JUDGMENT OF THE COURT (Fourth Chamber)

8 September 2011 *

In Joined Cases C-58/10 to C-68/10,

REFERENCES for a preliminary ruling under Article 267 TFEU from the Conseil d'État (France), made by decisions of 6 November 2009 and 28 December 2009, received at the Court on 3 February 2010, in the proceedings

Monsanto SAS (C-58/10 and C-59/10)**,**

Monsanto Agriculture France SAS (C-58/10 and C-59/10),

Monsanto International SARL (C-58/10 and C-59/10),

Monsanto Technology LLC (C-58/10 and C-59/10),

Monsanto Europe SA (C-59/10),

Association générale des producteurs de maïs (AGPM) (C-60/10),

Malaprade SCEA and Others (C-61/10),

* Language of the cases: French.

Pioneer Génétique SARL (C-62/10),

Pioneer Semences SAS (C-62/10),

Union française des semenciers (UFS), formerly Syndicat des établissements de semences agréés pour les semences de maïs (Seproma) (C-63/10),

Caussade Semences SA (C-64/10),

Limagrain Europe SA, formerly Limagrain Verneuil Holding SA (C-65/10),

Maïsadour Semences SA (C-66/10),

Ragt Semences SA (C-67/10),

Euralis Semences SAS (C-68/10),

Euralis Coop (C-68/10),

v

Ministre de l'Agriculture et de la Pêche,

intervening parties:

Association France Nature Environnement (C-59/10 and C-60/10),

Confédération paysanne (C-60/10),

THE COURT (Fourth Chamber),

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

Advocate General: P. Mengozzi,
Registrar: R. Şereş, Administrator,

having regard to the written procedure and further to the hearing on 9 February 2011,

after considering the observations submitted on behalf of:

— Monsanto SAS, Monsanto Agriculture France SAS, Monsanto International SARL, Monsanto Technology LLC and Monsanto Europe SA, by R. Saint-Esteben, C.-L. Vier, M. Pittie, P. Honoré and C. Vexliard, avocats,

— Association générale des producteurs de maïs (AGPM) and Others, by M. Le Prat and L. Verdier, avocats,

— Pioneer Génétique SARL, Pioneer Semences SAS, l'Union française des semenciers (UFS), formerly Syndicat des établissements de semences agréés pour les semences de maïs (Seproma), Caussade Semences SA, Limagrain Europe SA, Maïsadour Semences SA, Ragt Semences SA, Euralis Semences SAS and Euralis Coop, by A. Monod and B. Colin, avocats,

— Confédération paysanne, by H. Bras, avocat,

— the French Government, by G. de Bergues, S. Menez and R. Loosli-Surrans, acting as Agents,

— the Greek Government, by I. Chalkias and S. Papaïoannou, acting as Agents,

— the Austrian Government, by E. Riedl, acting as Agent,

— the Polish Government, by B. Majczyna and J. Sawicka, acting as Agents,

— the European Commission, by L. Pignataro-Nolin, M. Van Hoof and C. Zadra, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 22 March 2011,

gives the following

Judgment

1 The present references for a preliminary ruling concern the interpretation of Articles 12 and 23 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), Articles 20 and 34 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), and also 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).

2 The references have been made in the context of eleven sets of proceedings between, on the one hand, Monsanto SAS, Monsanto Agriculture France SAS, Monsanto International SARL, Monsanto Technology LLC, Monsanto Europe SA ('Monsanto', 'Monsanto Agriculture France', 'Monsanto International', 'Monsanto Technology' and 'Monsanto Europe' respectively) and various other applicants, including individuals and legal entities, and, on the other hand, the Ministre de l'Agriculture et de la Pêche (French Minister for Agriculture and Fisheries), with, as interveners, Association France Nature Environnement and Confédération paysanne, concerning the lawfulness of two provisional national measures which suspended, successively, the transfer and use of MON 810 maize seeds, which are genetically modified organisms ('GMOs'), and subsequently prohibited the planting of seed varieties derived from the line of that maize.

Legal context

European Union law

Directive 2001/18

3 Directive 2001/18, amended by Regulation No 1829/2003 and by Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 (OJ 2003 L 268, p. 24) ('Directive 2001/18'), governs the deliberate release of GMOs into the environment and the placing on the market of GMOs as or in products.

