OPINION OF ADVOCATE GENERAL MENGOZZI
delivered on 22 March 2011[1]

1. The present case, which arose from the joining of no fewer than 11 sets of proceedings, once again gives the Court occasion to rule on genetically modified organisms ('GMOs'). The fundamental legal problem to be resolved is, in essence, relatively limited. It is necessary, in relation to certain products authorised in the past under a given set of legislation, but whose authorisation is to be renewed and is governed by more recent legislation, to determine whether the rules of the first or second set of legislation, or even both, must be applied for the adoption of any emergency measures during the transitional period between the old and new authorisation.

I — Legislative framework

2. The product at issue is a variety of maize used as animal feed in the territory of the European Union. It is MON 810 maize developed by the company Monsanto SAS ('Monsanto') which, as a result of a genetic modification, is particularly resistant to certain parasites.

3. The legal framework relevant to the resolution of this case is made up of three sets of rules. Firstly, there are the rules relating to 'deliberate release into the environment', that is to say principally to the cultivation and sale of GMOs, contained in Directive 90/220 and now in Directive 2001/18. Secondly, there are the rules relating to food safety, more precisely Regulation No 178/2002. Thirdly, and lastly, there is Regulation No 1829/2003 which is the main set of legislation which the Court is called on to interpret in this case and by which the legislature sought to standardise as far as possible the legislation on GMOs. It partially replaced and partly completed the rules previously applicable.

1 — Original language: Italian.

A — *Directive 90/220/EEC*

4. Directive 90/220[2] was the first to introduce a uniform system for authorising the release into the environment of GMOs at Community level. The mechanism provided for therein was based generally on the grant of an authorisation by a Member State, subject to there not being opposition from the other Member States within a certain time-limit. In the event of disagreement, the European Commission had the power to take a decision. The authorisation granted by a Member State was in any event valid throughout the Community.

5. As will be seen below in a review of the facts of the present case, MON 810 was originally authorised under that directive.

B — *Directive 2001/18/EC*

6. Directive 2001/18[3] ('the directive') repealed and replaced Directive 90/220. The system for authorising the release of GMOs into the environment remained largely similar to that of the preceding directive, although certain amendments were made. In particular, the principle of limited duration of the authorisation (up to maximum of 10 years) was introduced and provision was made for a simplified procedure for renewing authorisations already granted under Directive 90/220.

7. Article 12 provides in particular:

'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 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.'

8. Article 17 of the directive, entitled 'Renewal of consent', provides for a specific, simplified renewal procedure for GMOs which

2 — 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).

3 — Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ 2001 L 106, p. 1).

were already authorised under Directive 90/220. That renewal had to be effected by 17 October 2006.

9. Article 22 of the directive, which reiterates a fundamental principle already to be found in Directive 90/220, provides that, '[w]ithout prejudice to Article 23, Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive.'

10. Article 23, 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 immediately inform the Commission and the other Member States of actions taken under this Article and give reasons for its decision ....

2. Within 60 days of the date of receipt of the information transmitted by the Member State, a decision shall be taken on the measure taken by that Member State in accordance with the regulatory procedure referred to in Article 30(2).'

C — *Regulation No 1829/2003*

11. Although its title may give the impression that it relates only to the consumption of GMOs as food or feed, Regulation No 1829/2003 [4] ('the regulation') has in fact introduced an integrated system which permits operators who wish to do so to obtain a single authorisation relating to both the cultivation and use for food of a genetically modified product. Furthermore, in the system established by the regulation, authorisation is not granted by an individual Member State but follows from a procedure which is carried out principally at European Union level.

4 — 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).

12. Article 17 of the regulation, which deals with applications for authorisation in respect of genetically modified feed, provides:

'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/EC and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC or, where the placing on the market of the GMO has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision;

...'

13. Article 20 of the regulation deals with the situation of GMOs which have been authorised previously under different legislative provisions. In particular, Article 20(1) provides that '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 ... in the case of products which have been authorised under Directives 90/220/EEC or 2001/18/EC, including use as feed, ... 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'.

14. Article 20(2) provides that '[t]he notification referred to in paragraph 1 shall be accompanied by the particulars mentioned in Article 17(3) and (5), as appropriate, which the Commission shall forward to the Authority and the Member States'.

