OPINION OF ADVOCATE GENERAL MISCHO

delivered on 25 November 1999 *

1. The phenomenal advances in scientific knowledge and applied research in recent decades have led to the creation of genetically modified organisms (hereinafter 'GMOs'). Aware of the potential value of such organisms in the agricultural sector, various industrial groups have acquired the means of producing them on a large scale, so as to create what they see as new and promising markets for themselves.

2. But this transition, from laboratory to market, of a product of operations performed on living organisms has raised many legitimate questions which have been the subject of debate, not to say confrontation, between those who are primarily concerned with the advantages, notably increased productivity, that large-scale use of GMOs may be expected to bring and those who fear that their use may lead to the kind of disaster that befell the sorcerer's apprentice and who emphasise the risks involved in the release and general use of GMOs. The scientists were divided and, as the dispute could not be settled, the political authorities at both national and Community level stepped in to provide a legislative framework, that is to say to lay down rules governing the use and marketing of GMOs.

3. When the administrative authorities charged by the legislature with issuing authorisations to place GMOs on the market as and when the need arises take a favourable decision on an application submitted to them, those not completely reassured by the adoption of those rules may still apply to the courts for a remedy on the ground that the conditions and procedure laid down by the legislature have not been duly observed.

4. The questions which the Conseil d'État (France) has referred to the Court for a preliminary ruling arise from a case of that kind. No fewer than five applications, including applications from Association Greenpeace France (hereinafter 'Greenpeace'), the Confédération Paysanne and Association Ecoropa France (hereinafter 'Ecoropa'), were submitted to that court, seeking the annulment of an order of 5 February 1998 of the Minister for Agriculture and Fisheries amending the official

* — Original language: French.

list of plant species and varieties grown in France so as to include a genetically modified species of maize produced by Ciba-Geigy Ltd, subsequently Novartis Seeds SA (hereinafter 'Novartis').

5. In support of their application, the plaintiffs argue *inter alia* that the same Minister's order of 4 February 1997, authorising the placing on the market of genetically modified lines of maize protected against corn borers and having increased tolerance to herbicides of the glufosinate ammonium family, that is to say of the same product, is unlawful.

6. That order itself followed Commission Decision 97/98/EC of 23 January 1997 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.[1] The Commission Decision was taken pursuant to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms.[2]

1 — OJ 1997 L 31, p. 69.
2 — OJ 1990 L 117, p. 15.

7. In addition to their application for annulment, some of the plaintiffs had also requested a stay of execution. The Conseil d'État granted that request by decision of 25 September 1998 on the ground that 'the aforementioned associations claim that the procedure prior to the issue of the contested order was irregular and in particular 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, that they invoke the principle of precaution ..., that this appears at the present stage of the proceedings to be a serious argument, such as to justify the annulment of the contested order, that having regard also to the nature of the consequences that might ensue were the contested order to be executed, there is reason in the circumstances of the case to uphold the applicant association's request for a stay of execution of this order'.

8. When it came to consider the substance of the applications, the Conseil d'État encountered a difficulty arising from the fact that the ministerial order of 4 February 1997, the alleged illegality of which formed the basis of much of the applicants' case, was issued after a highly complex procedure comprising successive national and Community phases.

The relevant Community provisions

9. Directive 90/220 contains the following provisions:

'Article 11

1. Before a GMO or a combination of GMOs are placed on the market as or in a product, the manufacturer or the importer to the Community shall submit a notification to the competent authority of the Member State where such a product is to be placed on the market for the first time. This notification shall contain:

...

Article 12

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.

...

Article 13

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.'

10. It is therefore clear that, between the examination of the notification by the Member State that has received it, an examination allegedly not carried out correctly in the present case, and the granting of consent, by ministerial order of 4 February 1997 in the present case, there is a Community phase during which the other Member States, the Commission, and possibly the Council, may intervene and which, in the present case, closed with Decision 97/98, which states in the first paragraph of Article 1(1) that:

'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 questions referred by the national court

11. Clearly, as the Conseil d'État points out, the reply to the applicants' argument impugning the legality of the Ministerial order of 5 February 1998 depends on the latitude available to the author of the order. To obtain clarification on this point, the Conseil d'État has put the following two questions to the Court:

'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"?'

12. While the first question does not call for any special comment, the same is not true of the second. At first sight it could appear to be a duplication of the first question, since it repeats *à propos* Decision 97/98 the point raised in general terms and in principle in that question, leading the Commission to propose a single reply to both questions.