4 Article 34 of Directive 2001/18 fixes 17 October 2002 as the latest date for its transposition. Article 36 repeals 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) as from 17 October 2002 and provides that references made to that directive are to be understood as being made to Directive 2001/18, in accordance with a correlation table set out in an annex thereto.

5 According to recitals 18 and 28 in the preamble thereto, Directive 2001/18, in the same way as Directive 90/220 previously, 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;

— a Community authorisation procedure for the placing on the market of the products concerned, where the intended use of the products involves the deliberate release of the organisms into the environment.

6 Recitals 50 and 51 in the preamble to Directive 2001/18 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 this Directive.

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

7 The detailed rules for renewal, before the deadline of 17 October 2006, of authorisations granted before 17 October 2002 pursuant to Directive 90/220 are governed by Article 17 of Directive 2001/18. Article 17(2) lists the documents, information and possible proposal to be included with the notification for renewal. Under Article 17(2) and (9), a notifier who filed that notification before 17 October 2006 may continue to place the GMOs on the market under the conditions specified in the initial consent until a final decision has been taken on renewal.

8 Articles 20, 21 and 24 of Directive 2001/18 set out specific detailed rules on monitoring, labelling and information to the public.

9 Article 23 of that directive, entitled 'Safeguard clause', provides:

'1. Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory.

The Member State shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public.

The Member State shall immediately inform the Commission and the other Member States of actions taken under this Article and give reasons for its decision, supplying its review of the environmental risk assessment, indicating whether and how the

conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.

2. Within 60 days … a decision shall be taken on the measure [at Community level]'.

10 Article 12 of Directive 2001/18, entitled 'Sectoral legislation', provides:

'1. Articles 13 to 24 shall not apply to any GMO as or in products as far as they are authorised by Community legislation which provides for a specific environmental risk assessment carried out in accordance with the principles set out in Annex II and on the basis of information specified in Annex III, without prejudice to additional requirements provided for by the Community legislation mentioned above, and [which provides] for requirements as regards risk management, labelling, monitoring as appropriate, information to the public and safeguard clause at least equivalent to that laid down in this Directive.

…

3. Procedures ensuring that the risk assessment, requirements regarding risk management, labelling, monitoring as appropriate, information to the public and safeguard clause are equivalent to those laid down in this Directive shall be introduced in a regulation of the European Parliament and of the Council. Future sectoral legislation based on the provisions of that regulation shall make a reference to this Directive....

…'

Regulation No 1829/2003

11 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.

12 Recital 9 states:

'The new authorisation procedures for genetically modified food and feed should include the new principles introduced in Directive [2001/18]. They should also make use of the new framework for risk assessment in matters of food safety set up by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [OJ 2002 L 31, p. 1]. Thus, 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 (Authority), of any risks which they present for human and animal health and, as the case may be, for the environment. This scientific evaluation should be followed by a risk management decision by the Community, under a regulatory procedure ensuring close cooperation between the Commission and the Member States.'

13 Recital 33 states:

'Where the application concerns products containing or consisting of a [GMO], the applicant should have the choice of either supplying an authorisation for the deliberate release into the environment already obtained under part C of Directive [2001/18], without prejudice to the conditions set by that authorisation, or of applying for the environmental risk assessment to be carried out at the same time as the safety assessment under this Regulation. In the latter case, it is necessary for the evaluation of the environmental risk to comply with the requirements referred to in Directive [2001/18] and for the national competent authorities designated by Member States for this purpose to be consulted by the Authority. In addition, it is appropriate to give the Authority the possibility of asking one of these competent authorities to carry out the environmental risk assessment. It is also appropriate, in accordance with Article 12(4) of Directive [2001/18], for the national competent authorities designated under the said Directive in all cases concerning GMOs and food and/or feed containing or consisting of a GMO to be consulted by the Authority before it finalises the environmental risk assessment.'

14 Recital 34 states:

'In the case of GMOs to be used as seeds or other plant-propagating materials falling within the scope of this Regulation, the [European Food Safety Authority] should be under an obligation to delegate the environmental risk assessment to a national competent authority. Nonetheless, authorisations under this Regulation should be without prejudice to the provisions of [in particular, 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 No 1829/2003, which provides in particular for] the rules and the criteria for the acceptance of varieties and their official acceptance for inclusion in [the common catalogue of varieties of agricultural plant species] …'

15 Article 2.9 of Regulation No 1829/2003 provides:

'For the purposes of this Regulation:

…

9. "genetically modified organism for feed use" means a GMO that may be used as feed or as a source material for the production of feed.'

