OPINION OF ADVOCATE GENERAL ALBER

delivered on 13 March 2003 [1]

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1 — Original language: German.

I — Introduction

1. The present reference for a preliminary ruling essentially concerns the question whether Italy was right to prohibit foods made from genetically modified maize which were placed on the market under the so-called simplified procedure, which merely requires a notification to the Commission.

2. Foods produced from genetically modified organisms but which no longer contain them may, under Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997

concerning novel foods and novel food ingredients, [2] be placed on the market by the Commission without prior authorisation if a national food assessment body has certified that the novel food is substantially equivalent to the traditional food. The person responsible must merely notify the Commission of the placing on the market and submit the opinion of the national authorities and other relevant documents. In contrast, placing on the market under a 'formal procedure' is authorised by the Commission; in the following, that procedure will therefore be referred to as the authorisation procedure.

3. Monsanto Europe SA and two other firms used the simplified procedure in 1997 and 1998 to notify the placing on the market of foods made from genetically modified maize. The competent United Kingdom food authority had previously certified substantial equivalence.

4. The Italian Republic thereupon imposed a temporary prohibition on the marketing and use of products produced from the notified maize lines, because of doubts concerning the absolute safety of the products. In the main proceedings, the applicant challenges the relevant Italian decree.

5. The Tribunale Amministrativo Regionale (Regional Administrative Court) del Lazio (Italy), before which the case was brought, questions the admissibility of the simplified procedure in those specific cases, since there are indications that residues of transgenic protein are contained in the foods. In addition, it questions whether that procedure is compatible with Articles 153 and 174 EC and takes sufficient account of the precautionary principle and other principles of Community law. It also points out that novel foods can in that way be placed on the market, with effects for the entire Community, although no full risk assessment, with the participation of all the Member States, has taken place. Finally, it raises questions concerning the power of a Member State to prohibit the placing on the market of such foods within its own territory alone.

2 — OJ 1997 L 43, p. 1.

II — Legal background

A — *Community law*

1. Directive 90/220/EEC [3]

6. Article 2 of that directive, subsequently referred to as the 'deliberate release directive', defines the concept of genetically modified organisms as follows:

'...

(1) "organism" is any biological entity capable of replication or of transferring genetic material.

(2) "genetically modified organism (GMO)" means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

...'

2. Regulation No 258/97

7. The second recital in the preamble to that regulation states:

'In order to protect public health, it is necessary to ensure that novel foods and novel food ingredients are subject to a single safety assessment through a Community procedure before they are placed on the market within the Community;... in the case of novel foods and novel food ingredients which are substantially equivalent to existing foods or food ingredients a simplified procedure should be provided for.'

3 — 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). With effect from 17 October 2002, that directive was replaced by Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ 2001 L 106, p. 1). The definition of a genetically modified organism, however, has remained unchanged, apart from the clarification that it does not refer to human beings.

8. Article 1 defines the scope of the regulation as follows:

'1. This Regulation concerns the placing on the market within the Community of novel foods or novel food ingredients.

2. This Regulation shall apply to the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories:

(a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC;

(b) foods and food ingredients produced from, but not containing, genetically modified organisms;

...'.

9. Article 3 provides:

'1. Foods and food ingredients falling within the scope of this Regulation must not:

— present a danger for the consumer,

— mislead the consumer,

— differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.

2. For the purpose of placing the foods and food ingredients falling within the scope of this regulation on the market within the Community, the procedures laid down in Articles 4, 6, 7 and 8 [4] shall apply on the

4 — Those articles lay down the authorisation procedure, which is not relevant to the present case.

basis of the criteria defined in paragraph 1 of this article and the other relevant factors referred to in those articles.

...

4. By way of derogation from paragraph 2, the procedure laid down in Article 5 [5] shall apply to foods or food ingredients referred to in Article 1(2)(b)... which, on the basis of the scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies [6] referred to in Article 4(3), are substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.

Where necessary, it may be determined in accordance with the procedure laid down in Article 13 whether a type of food or food ingredient falls under this paragraph.'

5 — That article concerns the simplified procedure.

6 — This refers to the national food assessment bodies.

10. Article 5 lays down the simplified procedure as follows:

'In the case of the foods or food ingredients referred to in Article 3(4), the applicant shall notify the Commission of the placing on the market when he does so. Such notification shall be accompanied by the relevant details provided for in Article 3(4). The Commission shall forward to Member States a copy of that notification within 60 days and, at the request of a Member State, a copy of the said relevant details. The Commission shall publish each year a summary of those notifications in the "C" series of the *Official Journal of the European Communities*.

...'

11. Article 12 grants the Member States the following competence to issue protection measures:

'1. Where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the

trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision.

2. The Commission shall examine the grounds referred to in paragraph 1 as soon as possible within the Standing Committee for Foodstuffs; it shall take the appropriate measures in accordance with the procedure laid down in Article 13. The Member State which took the decision referred to in paragraph 1 may maintain it until the measures have entered into force.'

12. Finally, Article 13 lays down the following procedural rules for the Commission:

'1. Where the procedure defined in this article is to be implemented, the Commission shall be assisted by the Standing Committee for Foodstuffs, [7] hereinafter referred to as the "Committee".

2. Matters shall be referred to the Committee by the Chairman either on his own initiative or at the request of the representative of a Member State.

3. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty 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 shall be weighted in the manner set out in that Article. The Chairman shall not vote.

4. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

(b) 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 shall act by a qualified majority.

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 shall be adopted by the Commission.'

7 — The Standing Committee for Foodstuffs, composed of representatives of the Member States (set up under Council Decision 69/414/EEC of 13 November 1969 (OJ, English Special Edition 1969 (II), p. 500)) is distinct from the Scientific Committee for Food, which is referred to in Article 11 (set up under Commission Decision 74/234/EEC of 16 April 1974 (OJ 1974 L 136, p. 1)). Under Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1), those committees have in the meantime been partly replaced and renamed.

3. Recommendation 97/618/EC [8]

13. Under Article 4(4) of Regulation No 258/97, the Commission is to publish recommendations concerning scientific aspects. On the basis of that provision, the Commission adopted Recommendation 97/618, the following passages of which are of importance in the present case.

14. Part I, point 3(3) of the Annex to Recommendation 97/618 sets out the concept of substantial equivalence as follows:

'The concept of "substantial equivalence" has been introduced by WHO (the World Health Organisation) and OECD (the Organisation for Economic Cooperation and Development) with particular reference to foods produced by modern biotechnology. In the terminology of the OECD, the concept of substantial equivalence embodies the idea that existing organisms used as foods or as food sources can serve as a basis for comparison when assessing the safety of human consumption of a food or food component that has been modified or is new. If a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety, keeping in mind that establishment of substantial equivalence is not a safety or nutritional assessment in itself, but an approach to compare a potential new food with its conventional counterpart.

... If a NF (novel food) has not been found to be substantially equivalent to an existing food or food component, this does not imply that it is unsafe. It just indicates that such a NF should be evaluated on the basis of its unique composition and properties.

...'

15. Part I, point 3(7) in the Annex, entitled 'Toxicological requirements', states:

'In principle, the toxicological requirements for NF need to be considered on a case-by-case basis. In establishing the need

8 — Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ 1997 L 253, p. 1).

for the provision of toxicological data three scenarios may be considered:

(1) substantial equivalence can be established to an accepted traditional food or food ingredient, in which case no further testing is needed;

(2) substantial equivalence can be established except for a single or few specific traits of the NF, in which case any further assessment of safety should focus specifically on these traits;

...'

16. In order to assess the substantial equivalence of genetically modified plants, Part I, point 5 (Identification of essential information for assessment of wholesomeness), subsection IV (Effect of the genetic modification on the properties of the host organism) of the annex to Recommendation 97/618 sets out the following indications:

'Where the genetic modification results in a new phenotype, the compositional consequences of this modification should be defined and tested. If, for example, a genetically modified plant is so designed as to express a naturally occurring insecticide, encoded by a gene derived from another organism, and has therefore become resistant to certain insect pests, then the toxicological profile of the introduced insecticidal component needs to be determined. The safety of this modification of the chemical composition can be evaluated by standard ecotoxicological procedures; it should include an assessment of the potential allergenicity. In addition, secondary effects (positional effects) have to be taken into consideration. These effects of the insertional event, e.g. the insertional mutation itself or genomic rearrangement, will influence the overall outcome of the genetic modification. A knowledge of the normal toxin production of the plant and the effect on it of various growth and culturing conditions to which the GM plant is subjected, as well as knowledge whether the new gene product appears in the final food, is essential. The same reasoning applies to nutritionally important components, especially in food plants.

...'

B — *Italian legislation*

17. The Prime Ministerial Decree of 4 August 2000 on the precautionary suspension of the marketing and use of certain transgenic products within the national territory under Article 12 of Regulation No 258/97 [9] (hereinafter 'the Decree') suspends the marketing and use of products derived from transgenic maize of the lines Bt-11, MON 810 and MON 809.

