JUDGMENT OF THE COURT

21 March 2000 *

In Case C-6/99,

REFERENCE to the Court under Article 177 of the EC Treaty (now Article 234 EC) by the Conseil d'État, France, for a preliminary ruling in the proceedings pending before that court between

Association Greenpeace France and Others,

and

Ministère de l'Agriculture et de la Pêche and Others

Third parties:

Novartis Seeds SA,

Monsanto Europe SA,

on the interpretation of Article 13(2) and (4) of 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 amended by Commission Directive 97/35/EC of 18 June 1997 adapting to technical progress for the second time Council Directive 90/220 (OJ 1997 L 169, p. 72),

* Language of the case: French.

THE COURT,

composed of: G.C. Rodríguez Iglesias, President, J.C. Moitinho de Almeida, L. Sevón and R. Schintgen (Presidents of Chambers), P.J.G. Kapteyn (Rapporteur), C. Gulmann, J.-P. Puissochet, G. Hirsch, M. Wathelet, V. Skouris and F. Macken, Judges,

Advocate General: J. Mischo,
Registrar: H. von Holstein, Deputy Registrar,

after considering the written observations submitted on behalf of:

— Association Greenpeace France, by A. Faro, of the Paris Bar,

— Confédération Paysanne, by M.-C. Etelin, of the Toulouse Bar, and M. Caussanel-Haji, of the Paris Bar,

— Association Ecoropa France and Étienne Vernet, by C. Lepage, of the Paris Bar,

— Novartis Seeds SA, by E. Baraduc-Bénabent, Advocate with rights of audience before the Conseil d'État and the Cour de Cassation, and E. Morgan de Rivery, of the Paris Bar,

— Monsanto Europe SA, by A. Lyon-Caen, F. Fabiani and F. Thiriez, Advocates with rights of audience before the Conseil d'État and the Cour de Cassation,

— the Italian Government, by U. Leanza, Head of the Legal Department of the Ministry of Foreign Affairs, acting as Agent, and O. Fiumara, Avvocato dello Stato,

— the Austrian Government, by C. Pesendorfer, Oberrätin at the Austrian Cancellery, acting as Agent,

— the Commission of the European Communities, by G. zur Hansen, Legal Adviser, and O. Couvert-Castéra, a national civil servant on secondment to the Legal Service, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Association Greenpeace France, represented by A. Faro; of Confédération Paysanne, represented by M.-C. Etelin; of Association Ecoropa France and Etienne Vernet, represented by C. Lepage; of Novartis Seeds SA, represented by E. Baraduc-Bénabent and E. Morgan de Rivery; of Monsanto Europe SA, represented by A. Lyon-Caen; of the French Government, represented by R. Abraham, Legal Affairs Director at the Ministry of Foreign Affairs, acting as Agent; of the Italian Government, represented by O. Fiumara; and of the Commission, represented by G. zur Hausen and O. Couvert-Castéra, at the hearing on 9 November 1999,

after hearing the Opinion of the Advocate General at the sitting on 25 November 1999,

gives the following

Judgment

1 By decision of 11 December 1998, received at the Court on 13 January 1999, the Conseil d'État referred to the Court for a preliminary ruling under Article 177 of the EC Treaty (now Article 234 EC) two questions on the interpretation of 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 amended by Commission Directive 97/35/EC of 18 June 1997 adapting to technical progress for the second time Council Directive 90/220 (OJ 1997 L 169, p. 72, hereinafter 'Directive 90/220').

2 Those questions have been raised in an appeal brought by Association Greenpeace France (hereinafter 'Greenpeace') seeking the annulment of the decree made on 5 February 1998 by the Minister for Agriculture and Fisheries amending the official list of plant species and varieties grown in France so as to include in that list a species of genetically modified maize produced by Ciba-Geigy Ltd, which has now become Novartis Seeds SA.

Community law

Directive 90/220

3 According to Article 1(1) of Directive 90/220, the objective of that directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment as regards the deliberate release of genetically modified organisms ('GMOs') into the environment and the placing on the market products containing, or consisting of, GMOs intended for subsequent deliberate release into the environment.