16 Article 15(1) of Regulation No 1829/2003 lays down as follows the scope of Section I, entitled 'Authorisation and supervision', of Chapter III, which concerns genetically modified feed:

'This Section shall apply to:

(a) GMOs for feed use;

(b) feed containing or consisting of GMOs;

(c) feed produced from GMOs.'

17 Articles 17 to 19 of Regulation No 1829/2003 govern the conditions for granting initial authorisations for genetically modified feed.

18 Article 17(5) provides, in particular, as follows:

'5. In the case of GMOs or feed containing or consisting of GMOs, the application shall also be accompanied by:

(a) the complete technical dossier supplying the information required by Annexes III and IV to Directive [2001/18] and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive [2001/18] or, where the placing on the market of the GMOs has been authorised under part C of Directive [2001/18] [consisting in Articles 12 to 24 thereof], a copy of the authorisation decision;

(b) a monitoring plan for environmental effects conforming with Annex VII to Directive [2001/18], including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.

In such case, Articles 13 to 24 of Directive [2001/18] shall not apply.'

19 Article 20, entitled 'Status of existing products', provides:

'1. … 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 mentioned in Article 17(3) and (5) …

…

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*.

…'

20 Articles 21 and 22(1), 24 to 26, and 29 set out detailed specific rules on supervision, labelling and information to the public.

21 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 [No 178/2002].'

Regulation No 178/2002

22 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 … 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 marketing, suspension of imports from third countries, suspension of use of the feed in question, laying down of special conditions for the feed in question or any other appropriate interim measure].

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 in accordance with the procedure referred to in Article 58(2), and the reasons for the Commission's decision shall be made public without delay.'

23 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.'

National law

24 Article L.535-2 of the French Code de l'environnement (Environment Code), in force until 27 June 2008, provides:

'I. — In every case where a new evaluation of the risks to public health or the environment caused by the presence of [GMOs] so justifies, the administrative authority may, at the cost of the authorisation holder or the holders of the [GMOs]:

(1) suspend the authorisation pending further information and, if necessary, order the withdrawal from sale of the products or prohibit their use;

(2) impose modifications to the conditions of deliberate release;

(3) withdraw the authorisation;

(4) order the destruction of the [GMOs] and, in the event of a failure by the beneficiary or of the holder of the authorisation, proceed to such destruction on its own initiative.

II. — Except in emergency cases, these measures may be implemented only if the beneficiary has been given the opportunity to present its observations.'

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

25 By 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 MON 810 maize, at the request of Monsanto Europe, on the basis of Directive 90/220.

26 In implementation of Article 1 of that decision and in accordance with Article 13 of Directive 90/220, the French Minister for Agriculture and Fisheries gave, by order of 3 August 1998, his written consent to that placing on the market, pursuant to Article 13(4) of Directive [90/220] 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).

27 On 11 July 2004, Monsanto Europe, acting pursuant to, inter alia, Article 20(1)(a) of Regulation No 1829/2003, notified MON 810 maize as an 'existing product' to the Commission.

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

29 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.

30 By order of 5 December 2007 suspending the transfer and use of MON 810 maize seed (JORF of 6 December 2007, p. 19748), the Minister for Agriculture and Fisheries, referring in general terms to the Code rural (Rural Code) and the Environment Code, suspended the authorisation for transfer to the end user and for the use in

national territory of MON 810 maize seed pending the publication of a law relating to GMOs and until 9 February 2008 at the latest.

31 On 6 February 2008, Monsanto, Monsanto Agriculture France, Monsanto International and Monsanto Technology brought an action for annulment of that order before the Conseil d'État (Council of State).

32 By order of 7 February 2008 suspending the planting of genetically modified maize seed varieties (*Zea mays* L. line MON 810) (JORF of 9 February 2008, p. 2462), the Minister for Agriculture and Fisheries, referring to Article 23 of Directive 2001/18, Regulation No 1829/2003, and also Article L.535-2 of the Environment Code, prohibited, on the national territory, 'the planting, with a view to placing on the market, of maize seed varieties derived from the genetically modified line of maize MON 810' until a decision had been taken on the application for renewal of the authorisation to place that organism on the market.