13. However, I for my part consider that the Conseil d'État is indeed putting two distinct questions to the Court:

— the first is concerned with whether the national authorities have a measure of discretion once 'the Commission has taken a favourable decision' within the meaning of Article 13(4) of Directive 90/220;

— the second seeks to ascertain whether, in view of its wording — 'the French authorities shall give consent to ["autorisent"] the placing on the market of the product' — and notwithstanding any irregularities that may be detected in the national authorities' examination of the notification, Decision 97/98 required the French authorities to give their consent in writing. In other words, the Conseil d'État wants to

know whether, if the answer to the first question is in the affirmative, certain circumstances, to be more precise the circumstances in the case before it, may confer on the national authorities a discretion to refuse to give consent which it had previously been established that they do not in principle enjoy.

14. The Conseil d'État is thus asking the Court two, and only two, distinct but related questions.

The scope of the referral to the Court

15. There can, in my view, be no question of the Court ruling on the validity of the Commission Decision, still less on that of Article 13(4) of Directive 90/220 as Ecoropa suggests. It is true that there have been occasions on which the Court was only asked to rule on a question of interpretation but considered that in order to give a useful reply to the national court that had referred the question it must also enter into an assessment of validity.

16. However, such occasions occur only rarely and in highly exceptional circumstances, since the Court has consistently held [3] that it is for the national court, which is familiar with all the aspects of the case, to determine the points on which it wishes to seek clarification before delivering its judgment and that the Court should confine itself to giving it the assistance it has sought within the framework of cooperation between courts established by Article 177 of the EC Treaty (now Article 234 EC).

17. In the present case, there can be no doubt that the Conseil d'État in no way expects the Court to consider the validity of the Community acts of which it has asked for an interpretation. In the first place, the wording of the questions gives no indication to that effect and, in the second place, the agent for the French Government mentions in his submission the possibility of referring questions on the assessment of validity to the Court, so it must be supposed that that possibility was considered by the Conseil d'État but was not pursued.

18. Similarly, there is in my view no need for the Court to consider the Community legislation on the marketing of seed. It is true that the ministerial order contested before the Conseil d'État concerns the inclusion of Novartis genetically modified maize in the official list of plant species and

3 — See, in particular, the judgments in Case 311/84 *CBEM* [1985] ECR 3261, paragraphs 9 and 10, and Joined Cases C-297/88 and C-197/89 *Dzodzi* [1990] ECR I-3763, paragraphs 31 to 34.

varieties grown in France, but the Conseil d'État considers that the questions of interpretation of Community law arise in connection with the previous ministerial order authorising the placing on the market of the said maize, and it is not for the Court to contradict it.

19. The rules governing the division of responsibilities between the national court and the Court, laid down in Article 177 of the Treaty, also preclude the Court from considering the conditions under which the national procedure for examining the Novartis notification was conducted, as a result of which the dossier was forwarded to the Commission with a favourable opinion.

20. The national court has sole jurisdiction to determine whether that procedure was regular and, in examining the second question, the Court must consider the possibility that it was irregular simply as a hypothesis for the purposes of argument, since although the Conseil d'État held that to be a plausible possibility when it pronounced the stay of execution, it certainly did not consider that it was established.

21. Before considering the first question, I should like to make one final observation.

22. Since the case in which it had occasion to employ the preliminary ruling procedure came before the Conseil d'État, the public authorities have decided under strong pressure to tighten up the regulations so that the issue of authorisation to market GMOs will be accompanied by more guarantees and, at Community level, a moratorium was declared some months ago. As the observations submitted in the case point out, the Commission has apparently decided, at least for the time being, not to institute proceedings under Article 169 of the EC Treaty (now Article 226 EC) against two Member States which, despite the provision contained in Article 13(5) of Directive 90/220, have prohibited the marketing in their territory of the Novartis maize that has received the consent of the French authorities within the meaning of Article 13(4) that is the very subject of the Conseil d'État's present doubts.

23. These are matters of fact and some might be tempted to think it inadmissible for the Court to leave them out of account.

24. However, in my view, that is precisely what it must do, since in this case it is not for the Court, because that is not its role, to settle a social or at the very least a political debate. It is simply required to answer questions of interpretation of certain acts of Community law in force at the time when the dispute arose which the court referring

the questions has to resolve. That, at any rate, is the strict line to which I propose to adhere in considering the two questions put to the Court by the Conseil d'État.