4 Article 4 of Directive 90/220 requires the Member States to ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs.

5 Part C of Directive 90/220 (Articles 10 to 18) contains specific provisions concerning the placing on the market of products containing GMOs. According to Article 11(5) of the directive, read in combination with paragraph (1), no product containing GMOs may be released into the environment before the competent authority of the Member State in which the product is to be placed on the market for the first time has given its written consent following a notification to that authority by the manufacturer or the importer into the Community. Article 11(1) to (3) of the directive specifies the information to be contained in that notification, which must, in particular, enable the national authority to carry out the risk assessment required by Article 10(1). That risk assessment must precede any consent.

6 Article 12 of Directive 90/220 provides:

'1. On receipt and after acknowledgement of the notification referred to in Article 11, the competent authority shall examine it for compliance with this Directive, giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product.

2. At the latest 90 days after receipt of the notification, the competent authority shall either:

(a) forward the dossier to the Commission with a favourable opinion, or

(b) inform the notifier that the proposed release does not fulfil the conditions of this Directive and that it is therefore rejected.

3. In the case referred to in paragraph 2(a), the dossier forwarded to the Commission shall include a summary of the notification together with a statement of the conditions under which the competent authority proposes to consent to the placing on the market of the product.

The format of this summary shall be established by the Commission in accordance with the procedure laid down in Article 21.

In particular where the competent authority has acceded to the request of the notifier, under the terms of the last subparagraph of Article 11(1), not to comply with some of the requirements of Annex III B, it shall at the same time inform the Commission thereof.

4. If the competent authority receives additional information pursuant to Article 11(6), it shall immediately inform the Commission and the other Member States.

5. For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account.'

7 Article 13 of Directive 90/220 provides:

'1. On receipt of the dossier referred to in Article 12(3), the Commission shall immediately forward it to the competent authorities of all Member States together with any other information it has collected pursuant to this Directive and advise the competent authority responsible for forwarding the document of the distribution date.

2. The competent authority, in the absence of any indication to the contrary from another Member State within 60 days following the distribution date referred to in paragraph 1, shall give its consent in writing to the notification so that the product can be placed on the market and shall inform the other Member States and the Commission thereof.

3. In cases where the competent authority of another Member State raises an objection — for which the reasons must be stated — and should it not be possible for the competent authorities concerned to reach an agreement within the period specified in paragraph 2, the Commission shall take a decision in accordance with the procedure laid down in Article 21.

4. Where the Commission has taken a favourable decision, the competent authority that received the original notification shall give consent in writing to the notification so that the product may be placed on the market and shall inform the other Member States and the Commission thereof.

5. Once a product has received a written consent, it may be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.

6. Member States shall take all necessary measures to ensure that users comply with the conditions of use specified in the written consent.'

8 Article 11(6) of Directive 90/220 provides that the notifier must inform the competent authority of any new information which has become available with regard to the risks of the product to human health or the environment, either before or after the written consent. According to Article 12(4) of Directive 90/220, information so received by the competent authority must immediately be forwarded by it to the Commission and the other Member States.

9 Article 16 of Directive 90/220 provides:

'1. Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2. A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 21.'

Decision 97/98

10 On 23 January 1997, the Commission adopted Decision 97/98/EC concerning the placing on the market of genetically modified maize (*Zea mays L.*) with the combined modification for insecticidal properties conferred by the Bt-endotoxin gene and increased tolerance to the herbicide glufosinate ammonium pursuant to Council Directive 90/220 (OJ 1997 L 31, p. 69).