33 By order of 13 February 2008 amending the order of 7 February 2008 suspending the planting of genetically modified maize seed varieties (*Zea mays* L. line MON 810) (JORF of 19 February 2008, p. 3004), the Minister for Agriculture and Fisheries deleted the words 'with a view to placing on the market' contained in the abovementioned order of 7 February 2008.

34 On 12 February 2008, the French authorities, notifying the latter order to the Commission, classified it as an 'emergency measure' under Article 34 of Regulation No 1829/2003. In that correspondence, they emphasised the need to take emergency measures designed to suspend the cultivation of MON 810 maize pursuant to the combined provisions of Article 34 of Regulation No 1829/2003 and Articles 53 and 54 of Regulation No 178/2002.

35 On 20 February 2008, notifying the Commission of the order of 13 February 2008, the French authorities stated that that order had been adopted pursuant to Article 23 of Directive 2001/18.

36 On 20, 21 and 25 February 2008, actions for annulment of the order of 7 February 2008, as amended by the order of 13 February 2008, were brought before the Conseil d'État by Monsanto, Monsanto Agriculture France, Monsanto International, Monsanto Technology, Monsanto Europe and various other applicants.

37 The Conseil d'État indicates that the applicants submit that MON 810 maize, which is a genetically modified variety of maize used for animal feed, henceforth comes solely within the scope of Regulation No 1829/2003, with the result that the Minister for Agriculture and Fisheries vitiated the contested orders by acting outside his powers in adopting an emergency measure which it was for the Commission to adopt or, at the very least, by an error of law in taking as the basis for those orders Article 23 of Directive 2001/18 and Article L.535-2 of the Environment Code, which transposes it into national law.

38 In those circumstances, the Conseil d'État decided to stay the proceedings and to refer the following questions, in each set of pending proceedings, to the Court of Justice for a preliminary ruling:

'1. Where a [GMO] constituting feed was placed on the market prior to the publication of Regulation [No 1829/2003] and the authorisation is maintained in force pursuant to Article 20 of that regulation, must the product at issue be regarded, before a decision has been taken on the application for a new authorisation which must be submitted pursuant to the regulation, as among the products to which the provisions of Article 12 of Directive [2001/18] … refer and, in that event, is the [GMO] subject, with respect to the emergency measures which may be adopted

after the issue of authorisation to place it on the market, only to Article 34 of Regulation [No 1829/2003] or, on the contrary, may such measures be adopted by a Member State on the basis of Article 23 of [Directive 2001/18] and the national provisions transposing it?

2. On the assumption that emergency measures may be adopted only within the framework of Article 34 of Regulation [No 1829/2003], may the authorities of a Member State adopt, and under what circumstances, [measures such as those under the order of 5 December 2007 (first action for annulment) and the order of 7 February 2008 (10 other actions), as amended by the order of 13 February 2008], on grounds of the containment of risk as referred to in Article 53 of Regulation [No 178/2002] or by way of the interim protective measures which may be adopted by a Member State on the basis of Article 54 of the same regulation?

3. On the assumption that the authorities of a Member State may intervene on the basis of Article 23 of Directive [2001/18] or on the basis of Article 34 of Regulation [No 1829/2003], or on both of those legal bases, the application[s] [raise] the question as to what degree of requirement, taking into account in particular the precautionary principle, is imposed, respectively, by Article 23 of the directive, under which the adoption of emergency measures such as a suspension of the use or provisional prohibition against use of the product is subject to the condition that the Member State must have "detailed grounds for considering that a GMO... constitutes a risk to... the environment" and by Article 34 of the regulation, under which the adoption of such a measure is subject to the condition that it be "evident" that the product is "likely to constitute a serious risk to... the environment", in terms of identifying the risk, evaluating its probability and assessing the nature of its effects?'

Consideration of the questions referred

Preliminary observations

39 It should be borne in mind that seeds derived from maize varieties such as those at issue in the main proceedings come within the scope of Directive 2002/53, under a combined reading of Article 1(1) thereof and Article 2(1). A of Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed (OJ, English Special Edition 1965-1966, p. 143), as amended most recently by Commission Directive 2009/74/EC of 26 June 2009 (OJ 2009 L 166, p. 40).