15. Furthermore, Article 20(4) adds that in respect of products already authorised under Directive 90/220/EEC or 2001/18/EC an application for renewal must be submitted '[w]ithin nine years from the date on which the products ... were first placed on the market, but in no case earlier than three years after the date of application of this Regulation'.

16. The regulation also contains a provision relating to the possibility of adopting emergency measures where there are risks to health or the environment. That provision

is Article 34. In line with the nature of the regulation, which centralised the grant of authorisations for GMOs, the power to adopt emergency measures is conferred in principle on the Commission. Article 34 is worded as follows:

'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, or where, in the light of an opinion of the Authority issued under Article 10 or Article 22, the need to suspend or modify urgently an authorisation arises, measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation (EC) No 178/2002.'

D — *Regulation No 178/2002*

17. The provisions of Regulation No 178/2002 [5] relevant to the present case are those referred to in Article 34 of Regulation No 1829/2003, that is to say, Articles 53 to 54.

18. Article 53, entitled 'Emergency measures for food and feed of Community origin or imported from a third country', sets out the measures which can be taken to block or limit, where necessary, the marketing of food or feed which could pose risks. With regard to the power and conditions for adopting those measures, it provides 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 in accordance with the procedure provided for in Article 58(2) 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.'

19. Article 54 supplements the preceding article by laying down a procedure which permits the Member States to intervene if the Commission fails to act. That article provides:

'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

5 — 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).

immediately inform the other Member States and the Commission.

...

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

II — Facts, the proceedings before the national court and the questions referred

20. The genetically modified MON 810 maize was authorised in the territory of the Community for the first time in 1998, under Directive 90/220. The notification of placing on the market was sent to the French authorities, which forwarded it to the Commission with a favourable opinion. By decision of 22 April 1998 [6] the Commission gave notice of its consent and France granted the authorisation by order of 3 August 1998. [7]

21. Monsanto, the holder of the authorisation, never applied for renewal thereof under Directive 2001/18. Instead, it notified MON 810, within the prescribed time-limit, as an existing product in accordance with Article 20(1) of Regulation No 1829/2003. Subsequently, in 2007, Monsanto applied for renewal of the authorisation under Article 20(4). Under Article 23(4) of Regulation No 1829/2003, the existing authorisation continues in effect during the renewal procedure.

22. On 5 December 2007 an order [8] prohibited the transfer and use of MON 810 maize seed in the territory of the French Republic. It stated that an assessment of the effects of MON 810 on the environment and health was under way, but contained no reference to the rules of European Union law on which the measure was based. The Commission states that the measure in question was never notified to it.

23. Subsequently, on 7 February 2008 a new order, [9] which was amended a few days later by another order of 13 February, [10] referring to the doubts expressed about MON 810 by a recently constituted *Comité de préfiguration de la Haute Autorité sur les organismes génétiquement modifiés* (Provisional Committee of the High Authority for genetically

6 — 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 Council Directive 90/220/EEC (OJ 1998 L 131, p. 32).

7 — JORF, 5 August 1998, p. 11985.

8 — JORF, 6 December 2007, p. 19748.

9 — JORF, 9 February 2008, p. 2462.

10 — JORF, 19 February 2008, p. 3004.

modified organisms), placed a general prohibition on the cultivation of MON 810. The grounds for the measure refer generally to both the directive and the regulation, but the only rule of European Union law specifically mentioned is Article 23 of the directive.

24. According to the Commission, the order of 7 February 2008 notified to it on two occasions, first on 11 February 2008 as a measure adopted under Article 23 of the directive and then, the following day, on 12 February 2008, as a measure under Article 34 of Regulation No 1829/2003.

25. The prohibition on the cultivation of MON 810 imposed by the French authorities was contested in various actions before the Conseil d'État, which stayed proceedings and referred the following questions to the Court for a preliminary ruling: [11]

'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], 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

11 — The wording cited here is that of the questions in Case C-58/10. The questions raised in the other cases are identical with the sole difference that the national rule stated in the second question is, in those cases, the order of 7 February 2008.

legal bases, the application raises 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?'