11 That decision is worded as follows:

'Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, as amended by Commission Directive 94/15/EC, and in particular Article 13 thereof,

Whereas Articles 10 to 18 of Directive 90/220/EEC lay down a Community procedure enabling the competent authority of a Member State to give consent to the placing on the market of products consisting of genetically modified organisms;

Whereas a notification concerning the placing on the market of such a product has been submitted to the competent authority of a Member State (France);

Whereas the competent authority of France subsequently forwarded the dossier to the Commission with a favourable opinion; whereas the competent authorities of other Member States have raised objections to the said dossier;

Whereas, therefore, in accordance with Article 13(3) of Directive 90/220/EEC, the Commission is required to take a decision in accordance with the procedure provided for in Article 21 of that Directive;

Whereas, having examined each objection in the light of the provisions of Directive 90/220/EEC and analysed the information supplied in the dossier, the Commission reached the following conclusions:

— the applicant provided information on all the newly introduced genes, and not only those expressed,

— the risk assessment took account of all the introduced genes whether expressed or not. Assessment was also made in this case of the risks from the presence of the non-expressed β-lactamase gene with a bacterial promoter,

— in the case of products intended for use as human food or animal feed, risk assessment under Directive 90/220/EEC determines whether the genetic modification is liable to result in any toxic or other harmful effects for human health and the environment,

— there is no reason to believe that the introduction of these genes into maize will have any adverse effects on human health or the environment,

— possible development of resistance to the truncated CryIA(b) protein in insects cannot be considered an adverse environmental effect, as existing agricultural means of controlling such resistant species of insects will still be available,

— there are no safety grounds for mentioning on the label that the product has been obtained by genetic modification techniques,

— the label should indicate that the plants have increased tolerance to the herbicide glufosinate ammonium;

Whereas authorisation of chemical herbicides, and assessment of how their use impacts on human health and the environment, are governed by Council

Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, as last amended by Commission Directive 96/68/EC, and not by Directive 90/220/EEC;

Whereas the product under consideration has been notified for unrestricted use, including human food and animal feed;

Whereas this Decision does not exclude the application, in compliance with Community law, of Member State provisions on human food or animal feed safety to the extent that they are not specifically related to the genetic modification of the product or its components;

Whereas Article 11(6) and Article 16(1) of Directive 90/220/EEC provide additional safeguards if new information on risks presented by the product becomes available;

Whereas the committee set up by Article 21 of Directive 90/220/EEC and consulted by written procedure on 8 March 1996 has not delivered an opinion on the measures laid down in a draft Commission decision;

Whereas the Council did not take a decision on a proposal from the Commission within the time provided for in the fifth paragraph of Article 21 of Directive 90/220/EEC; whereas, consequently, it falls to the Commission to adopt the proposed measures;

Whereas the respective opinions of the Scientific Committee for Animal Nutrition established by Commission Decision 76/791/EEC, that of the Scientific Commission for Food established by Commission Decision 95/273/EC and finally that of the Scientific Committee for Pesticides established by Commission Decision 78/436/EEC, asked by the Commission to confirm that there is no reason to believe that the introduction of the genes concerned into the maize would have any adverse effects on human health or on the environment, did not identify any new elements which would justify any different decision,

has adopted this decision:

Article 1

1. Without prejudice to other Community legislation and subject to paragraphs 2 and 3, the French authorities shall give consent to the placing on the market of the following product, notified by Ciba-Geigy Limited (Ref. C/F/94/11-03), in accordance with Article 13 of Directive 90/220/EEC.

The product consists of inbred lines and hybrids derived from a maize (*Zea mays L.*) line (CG 00256-176) which has been transformed using plasmids containing:

(i) one copy of the *bar* gene, from *Streptomyces hygroscopicus*, (encoding a phosphinothricin acetyltransferase), under the regulation of the 35S promoter and the 35S terminator from the cauliflower mosaic virus (CaMV);

(ii) two copies of a synthetic truncated gene encoding an insect control protein representing the active portion of the CryIA(b) δ-endotoxin, from *Bacillus thuringiensis subsp. kurstaki* strain HD1-9 and containing intron # 9 from the maize phosphoenolypyruvate carboxylase gene;

the first copy is under the regulation of a promoter from the maize phosphoenolpyruvate carboxylase gene and the CaMV 35S terminator, and the second copy under the regulation of a promoter derived from a maize calcium-dependent protein kinase gene and the CaMV terminator;

(iii) the prokaryotic gene *bla* (coding for a β-lactamase conferring resistance to ampicillin) under prokaryotic promoter.