III — Facts of the case and proceedings

18. The companies Monsanto Agricoltura Italia SpA, established in Lodi (Italy), Monsanto Europe SA, established in Brussels (Belgium), Syngenta Seeds SpA, established in Orrigio (Italy) (formerly Novartis Seeds SpA), Syngenta Seeds AG, established in Basel (Switzerland) (formerly Novartis Seeds AG), Pioneer Hi Bred Italia SpA, established in Malagnino (Italy) and Pioneer Overseas Corporation, established in Des Moines (USA) (hereinafter 'Monsanto and others') are involved in the development of genetically modified crop plants for use in agriculture.

9 — GURI No 184 of 8 August 2000, p. 9.

19. By two decisions of 22 April 1998, the Commission authorised, on the basis of Article 13 of the deliberate release directive, the placing on the market of maize kernels from the lines Bt-11 and MON 810 — under Article 1 of both decisions — without prejudice to Regulation No 258/97. [10]

20. In parallel to the procedure under the deliberate release directive, on 10 December 1997 Monsanto Europe SA notified the Commission under the simplified procedure laid down in Article 5 of Regulation No 258/97 of the placing on the market of foods containing flour and other products from genetically modified maize of the line MON 810. Similar notifications were subsequently submitted on 30 January 1998 and on 14 October 1998 by Novartis Seeds AG with respect to products derived from Bt-11 maize and by Pioneer Overseas Corporation with respect to products derived from MON 809 maize.

21. Foreign genes were inserted into the genome of those maize lines which render that maize resistant to certain pests. A gene derived from *Bacillus thuringensis* is used for that purpose, which expresses a toxin that kills certain insects. Other genes

10 — Commission Decision 98/292/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line Bt-11), pursuant to Directive 90/220/EEC (OJ 1998 L 131, p. 28), and Commission Decision 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Directive 90/220/EEC (OJ 1998 L 131, p. 32).

inserted into Bt-11 and MON 809 render the maize resistant to certain herbicides.

22. The notifications to the Commission were accompanied by the opinions of the United Kingdom Advisory Committee on Novel Foods and Processes (ACNFP) of September 1996, which the United Kingdom Ministry of Agriculture, Fisheries and Food forwarded to the companies by letter of 14 February 1997. The ACNFP concluded in those opinions that the foods derived from the genetically modified maize lines in question were substantially equivalent to products from conventional maize.

23. The Commission forwarded the notifications to the Member States on 5 and 6 February 1998, and on 23 October 1998, and published them in the *Official Journal of the European Communities*. [11]

24. It is true that the Commission and the Member States had agreed, in the context of the Standing Committee for Foodstuffs, no longer to apply the simplified procedure, with effect from January 1998, to products made from genetically modified organisms which still contain traces of transgenic protein. None the less, the Commission considered it appropriate to use that procedure for the last time even after that date for products derived from MON 809 maize and Bt-11 maize, since products derived from similar maize lines had already been placed on the market under the simplified procedure and the applicant had already received a positive opinion from the United Kingdom food assessment bodies in February 1997.

25. By letters of 23 November 1998, 4 February 1999 and 2 April 1999 to the Commission, the Italian health ministry called for the use of the authorisation procedure and asked to see the toxicological and allergenicity assessments for the products. The Commission did not reply to those letters itself. It took the letters as requests for information, which, in accordance with its practice, it forwarded to the firms, for them to make the information which had been requested immediately available to the Member State.

26. By letters of 23 December 1999 and 5 June 2000 to the Commission, the Italian health ministry claimed that 'substantial equivalence', the condition for the use of the simplified procedure, had not been met and expressed a general objection to the use of that procedure. The Commission countered those objections by letter of 10 March 2000. In their further reply of

11 — OJ 1998 C 200, p. 16 and OJ 1999 C 181, p. 22.

10 July 2000, however, the Commission acknowledged the need to review the legal framework in order to ensure greater clarity and reported that the Scientific Committee for Food had been charged with carrying out a comprehensive examination.

27. In opinions by the Italian Consiglio Superiore di Sanità of 16 December 1999 and by the Italian Istituto Superiore di Sanità (hereinafter 'ISS') of 4 and 28 July 2000, those institutes also expressed their reservations about the substantial equivalence of the products derived from genetically modified maize. That maize contained between 0.04 and 0.30 parts per million of transgenic protein. Nevertheless, the ISS excluded any health risk to people or animals on the basis of the available scientific knowledge.

28. On the basis of Article 12 of Regulation No 258/97, on 4 August 2000 the Italian Republic adopted the Decree referred to in paragraph 16. In support of the Decree it explained, *inter alia*, that the absence of detailed information and the renewed interest by the Scientific Committee for Food gave rise to circumstances which provided grounds for the temporary suspension of marketing. The Italian Republic informed the Commission and the Member States of those measures in accordance with Article 12(1) of Regulation No 258/97.

29. The Scientific Committee for Food came to the conclusion, in its opinion of 7 September 2000, that the evidence put forward in the Italian opinions of 16 December 1999 and 28 July 2000 did not provide detailed scientific grounds for considering that human health was endangered.

30. The Commission refrained from adopting a measure concerning that decree under Article 12(2) in conjunction with Article 13 of Regulation No 258/97, since its draft decision had received no support in the Standing Committee for Foodstuffs. On the contrary, in the committee meetings that took place on 18 and 19 October 2000, several Member States expressed concern at the use of the simplified procedure for products derived from genetically modified organisms. Before adopting a decision concerning the Decree, clarification was necessary in respect of the criterion of substantial equivalence.

31. Monsanto and others and the Associazione Nationale per lo Svilupo delle Biotecnologie (Assobiotec, the national Association for the Development of Biotechnology) brought an action on 13 November 2000 before the Tribunale Amministrativo

Regionale del Lazio asking for annulment of the Decree of 4 August 2000 and compensation for damage arising from the prohibition on the marketing of their products.

Questions referred for a preliminary ruling

32. In the circumstances, the Tribunale Amministrativo Regionale del Lazio, by order of 18 April 2001, made an order for reference to the Court. Although the order for reference does not set out precise questions, the following questions may nevertheless be deduced from the statements of reasons:

(1) Is Article 3(4) of Regulation No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients to be interpreted to mean that foods and food ingredients within the meaning of Article 1(2)(b) of the Regulation are to be considered substantially equivalent to existing foods and food ingredients and may therefore be placed on the market by means of the simplified procedure, following a notification in accordance with Article 5 of the regulation, even if those foods and food ingredients contain residues of transgenic protein?

(2) If the answer to the first question is negative and the use of the simplified procedure in accordance with Article 5 of Regulation No 258/97 was therefore inadmissible, what are the consequences

— for the power of the Member States to adopt measures such as the Decree of 4 August 2000 on the basis of the precautionary principle, which is given particular expression in Article 12 of Regulation No 258/97, and

— for the allocation of the burden of proof as regards risks to human health and the environment arising from the new product?

(3) Does it affect the answer to the second question if the simplified procedure is assumed to constitute tacit consent by the Commission, and does it follow that such tacit consent must be considered unlawful if the answer to the second question is negative?

(4) If the answer to the first question is affirmative, is Article 5 of Regulation No 258/97 compatible with Articles 153 and 174 EC, as well as with the precautionary principle and the principles of proportionality and reasonableness, in so far as

— it does not provide for a full assessment of the safety of the foods and food ingredients with regard to the risks they pose to human health and the environment and does not ensure the participation of the Member States and of their scientific bodies, although that participation is indispensable to the protection of those values, as emerges from the normal procedure provided for in Article 6, and

— such a simplified procedure can be used solely in order to speed up and simplify the administrative procedure for the placing on the market of foods and food ingredients for which, since they contain residues of transgenic protein, no information is available concerning their full effects on the health of consumers, human consumption and the environment, as can be generally deduced from Recommendation 97/618/EC?

33. Monsanto and others, the Italian and Norwegian Governments, the European Parliament, the Council and the Commission have submitted observations to the Court. The contents of their observations are presented in the context of the legal assessment of the individual questions referred.

IV — Legal assessment

A — *Applicability of the simplified procedure to foods derived from genetically modified organisms which still contain residues of transgenic protein (first question referred)*

1. Arguments of the parties

34. *Monsanto and others* point out, first, that the question essentially concerns interpretation of the concept of substantial equivalence. The evaluation of substantial equivalence is not, however, a question of interpreting Community law, but rather a scientific question.

35. The procedure under Article 5 of Regulation No 258/97 is applicable to foods which are produced from genetically

modified organisms but do not contain them and which are substantially equivalent to conventional foods. Since it is not disputed that the remaining traces of transgenic protein are not genetically modified organisms, only substantial equivalence is at issue.