40 Under Article 16(1) of Directive 2002/53, Member States are required to ensure that, with effect from their inclusion in the common catalogue of varieties of agricultural plant species, provided for in Article 17 thereof, seeds of varieties accepted in accordance with that directive or in accordance with principles corresponding to those of that directive are not made subject to any marketing restrictions relating to variety, save as provided for in Articles 16(2) or 18 of Directive 2002/53 (see, to that effect,Case C-165/08 *Commission* v *Poland* [2009] ECR I-6843, paragraph 62).

41 It should be noted that the Member State concerned in the main proceedings has not relied on Articles 16(2) or 18 of Directive 2002/53 in order to be allowed to prohibit MON 810 maize seeds under the conditions set out in those provisions.

42 In that context, the answers given to the questions referred in the present cases are without prejudice to Directive 2002/53.

The first question

43 The first question relates to the conditions under which a measure of provisional suspension or prohibition may be adopted by a Member State in respect of an 'existing product', within the meaning of Article 20 of Regulation No 1829/2003, which was authorised under Directive 90/220, a directive which was repealed and replaced by Directive 2001/18.

44 That question raises the issue of the legal basis for such a measure.

45 The Austrian Government submits that Monsanto notified MON 810 maize as an existing product for the purpose of use in feed and food, but not for use as seeds. It therefore has doubts as to whether the product in question may still be regarded as having been lawfully placed on the market as seeds following the expiry of the period for notification of existing products.

46 It is therefore appropriate to begin by addressing the issue of whether the use of GMOs as seed notified under Article 20 of Regulation No 1829/2003 is covered by that provision.

47 Regulation No 1829/2003 constitutes an implementation of Article 12(3) of Directive 2001/18.

48 It is common ground that Monsanto did not notify the MON 810 maize under Article 17(2) of Directive 2001/18 before the deadline of 17 October 2006 laid down by that article.

49 It is also common ground that Monsanto notified that maize pursuant to Article 20(1) of Regulation No 1829/2003 as an 'existing product' coming under Section 1 of Chapter III of that regulation.

50 It follows from the wording of recital 34 in the preamble to that regulation and, with regard to feed, from Articles 16(7) and 18(3)(c) thereof that the use of GMOs as seeds is covered by the authorisation granted for those GMOs under that regulation, without prejudice to Directive 2002/53.

51 As regards existing products, the question therefore arises as to whether Article 20 of Regulation No 1829/2003, in so far as it provides, subject to the conditions which it lays down, that 'products falling within the scope of this Section [1] … may continue to be placed on the market, used and processed …', also covers use as seeds of GMOs notified as existing products on the basis of Article 20.

52 It should be borne in mind in this regard that products notified on the basis of Article 20(1) of Regulation No 1829/2003 must come within the scope of Section 1 of Chapter III of that regulation, and that it is clear from Article 15(1) thereof that that section covers, inter alia, 'GMOs for feed use'.

53 Moreover, under Article 2.9 of Regulation No 1829/2003, that expression is to be understood as encompassing, in particular, a 'GMO that may be used as … a source material for the production of feed', a definition which can include seeds.

54 Consequently, GMO seeds come within Section 1 of Chapter III of Regulation No 1829/2003. They can therefore come, in particular, within the scope of Article 20(1) thereof.

55 As the latter provision authorises the continued use of the products which it governs, it covers the use, as seeds, of products which have been notified.

56 In that regard, it is for the national court to ascertain whether products such as MON 810 maize, which were authorised as, inter alia, seeds for the purpose of planting pursuant to Directive 90/220, were in fact notified on the basis of Article 20(1) of Regulation No 1829/2003.

57 In the light of the foregoing considerations, the Court finds that Regulation No 1829/2003 provides sufficient interpretative information for the purpose of answering the first question, without its being necessary to interpret specifically Article 12 of Directive 2001/18.

58 Accordingly, the Court finds that, by its first question, the referring court is asking, in essence, whether, in circumstances such as those of the disputes in the main proceedings, GMOs such as MON 810 maize, which were authorised as, inter alia, seeds for the purpose of planting under Directive 90/220 and which were notified as existing products in accordance with the conditions set out in Article 20 of Regulation No 1829/2003, and were subsequently the subject of a pending application for renewal of authorisation, may have their use or sale provisionally suspended or prohibited under Article 23 of Directive 2001/18, or whether such measures may be adopted pursuant to Article 34 of Regulation No 1829/2003.