2. The consent covers any progeny derived from crosses of this product with any traditionally bred maize.

3. Without prejudice to other labelling required by Community legislation, the label of each package of seeds shall indicate that the product:

— protects itself against corn borers, and

— has increased tolerance to the herbicide glufosinate-ammonium.

Article 2

This Decision is addressed to the Member States.'

French law

12 Law No 92-654 of 13 July 1992 on the control of the use and release of genetically modified organisms and amending Law No 76-663 of 19 July 1976 on plant classified for the protection of the environment lays down, in Articles 15 and 16, the procedure to be followed in order to obtain authorisation to place on the market a product composed in whole or in part of a GMO. The placing on the market must be the subject of prior authorisation, which must be issued by the administrative authority after an assessment of the risks for public health or for the environment (Article 15). Authorisations issued by other Member States are deemed equivalent to national authorisations for the purposes of the Law (Article 16, first paragraph). However, where there are good reasons for considering that a product authorised by another Member State presents risks for public health or for the environment, the administrative authority may provisionally restrict or prohibit its use or placing on the market (Article 16, second paragraph).

13 Decree No 81-605 of 18 May 1981, adopted in implementation of the Law of 1 August 1905 on the prevention of offences relating to trade in seeds and plants, amended by Decree No 93-1177 of 18 October 1993, adopted in implementation, as regards plants, seeds and propagating materials, of Title III of Law

No 92-654 of 13 July 1992 (hereinafter 'Decree No 81-605'), lays down the rules applicable to the authorisation of the placing on the market of plants, seeds and propagating materials.

14 According to Article 4-1 of Decree No 81-605, the Minister for Agriculture is to issue, upon a favourable opinion from the Minister for the Environment, the authorisations required for any release intended to produce seeds or plants which are to be placed on the market. The last paragraph of that provision provides that, where the seeds or propagating material have been included in a list or annexed register, the registration decree is to constitute authorisation. However, according to Article 15-1 of Decree No 81-605, where the genetically modified seed or propagating material has not been the subject of such registration, the required authorisation is to be issued by decree of the Minister for the Environment.

15 According to Article 6-1, point II, of Decree No 81-605, examination of the application for authorisation by the competent administrative authority must lead within 90 days either to a decision rejecting the application or to transmission of the application dossier to the Commission with a favourable opinion. Article 6-1, point III, of Decree No 81-605 provides that, where no objection has been raised by another Member State at the end of the period of 60 days following the date of distribution of the dossier by the Commission, authorisation may be given only after a decision of the competent Community authority.

16 Article 7-1 of Decree No 81-605 allows the administrative authority to re-examine the authorisation granted and to take certain measures if a fresh assessment of the risks for human health or the environment justify this. According to Article 8-1 of Decree No 81-605, an applicant for authorisation must notify the Minister for Agriculture of any new information relating to the risks constituted by the GMO or the GMOs to public health or the environment known either before or after the obtaining of the authorisation and, where appropriate, must take protective measures himself.

The facts and the questions referred for a preliminary ruling

17 Following Decision 97/98, the French Minister for Agriculture, Fisheries and Food adopted, on 4 February 1997, a decree authorising the placing on the market of a genetically modified maize (*ZEA mays L.*) protected gainst corn borers and having increased tolerance to herbicides of the glufosinate-ammonium family (hereinafter 'the decree of 4 February 1997'), which constitutes the 'consent in writing' provided for in Article 13 of Directive 90/220. On 5 February 1998, the same minister adopted a decree modifying the official list of plant species and varieties grown in France (maize seeds) (hereinafter 'the decree of 5 February 1998'). The purpose of that decree was to authorise the marketing of seeds of certain varieties of genetically modified maize.