The first question

25. Does a Member State which has received a notification concerning the placing on the market of a GMO and forwarded the dossier to the Commission with a favourable opinion still have a measure of discretion to refuse its consent where no other Member State has raised an objection, or where any objections that were raised have been withdrawn, or where, as in the case with which the Conseil d'État is confronted, the Member States have not reached agreement and the Commission has been asked to intervene and has itself taken a favourable decision?

The wording of Article 13

26. In the light of paragraphs 2 and 4 of Article 13 of Directive 90/220, both of which state that in such a case the competent authority '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', the answer to that question can only be in the negative.

27. The use of the present indicative and the construction of the sentence in the French version of Directive 90/220 indicate without any shadow of a doubt that the provision imposes an obligation on the Member State in question.

28. A favourable decision on the part of the Commission, to confine ourselves to paragraph 4 — though the same observations could be made about paragraph 2 — , does not give the Member State an option, does not afford it an opportunity to give its consent, but requires it to do so.

29. To interpret paragraph 4 as meaning that a 'favourable decision' by the Commission has no more value than a favourable opinion, leaving the Member State free to give or refuse consent, would be tantamount to rewriting it.

30. The unambiguous nature of the wording of paragraph 4, in respect of grammar and style, is not peculiar to the French but is to be found in other language versions too, notably the English which states that 'the competent authority ... shall give consent in writing'.

31. As the Italian Government has most appositely pointed out, no one would

dream of seriously maintaining that, should the Commission take an *unfavourable decision*, it would merely be giving an opinion that would leave the Member State free to authorise the marketing of the GMO in question notwithstanding.

32. In the context of one and the same procedure, the legal nature of a decision and the question whether or not it is binding cannot depend on whether it is favourable or unfavourable.

33. I cannot therefore subscribe to the view expressed by Ecoropa that, had the legislature intended to impose a real obligation on the Member State to give its consent, it would have had to employ a form of words such as 'where the Commission has taken a favourable decision, the competent authority must authorise the placing on the market of the product'.

34. At the very most I can admit that it would perhaps have been preferable if, instead of referring to the competent authority giving consent, Directive 90/220 had stated that the competent authority 'shall issue the requested authorisation', but that in no way alters the consequences entailed by the use of the mandatory form of the verb in paragraph 4.

35. Having reached this point in the argument, it might be tempting to think that, as the wording itself is perfectly unambiguous, there is no need to pursue the matter any further because, even if factors extraneous to the provision in question were to suggest some other interpretation, there would still be no getting past the fact that those were the terms that were actually used.

36. While I consider that it is absolutely right to accord pride of place to the word and that some methods of interpretation take precedence over others, I do not think the matter ends there and I therefore propose to consider, as the observations submitted by the various intervening parties ask us to do, whether the conclusion that follows from a simple reading of Article 13(4) is confirmed or, on the contrary, invalidated by taking into account the context in which that provision came into being.

The role placed on the Community in the authorisation procedure for placing on the market

37. In the first place I should point out that, as Novartis has noted, the preamble to Directive 90/220 states that it is necessary to establish a Community authorisation procedure for the placing on the market of products containing, or consisting of, GMOs.

38. There are, of course, some Community authorisation procedures which cannot be said to end in a decision that is binding in the sense of absolutely requiring a Member State to act in a particular way. Thus, if a Member State intends to grant aid to certain undertakings it must, under Article 93(3) of the EC Treaty (now Article 88(3) EC), go through the procedure laid down in paragraph 2 of that article.

39. However, even if it has obtained a positive response from the Commission or the Council, it remains at liberty to decide in the end not to grant the aid in question if, for example, it finds it no longer has the necessary resources.

40. Similarly, an undertaking which has sought permission to market a GMO and has obtained the Member State's consent in writing after the Community procedure has run its course is not thereby obliged actually to place the substance in question on the market (though it would be surprising if it did not do so).

41. On the other hand, once a Member State has agreed to forward the notification to the Commission and has obtained a favourable decision, it cannot reverse the process unless, as we shall see later on, it becomes clear *a posteriori* that the Commission, when it gave its consent, was unaware of essential information about the risks involved in releasing the product in question.

42. In such cases, the Member State is not seeking authorisation for itself alone and the outcome of the procedure will have a direct effect on all the Member States, in that they will no longer have the right to refuse to market the product in question.