36. The concept of substantial equivalence, as developed in various fora (FAO/WHO and OECD, the United Nations Food and Agriculture Organisation and World Health Organisation and the Organisation for Economic Cooperation and Development) and taken up in Recommendation 97/618, does not require the foods being compared to be identical. For that reason, the presence of transgenic protein in products produced from genetically modified organisms does not preclude substantial equivalence.

37. *The Italian Government* argues that the simplified procedure can apply only where substantial equivalence has been established. That is a scientific rather than a legal question. As Point 3.3 of Recommendation 97/618 implies, the criterion of substantial equivalence is instrumental in character and is present only where the factors (composition, nutritional value, etc.) mentioned in Regulation No 258/97 concur.

38. The ISS determined, however, that traces of the protein encoded by the inserted gene are contained in the maize products even after processing. Whether or not the foods are harmful to human health therefore requires an evaluation under the authorisation procedure, with the participation of the authorities of the Member States. The simplified procedure is not applicable.

39. The *Norwegian Government* analyses various sources which develop and interpret the concept of substantial equivalence; in particular, it refers to Points 3.3 and 3.7 of Recommendation 97/618, the summary records of the meetings on 18 and 19 October 2000 of the Standing Committee on Foodstuffs, the various reports of the FAO/WHO and the OECD and an evaluation carried out by the International Life Science Institute (ILSI) in 1996.

40. The Norwegian Government draws the following conclusions from those documents:

— The establishment of substantial equivalence is not a safety assessment in itself, but merely the starting point for the safety assessment.

— The prerequisite for establishing substantial equivalence is a comparison between the composition of the genetically modified organism with the composition of its conventional counterpart.

— The comparison requires data on transgenic DNA.

— There is a certain degree of freedom in choosing the elements to be compared, with respect to the food source, the food product and molecular levels.

— Plants or foods containing an inserted trait which does not occur naturally in the parent plant could be considered substantially equivalent except for the inserted trait, which should then be the focus of safety testing.

— Further, consensus is needed on the practical application of the principle of substantial equivalence.

41. The Norwegian Government is of the opinion that a separate study of the genetic modification and its effects must take place when the substantial equivalence of foods derived from genetically modified organisms is being examined. It considers an examination of foods as a whole to be unsuitable. In general it considers that foods which contain transgenic protein are not substantially equivalent and that the simplified procedure is accordingly not applicable. Since the insertion of a gene can give rise to unexpected secondary effects, foods derived from genetically modified organisms should not be allowed to be placed on the market without a full safety assessment.

42. According to the *European Parliament*, the question of substantial equivalence and the applicability of the simplified procedure is a question of fact, which the referring court must decide.

43. The *Commission*, in a first step, states that the products in question merely contain transgenic protein but are not genetically modified organisms capable of reproduction. The applicability of Article 5 of Regulation No 258/97 is therefore in principle established.

44. Regulation No 258/97 and Recommendation 97/618 contain criteria for estab-

lishing substantial equivalence. As a result of scientific debate, however, the establishment of substantial equivalence has become less important, [12] although there is agreement that it represents an important step in the evaluation process. None the less, merely establishing substantial equivalence does not constitute a full safety assessment. For that reason, the Commission agreed with the Member States to discontinue use of the simplified procedure as from January 1998; nor did it include that procedure in its proposal for a (new) regulation concerning genetically modified food- and feedstuffs. [13]

45. In the meantime, it is no longer possible to consider foods which contain transgenic protein as traditional food without further examination. At the time when the placing on the market of the contested foods was notified, however, substantial equivalence was still assumed, so that the use of the simplified procedure in that case was justified in view of the legal situation and the state of science at the time. Moreover, it was undisputed that the foods did not represent a threat to the environment or to human health.

12 — The Commission refers in that connection to the work of the FAO and WHO. In addition, it cites two reports by the OECD: the *Report of the OECD workshop on the toxicological and nutritional testing of novel foods* (1998) and the *Report of the task force for safety of novel foods and feeds* (2000).

13 — Proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed of 25 July 2001, COM(2001) 425 final; printed without explanatory memorandum in OJ 2001 C 304 E, p. 221.

46. It is primarily a question of fact whether the foods at issue were rightly classified as substantially equivalent. At the time of the placing on the market, there were no scientific findings available which would have raised doubts as regards that result. In the light of the fact that the foods are in fact harmless, it appears that general objections to the applicability of the simplified procedure rather than concrete scientific findings as to possible risk motivated the adoption of the Decree.

2. Assessment

(a) Preliminary observation on the facts of the case and the interpretation of the questions referred

47. It cannot be clearly inferred, either from the order for reference or from the papers in the case, which specific foods or food ingredients from the three genetically modified maize lines at issue were placed on the market, nor precisely what their purpose is. It appears essentially to involve flour.

48. In any event, those involved agree that the production processes for those foods — the ACNFP refers to dry milling and wet

milling — results in the destruction of the genetically modified DNA of the maize plants. It can therefore be assumed that organisms within the meaning of Article 2(1) of the deliberate release directive, capable of multiplying or of transferring genetic material, are no longer present. The use of the simplified procedure is therefore possible if the further condition, that there be substantial equivalence, is also fulfilled.

49. By its first question, the national court seeks an interpretation of the concept of substantial equivalence. Above all, it wishes to know whether there can be substantial equivalence even when foods continue to contain traces of transgenic protein.

50. The representatives of Monsanto and others have admitted, in the oral procedure, that foods derived from genetically modified maize could in fact contain representative traces. However, those were small amounts of transgenic protein, from 0.04 to 0.30 ppm. That value, which is mentioned in the recitals of the Decree and in the ISS opinion of 4 July 2000, to which the national court refers, [14] relates to representative traces in maize plants *before* their processing into maize flour. However, processing results in the denaturation of the transgenic protein present in the plants. [15] In the light of the comments by the parties before the Court of Justice, however, the opinion of the ACNFP [16] — that the processing of maize results in the complete denaturation of all gene products — does not appear to be correct.

51. In addition, it should be pointed out that none of the parties, including the Italian Government, has stated that the contested foods present a risk to human health. For that reason, the ISS, despite its doubts as to the substantial equivalence of products derived from genetically modified maize compared to conventional products, concludes in its opinion that, on the basis of the present state of knowledge, risks can be excluded. The Scientific Committee for Food, in its opinion of 7 September 2000, also confirms that no detailed scientific grounds can be inferred from the comments by the ISS which would point to a danger to human health.

52. The question of the interpretation of the concept of substantial equivalence is a

14 — Paragraph 9 of the order for reference.

15 — An underlying question is whether denatured proteins may perhaps also pose risks, such as provoking allergies. For it was not disputed in the findings that, in any event, small amounts of transgenic proteins in non-denatured form are also present in the foods.

16 — ACNFP opinions (communicated by letter of 14 February 1997) on the substantial equivalence of products derived from maize lines MON 809 (paragraph 17), MON 810 (paragraph 20) and Bt-11 (paragraph 20).

point of law, which the Court of Justice must answer under the procedure for a preliminary ruling. It is distinct from fact-finding as to whether foods derived from genetically modified maize lines are in fact substantially equivalent to products made from conventional maize. If that assessment is necessary, it must be made by the competent national food assessment bodies under the simplified procedure, or by the bodies referred to under the procedure in Article 13 of Regulation No 258/97.

(b) Alternative interpretations possible under the wording of Article 3(4) of Regulation No 258/97

53. According to the wording of Article 3(4) of Regulation No 258/97, substantial equivalence is to be determined on the basis of a comparison between food produced from genetically modified maize and corresponding products made from conventional maize. The comparison is to consider their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.

54. It is not clear what the comparison is to cover. It could perhaps be limited to comparing the concentration of basic components, such as fats, carbohydrates, proteins, minerals and vitamins, which could be investigated by basic chemical testing methods. If changes were detectable at that level, they could be judged to be indicative of expected or unexpected effects from the newly inserted gene. The compared products would in that case probably not be substantially equivalent. On the other hand, transgenic protein in very small amounts, which is only detectable using specific methods, would remain undetected under that superficial comparison. The text of the Regulation does not provide any basis for determining how far the comparative analysis must be taken.

55. If substances expressed by the inserted gene are also included in the comparison, it is clear that the novel food in any event differs from its conventional counterpart inasmuch as those materials have not been completely eliminated during the processing of the novel food. On the assumption that the transgenic protein in the present case serves a particular purpose only during the growth phase of the maize plants, but not in the foods subsequently produced from those plants, they could be considered undesirable substances within the meaning of Article 3(4) of Regulation No 258/97. The presence of those undesirable substances would then constitute a further difference between the conventional and the novel food.

56. Two interpretations are possible in that situation:

— According to a narrow interpretation of the concept of substantial equivalence, such as that put forward by the Italian and Norwegian Governments, the result of any difference in the composition or the level of undesirable substances is that substantial equivalence ceases to exist.