18 Greenpeace applied to the Conseil d'État to have the decree of 5 February 1998 suspended or annulled.

19 The application for suspension of operation of that decree was the subject of a decision of the Conseil d'État of 25 September 1998, by which application of the decree was suspended on the ground that a plea raised by Greenpeace appeared to have considerable force and to be capable of justifying its annulment and that application of the decree could entail consequences such as to justify an order for its suspension. The plea advanced by Greenpeace, found to have considerable force at the time when the Conseil d'État ordered suspension of application of the decree, was that the decree had been adopted following an irregular procedure and that it infringed the precautionary principle.

20 In its decision of 25 September 1998, the Conseil d'État stated in particular that Greenpeace contended that 'the opinion of the Committee for the Study of the Release of Products of Biomolecular Engineering had been delivered on the basis of a dossier that was incomplete inasmuch as it did not include information that would allow an assessment of the impact on public health of the ampicillin-resistant gene contained in the varieties of transgenic maize that were the subject of the application for authorisation'.

21 The action for annulment brought by Greenpeace against the decree of 5 February 1998 was joined by the Conseil d'État to four other applications, all seeking the annulment of that decree, lodged by three other associations and, in the last case, by three private individuals.

22 A number of pleas concerning the formal legality and the substantive legality of the decree of 5 February 1998 have been raised by the applicants in the main proceedings. In particular, they claim that the decree is unlawful on the ground that the decree of 4 February 1997 pursuant to which it was adopted was itself unlawful. It is contended in particular that the decree of 4 February 1997 authorising the placing on the market of the maize lines in question in the main proceedings is unlawful on the ground that the administrative procedure followed by the French authorities before the dossier was forwarded to the Commission was irregular.

23 It was in those circumstances that the Conseil d'État decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Must the provisions of Council Directive 90/220/EEC of 23 April 1990 be interpreted as meaning that if, after an application to place a genetically modified organism on the market has been forwarded to the Commission of the European Communities, no Member State has raised an objection as provided for in Article 13(2) of Directive 90/220, or if the Commission of the European Communities has taken a "favourable decision" pursuant to Article 13(4), the competent authority which forwarded the application to the Commission with a favourable opinion is obliged to give the "consent in writing" allowing the product to be placed on the market, or does that authority retain a discretion not to give such consent?

(2) Must the decision of the Commission of the European Communities of 23 January 1997 under which "the French authorities are to authorise the

placing on the market of the product ... notified by Ciba-Geigy Limited" be interpreted as requiring the French Government to give its "consent in writing"?'

The first question

24 By its first question the national court asks whether a Member State which has received a notification relating to the placing on the market of a GMO and which has forwarded the dossier to the Commission with a favourable opinion, and where no other Member State has raised an objection or the Commission has adopted a favourable decision, enjoys a discretion allowing it not to give its consent.

25 It should be pointed out first of all that Article 13(4) of Directive 90/220 provides: 'Where the Commission has taken a favourable decision, the competent authority that received the original notification shall give consent in writing to the notification so that the product may be placed on the market' and that, according to Article 13(2), the same obligation exists if that authority has not received any indication to the contrary from another Member State within 60 days following the date on which the Commission distributed the dossier.

26 In this regard, Greenpeace argues that, although Article 13(4) of Directive 90/220 might suggest that the competent authority must give its consent, such a reading is not compatible with the preamble to or the general scheme of the directive. Furthermore, in its submission, the definition of the term 'consent' would presuppose in every case an expression of free agreement.

27 According to Ecoropa, an interpretation of Article 13(4) of Directive 90/220 to the effect that the Member State is obliged to give its consent in writing so as to allow the marketing of the product when the Commission has taken a favourable decision is excluded by the terms of that provision. In this regard, Ecoropa argues in particular that, if there had been no scope for the exercise of discretion, the wording of the provision would have been different.

28 It must be observed first of all that, whilst another wording might have made it more explicit that the Member States' powers were circumscribed, the fact remains that both the use, in the French version of Article 13(2) and (4) of Directive 90/220, of the present indicative and the construction in the sentences in that provision indicate clearly and unequivocally that the Member State concerned is obliged to give its consent.