27. More specifically, it is necessary to clarify whether, in a case such as the present one, the power to adopt emergency measures where necessary lies primarily with the Member States, in accordance with the mechanism laid down in Article 23 of the directive, or with the Commission, pursuant to Article 34 of the regulation.

28. It is worth emphasising that the problem concerns only the 'transitional' stage in which the product has not yet obtained renewal of the authorisation. Although the matter is not covered by the present proceedings, it does not appear possible seriously to question the fact that, once authorisation has been renewed under the regulation, the rules of that regulation alone must be applied. Therefore, as regards emergency measures, it will be possible to adopt them solely on the basis of Article 34 of the regulation.

III — Consideration of the first question referred

26. By its first question, the national court asks which legal scheme must be applied to a product which was authorised on the basis of Directive 90/220 and then notified as an existing product in accordance with Regulation No 1829/2003, on the basis of which the renewal of authorisation was then applied for.

29. In the view of the French Government, whose view is, in essence, shared by the Austrian, Greek and Polish Governments, in a situation such as that in the present case Article 23 of the directive remains applicable and a Member State may therefore rely on it to adopt emergency measures directly. The Commission (and Monsanto and the other applicant companies in the main proceedings) hold the opposite view, to the effect that the notification of MON 810 as an 'existing product' in accordance with the regulation renders Article 23 of the directive

inapplicable, in particular on account of Article 12 thereof.

30. I note that, from a legal standpoint, the core issue in the main proceedings appears to consist in determining the scope of Article 12 of Directive 2001/18. As is apparent from the description of the legal framework, that article precludes the applicability of certain provisions of the directive, including Article 23 relating to emergency measures, to GMOs '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 … and 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'.

31. Thus, as we see, Article 23 of the directive is not applicable, on account of Article 12 thereof, to GMOs which satisfy certain specific requirements: (1) they must be GMOs 'authorised by Community legislation' (other than the directive, evidently); (2) that legislation must provide for an environmental risk assessment of the type required by the directive; and (3) that legislation must impose obligations at least equivalent to those of the directive as regards labelling and information to the public, etc.

32. It is therefore necessary to determine whether a GMO authorised under Directive 90/220 and notified in accordance with Regulation No 1829/2003 meets the requirements set out in the preceding paragraph.

33. I note first that, obviously, Article 12 of the directive could not refer expressly to the regulation since the latter postdates the directive by two years.

34. As regards more specifically the requirements listed in Article 12 of the directive, it should be noted that it is clear that MON 810 maize was authorised on the basis of requirements at least equivalent to those laid down in the directive, in that it was authorised *precisely on the basis of the directive* (or, more accurately, under Directive 90/220, which Directive 2001/18 consolidated by replacing it). [12] However, what characterises MON 810 is the fact that, by opting to notify it solely under the regulation and not under Directive 2001/18, Monsanto sought to subject that product to a legal scheme based exclusively on Regulation No 1829/2003 in order to take advantage of the greater simplicity offered by the 'single authorisation' system for cultivation and marketing. If MON 810 had also (or solely) been notified as an 'existing product'

12 — See, in particular, recital 3 in the preamble to Directive 2001/18.

in accordance with Article 17 of Directive 2001/18, there would be no doubt that Article 23 of the directive was applicable.

35. Therefore, it is necessary to determine whether, in fact, the conditions for placing on the market and/or cultivation imposed by the regulation are at least equivalent to those laid down in the directive.

36. The fact that the first of the conditions laid down in Article 12 of the directive is that the product be 'authorised' by European Union legislation (other than the directive) does not constitute, in my view, a factor which is capable of precluding the applicability of Article 12 to a product which is simply 'notified' in accordance with the regulation. It is established that, in the absence of notification in accordance with the regulation, MON 810 could no longer be either cultivated or placed on the market. Consequently, to all practical purposes, it is precisely notification within the meaning of the regulation which is the factor that 'authorises' the products to be cultivated and/or placed on the market in the territory of the European Union. Moreover, what is relevant are the conditions for cultivation and/or placing on the market, beyond the formal designation of the legislation which permits them ('notification' or 'authorisation').

37. In that regard, the combined provisions of Article 20(2) and 17(5)[13] of Regulation No 1829/2003 indicate clearly that, in order to notify an existing product in accordance with the regulation, all the necessary information for the purposes of Annexes II, III and IV of Directive 2001/18 must be provided.