43. Several Member States may have supported the application of the State that initiated the procedure and they will have an interest in seeing it end with a definite decision to go ahead.

44. Another Member State may also have received a notification from the same undertaking and may have refrained from forwarding it to the Commission with a favourable opinion merely because it knew that the first Member State had already done so.

45. If the first Member State could freely decide, entirely on its own, not to give its consent in writing, the second Member State could then initiate a fresh procedure leading, in the absence of any new factors, to another favourable decision which would then be binding on the first Member State. In that case, the first Member State would no longer be able to oppose the marketing of the product in its territory.

46. It must therefore be concluded that a necessary effect of the Directive is that, after the procedure established by Directive 90/220 has run its course, a Member State is no longer free to decide unilaterally whether or not to grant a request for authorisation submitted to it by a GMO producer.

47. Establishing a Community procedure necessarily involves more than merely harmonising national procedures. Moreover, it is worth dwelling for a moment on the characteristics of this Community procedure. Directive 90/220 draws a fundamental distinction between the deliberate release of GMOs into the environment for research and development purposes or for any other purpose than for placing on the market, covered in part B, and the placing on the market of products containing GMOs, which is the subject of part C.

48. In the first case, which constitutes the lesser risk, being by definition confined to experiment within a limited framework, Directive 90/220 leaves it to the Member State that has received a request for authorisation to take whatever decision it deems appropriate, although it lays down a number of procedural and substantive rules which the Member State must follow and sets up a system for informing the Commission and the other Member States.

49. In the second case, the Community role is much more extensive. True, under Article 12(2) of Directive 90/220, a Member State which has received a notification of intent to place on the market decides alone, albeit subject to review by the courts, either to forward the dossier to the Commission with a favourable opinion or to inform the notifier that the proposed release does not fulfil the conditions laid down in the Directive and that it is therefore rejected.

50. But, once it has chosen to follow the first course, the decision is no longer in its hands alone, since the other Member States and the Commission, and possibly the Council too, may intervene under the conditions set out in Article 13 of Directive 90/220.

51. Once it has the dossier submitted by the Member State that has given a favourable opinion, the Commission forwards it to the other Member States together with any other information it may have collected.

52. It is then for them to form an opinion as to the advisability of granting authorisation to place on the market and, if they think it should not be granted, to present their reasoned objections to the competent authority of the Member State that received the notification.

53. If there are no objections or if objections originally raised are withdrawn after discussion among the various Member States, it must be concluded that all the Member States really are agreed that authorisation should be granted. Can it seriously be supposed that such agreement has no more effect than a mere opinion, leaving the Member State that initiated the whole procedure free to decide not to give its consent for reasons of its own, which it did not divulge in the discussion prompted by the Commission's forwarding the dossier to the other Member States?

54. I have already given some of the arguments against such a view. It would, moreover, be incompatible with the duty to act in good faith which should govern the relations between the Member States and the Community and the Member States' relations with one another.

55. A Member State which has given a favourable opinion on a notification must be supposed to have decided to give its consent unless the joint examination of the dossier by all the Member States, which also have the benefit of information supplied by the Commission, produces justifiable reasons for refusing it. The other Member States are not going to marshal the substantial resources required to examine a dossier on placing a GMO on the market merely in order to produce an opinion for a Member State to treat as it thinks fit.

56. If they do so, it is — as Monsanto Europe SA (hereinafter 'Monsanto'), an intervening party in the main proceedings, has observed — because they are required to take a joint decision with which they must all subsequently comply. It must also be noted at this point that, if it were to be admitted that a Member State which has forwarded a notification with a favourable opinion could subsequently refuse to give its written consent, even if the other Member States had not raised objections or had withdrawn the objections originally raised, the situation thus created would be strange, to say the least. That Member State, and that Member State alone, would be able to prevent the GMO from being marketed simply by refusing its consent. If a Member State which had forwarded a notification with a favourable opinion gave its consent, with the agreement of all the other Member States, the only way in which they would be able to prevent the GMO in question from being placed on the market would be to avail themselves of the opportunity to take protective measures afforded by Article 16 of Directive 90/220, to which I shall return later.

57. If the agreement of all the Member States cannot be obtained, the situation is not irremediable. The refusal of one or more Member States to withdraw objections they have raised does not preclude a Member State which has given a favourable opinion on the notification submitted to it from simply giving its consent.