29 Furthermore, the meaning and content of that provision are reflected in other language versions of Directive 90/220, in particular in the English version ('The competent authority ... shall give its consent in writing').

30 Consequently, having regard to the terms of Article 13(2) and (4) of Directive 90/220, that provision places the Member State concerned, in the cases there referred to, under an obligation to issue its consent in writing.

31 The next question to be examined is whether, as the applicants in the main proceedings claim, the procedural context of Article 13(2) and (4) precludes such an interpretation.

32 In this regard, Greenpeace and Confédération Paysanne argue that, since it is clear from Article 13(2) and (4) of Directive 90/220 that authorisation to place a product on the market is based on the consent in writing given by the competent national authority, an interpretation such as that set forth in paragraph 30 above would mean that the Commission's favourable decision, and not that of the competent national authority, would constitute authorisation to place the product on the market, thus depriving the Member States of any discretion before they give their consent.

33 On this point, it must be emphasised that, for the purposes of implementing a Community procedure for authorising the placing on the market of products containing GMOs, the Community legislature, in Articles 10 to 18 of Directive 90/220, has provided for close cooperation between the Commission and the competent authority of the Member State in which the product is to be placed on the market for the first time.

34 According to Articles 12 and 13 of the directive, the procedure for authorising the placing on the market of products containing GMOs consists of two stages.

35 First, as regards the competent national authority, it follows from Article 12(1) of Directive 90/220 that that authority, after receiving the notification, referred to in Article 11, from the manufacturer or the importer concerned must examine whether that notification is in compliance with Directive 90/220, giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product. According to Article 12(2), at the latest 90 days after receipt of the notification, the competent authority is to forward the dossier to the Commission with a favourable opinion or inform the notifier that the proposed release does not fulfil the conditions of Directive 90/220 and that it is therefore rejected.

36 Article 12(3) of Directive 90/220 provides that the dossier forwarded to the Commission is to include a summary of the notification together with a statement of the conditions under which the competent authority 'proposes to consent to the placing on the market of the product'.

37 Thus, the purpose of the national stage of the procedure for placing products containing GMOs on the market is, according to the seventeenth recital of the preamble to Directive 90/220, to enable the competent authority to give its favourable opinion followed, where appropriate, by its consent in writing only after it has been satisfied that the release will be safe for human health and the environment.

38 Secondly, as far as the Commission is concerned, Article 13(1) of Directive 90/220 provides that it is to forward the dossier to the competent authorities of all Member States together with any other information which it has collected pursuant to the directive. The national competent authority is to give its consent in the absence of any indication to the contrary from another Member State, as provided for in Article 13(2), or, in the case envisaged in paragraph (4), where the Commission has taken a favourable decision in accordance with the procedure provided for in Article 21 of Directive 90/220 to which Article 13(3) of the directive refers.

39 It follows that the procedure for authorising the placing on the market of a product containing GMOs, envisaged in Directive 90/220, comes into operation only at the end of a procedure during which the national authorities have adopted a favourable opinion on the basis of the examination provided for in Article 12(1) of the directive and have thus had the opportunity fully to exercise their own powers to assess the risks which the release of products containing GMOs entails for human health and the environment.

40 Finally, the applicants in the main proceedings argue that an interpretation of Article 13(2) and (4) of Directive 90/220 to the effect that the Member States' powers are circumscribed would be contrary to the precautionary principle.

41 It must be pointed out in this regard that, according to the eighth recital of the preamble to Directive 90/220, the directive establishes 'harmonised procedures and criteria for the case-by-case evaluation of the potential risks arising from the deliberate release of GMOs into the environment'. According to the ninth recital, such a case-by-case assessment should always be carried out prior to a release.

42 As is clear from paragraph 39 above, it is to that end that the competent national authorities have a power of assessment for the purpose of ensuring that the notification referred to in Article 11 of the directive is in conformity with its requirements, giving particular attention to the assessment of the risks arising from the placing on the market of products containing GMOs for the environment and human health, as provided for in Article 12(1) of Directive 90/220 and as mentioned in the third recital.