59 It should be borne in mind in this regard that Article 20(5) of Regulation No 1829/2003 provides that '[p]roducts referred to in paragraph 1 … shall be subject to the provisions of this Regulation, in particular Articles 21, 22 and 34, which shall apply *mutatis mutandis*'.

60 That wording thus makes it explicitly clear that Article 34 of Regulation No 1829/2003 is applicable.

61 It also provides that existing products are covered by other provisions of that regulation, such as headings (a) and (b) of the first subparagraph of Article 17(5), which provides for the provision of various types of information relating to the product in question and adds, in the second subparagraph that '[i]n such case, Articles 13 to 24 of Directive [2001/18] shall not apply'.

62 It thus results from a combined reading of Articles 20(5) and 17(5) of Regulation No 1829/2003 that, when the information referred to in the first subparagraph of Article 17(5) is provided in support of the notification of an existing product, Article 23 of Directive 2001/18 does not apply.

63 The answer to the first question is therefore that, in circumstances such as those of the disputes in the main proceedings, GMOs such as MON 810 maize, which were authorised as, inter alia, seeds for the purpose of planting under Directive 90/220 and which were notified as existing products in accordance with the conditions set out in Article 20 of Regulation No 1829/2003, and were subsequently the subject of a pending application for renewal of authorisation, may not have their use or sale provisionally suspended or prohibited, by a Member State, under Article 23 of Directive 2001/18; such measures may, however, be adopted pursuant to Article 34 of Regulation No 1829/2003.

The second question

64 By its second question, the referring court asks, in essence, whether Article 34 of Regulation No 1829/2003 authorises a Member State to adopt emergency measures in circumstances such as those of the main proceedings.

65 The order of 5 December 2007, that of 7 February 2008 and the order of 13 February 2008, which amended the terms of the latter, were published in the *Journal officiel de la République française* on 6 December 2007, 9 February 2008 and 19 February 2008 respectively. According to the statements made by the French Government, which it is for the national court to verify, those orders were notified to the Commission on 9, 12 and 20 February 2008 respectively.

66 In that regard, it must be held that, as is evidenced by the wording of Article 34 of Regulation No 1829/2003, that provision, first, lays down the substantive conditions under which a product authorised by that regulation or in accordance therewith may be the subject of emergency measures and, second, refers, as regards the conditions for adopting those measures, to the 'procedures provided for in Articles 53 and 54 of Regulation [No 178/2002]'.

67 Thus, Article 34 of Regulation No 1829/2003 does not make the adoption of emergency measures subject to the substantive conditions provided for in Article 53 of Regulation No 178/2002.

68 It should also be noted that Article 53 of Regulation No 178/2002 concerns emergency measures which may be taken by the Commission, with the adoption of such measures by the Member States coming under Article 54 of that regulation.

69 Consequently, a Member State wishing to adopt emergency measures pursuant to Article 34 of Regulation No 1829/2003 must comply, not only with the substantive conditions laid down in that article, but also with the procedural conditions provided for in Article 54 of Regulation No 178/2002.

70 Those conditions are set out in Article 54(1) of Regulation No 178/2002, which requires Member States, first, to inform the Commission 'officially' of the need to take

emergency measures and, second, where the Commission has not acted in accordance with Article 53 of that regulation, to inform 'immediately' the other Member States and the Commission of the interim protective measures adopted.

71 Those conditions must be interpreted not only in the light of the wording of that provision, but also in the light of the purpose of Regulation No 1829/2003 and the precautionary principle, in order to ensure a high level of protection of human life and health, whilst taking care to ensure the free movement of safe and wholesome food and feed, which is an essential aspect of the internal market (see, by analogy, Case C-6/99 *Greenpeace France and Others* [2000] ECR I-1651, paragraph 44, and Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraph 110).

72 In that regard, it must be held that, although Article 54(1) of Regulation No 178/2002 does not introduce the obligation to inform the Commission within a specific time, it is nevertheless clear from the specific indication that the Member State concerned is to inform the Commission and the other Member States 'immediately' of the emergency measures adopted, and from the fact that the Commission must then, within 10 working days, initiate the procedure provided for in Article 58(2) of that regulation, that the Member State concerned must inform the Commission as quickly as possible both of the need to take emergency measures and, as necessary, of the content of the measures adopted.