— Taking as a basis the broader concept put forward by Monsanto and others, substantial equivalence remains established when differences exist but the substances or properties which are found only in the novel food demonstrably pose no risk to human health.

57. The wording of the Regulation at first glance allows both interpretations. Since substantial equivalence rather than identity or conformity of composition is at issue, the broader interpretation can be given preference. On the other hand, the choice of that concept could also be explained by the fact that only variations within a specific range with respect to the level of various constituents which are important for nutritional physiology (carbohydrates, fats, proteins, minerals, etc.) were considered innocuous. [17]

58. The concept of substantial equivalence has become a legal concept in Community law through its insertion into Regulation No 258/97. Nevertheless, the interpretation must also take into account the scientific context within which that concept was developed. In that regard, it must first be considered whether that aspect of the concept was discussed in greater detail during the legislative procedure. The scientific facts which are clarified in the work of various international bodies — where the concept of substantial equivalence was originally developed — and in Recommendation 97/618 must subsequently be considered.

(c) The concept of substantial equivalence in the legislative procedure [18]

59. The concept of substantial equivalence did not yet figure in the Commission's

17 — Analogous variations in composition also occur under natural conditions and represent a significant problem when comparing novel and traditional foods in order to determine substantial equivalence. The OECD has therefore begun to draw up profiles for various useful plants, with details on constituents and their natural variations as a basis for comparison (see, for example, Consensus Document on Compositional Considerations for New Varieties of Maize (Zea Mays): Key Food and Feed Nutrients, Anti-nutrients and Secondary Plant Metabolites, *OECD Environmental Health and Safety Publications, Series on the Safety of Novel Foods and Feeds*, No 6, 2002).

18 — See generally, on the completion of the legislative procedure and the main points of contention during the development of Regulation No 258/97: D. Groß, *Die Produktzulassung von Novel Food*, Berlin 2001, p. 133 et seq. and p. 144 et seq., and R. Streinz, 'Der Stand der europäischen "Novel Food" - Diskussion', *Zeitschrift für das gesamte Lebensmittelrecht*, 1996, p. 123.

original proposal of 1992.[19] Under that proposal, however, the regulation was in any case to apply only to foods produced by processes resulting in a significant change in their composition, nutritional value and/or their intended use. In addition to many other criticisms, the European Parliament in its first reading objected to the restriction of the field of application to *clearly* altered foods.[20]

60. In its amended proposal of 1993, the Commission wanted foods produced from genetically modified organisms which had not undergone any significant change by comparison with the corresponding conventional product not to be subject to any regulation.[21]

61. It was only in the common opinion adopted by the Council two years later that the scope of application was defined, in Articles 1, 3(4) and 5, in its present formulation. However, no clue as to the interpretation of the concept of substantial equivalence, introduced here for the first time, in connection with the simplified procedure, can be inferred from the statement of reasons for the common position. That concept was not questioned or discussed in subsequent procedures. Rather, the discussions concentrated mainly on labelling provisions.[22]

62. In summary, it can be stated that foods derived from genetically modified organisms which are substantially equivalent to comparable conventional products were perhaps not covered by the Regulation at all under the Commission's original proposal[23] and therefore — apart from approval under the deliberate release directive — could have been placed on the market without any authorisation in accordance with legislation concerning food. The scope of application of the Regulation was first enlarged during subsequent phases of the legislative procedure, although only a simplified procedure for those products was introduced. The documents from the legislative procedure which led to the adoption of Regulation No 258/97 provide no information, however, concerning the interpretation of the concept of substantial equivalence.

19 — See Article 1 of the Commission proposal of 7 July 1992, COM (92) 295 (OJ 1992 C 190, p. 3).

20 — See the amendments adopted by the European Parliament at its first reading, No 14 (OJ 1993 C 315, pp. 139 and 142).

21 — Article 1(2)(b) of the amended Commission proposal of 1 December 1993, COM (93) 631 final (OJ 1994 C 16, p. 10).

22 — See the amendments adopted by the European Parliament at its second reading (OJ 1996 C 96, p. 26).

23 — See R. Streinz, p. 130 (cited in footnote 18).

(d) The scientific context of the concept of substantial equivalence

63. The evaluation of novel foods presents particular challenges. [24] Foodstuffs are as a rule a complex mixture of various substances. In that respect, they differ from artificial food additives or from medicines, which are composed of specific active ingredients. The toxicological effects or secondary effects of those substances, whose composition is precisely known, can be studied in isolation both *in vitro* and *in vivo*, for example through animal testing. On the other hand, animal feeding studies using foods intended for human consumption are frequently unsuccessful because laboratory animals cannot tolerate a 'high dose' of that food purely for reasons of nutritional physiology.

64. In the light of those fundamental difficulties, the OECD in 1993, in its report *Safety Evaluation of Foods Derived by Modern Biotechnology* (hereinafter 'the 1993 OECD report'), [25] developed the determination of substantial equivalence as a first step in a safety assessment of food produced by biotechnology. [26] The starting point for that concept is the idea that mankind has for centuries gained experience of conventional foods. Even when conventional foods are not free of dangerous substances, there is none the less wide-ranging agreement that they can be considered safe, on the basis of that experience and with regard to acquired knowledge. That same evaluation should apply to a novel food which is substantially equivalent to a conventional food. In particular, the OECD proposes the following conditions for demonstrating substantial equivalence:

'A demonstration of substantial equivalence takes into consideration a number of factors, such as:

— knowledge of the composition and characteristics of the traditional or parental product or organism;

— knowledge of the characteristics of the new component(s) or trait(s) derived, as appropriate, from information concerning: the component(s) or trait(s) as expressed in the precursor(s) or paren-

24 — See Point 3.1 of Recommendation 97/618.

25 — Available over the internet from www.oecd.org/EN/documents/0,,EN-documents-27-nodirectorate-no-15-no-27,00.html.

26 — See in particular pp. 11 to 13 of the 1993 OECD report.

tal organism(s); transformation techniques (as related to understanding the characteristics of the product) including the vector(s) and any marker genes used; possible secondary effects of the modification; and the characterisation of the components or trait(s) as expressed in the new organism; and

— knowledge of the new product/organism with the new components or trait(s), including the characteristics and composition [i.e. the amount of the components or the range(s) of expression(s) of the new trait(s)] as compared with the conventional counterpart(s) (i.e. the existing food or food component).

Based on a consideration of the factors in the paragraph above, knowledge that a new food or food component(s) was derived from organism(s) whose newly introduced traits have been well-characterised, together with a conclusion that there is reasonable certainty of no harm as compared with its conventional or traditional counterpart, means that a new food or food component(s) can be considered substantially equivalent.'

65. The obvious starting point of the OECD formulation is that the newly inserted trait and its expression products must be taken into account when considering substantial equivalence. Consequently, the examination of substantial equivalence cannot be restricted to a (superficial) analytical comparison of easily detectable substances.

66. Nevertheless, according to that formulation, substantial equivalence cannot be rejected merely because certain amounts of transgenic protein are present in the novel food. Rather, a safety assessment of the newly introduced trait must be carried out, in addition to a comparison between the composition of the foods, which takes into account how it functions in the original organism and the insertion techniques used.

67. In 1996, a joint working group of the FAO (United Nations Food and Agriculture Organisation) and the WHO (World Health Organisation) examined the topic and published the report *Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety* (hereinafter, the '1996 FAO/WHO report'). [27] That report pointed out, first of all, that the determination of substantial equivalence is not in itself a

27 — Available on the internet, www.fao.org/es/ESN/food/pdf/biotechnology.pdf.

safety assessment. It is merely a dynamic analytical procedure to examine the safety of novel foods in comparison with their traditional counterparts. For the expert groups, an examination of equivalence can lead to the three following results:

— The novel food is substantially equivalent to the traditional one.

— There is substantial equivalence with the exception of specific traits.

— The novel food is not substantially equivalent.

68. The specific differences in foods belonging to the second category typically arise, according to the FAO/WHO expert groups, as the result of the insertion of genetic material which encodes new proteins or causes the production of new components in the host organism. In the case of substantial equivalence with the exception of one or several of the new traits, further safety assessments should focus on those traits.

69. The participants in an OECD workshop endorsed that position taken by the FAO/WHO expert groups.[28] It is noteworthy that in the report on that workshop, plants which have developed resistance to certain insects as the result of the introduction of a *Bacillus thuringensis* gene were put forward as an example of the second category.[29] Plants thus modified, and products derived from those plants, are thus considered novel foods which are substantially equivalent to their conventional counterparts, with the exception of the newly introduced trait of insect resistance.

70. Nevertheless, it is still not clear what conclusions should be drawn if, following appropriate further assessment, the divergent traits or components prove not to be dangerous to human health. For the purpose of interpreting the legal concept in Regulation No 258/97, it would be decisive if the novel food could in that case be considered substantially equivalent as a whole.