58. Here too, a Member State cannot by raising an objection arrogate to itself the power to ban a GMO throughout the Community market. All it can do is cause

the Commission to intervene, as provided in Article 13(3) of Directive 90/220. The Commission will then follow the procedure laid down in Article 21 of the Directive, that is to say the procedure known as 'IIIa' in committee jargon.

The role assigned to the Commission

59. In that procedure, the Commission submits a draft of measures to be taken to a committee composed of representatives of the Member States and chaired by its own representative. The committee delivers its opinion on the draft within a time-limit which the chairman may lay down according to the urgency of the matter. The opinion is delivered by the majority laid down in Article 148(2) of the EC Treaty (now Article 205(2) EC) in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee are weighted in the manner set out in that article. The chairman does not vote.

60. The Commission adopts the measures envisaged if they are in accordance with the opinion of the committee.

61. If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council acts by a qualified majority.

62. If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures are adopted by the Commission.

63. Where the decision taken at the end of this procedure, either by the Commission or the Council, is favourable, the observations I made earlier about what happens if the Member States reach agreement apply in this case too.

64. The useful effect of intervention by the institutions is not confined merely to authorisation to give consent to the decision they adopt. The procedure laid down in Article 21 of Directive 90/220 is intended to enable a decision to be reached as to whether or not the marketing of a GMO should be authorised, despite differences of opinion between Member States that could not be resolved in any other way.

65. Such a decision is, of course, subject to review by the courts, in this case the Court of Justice. But until such time as the court declares that it is invalid, it is binding on the Member State to which it is addressed and, through the effect attached to the

consent given by that State under Article 13(5) of Directive 90/220, on all the other Member States.

The legal basis of the Directive

66. In the second place, it must be borne in mind that Directive 90/220 was adopted on the basis of Article 100a of the EC Treaty (now, as amended, Article 95 EC), which empowers the Council to adopt measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

67. This is not without relevance, as Novartis and Monsanto have rightly pointed out, with regard to the question we are considering. Since such measures take as a base a high level of protection concerning health, safety, environmental protection and consumer protection, as provided in paragraph 3 of that article, they cannot in principle accommodate the application of national measures to protect those interests. Should a Member State nevertheless propose to have recourse to such measures, it must submit to review by the Commission, which it is not required to do should it propose to adopt environmental measures that are stricter than those adopted by the Community on the basis of Article 130s of the EC Treaty (now, as amended, Article 175 EC). Article 130t of the EC Treaty (now Article 176 EC) provides that: 'The protective measures adopted pursuant to Article 175 shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with this Treaty. They shall be notified to the Commission'.

68. Now, if it were to be admitted that a Member State could refuse to give its consent to the placing on the market of a GMO, despite a favourable decision on the subject at Community level, it would in fact be tantamount to recognising that that Member State had a right to adopt more protective measures, contrary to the type of harmonisation undertaken by acting within the framework of Article 100a of the Treaty.

69. In the third place, it must be pointed out that, as Novartis has observed, the authorisation procedure established by Directive 90/220 is not as unusual as might be supposed, since there are comparable procedures for the placing on the market of medicinal products and a similar procedure for laying down rules for the labelling of dangerous substances, with in each case provision for the Commission, should the Member States fail to agree, to take a decision that will be binding on all of them in the interest of the free movement of goods.

Giving due respect to the principle of precaution

70. One more, highly important, question remains to be considered. If Article 13(4) of Directive 90/220 is interpreted as requiring a Member State to give its consent once the Commission has taken a favourable decision or the Member States have been able to reach a consensus, is there not a risk that the principle of precaution may be disregarded? No one has dared to suggest that that principle applies only in cases where the Community legislature adopts rules on the environment under Article 130s of the Treaty and that it may be disregarded in cases where Article 100a provides the legal basis.

71. It should be noted first of all that, according to Principle 15 of the Rio Declaration on Environment and Development of 14 June 1992, where there are threats of serious or irreversible damage associated with certain human activities, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

72. On the other hand, it does not require an activity to be prohibited or subjected to draconian restrictions whenever it cannot be scientifically proved that there is absolutely no risk attaching to it, since it is common knowledge that lawyers have always described proving a negative as *probatio diabolica* and not without reason.

73. The plaintiffs in the main proceedings who have given their views during the procedure before the Court have made much of the fact that the principle of precaution would be flouted if the Member State that initiated the procedure were to be denied the right unilaterally to refuse to give its consent.