38. Consequently, a product such as MON 810, once it has been authorised under Directive 90/220, may remain on the market under the regulation only after notification, which must include *all the information necessary to obtain authorisation in accordance with the directive*.

39. The other requirements laid down in Article 12 of the directive would also appear to be satisfied by the regulation, which includes, in particular, Article 29 relating to public access to information, Articles 12 to 14 and 24 to 26 relating to labelling, and of course Article 34 relating to emergency measures,. It may also be worth noting that recital 33 in the preamble to the regulation states that the evaluation of the environmental risk carried out pursuant to the regulation must 'comply with the requirements referred to in Directive 2001/18/EC'. More generally, recital 9 refers to the need for the 'new authorisation procedures' to observe 'the new principles introduced in Directive 2001/18/EC'.

13 — These are rules relating to products intended for animal consumption, such as MON 810. As regards products intended also for human consumption, the corresponding rules are Articles 5 and 8 of the regulation.

40. There is, moreover, no doubt that the intention of the legislature is that Regulation No 1829/2003 can replace entirely the system laid down in the directive where the holder of a product so wishes. [14] It would leave the effectiveness of the regulation open to question if it were necessary still to regard the provisions of the directive as applicable also to products which, from a legal point of view, are governed entirely by the regulation.

41. Moreover, even if Article 12 of Directive 2001/18 were not applicable to a product notified under Regulation No 1829/2003, such as MON 810, the possibility of using the safeguard clause provided for in Article 23 of the directive would be uncertain in a case such as the present one. It should be borne in mind that MON 810 *was never authorised under Directive 2001/18* and that the authorisation granted under the previous directive could continue in effect *only as notified under Regulation No 1829/2003*. It seems doubtful, therefore, that a provision (Article 23) of a 2001 directive could effect a substantive amendment to a 2003 regulation (in particular Article 34 thereof) which does not provide explicitly for any such derogation.

42. It is imperative to emphasise that the option of choosing between Article 23 of the directive and Article 34 of the regulation as a legal basis for adopting emergency measures is not an option of choosing between 'stronger' protection (under the directive) and 'weaker' protection (under the regulation). Despite the slightly different wording of the two provisions, to which I will return when discussing the third question, the only significant difference is the party called on to adopt the measure, namely a Member State in the case of the directive and the Commission in the case of the regulation. Clearly, however, it cannot be considered that the Commission – which, it should be remembered, received all the relevant documentation when the product was notified – provides 'weaker' guarantees than a Member State. On the contrary, since the essential objective of European Union legislation on GMOs is to reconcile the free movement of goods with the protection of health, [15] there is indubitable rationality in

14 — See also the *travaux préparatoires* for the regulation, in the course of which the Commission presented its proposal from the outset as designed to introduce a 'one door - one key' system, making it possible to obtain a single, authorisation valid both for the release of a GMO into the environment and the use thereof in food and/or feed. See, for example, paragraph 3 of the introduction to the initial Commission proposal of 25 July 2001, COM(2001) 425 final (OJ 2001 C 304 E, p. 221).

15 — See recitals 1 to 3 in the preamble to Regulation No 1829/2003. In case-law see, for example, by analogy, Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraph 74 and 106.

choosing to confer on the Commission the power to take emergency measures.

43. Thus, in the discussion of the first question, the reference to the precautionary principle is entirely irrelevant. As will be seen in the analysis of the third question, that principle is essential for determining *whether and to what extent* an emergency measure may be adopted, but has no bearing on determining *who* is competent to adopt it.

44. To recapitulate what is set out in the preceding paragraphs, Article 23 of the directive cannot be considered to be applicable in the present case. That is because the application thereof is precluded by Article 12 of the directive and, more generally, because MON 810 was never notified under Directive 2001/18.

45. I therefore consider that the answer to the first question referred is that, in the case of a GMO authorised in accordance with Directive 90/220, notified as an existing product pursuant to Regulation No 1829/2003 and in respect of which the authorisation renewal procedure is pending, any emergency measures may be adopted only on the basis of the regulation, in particular Article 34 thereof.