28 — OECD, *Food Safety Evaluation*, 1996, Annex 1, p. 163 et seq.

29 — OECD, *Food Safety Evaluation*, 1996, Annex 1, p. 163.

71. Subsequent publications by the OECD and by FAO/WHO continued to employ and refine the concept of substantial equivalence. [30] At the same time, the development of new testing methods moved to the fore, in an attempt to ascertain potential toxicity and allergenicity [31] resulting from the genetic modification of encoded proteins.

72. However, the concept continued to meet with criticism. [32] Objections were raised that it was too imprecise and merely served as a pretext to avoid having to carry out comprehensive toxicological and allergenicity testing on novel foods. [33] Other criticism considered it a contradiction in terms to test foodstuffs known to differ from one another as the result of the insertion of a new trait for the purpose of establishing their equivalence. [34] Finally, it was pointed out that testing for substantial equivalence by comparing composition would provide only limited information as to unexpected effects arising from genetic modification. [35] As a result of that criticism, the Commission's 2001 proposal for a (new) regulation on genetically modified foodstuffs and feedstuffs no longer provided a simplified procedure for genetically modified foods which are substantially equivalent to traditional foods. [36]

73. Independently of that criticism, it must be concluded that the work of the international organisations described here has not, in the final analysis, made it possible to answer the question whether equivalence within the meaning of Regulation No 258/97 can also be assumed when a novel food contains traces of transgenic protein which has, however, been shown to be of no concern as regards human health. It is clear, nevertheless, that establishing substantial equivalence is not limited to comparing the level of easily detectable components relating to nutritional physiology.

30 — See *Report of the OECD Workshop on the Toxicological and Nutritional Testing of Novel Food*, 1998; *Safety aspects of genetically modified foods of plant origin, Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology*, 2000. A summary of the development can be found in the publication by the British Royal Society, *Genetically modified plants for food use and human health — an update*, Policy document 4/02, February 2002.

31 — See Evaluation of Allergenicity of Genetically Modified Foods, *Report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology*, 2001.

32 — Summary: The Royal Society, p. 5 et seq. (cited in footnote 30).

33 — E. Millstone et al., *Beyond 'Substantial equivalence'*, Nature 1999, Vol. 401, p. 525.

34 — The Royal Society of Canada, *Elements of Precaution: Recommendations on the Regulation of Food Biotechnology in Canada*, 2001, p. 180 et seq. (www.rsc.ca/foodbiotechnology/index/EN.html).

35 — H.A. Kuiper, *Food Safety Evaluation of Genetically Modified Foods as a Basis for Market Introduction*, Ministerie van Economische Zaken, Den Haag (Ministry for Economic Affairs, The Hague), 1998, p. 11 (available by internet, on: www.ez.nl).

36 — See p. 4 of the proposal's statement of reasons (cited in footnote 13).

(e) Recommendation 97/618

74. In the passages from Recommendation 97/618 cited above,[37] the Commission turns its attention to the concept of substantial equivalence. Its observations on that question are obviously based on the findings in the 1993 OECD report and the 1996 FAO/WHO report. They present the same dilemma as arose in connection with the 1996 FAO/WHO report, namely, how to evaluate the case where substantial equivalence is established, with the exception of certain traits which further studies show to be safe.

75. However, it should be borne in mind that the Recommendation, in accordance with its legal basis in Article 4(4) of Regulation No 258/97, refers to the scientific aspects of the information necessary to support an application for an authorisation. Under the simplified procedure at issue, laid down in Article 3(4) and Article 5 of Regulation No 258/97, however, no application for the issue of an authorisation for placing on the market is required. Rather, the requirements are addressed to companies which want to submit an application to the national food assessment body under the application procedure laid down in Article 4(1), and to those assessment bodies which carry out the initial assessment of those applications under Article 6.

76. Even if the criterion of substantial equivalence in Regulation No 258/97 is mentioned only in connection with the simplified procedure, it is nevertheless not surprising that it is considered in connection with the authorisation procedure in the Recommendation, since it constitutes a general instrument for evaluating genetically modified foods. Substantial equivalence can also, for example, play an important role in assessing foods to which the simplified procedure does not apply because they still contain genetically modified organisms or are themselves such organisms.

77. Given that background, it is not surprising that the Recommendation provides no standard for a clear Yes or No to the question of substantial equivalence. While the determination of substantial equivalence is an important aspect of formal authorisation, it is nevertheless not decisive. The conditions for an authorisation to place novel foods on the market are, under Article 3(1) of Regulation No 258/97, that it does not present a danger to the consumer, does not mislead the consumer and/or does not differ from conventional

37 — Points 14 to 16.

foods to an extent that their normal consumption would be nutritionally disadvantageous. For that reason, the approval of novel foods is possible primarily for novel foods which are only partly or not at all substantially equivalent to comparable conventional foods. The absence of substantial equivalence does not mean that the novel food is not safe but merely that it must be assessed on the basis of its own composition and properties. [38]

78. As a result, it is also not possible to draw any conclusive indication from Recommendation 97/618 — or from the work of international bodies — on how to interpret the concept of substantial equivalence in Article 3(4) of Regulation No 258/97 in a case such as the present one.

79. For that reason, it is necessary to consider which of the two possible interpretations set out in paragraph 56 best accords with the meaning and purpose of the Regulation and with the broader regulatory context.

38 — Recommendation 97/618, point 3.1.

(f) Interpretation in the light of the meaning and purpose of the Regulation and with regard to the regulatory context

80. When interpreting the Regulation, it must be taken into account that the placing on the market of conventional foods generally does not require an approval. On the other hand, there is no experience over the years in relation to novel foods as there is in relation to traditional foods. Moreover, it cannot be excluded that novel foods could pose risks to human health.

81. In order to avert those risks, without at the same time setting up overly high hurdles to the placing on the market of novel foods which barely differ from conventional foods, the Community legislature chose a progressive regulatory model, oriented towards the principle of proportionality. [39] For the group of novel foods which is considered to have slight potential for risk, which includes foods within the meaning of Article 1(2)(b), which are produced from but do not contain geneti-

39 — See U. Di Fabio, 'Bio- und Gentechnikrecht', in: Rengeling (ed.), *Handbuch zum europäischen und deutschen Umweltrecht*, Volume II, 1998, pp. 558 and 621.

cally modified organisms, it merely provided for the simplified procedure under Article 3(4) and Article 5 of Regulation No 258/97, where there is substantial equivalence. It thereby went beyond the proposal by the Commission, according to which — at least in the case of insignificant modifications — no approval whatsoever would have been required.

82. The fact that the practical scope of application for the simplified procedure would be extremely limited if even the smallest trace of transgenic protein were to preclude the use of that procedure argues against the narrow interpretation of the concept. The genetic modification of crop plants as a rule brings about the coding of proteins which would not naturally be found in those plants. It must be very rare in practice that transgenic proteins are fully eliminated during the processing of plants into food. [40]

83. Under the narrow interpretation, only foods could be placed on the market under the simplified procedure which differ from conventional foods as the result of being derived from genetically modified organisms but which — as far as is known — do not show the slightest difference in composition. The question then, of course, is whether in that case a special marketing notification is necessary. It could perhaps be justified on the ground that unforeseen changes in comparison with conventional foods could have occurred. Specific notifications or approvals only make sense, however, where such possible changes in food can be detected and ascertained under the current level of science.

84. Under the broad interpretation, on the other hand, foods can also be placed on the market under the simplified procedure which have been produced from a genetically modified organism and which — without containing the organism as such — still exhibit traces of the substances resulting from genetic modification. Those anomalies in composition justify subjecting novel foods to specific procedures anyway before they can be placed on the market.

85. Nevertheless, under the broad interpretation, the rule set out in the first indent of Article 3(1) must also be considered, namely that the food is not to present a danger for the consumer. In that regard, it should be borne in mind that it is not merely knowledge about the host plant which is available for consideration when assessing substantial equivalence. On the contrary, the plant from which the introduced trait is derived and the protein for

40 — Examples of corresponding processing referred to in the literature are the distillation of oil from genetically modified rape or the refining of sugar from genetically modified sugar beets.

which it codes are generally also known. If further examination of the divergent trait and of the new components of the foods ensures that effects on human health can be ignored and that risk to consumers can therefore be largely excluded, that rule will also be taken into account when marketing takes place under the simplified procedure.

86. The comparatively minor requirements laid down for marketing under the simplified procedure can be cited against the broad interpretation. Under Article 3(4) of Regulation No 258/97, anyone wishing to place a novel food on the market has two ways in which to determine substantial equivalence. He can take as a basis available and generally recognised scientific findings, or — as in the present case — the opinion of a national food assessment body. In the former case, the person responsible can market the novel food without previous examination or recognition of substantial equivalence by an official body. Since Article 5 of the Regulation also does not lay down any prescribed period [41] in which the Commission or a Member State may raise objections to the placing on the market, in the final analysis control is only possible after the fact in this case.