43 As regards the competent authorities of the other Member States, Article 13(2) and (3) of Directive 90/220 provides that these may raise objections before the competent authority concerned gives its consent to the notification.

44 Next, observance of the precautionary principle is reflected in the notifier's obligation, laid down in Article 11(6) of Directive 90/220, immediately to notify the competent authority of new information regarding the risks of the product to human health or the environment and the competent authority's obligation, laid down in Article 12(4), immediately to inform the Commission and the other Member States about this information and, secondly, in the right of any Member State, provided for in Article 16 of the directive, provisionally to restrict or prohibit the use and/or sale on its territory of a product which has received

consent where it has justifiable reasons to consider that it constitutes a risk to human health or the environment.

45 It must be added that the system of protection put in place by Directive 90/220, in particular by Articles 4, 12(4) and 16, necessarily implies that the Member State concerned cannot be obliged to give its consent in writing if in the meantime it has new information which leads it to consider that the product for which notification has been received may constitute a risk to human health and the environment.

46 In such a case, the Member State concerned must immediately inform the Commission and the other Member States about this information in order that, within the period laid down in Article 16(2) of Directive 90/220, a decision may be taken on the matter in accordance with the procedure provided for in Article 21 of the directive.

47 It follows from the foregoing that Directive 90/220 is to be interpreted as meaning that, if, after an application for placing a GMO on the market has been forwarded to the Commission, no Member State has raised an objection, in accordance with Article 13(2) of the directive, or if the Commission has taken a 'favourable decision' under paragraph (4) of that provision, the competent authority which forwarded the application, with a favourable opinion, to the Commission must issue the 'consent in writing', allowing the product to be placed on the market. However, if in the meantime the Member State concerned has new information which leads it to consider that the product for which notification has been received may constitute a risk to human health and the environment, it will not be obliged to give its consent, provided that it immediately informs the Commission and the other Member States about the new information in order that, within the period laid down in Article 16(2) of Directive 90/220, a decision may be taken in the matter in accordance with the procedure provided for in Article 21 of that directive.

The second question

48 It is clear from the national court's file that, by its second question, it is asking essentially whether the Commission's 'favourable decision' obliges the competent national authority to give its 'consent in writing', notwithstanding any irregularities which might be found by a court in the conduct of the examination of the notification by that authority and which are such as to call in question the legality of the decision to forward the dossier with a favourable opinion to the Commission.

49 As pointed out in paragraph 47 above, when the Commission has taken a 'favourable decision' under Article 13(4) of Directive 90/220, the competent authority which forwarded the application with a favourable opinion to the Commission must, save in the circumstances mentioned at the end of that paragraph, issue the 'consent in writing' allowing the product to be placed on the market.

50 Such an obligation presupposes that, pursuant to Article 12(2)(a) of Directive 90/220, the competent national authority has forwarded the dossier to the Commission with a favourable opinion and has thus initiated the Community phase of the procedure for authorising the product concerned to be placed on the market.

51 Thus, that decision of the competent authority is the prerequisite for the Community procedure and, in the absence of any indication to the contrary from another Member State within the period laid down in Article 13(2) of the directive, may even determine its outcome.

52 Since the favourable opinion of the competent national authority is based on the results of the examination of the notification provided for in Article 12(1) of Directive 90/220, it is necessary to examine the effect on the validity of the Commission's favourable decision of any irregularities in the conduct of that

examination which are such as to call in question the legality of the decision to forward the dossier with a favourable opinion to the Commission.

53 Since it is an act adopted by a national authority, it is for the national courts to decide on the regularity of the examination of the notification provided for by Article 12(1) of Directive 90/220 and on the consequences which any irregularities in the conduct of that examination might have on the legality of the decision taken by the competent authority, under Article 12(2)(a) of that directive, to forward the dossier to the Commission with a favourable opinion.