IV — Consideration at the second question referred for a preliminary ruling

46. By the second question, the Court is asked whether, if the only emergency measures that can be used are those referred to in Article 34 of the regulation – as I have proposed the Court should rule – a Member State may none the less adopt unilateral measures as the French Republic did in the present case.

47. The question would at first blush, appear simple to resolve. Article 34 of the regulation refers, in respect of the adoption of emergency measures, to Articles 53 and 54 of Regulation No 178/2002, which provide for action by the Commission as a matter of priority (Article 53) and action by a Member State only by way of alternative where the Commission fails to act (Article 54). Consequently, it would appear clear from an initial appraisal that a Member State may not adopt unilateral emergency measures without having first informed the Commission and requested it to act under Article 53 of Regulation No 178/2002.

48. The Commission and Monsanto took these considerations in particular as a basis for maintaining that, under applicable European Union legislation, the French Government was unable to prohibit MON 810 unilaterally without first requesting the Commission to act.

49. There is, however, a difficulty which was highlighted by the other parties who submitted observations in the present case. It arises from the wording of the abovementioned Article 53 of Regulation No 178/2002. As we saw earlier, that provision establishes that the Commission is to adopt appropriate measures where the problem 'cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned'. In other words, the provision confers on the Member States, for the purpose of adopting emergency measures, a role which *overrides* that conferred on the Commission, following the classic model of the principle of subsidiarity.

50. However, I consider that this is not so in the case of GMOs; an examination of the applicable provisions confirms the rule that the power to adopt emergency measures relating to GMOs under Article 34 of Regulation No 1829/2003, read in conjunction with Articles 53 and 54 of Regulation No 178/2002, lies principally with the Commission and not the Member States.

51. It should be noted that the subsidiarity clause which, in Article 53 of Regulation No 178/2002, restricts the Commission's power to act to cases in which the national authorities are unable to act satisfactorily is a *condition for the applicability of Article 53 in the context of the regulation in which it is placed*. Regulation No 178/2002, it must be remembered, has a very broad scope: it deals with food and feed generally, and not GMOs specifically. The conditions for applying those provisions laid down in Article 53 are applicable generally to all cases in which emergency food-related measures are necessary. In relation to GMOs authorised under Regulation No 1829/2003, however, the legislature chose to lay down a specific rule which departs from the 'normal' scheme for adopting emergency measures.

52. In particular, in this context the possibility of applying Article 53 of Regulation No 178/2002 where there are risks as referred to in Article 34 of Regulation No 1829/2003 *arises directly from Article 34*, which provides that on certain conditions 'measures shall be taken under *the procedures* provided for in Articles 53 and 54 of Regulation (EC) No 178/2002'.[16] It should be observed that Regulation No 1829/2003 does not refer to the *condition of applicability* of Articles 53 and 54 of Regulation No 178/2002 – the triggering of which is strictly linked to the context of the latter regulation – which consists in the existence of a risk which 'cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned'. On

16 — Emphasis added.

the contrary, Regulation No 1829/2003 refers only to the '*procedures*' provided for in those articles which consist, on the one hand, of the possibility of action by the Commission (Article 53) and, on the other, the possibility of interim action by the Member States where the Commission fails to act (Article 54).

53. Articles 53 and 54 of Regulation No 178/2002 are therefore relevant in the case of GMOs authorised under Regulation No 1829/2003 only with regard to the *procedures* for adopting the measures and not the *conditions* under which emergency measures can be adopted. Furthermore, those procedures are based unequivocally on the exercise of two separate powers, namely a principal power of the Commission and a merely subsidiary and exceptional power of the Member States.

54. In conclusion, it should further be noted that, also in the context of GMOs, the role conferred on the Member States for the adoption of emergency measures, although not equivalent to that of the Commission in whom the principal power to adopt measures is vested, is nevertheless highly significant, as is clear from the wording of the applicable provisions. On the one hand, as we can see clearly from the foregoing, under Article 53 of Regulation No 178/2002 the Member States may request the Commission to adopt emergency measures. On the other, where the Commission fails to act promptly in spite of the Member States' requests, the Member States may, under Article 54, adopt 'interim protective measures'.