87. That circumstance may be a weakness of the simplified procedure, which should be acknowledged when answering the fourth question referred for a preliminary ruling. That potential disadvantage does not, however, preclude a broad interpretation of the concept of substantial equivalence. That is, inasmuch as there is no mandatory requirement for prior examination by an official body of the conditions for placing on the market under the simplified procedure, it is not possible to prevent those conditions being disregarded, no matter how stringent they might be.

88. Finally, consideration of the regulatory context supports a broad interpretation. Under Article 5 of Regulation No 258/97, the provisions of Article 8 are also to apply to the labelling of foods classified as substantially equivalent. Under Article 8(1)(a), the labelling must inform the consumer in particular about the characteristics or food properties of the novel food which has rendered it no longer (fully) equivalent to an existing food.

89. The concept of 'equivalence' within the meaning of Article 8 is therefore narrower than the concept of 'substantial equivalence' in Article 3(4). The legislature clearly started out with the idea that there are foods which are *substantially* equivalent

41 — See Gross, cited in footnote 18, p. 311 et seq.

but must nevertheless be specifically labelled because they are not *fully* equivalent. Certain differences therefore do not exclude a determination of substantial equivalence but merely trigger a specific labelling requirement.

90. Moreover, in accordance with Article 8(1)(b), it must be clear from the labelling when a novel food contains substances which are not present in a fully equivalent food and which could have an effect on the health of particular groups of people. Therefore, even taking as a basis the narrower concept of equivalence in Article 8, it cannot be excluded that the composition of novel and conventional foods differ from one another. The novel food can even — in contrast to the equivalent product — contain substances which could affect the health of at least some groups of people.

91. Finally, it should once again be pointed out that the concept of substantial equivalence is merely an instrument for the assessment of novel foods. That assessment cannot disregard the actual objective of the Regulation, namely to exclude risks to human health. The concept of substantial equivalence must also be oriented towards that objective.

(g) Finding

92. The answer to the first question referred must therefore be that Article 3(4) of Regulation No 258/97 is to be interpreted to mean that the foods or food ingredients referred to in Article 1(2)(b) of the Regulation are to be considered substantially equivalent to existing foods and food ingredients and, as a result, may be placed on the market under the simplified procedure through a notification pursuant to Article 5 of the Regulation, even when those foods and food ingredients still contain residues of transgenic protein but it has been demonstrated that those substances do not present a danger for the consumer.

93. To be clear, it should again be emphasised that that is not a definitive decision concerning the substantial equivalence of the specific foods covered by the contested Italian decree. Nor does it answer the question of whether the relevant reports by the ACNFP, in particular as regards the innocuousness of the protein encoded by the introduced gene, were properly carried out [42] and are appropriate. Rather, under the second subparagraph of Article 3(4) in conjunction with Article 13 of Regulation

42 — In that regard, it is worthy of note that the opinions of the ACNFP appear to have been drawn up prior to the entry into force of Regulation No 258/97. However, they were first sent by the Ministry following its entry into force.

No 258/97, is it the task of the Commission to examine, in cooperation with the Standing Committee for Foodstuffs, whether the conditions for the use of the simplified procedure have been satisfied.

B — *Powers of the Member States to adopt protective measures against the placing on the market of novel foods (second question referred for a preliminary ruling)*

94. The referring court poses the second question referred for a preliminary ruling only in the case where the answer to the first question is negative, that is to say, if novel foods cannot be considered substantially equivalent to existing foods inasmuch as they contain traces of transgenic material. Under the solution proposed here, however, that circumstance does not preclude substantial equivalence, and there is thus no need to answer the second question.

95. Nevertheless, it appears appropriate to consider that question in detail, for the following reasons. First, despite the solution I have proposed to the first question, it has not been determined whether the contested food can in fact be considered substantially equivalent.

Secondly, the Member State can be entitled to adopt protective measures under Article 12 of Regulation No 258/97 even when the foods in question are legally classified as substantially equivalent at the time of being placed on the market. Thirdly, the answer is provided in case the Court of Justice does not share the interpretation of the concept of substantial equivalence which is here proposed and comes to a different answer to the first question referred for a preliminary ruling.

1. Submissions by the parties

96. *Monsanto and others* consider that the wording of Article 12 of Regulation No 258/97 is clear. It allows Member States to act only when they have in their possession new scientific information, which was not the case when the Decree was adopted.

97. The question, therefore, is essentially whether a Member State which considers that the provisions concerning the simplified procedure are invalid can adopt protective measures on the basis of the precautionary principle, even when the conditions set out in Article 12 are not met. That would lead to the result that a Member State could unilaterally decide

the validity of a Community regulation, which according to the case-law [43] it is not, however, entitled to do. Accordingly, neither Article 12 nor the precautionary principle can be put forward as a basis for the national measures.

98. The *Italian Government* considers that Article 12, in conjunction with Article 13, provides a procedure for reviewing the approval of novel foods under which the Member State and the Commission work together.

99. Under Article 12, a Member State may temporarily suspend the marketing of a novel food which has been placed on the market under the simplified procedure and therefore has not undergone a comprehensive safety assessment. As a condition, the Member State must produce scientific substantiation for the absence of substantial equivalence and the resulting inapplicability of the simplified procedure. The Commission subsequently reviews that scientific substantiation under the procedure laid down in Article 13.

100. The *Norwegian Government* points out that a Member State which has doubts as to substantial equivalence can request that the Article 13 procedure expressly referred to in Article 3(4) be carried out. If, under that procedure, consideration of all the scientific information establishes that the novel food is not in fact substantially equivalent to a conventional food, its marketing must be suspended until it has been approved under the authorisation procedure.

101. Until the relevant determination under Article 13 has been made, the Member State may suspend marketing under Article 12, provided that the conditions for the use of that safeguard clause are satisfied. Accordingly, the Member State may act when, as a result of new information or a reassessment of existing information, detailed grounds exist for considering that the use of the novel food endangers human health or the environment.

102. The Court of Justice has held [44] that such safeguard clauses give expression to

43 — Monsanto and others refer, *inter alia*, to Case 101/78 *Granaria* v *Hoofdproduktschap voor Akkerbouwprodukten* [1979] ECR 623, paragraphs 4 and 5, and Case 128/78 *Commission* v *United Kingdom* [1979] ECR 419, paragraphs 9 and 10.

44 — See the comparable provision in Article 16 of the deliberate release directive judgment in Case C-6/99 *Greenpeace France and Others* [2000] ECR I-1651, paragraph 44.

the precautionary principle and must therefore be interpreted in keeping with that principle, which is set out in Article 174(2) EC. According to the precautionary principle, there is no need to provide complete proof of a risk to the environment or to human health; rather, protective measures are already justified where a preliminary and objective scientific risk evaluation gives reasonable grounds for concern that the potentially dangerous effects on the environment, human health, animal and plant health may be inconsistent with the Community's high level of protection.[45]

103. In the alternative, the Norwegian Government argues as follows. Article 12 allows measures in cases where new information emerges concerning novel foods 'complying with this Regulation'. It is highly questionable whether the contested foods comply with the Regulation, since they were placed on the market under the simplified procedure despite doubts concerning their substantial equivalence.

104. After the Italian Government unsuccessfully attempted to trigger the assessment procedure under Article 13, it was entitled to invoke the safeguard clause in Article 12 in order to obtain the information needed to evaluate substantial equivalence.

105. It is for the Commission to examine the Italian marketing prohibition and to take action under Article 13, if appropriate. Since the Commission has not adopted any measures under that provision, the national measures may be maintained. It is incumbent on the Commission alone, and not on the national court, to review the Decree in accordance with the criteria in Article 12.

2. Appraisal

(a) Preliminary observations on the justification of national measures by direct reference to the precautionary principle

106. The second question relates to the power of the Member States to adopt protective measures on the basis of the 'precautionary principle, which is given particular expression in Article 12 of

45 — The Norwegian Government refers, in that connection, to point 3 of the Communication from the Commission on the precautionary principle of 2 February 2000 (COM [2000]1 final).

Regulation No 258/97'. However, the precautionary principle is not expressly mentioned as a legal basis in the recitals in the preamble to the Italian decree. In view of the formulation of the question referred for a preliminary ruling, the importance of the precautionary principle in that connection should briefly be considered before the provisions of the Regulation are discussed in greater detail.

107. The Italian decree constitutes a measure having equivalent effect to a quantitative restriction within the meaning of Article 28 EC. It is settled case-law that a Member State can no longer invoke Article 30 EC and the major needs recognised therein to justify such a restriction when a Community harmonisation measure has been adopted in order to implement a specific objective which is to be achieved through recourse to Article 30. [46]

108. The objective of the precautionary principle is to protect the environment, as well as human life and animal and plant life, when no concrete threat to those resources has yet been demonstrated but initial scientific findings indicate a possible risk. The precautionary principle therefore sets out a rule for action in situations of uncertain risk, where there is an inseparable connection between that principle and a potential risk to objects of legal protection.