74. I see two reasons for not sharing their fears on that score.

75. The first is that the whole procedure is organised by Directive 90/220 precisely so as to bring into the open, at each stage, any risks associated with placing the GMO in question on the market so that it therefore appears impossible that the principle of precaution should ultimately be abandoned.

76. A Member State that receives a notification is required to obtain from the notifier a great deal of information, listed in Article 11 of Directive 90/220, and to examine the notification, pursuant to Article 12, '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'.

77. If the competent authority considers that it needs more information, it may ask

for it and, as specified in Article 12(5) of Directive 90/220, the time required to obtain it will not be taken into account for the purpose of calculating the period it is allowed for taking its decision.

78. Where the dossier is forwarded to the Commission 'with a favourable opinion', it must meet certain requirements, as provided in paragraph 3 of that article.

79. As I have already mentioned, when the Commission forwards the dossier to the other Member States, it must also append any information it may have collected.

80. At the next stage, that is to say when the other Member States have received the dossier, any of them may raise objections. However, the reasons for the objections must be given, so that there can be a genuine discussion of the risks that may be associated with the GMO in question.

81. No one can force a Member State to withdraw an objection if it considers that it has not received a satisfactory answer on the subject.

82. Where, failing agreement between the Member States, the final decision falls to the institutions, each Member State will again have an opportunity to expound its views and express its reservations in the committee appointed to assist the Commission and possibly in the Council, if the dossier is submitted to it.

83. Before taking its decision, the Commission obtains opinions from various scientific committees. In the present case, it consulted the Scientific Committee on Animal Nutrition, the Scientific Committee for Food and the Scientific Committee for Pesticides.

84. Lastly, it should be noted that Article 11(6) of Directive 90/220 provides that:

'If new information has become available with regard to the risks of the product to human health or the environment, either before or after the written consent, the notifier shall immediately:

— revise the information and conditions specified in paragraph 1,

— inform the competent authority,

and

— take the measures necessary to protect human health and the environment.'

85. Under these conditions, it seems to me scarcely credible to maintain that observance of the principle of precaution may be at risk, unless it is to be supposed that all the authorities invited to participate in the decision-making procedure are deliberately disregarding the injunctions of Article 4(1) of Directive 90/220, which provides that: 'Member States shall 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'.

86. My second reason for asserting that the principle of precaution is not in danger of being flouted is that there is a safeguard clause, set out in Article 16 of Directive 90/220 in the following terms:

'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.'

87. This provision, allowing any Member State to prohibit the marketing of a GMO provisionally but, as we shall see in a moment, *at any time*, provided that it has justifiable reasons to think that the product, despite having received consent, constitutes risks that were not, or could not be, taken into account during the procedure ending in a favourable decision and that it informs the Commission accordingly so that a further decision may be taken following the procedure laid down in Article 21 of Directive 90/220, seems to me to be such as to reassure those who are most demanding about scrupulous compliance with the principle of precaution.

88. It is true that, on a purely literal reading of the provision, it would appear that Member States may avail themselves of the opportunity afforded by Article 16 of Directive 90/220 only if consent has already been given.

89. However, in the light of the observations submitted to the Court not only by the intervening Member States and the Commission but also, it should be noted, by Novartis, I consider that, where a risk that has not been taken into consideration becomes apparent after the Commission has taken a favourable decision but before the Member State has given its consent, it must be possible for the Member State concerned to defer giving its consent. It should in practice be extremely rare for placing on the market to be stopped in this way, even before consent has been given in writing, since, even if Article 13(4) of Directive 90/220 does not specify the period within which consent must be given, there are grounds for considering that Article 5 of the EC Treaty (now Article 10 EC) requires the Member State in question to comply with the decision quickly.

90. It would be placing too narrow an interpretation on Article 16 and disregarding the fundamental rule laid down in Article 4 of Directive 90/220 to hold that, once the Commission had taken a favourable decision, consent must absolutely and automatically be given, even if its effects are to be suspended a moment later. It will be a purely provisional suspension, however, as the matter will have to be settled within three months in accordance with the procedure laid down in Article 21 of Directive 90/220.

91. The principle of precaution may therefore come into play at all stages of the procedure.

92. In the light of all these considerations, I take the view that, subject to recourse in good faith to the safeguard clause contained in Article 16 of Directive 90/220, a Member State which has forwarded to the Commission an application for authorisation to place a GMO on the market has no discretion to refuse to give its consent in writing. It must consequently give such consent where there is no objection to the application by any other Member State or where the Commission has taken a favourable decision pursuant to Article 13(4) of Directive 90/220.