73 Accordingly, in the light of the urgent nature of the intervention of the Member State concerned and the objective of public-health protection pursued by Regulation No 1829/2003, Article 54(1) of Regulation No 178/2002 must be interpreted as requiring, in the same way as, moreover, under Article 23 of Directive 2001/18, that, in the event of an emergency, the Commission be informed no later than the time at which the emergency measures are adopted by the Member State concerned.

74 The answer to the second question is therefore that Article 34 of Regulation No 1829/2003 authorises a Member State to adopt emergency measures only in accordance with the procedural conditions set out in Article 54 of Regulation No 178/2002, compliance with which it is for the national court to ascertain.

The third question

75 By its third question, the referring court asks, in essence, what degree of requirement Article 34 of Regulation No 1829/2003 imposes on the Member States in respect of the adoption of emergency measures, in so far as it makes such measures subject to the existence of a situation which is 'likely' to constitute a 'serious risk' to human health, animal health or the environment.

76 It should be borne in mind in this regard that the expressions 'likely' and 'serious risk' must be understood as referring to a significant risk which clearly jeopardises human health, animal health or the environment. That risk must be established on the basis of new evidence based on reliable scientific data.

77 Protective measures adopted under Article 34 of Regulation No 1829/2003 cannot validly be based on a purely hypothetical approach to the risk, founded on mere assumptions which have not yet been scientifically verified. On the contrary, such protective measures, notwithstanding their temporary character and even if they are preventive in nature, may be adopted only if they are based on a risk assessment which is as complete as possible in the particular circumstances of an individual case, which indicate that those measures are necessary (see, to that effect, *Monsanto Agricoltura Italia and Others*, cited above, paragraphs 106 and 107).

78 It should be emphasised that, in the light of the overall scheme provided for by Regulation No 1829/2003 and its objective of avoiding artificial disparities in the treatment of a serious risk, the assessment and management of a serious and evident risk ultimately come under the sole responsibility of the Commission and the Council, subject to review by the European Union Courts.

79 It follows that, at the stage of adoption and implementation by the Member States of the emergency measures referred to in Article 34 of Regulation No 1829/2003, as long as no decision has been adopted in that regard at European Union level, the national courts before which actions have been brought to test the lawfulness of such measures have jurisdiction to assess the lawfulness of those measures having regard to the substantive conditions provided for in Article 34 of Regulation No 1829/2003 and the procedural conditions laid down in Article 54 of Regulation No 178/2002, whilst the uniformity of European Union law may be ensured by the Court of Justice under the preliminary-ruling procedure since, if a national court has doubts as to the interpretation of a provision of European Union law, it may, or must, in accordance with the second and third paragraphs of Article 267 TFEU, refer a question to the Court of Justice for a preliminary ruling (see, by analogy, Case C-375/07 *Heuschen & Schrouff Oriëntal Foods Trading* [2008] ECR I-8691, paragraphs 63 and 67).

80 However, where, in one case, the Commission has referred a matter to the Standing Committee on the Food Chain and Animal Health and a decision has been adopted at European Union level, the factual and legal assessments relating to that case and contained in such a decision are binding on all bodies of the Member State which is the addressee of such a decision, in accordance with Article 288 TFEU, including its courts which are called on to assess the lawfulness of measures adopted at national level (see, by analogy, *Heuschen & Schrouff Oriëntal Foods Trading*, cited above, paragraph 64).

81 The answer to the third question is therefore 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.

Costs

82 Since these proceedings are, for the parties to the main proceedings, a step in the actions pending before the national court, the decisions on costs are 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. **In circumstances such as those of the disputes in the main proceedings, genetically modified organisms such as MON 810 maize, which were authorised as, inter alia, seeds for the purpose of planting under Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms and which were notified as existing products in accordance with the conditions set out 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, and were subsequently the subject of a pending application for renewal of authorisation, may not have their use or sale provisionally suspended or prohibited, by a Member State, under Article 23 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; such measures may, however, be adopted pursuant to Article 34 of Regulation No 1829/2003.**

2. **Article 34 of Regulation No 1829/2003 authorises a Member State to adopt emergency measures only in accordance with the procedural conditions set out in Article 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, compliance with which it is for the national court to ascertain.

3. With a view to the adoption of emergency measures, Article 34 of Regulation No 1829/2003 requires 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.

[Signatures]