109. The Decree fundamentally seeks to protect consumers from dangers to their health which might arise from foods derived from genetically modified maize. The Italian legislation cannot, however, be justified by reference to the goal of protecting health within the meaning of Article 30 EC, since Regulation No 258/97 also pursues that objective. [47] In addition, Regulation No 258/97 constitutes a uniform rule for the approval of novel foods, so that the Member States no longer have any margin to adopt more restrictive national rules.

110. The power of the Member States to adopt protective measures is regulated definitively in Article 12 of Regulation No 258/97. Direct recourse to general principles of law or imperative needs in the general interest in order to justify restrictions on the free movement of goods is therefore excluded. That is the case even where the Member State considers that the harmonised provisions for placing goods on the market under the simplified pro-

46 — Judgment in Case C-241/01 *National Farmers' Union II* [2002] ECR I-9097, paragraph 48, Case C-350/97 *Monsees* [1999] ECR I-2921, paragraph 24, and Case C-5/94 *Hedley Lomas* [1996] ECR I-2553, paragraph 18.

47 — See the second recital in the preamble to Regulation No 258/97, cited above in paragraph 7.

cedure are invalid. A Community regulation must be considered valid and binding on the Member States unless it has been annulled or repealed by the competent Community Court. [48] The question of whether the Regulation's provisions are invalid because they do not take sufficient account of the precautionary principle must be examined in the context of the fourth question referred for a preliminary ruling.

111. As the Court of Justice has established, 'in the European Community, which is a community based on law, a Member State is bound to comply with the provisions of the Treaty and, in particular, to act within the framework of the procedures provided for by the Treaty and by the applicable legislation'. [49]

112. That does not, however, mean that the precautionary principle is without any importance in the present case. It is settled case-law that a provision of secondary Community law should to the greatest extent possible be interpreted so as to be compatible with the EC Treaty and with the general principles of Community law. [50] In the framework of that interpretation, the precautionary principle must also be taken into account.

48 — See the case-law cited in footnote 43.

49 — *National Farmers' Union II* (cited in footnote 46, paragraph 50).

50 — Joined Cases 201/85 and 202/85 *Klensch* v *Secretary of State* [1986] ECR 3477, paragraph 21, Case C-314/89 *Rauh* [1991] ECR I-1647, paragraph 17, and Case C-181/96 *Wilkens* [1999] ECR I-399, paragraph 19.

(b) Powers of the Member States to adopt protective measures on the basis of Regulation No 258/97

113. Italy expressly based the Decree on Article 12 of Regulation No 258/97. [51] Before looking at that provision more closely, it is first necessary to examine what powers the second subparagraph of Article 3(4) in conjunction with Article 13 grants the Member States. The Italian Government particularly mentioned, as a basis for the measure, that it had doubts as to the substantial equivalence of foods produced from genetically modified maize. As the Norwegian Government rightly observed, where there are doubts with regard to the conditions for use of the simplified procedure, in particular as regards substantial equivalence, the second subparagraph of Article 3(4) in conjunction with Article 13 is relevant in the first instance.

114. It should be noted that Article 13 lays down a general procedure for action by the Commission in cooperation with the Standing Committee for Foodstuffs and provides no information concerning the substantive powers of the Commission and the Member States. The relevant substantive

51 — See the first recital in the preamble to the Decree.

provisions of the Regulation concerning the procedure under Article 13, and in particular the second subparagraph of Article 3(4) and Article 12(2), establish the cases to which that procedure applies.

(i) The second subparagraph of Article 3(4) in conjunction with Article 13

115. Under the second subparagraph of Article 3(4), the procedure laid down in Article 13 can be used to determine whether a food satisfies the conditions of use for the simplified procedure. It gives the Commission the right to determine, assisted by the Standing Committee for Foodstuffs, whether a novel food is substantially equivalent to a conventional food. In the case where the Standing Committee for Foodstuffs does not approve the Commission's draft decision to that effect, the Commission can, under Article 13(4), submit a proposal for a decision to the Council or — if the Council fails to act — itself adopt the proposed decision.

116. The second subparagraph of Article 3(4) in conjunction with Article 13 thus constitutes an instrument for reviewing the applicability of the second subparagraph of Article 3(4). The rules take into account the circumstance that the applicability of the second subparagraph of Article 3(4) is first examined only by the party which is placing the food on the market on that basis. It is possible that only the aspect of substantial equivalence has at that stage already been subject to assessment by a national body, to the extent that the responsible party has referred to the opinion of a food assessment body and has not invoked 'scientific evidence... generally recognised' within the meaning of Article 3(4).

117. Apart from the question of whether it is correct to consider the food as substantially equivalent, that procedure contains no risk assessment component. Were the Commission to conclude that the conditions of use for the simplified procedure are not present, marketing would be suspended and an application for approval under the authorisation procedure would have to be submitted. Only under that procedure could any dangers be further assessed.

118. The wording of the second subparagraph of Article 3(4) does not make clear on whose initiative the procedure to review the conditions of use in Article 13 is to be instituted. The matter can be referred to the Standing Committee for Foodstuffs under Article 13(2), *inter alia*, at the request of

the representative of a Member State. However, under Article 13(3) only the Commission has the right to submit to the Standing Committee for Foodstuffs a draft of the measures to be taken.

119. However, the following consideration suggests that Member States have the right to apply for a Commission decision under the second subparagraph of Article 3(4) in conjunction with Article 13: In contrast to the simplified procedure, under the authorisation procedure the Member States have wider opportunities for cooperation. In particular, under Article 6(4) they may present a reasoned objection to the approval and thereby compel an approval decision to be taken under the committee procedure provided for in Article 13. The review under the second subparagraph of Article 3(4) in conjunction with Article 13 can be decisive in determining the use of the authorisation procedure rather than the simplified procedure. Therefore, in order for the Member State to have a comprehensive right to take part in the authorisation procedure, it must be able to request a review of the conditions of use for the simplified procedure. It can thereby ensure that, when an evaluation results in a negative finding, an authorisation procedure which includes a suitable role for the Member States is carried out.

120. In order for the Member State to be able to assess whether it should apply for a review under the second subparagraph of Article 3(4) in conjunction with Article 13, it has the right under Article 5 to request information in respect of novel foods which are placed on the market under the simplified procedure.

121. Corresponding to the Member States' right of application is a duty on the part of the Commission, in the case of such an application, to take all the necessary steps to adopt a decision under the procedure laid down in Article 13, which the Member State can challenge if it considers that the Commission's evaluation is flawed. If no decision is adopted, it is open to the Member State to bring proceedings for a failure to act.

122. However, it must be held that a Member State — apart from that right of application — is not entitled to take measures under the provisions described above if it has doubts as regards the applicability of the simplified procedure.

123. In that regard, it is uncertain what meaning should be attached to the letters of the Italian Government of 23 November 1998, 4 February 1999, 2 April 1999 and 23 December 1999.

124. The first two letters refer only to products derived from MON 809 maize. The Italian Government states in those letters that an authorisation procedure should be carried out. In its second letter, it lists the various pieces of information which must still be provided for the purpose of a comprehensive risk assessment. In particular, the information concerning undesirable substances remains to be completed within the framework of the determination of substantial equivalence.

125. The third letter, on the other hand, relates, *inter alia*, to the notifications for the placing on the market of foods derived from MON 810 maize and Bt-11 maize. In that letter, the Italian Government asks the Commission to make available to it, pursuant to Article 5 of Regulation No 258/97, the documentation required for an evaluation of those products. Referring to Article 12, it points to the possibility that national protective measures could be taken on the basis of the precautionary principle.

126. The second and third letters are primarily intended to obtain additional information. The Commission understood that to be the purpose of the letters and, according to its practice, forwarded them to the responsible companies for a direct response. According to the statements made by Monsanto and others during the oral procedure, which were not contradicted by the Italian Government, they supplied all the information which was requested.

127. Nevertheless, in the letter of 23 December 1999, the Ministry of Health raised objections to the use of the simplified procedure, on the ground that substantial equivalence was not established. In addition, it expressly referred to the assessment procedure under the second subparagraph of Article 3(4) in conjunction with Article 13.

128. The Commission replied to that letter by letter of 10 March 2000 and asked the Italian Government for scientific evidence to substantiate the absence of substantial equivalence. However, it appears that the Commission had itself not yet introduced the review procedure with the participation of the Standing Committee for Foodstuffs, after the Italian Government had clarified its position by letter of 5 June 2000. Rather, by letter of 10 July 2000, the Commission admitted the need for further assessment.