The second question

93. Does the conclusion I have reached on the first question apply unreservedly to Decision 97/98, irrespective of the factors which caused the Conseil d'État to doubt whether that was in fact the case and which I have recapitulated above?

94. In my view, the answer to that question must be that it does. That Decision which, be it noted in passing, is addressed in accordance with Article 2 thereof to the Member States and not just to the French Republic, is perfectly clear and unambiguous in its wording even if it does not employ exactly the same terms as Directive 90/220. It does not purport to be a

'favourable decision' or refer to giving consent but states, in the first paragraph of Article 1(1), that:

'Without prejudice to other Community legislation and subject to paragraphs 2 and 3, the French authorities shall give consent to ["autorisent"] 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.'

95. It is invested, as such, with the authority conferred by Article 189 of the EC Treaty (now Article 249 EC) on decisions taken by the Commission. It is presumed to be valid for so long as the Court, which has sole jurisdiction in the matter, has not declared it to be invalid, which, as I have already pointed out, the Conseil d'État is not asking the Court to do.

Irregularities in the conduct of the national procedure and validity of the Community decision

96. But does that mean that no attention is to be paid to any irregularities the Conseil d'État might happen to find in the competent French authority's examination of the dossier before it was forwarded with a favourable opinion to the Commission? I do not think so.

97. It is true that, as the Commission observed, referring in this connection to the judgment in *Oleificio Borelli* v *Commission*,[4] since any irregularity that might affect a national procedure which must precede the adoption of a Community decision, in accordance with the Community rules themselves, and on the outcome of which the Community institutions will rely in making their own decision, it cannot in any way affect the validity of that decision.

98. That judgment may appear to be harsh but it is based on very sound reasons which, in my view, preclude any possibility of calling it into question. It is impossible to see how the Community Court, which has sole jurisdiction to declare a Community act invalid, could form an opinion as to the existence of an irregularity with respect to national law when it has no jurisdiction to interpret or apply that law in the context of the jurisdiction conferred on it under Articles 173 of the EC Treaty (now, as amended, Article 230 EC) and 177 of the Treaty.

99. To call into question the division of powers between the national court and the Court, as defined in the case-law of the Court, would in my view be most unwise and would do nothing to promote the cause of respect for the rule of law within the Community legal order.

4 — Case C-97/91 [1992] ECR I-6313.

100. However, the fact that an irregularity in the national procedure does not affect the validity of the subsequent Community act must not be misunderstood, particularly in a case such as the present one where, unlike the situation that obtained in *Oleificio Borelli* v *Commission* cited above, we do not have an unfavourable national decision, which would necessarily have led to an unfavourable decision by the Community, but on the contrary a favourable one, which, it is true, did not automatically entail a favourable decision by the Community but did make it possible.

101. It should be noted that, in the system of Directive 90/220, if a Member State rejects a notification addressed to it, the procedure for the authorisation of the GMO in question is definitively closed and the Commission does not even have to be informed of the rejection, whereas the act of forwarding the dossier with a favourable opinion is entirely without prejudice to the eventual outcome.

102. Since the dossier is examined by the other Member States and possibly, if they raise and maintain objections, by the Commission, any irregularities there may have been in the national procedure will not in principle have irreversible consequences.

103. However, that does not mean that such irregularities ought not to be penalised by the national court if they are referred to it. On the contrary, it follows from the judgment in *Oleificio Borelli* v *Commission*, cited above, that where a national procedure must, by virtue of Community law itself, precede the Community decision, the national legal order must, as the Italian and Austrian Governments pointed out, ensure that those concerned have an opportunity to have the regularity of that procedure reviewed by the national courts even if, as a preparatory procedure, it could be held by the national legal order not to be open to appeal.

104. It is true that in the case in which the judgment was delivered in *Oleificio Borelli* v *Commission*, cited above, the national decision at issue was unfavourable but I do not see how it could be claimed that judicial review in domestic law should be available only in such cases.

105. It can only be the prior national procedure as such, irrespective of whether its outcome is favourable or unfavourable, that is subject to review by the national court.