55. To conclude my examination of the second question, I therefore propose that it be answered to the effect that, in the context of the procedure for adopting emergency measures as provided for in Article 34 of Regulation No 1829/2003, the Member States may adopt unilateral measures only on an interim basis, in accordance with the detailed rules laid down in Article 54 of Regulation No 178/2002, and only where, although a Member State has proposed adopting emergency measures, the Commission has failed to act promptly.

V — Consideration of the third question

56. By the third question, the referring court asks the Court to specify what conditions – in particular as regards possible risks – justify the adoption of emergency measures under Article 23 of the directive and Article 34 of the regulation respectively.

57. In the light of the answers which I have proposed should be given to the first two

questions, there may be no need to answer the third. Since the French Government did not have the authority to adopt unilateral measures without having first brought the problem to the Commission's attention, the conditions under which emergency measures may be adopted are not relevant to the decision in the main proceedings.

58. However, I consider that it is useful to examine this question as well, for two reasons. First, should the Court not concur in my view on the preceding questions and, second, because although, in my view, the French Republic could not adopt those measures immediately, it could request the Commission to do so and clarification by the Court could, in that situation, avoid subsequent uncertainties or inconsistencies.

59. From a literal point of view, as we have seen in the description of the legal framework, the conditions for applying emergency measures are described in different terms in Article 23 of the directive and Article 34 of the regulation. Under Article 23 of the directive, the Member States may adopt emergency measures where, on the basis of new information, they have 'detailed grounds for considering that a GMO … constitutes a risk to human health or the environment'. Article 34 of the regulation, on the other hand, restricts the adoption of such measures to cases where it 'is evident that [the GMOs] are likely to constitute a serious risk to human health, animal health or the environment, or where, in the light of an opinion of the Authority issued under Article 10 or Article 22, the need to suspend or modify urgently an authorisation arises'.

60. As can be readily seen, the two sets of wording are not identical and, at first glance, that of Article 23 of the directive appears to permit the adoption of emergency measures in more cases, since it speaks merely of a 'risk' without requiring that it be 'serious' as the regulation does. Furthermore, whilst the directive requires that a Member State have 'detailed grounds' for considering that there is a risk, the regulation requires that the risk be 'evident'.

61. The difference in wording can be explained by the different scope that the emergency measures can have in the two cases. An emergency measure within the meaning of Article 23 of the directive has a scope limited to a Member State, whilst a measure taken pursuant to Article 34 of the regulation produces its effects throughout the European Union. Consequently, it may appear reasonable to reflect more before adopting measures which have particularly far-reaching consequences.

62. I consider, however, that these differences should not be overrated and that, beyond the

lexical differences, the conditions for having recourse to the two types of measures can be considered to be fairly similar.

63. Firstly, Article 34 of the regulation, unlike Article 23 of the directive, provides that the Commission may adopt emergency measures, in addition to where a serious risk manifestly exists, in any case in which the European Food Safety Authority issues an opinion stating the need to suspend or modify urgently an authorisation. The opinion of the Authority is issued pursuant to Articles 10 (in respect of food) and 22 (in respect of feed) of the regulation, and can be issued at the request of a Member State or the Commission, or on the initiative of the Authority itself. However, what is important is that the reasons why the opinion may suggest that the authorisation be suspended or modified urgently are *not specified in the regulation* and are therefore within the discretion of the Authority which, on the basis of its technical expertise, must establish whether a GMO 'still meets the conditions set by this Regulation'.

64. Secondly, the precautionary principle, of which the safeguard clauses, such as Article 23 of the directive and Article 34 of the regulation, are expressions, is a factor which makes a decisive contribution to standardising the conditions laid down in the directive and the regulation. [17] That principle which, with regard to the environment, is enshrined in Article 191(2) TFEU, means, according to settled case-law, that '[w]here there is uncertainty as to the existence or extent of risks …, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent'. [18]

65. The Treaty contains no definition of the precautionary principle, but wording similar to that developed in the case-law is to be found in secondary law. In particular, Article 7 of the Regulation No 178/2002, which is not directly applicable in the present case, but can certainly be taken into account, provides as follows:

'1. In specific circumstances where, following an assessment of available information,

17 — *Monsanto Agricoltura Italia and Others*, cited in footnote 15, paragraph 110.