54 It should also be observed that, where the administrative implementation of a Community decision is a matter for the national authorities, the judicial protection guaranteed by Community law affords individuals the right to challenge, indirectly, the legality of that decision before the national court and to ask it to refer questions to the Court of Justice for a preliminary ruling on the validity of that decision. In such a case, the Court of Justice alone has competence to declare a Community act to be invalid (see the judgment in Case 314/85 *Foto Frost* [1987] ECR 4199, paragraph 17).

55 It follows that, where the national court finds that, owing to irregularities in the conduct of the examination of the notification by the competent national authority provided for in Article 12(1) of Directive 90/220, it was not proper for that authority to forward the dossier with a favourable opinion to the Commission as provided for in paragraph 2 of that provision, that court must refer the matter to the Court of Justice for a preliminary ruling if it considers that those irregularities are such as to affect the validity of the Commission's favourable decision, setting out the reasons for which it believes that the decision must be held to be invalid and, if necessary, ordering suspension of application of the measures for implementing that decision until the Court of Justice has ruled on the question of validity (see, to this effect, the judgment in Joined Cases

C-143/88 and C-92/89 *Zuckerfabrik Süderdithmarschen and Zuckerfabrik Soest* [1991] ECR I-415, paragraph 24).

56 Should the Court of Justice hold that the Commission's favourable decision is unlawful, the conditions for the issue of the consent in writing by the competent authority laid down in Article 13(2) and (4) of Directive 90/220 would not be fulfilled and the consent in writing would therefore not have been validly given or could not be validly given.

57 It follows from the foregoing that, where the national court finds that, owing to irregularities in the conduct of the examination of the notification by the competent national authority provided for in Article 12(1) of Directive 90/220, it was not proper for that authority to forward the dossier with a favourable opinion to the Commission as provided for in paragraph (2) of that provision, that court must refer the matter to the Court of Justice for a preliminary ruling if it considers that those irregularities are such as to affect the validity of the Commission's favourable decision, if necessary ordering the suspension of application of the measures for implementing that decision until the Court of Justice has ruled on the question of validity.

Costs

58 The costs incurred by the French, Italian and Austrian Governments and the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings,

a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT,

in answer to the questions referred to it by the Conseil d'État by decision of 11 December 1998, hereby rules:

1. Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, as amended by Commission Directive 97/35/EC of 18 June 1997 adapting to technical progress for the second time Council Directive 90/220, is to be interpreted as meaning that, if, after an application for placing a GMO on the market has been forwarded to the Commission, no Member State has raised an objection, in accordance with Article 13(2) of that directive, or if the Commission has taken a 'favourable decision' under paragraph (4) of that provision, the competent authority which forwarded the application, with a favourable opinion, to the Commission must issue the 'consent in writing', allowing the product to be placed on the market. However, if in the meantime the Member State concerned has new information which leads it to consider that the product for which notification has been received may constitute a risk to human health and the environment, it will not be obliged to give its consent, provided that it immediately informs the Commission and the other Member States about the new information in order that, within the period laid down in Article 16(2) of Directive 90/220, a decision may be

taken in the matter in accordance with the procedure provided for in Article 21 of that directive.

2. Where the national court finds that, owing to irregularities in the conduct of the examination of the notification by the competent national authority provided for in Article 12(1) of Directive 90/220, it was not proper for that authority to forward the dossier with a favourable opinion to the Commission as provided for in paragraph (2) of that provision, that court must refer the matter to the Court of Justice for a preliminary ruling if it considers that those irregularities are such as to affect the validity of the Commission's favourable decision, if necessary ordering the suspension of application of the measures for implementing that decision until the Court of Justice has ruled on the question of validity.

Rodríguez Iglesias		Moitinho de Almeida
Sevón	Schintgen	Kapteyn
Gulmann	Puissochet	Hirsch
Wathelet	Skouris	Macken

Delivered in open court in Luxembourg on 21 March 2000.

R. Grass

Registrar

G.C. Rodríguez Iglesias

President