Consequences arising from the detection of irregularities in the national procedure

106. What will be the effect and utility of a finding by the national court, having the status of *res judicata*, that the national procedure was vitiated by irregularities justifying the annulment of the ensuing national decision, in this case the decision to forward the dossier to the Commission with a 'favourable opinion', if there is no possibility of calling into question the judgment in *Oleificio Borelli* v *Commission*, cited above?

107. That, as the Commission has explained, will depend on the nature of the irregularity revealed by the judicial review.

108. If the irregularity is formal in the broad sense, for example if it consists of failure to append a signature to a report of otherwise uncontested veracity, or late dispatch of an invitation to a meeting, or else failure to obtain the countersignature of an authority that should be associated in the taking of the decision, there are in my view grounds for considering that it should have no effect on the obligation to give consent, laid down in Directive 90/220.

109. But if the irregularity led the competent authority to give a favourable opinion when the notification would otherwise have been rejected and if, to be more precise, it was such as to conceal a genuine risk constituted by the GMO in question, then clearly it cannot be treated in the same way since, in that case, the principle of precaution will apply.

110. What consequence must be attached to it in that event? Here again, it seems to me that there are two possibilities.

111. Either the examination of the dossier after it was forwarded to the Commission afforded an opportunity to detect the risk in question and thus to assess whether or not it justified preventing the GMO in question from being placed on the market. In that case, it must be considered that there is no reason to call into question the obligation to give consent, or the consent itself if it has already been given.

112. Or the risk concealed in the course of the national procedure was not examined during the subsequent procedure either and the irregularity must be considered to be extremely serious with regard to the requirements of the principle of precaution. In that case, it must affect the authorisation to place the product on the market.

113. It will be for the Member State that forwarded the notification with a favourable opinion to alert the other Member States and the Commission without delay and, without even waiting for the Commission to respond, avail itself of the opportunities afforded by Article 16 of Directive 90/220, which I explained at length above.

114. Should it fail to do so, it would be in breach of the obligations imposed on it under Article 4(1) of Directive 90/220 and could be held responsible. Once alerted, the Commission will draw all the necessary conclusions from the failure to take account of a genuine risk to health or environmental protection since, as it stated in its observations, a 'favourable' decision in a situation where the facts call for an 'unfavourable' decision, and *vice versa*, is unlawful and must be corrected.

115. The utility of review of the national procedure by the national court is thus patently clear. It will provide an opportunity, and there can never be too many opportunities, to verify that the requirements of the principle of precaution have not been disregarded. In any event, it may, if it leads to an annulment and if the grounds of that annulment are among those I have just mentioned, enable the Commission to detect an irregularity and remedy it without delay and possibly allow the Community Court, if the matter is referred to it, to annul a favourable decision taken in error.

116. I will add one last observation, not on the review of the original national procedure by the national court but on the review of the consent given by the competent national authority which that court may be called upon to conduct, as in the case that occasioned the present referral for a preliminary ruling.

117. As I explained in reply to the first question, a national authority which gives its consent after it has been notified of the Commission's favourable decision, or after agreement has been reached among the Member States, is exercising a mandatory duty and that must obviously be taken into account by the national court. Clearly, it is not for me to set limits here to the review which that court may conduct but it should nevertheless be borne in mind that, whatever its own convictions on the subject may be, it cannot assume that the Commission's favourable decision is unlawful unless it has obtained confirmation from the Court that it is unlawful through the preliminary ruling procedure or can rely on a declaration of annulment by the Court in the context of an action based on Article 173 of the Treaty.

118. To return to the subject of the second question, I consider that Decision 97/98 is to be interpreted as requiring the French Government to give its consent in writing unless it avails itself of the opportunity afforded by Article 16 of Directive 90/220, should it consider that the conditions are fulfilled for that provision to apply.

Conclusions

119. Having concluded my deliberations, I propose that the Court rule as follows:

(1) Subject to recourse in good faith to the safeguard clause contained in Article 16 of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, a Member State which has forwarded to the Commission an application for authorisation to place a GMO on the market has no discretion to refuse to give its consent in writing. It must consequently give such consent where there is no objection to the application by any other Member State or where the Commission has taken a favourable decision pursuant to Article 13(4) of Directive 90/220.

(2) Commission Decision 97/98/EC of 23 January 1997 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 Directive 90/220 must be interpreted as requiring the French Government to give its consent in writing unless it avails itself of the opportunity afforded by Article 16 of Directive 90/220, should it consider that the conditions are fulfilled for that provision to apply.