, which is contrary to the system established by Regulation No 1829/2003.

65. Furthermore, such an interpretation of Article 26a of Directive 2001/18 would have the effect of allowing the Member States to prohibit the cultivation in their territory of a GMO authorised under Regulation No 1829/2003 and accepted for inclusion in the common catalogue in accordance with Directive 2002/53 outside the procedures which those two texts provide for that purpose, and would therefore constitute an easy means of circumventing those procedures.

66. It is of course still open to the Member States under Article 26a of Directive 2001/18 to adopt measures to ensure the coexistence of genetically modified, conventional and organic crops, be it at national, regional or local level, at any time, in accordance with the principle of proportionality. However, Member States may not rely on the fact that they have not drawn up and implemented coexistence measures, albeit for reasons relating to the internal division of powers, in order in the meantime to prohibit the cultivation in their territory of a GMO authorised under Regulation No 1829/2003 and accepted for inclusion in the common catalogue in accordance with Directive 2002/53.

67. Taking those factors into account, I therefore propose that the Court's answer to the referring court should be that Article 26a of Directive 2001/18 is to be interpreted as meaning that it does not allow a Member State to oppose the cultivation in its territory of a GMO authorised under Regulation No 1829/2003 and accepted for inclusion in the common catalogue in accordance with Directive 2002/53 pending the adoption at national, regional or local level of measures to avoid the unintended presence of GMOs in other crops.

III – Conclusion

68. In the light of the foregoing considerations, I propose that the Court's answer to the Consiglio di Stato should be as follows:

Genetically modified organisms such as hybrids of genetically modified maize derived from MON 810, which were authorised in particular as seeds for cultivation, pursuant to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, and which, in accordance with the conditions laid down in 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, were notified as existing products, were then the subject of an application for renewal of that authorisation which is currently under consideration, and were accepted for inclusion in the common catalogue of species of agricultural plants provided for in Council Directive 2002/53/EC of 13 June 2002, as amended by Regulation No 1829/2003, may not be subjected to a national authorisation procedure.

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 Directive 90/220, as amended by Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008, is to be interpreted as meaning that it does not allow a Member State to oppose the cultivation in its territory of genetically modified organisms pending the adoption at national, regional or local level of measures to avoid the unintended presence of genetically modified organisms in other crops.