18 — Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 63. See also, more recently, Case C-95/01 *Greenham and Abel* [2004] ECR I-1333, paragraph 43, and Case C-504/04 *Agrarproduktion Staebelow* [2006] ECR I-679, paragraph 39.

the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.'

66. Therefore, in the light of the precautionary principle and the interpretation placed thereon by the Court of Justice and legislation of the European Union, in order to adopt emergency measures, irrespective of whether they are adopted under Article 23 of the directive or Article 34 of the regulation, there must be a significant risk, that is to say, not a merely hypothetical risk, [19] of adverse effects on health or the environment. It is not essential for the risk to be precisely quantifiable from the outset, however, the specification that the risk must be 'serious' in accordance with Article 34 of the regulation must, in my view, be construed as meaning that the probability of a harmful event occurring is real and not within the normal limits of the risk inherent in any human activity.

67. It is impossible to define beforehand precisely what level of risk generally justifies the adoption of emergency measures. Case-law couched in abstract terms would be of little or no use for the decisions which must be taken in practice. The assessment of the risk must be carried out on a case-by-case basis by the party called on to adopt the decisions and thus, in the case of Article 34 of the regulation, by the Commission.

68. In other words, and formulating the idea in more general terms in relation to Article 34 of the regulation, for the adoption of emergency measures, there must (a) clearly be a risk that harm will be caused, and (b) a significant probability that the harm in question will occur, even though it has not necessarily

19 — *Monsanto Agricoltura Italia and Others*, cited in footnote 15, paragraph 106.

been determined precisely (the 'serious' nature of the risk interpreted in the light of the precautionary principle).

69. The threshold of the probability of the harm justifying the adoption of emergency measures occurring cannot be determined in advance because, as we have seen, that would constrain the parties called on to take the decisions in an excessively rigid manner and, under the precautionary principle, a measure can be adopted even where there is still a degree of uncertainty as to the actual probability of the harmful event occurring. Furthermore, in their case-by-case assessment, the competent authorities will naturally be inclined to assess the acceptable percentage of risk on the basis of a cost/benefit ratio: the greater the benefits brought by a product, the greater the level of risk which will be deemed acceptable.

70. The decisions taken by the competent authorities are naturally subject as such to judicial review. In the case of the Commission, which is competent under Article 34 of the regulation, review naturally lies with the courts of the European Union and therefore in the final analysis with the Court of Justice. Since the decisions which must be adopted in that sector require, by their very nature, complex technical assessments, judicial review will, according to constant case-law, have to be limited to verifying whether the relevant procedural rules have been complied with, whether the facts accepted by the Commission have been accurately stated and whether there has been a manifest error of assessment or a misuse of powers. [20]

71. I therefore propose that the Court answer the third question referred to the effect that, in order to adopt emergency measures relating to genetically modified organisms pursuant to Article 34 of the regulation, it is necessary for the existence of a risk to human health, animal health or the environment to be established, which is not merely hypothetical, and for the probability of such harm occurring to be significant, even though it has not necessarily been determined precisely.

20 — See, for example, Case C-77/09 *Gowan Comércio* [2010] ECR I-13533, paragraph 56, and case-law cited. With specific reference to the adoption of emergency measures see *National Farmers' Union and Others*, cited in footnote 18, paragraph 39.

VI — Conclusion

72. In conclusion, I propose that the Court answer the questions referred for a preliminary ruling by the Conseil d'État as follows:

1. In the case of a genetically modified organism (GMO) authorised under Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, notified as an existing product pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed and in respect of which the authorisation renewal procedure is pending, any emergency measures may be adopted only on the basis of the regulation, in particular Article 34 thereof.

2. In the procedure for adopting emergency measures provided for in Article 34 of Regulation No 1829/2003, the Member States may adopt unilateral measures only on an interim basis, in accordance with the detailed rules laid down 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, and only where, although a Member State has proposed adopting emergency measures, the European Commission has failed to act promptly.

3. In order to adopt emergency measures relating to genetically modified organisms pursuant to Article 34 of Regulation No 1829/2003, it is necessary for the existence of a risk to human health, animal health or the environment to be established, which is not merely hypothetical, and for the probability of such harm occurring to be significant, even though it has not necessarily been determined precisely.