129. The Commission's conduct is all the more surprising in that, in early 1998, it had already agreed with the Member States on a moratorium on the use of the simplified procedure, precisely on the basis of the problem related to the concept of substantial equivalence.

130. Moreover, it should be pointed out that, while it is true in principle that the aim should be to carry out an examination of the conditions of use for the simplified procedure at an early stage, the second subparagraph of Article 3(4) sets no time-limit for that examination. The commercial confidentiality of the responsible firms could, in addition, preclude that examination for a certain time after placing on the market in specific cases.

131. However, the mere failure of the Commission to act — that is, in the absence of the conditions laid down in Article 12 — does not justify unilateral action by Italy. Rather, the Italian Government should have brought an action for failure to act against the Commission, which has sole responsibility for initiating the examination procedure.

(ii) Article 12

132. However, Article 12 expressly entitles the Member States to take measures on their own initiative. Under that provision, they have a certain competence as regards supervision and emergency action, in the case where novel foods which were at one time placed on the market in accordance with the Regulation are later none the less considered questionable as the result of new information or a reassessment of existing information. That competence exists regardless of which procedure was used to authorise the product in question.

133. In contrast to the Commission proposal for a revised regulation on the authorisation of genetically modified foods, [52] Regulation No 258/97 does not provide for any systematic supervision of products placed on the market under the harmonised procedure. However, Article 12 permits the Member States to act when specific indications appear to call for a reassessment and thereby establishes the possibility of product control at national level.

52 — See, in particular, Article 6(3)(k) and Article 6(5)(b) in conjunction with Article 10 of the proposal for a regulation concerning genetically modified foods and novel food ingredients (cited in footnote 13).

134. Under Article 12(1), the Member State must have 'detailed grounds' for concerns about potential risk. That condition is to be interpreted with reference to the precautionary principle. [53] Although Article 174(2) EC expressly mentions that principle as only one of the principles underlying environmental policy, it is nevertheless clear from the case-law that the principle of preventive action is also to be observed in other policy areas. [54]

135. The precautionary principle has not yet been fully defined in the case-law of the Court of Justice. Nevertheless, in *BSE*, the Court already pointed out the following: [55]

'Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.'

136. In areas where the legal provisions are not yet harmonised, the Court of Justice also grants the Member States, in situations of uncertain risk, a wide degree of latitude to protect human health by taking measures which restrict the free movement of goods, although they must observe the principle of proportionality. [56]

137. According to the precautionary principle, as understood by the Commission in its Communication on the use of the precautionary principle, [57] conclusive scientific evidence of the reality of risk is not required. [58] Action is therefore appropriate even where cause for concern is based on preliminary scientific findings. The enormous importance of human health as the object of legal protection accordingly lowers the threshold for triggering action by a State or the Community.

138. On the other hand, the free movement of goods cannot be entirely ignored in that

53 — See, for the corresponding rule in Article 16 of the deliberate release directive, *Greenpeace France* (cited in footnote 44, paragraph 44).

54 — Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraph 100 — *BSE* judgment, and Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 64 ('*National Farmers' Union I*').

55 — *BSE*, paragraph 99 (cited in footnote 54); see also *National Farmers' Union I*, paragraph 63 (cited in footnote 54).

56 — Case 178/84 *Commission* v *Germany* [1987] ECR 1227, paragraph 41; Case C-347/89 *Eurim-Pharm* [1991] ECR I-1747, paragraph 26; and Case C-121/00 *Hahn* [2002] ECR I-9193, paragraph 38.

57 — Cited in footnote 45.

58 — See also, to that effect, Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR I-3305, paragraph 142.

assessment. For that reason, not every claim or scientifically unfounded presumption of potential risk to human health or the environment can justify the adoption of national protective measures. Rather, the risk must be adequately substantiated by scientific evidence. [59]

139. In order to ensure the uniform implementation of the Regulation, Article 12(2) requires, with reference to the procedure in Article 13, that the Commission examine the temporary national measures. The crux of that examination is whether the grounds on which the Member State acted in fact justify restrictions. It is thereby incumbent upon the Member State which wishes to restrict the marketing of a product which has duly been placed on the market to state and to provide evidence for those grounds. None the less, on the basis of the precautionary principle, the Member State need only furnish proof of preliminary scientific findings which indicate cause for concern.

140. If the Commission shares the misgivings of the Member State, it will adopt appropriate Community-wide measures under Article 13. The Member State may maintain its temporary measures until those measures come into force. It is not clear what the consequences are for the national measures if the Commission does not share the Member State's assessment and does not adopt any Community-wide measures.

141. That case is not explicitly governed under the Regulation. However, it is in accordance with the spirit and the letter of the Regulation that the Commission should in that case adopt an explicit decision under the Article 13 procedure in which it states that the scientific grounds put forward by the Member State do not provide grounds for the adoption of measures. If the Commission cannot come to an agreement with the Standing Committee for Foodstuffs, it must refer the matter to the Council and, if the latter does not act, it must itself adopt the decision. Consequent on such a Commission decision, the Member State would have to revoke its temporary measure.

142. Only such a decision by the Commission can establish the necessary legal certainty. It is true that the mere failure by the Commission to act over a prolonged period also expresses its opinion that the adoption

59 — See the EFTA Court judgment in Case E-3/00 *EFTA Surveillance Authority* v *Norway*, not yet published, paragraphs 36 to 38, and the judgment by the Court of First Instance in *Pfizer*, paragraphs 143 and 144 (cited in footnote 58).

of measures is not necessary, since rapid action is generally required when new risks are identified, particularly as regards food safety.

143. However, the Member State and the affected companies are for some time left in the dark about whether the Commission does not wish in fact to act, is still examining the need for measures, or has already prepared measures. That uncertainty is in particular due to the fact that neither Article 12(2) nor Article 13 sets a time-limit within which the Commission is to act. Rather, Article 12(2) merely states that the Commission is to examine the grounds 'as soon as possible'.

144. An examination of the steps which the Commission took following the notification of the Decree makes clear that it in fact obtained an opinion from the Scientific Committee for Food.[60] However, it refrained from submitting a proposal for measures to the Standing Committee for Foodstuffs under the Article 13 procedure and had even withdrawn the proposal which it had submitted.

145. It follows from the preceding observations, however, that the Commission was in any event required to adopt a decision or to refer to the Council. In principle, the Italian Republic is therefore required to revoke its temporary measure only once the competent Community body has taken a decision as to whether the protective measure is justified and a corresponding measure at Community level should accordingly be adopted, or whether the measure is not justified.

146. It is questionable, however, whether the Italian Government actually has adequate grounds for adopting the Decree. The Commission and the Council have wide discretion when examining the complex scientific circumstances to be assessed under the Article 13 procedure. The Court of Justice can therefore only review the decision of the competent Community bodies to determine whether there is a manifest error of assessment or an abuse of discretion or whether the body has clearly overstepped the bounds of its competence.[61] It is not the task of the Court of Justice to substitute its assessment for the assessment of the Commission, when the latter has failed to act.

147. In that respect, it is not sufficient to find fault with the use of the simplified procedure on the basis of an alleged absence of substantial equivalence. As has

60 — Article 11 of Regulation No 258/97 states that '[t]he Scientific Committee for Food shall be consulted on any matter falling within the scope of the Regulation likely to have an effect on public health.'

61 — See Case C-180/96, paragraph 60 (cited in footnote 54), and Case 98/78 *Racke* v *Hauptzollamt Mainz* [1979] ECR 69, paragraph 5.

already been stated, the absence of substantial equivalence does not necessarily mean that a food endangers human health or the environment. Only such risks can justify action under Article 12. Moreover, the second subparagraph of Article 3(4) in conjunction with Article 13 provides a special procedure for the assessment of the applicability of the simplified procedure.

148. While the alleged absence of substantial equivalence is the main argument of the Italian Government, it seems in addition to have concerns as regards the harmlessness of the food, as can be gathered from the opinion of the Scientific Committee for Food of 7 September 2000.

149. The committee did not consider those concerns to be valid. The fact that the Commission and the Member States agreed in early 1998 on a moratorium as regards the further use of the simplified procedure could, however, indicate doubts as to the absolute safety of foods which contain residues of transgenic protein and for which only substantial equivalence has been assessed. The Commission's explanation as to why it continued to use the procedure despite the moratorium in two individual cases, as a continuation of its earlier practice, is not convincing. Were there in fact to be scientifically substantiated concerns as regards the harmlessness of products which contain residues of transgenic protein, the protection of legitimate expectations for the manufacturer of that product could not justify an approval under the simplified procedure.

150. In the final analysis, however, it is not clear what conclusions can here be drawn on the basis of the moratorium and the Commission's seemingly inconsistent conduct. Whether Italy's concerns with regard to the products derived from genetically modified maize which are affected by the marketing prohibition are or were scientifically substantiated must be determined by the Commission or the Council in each individual case, under the Article 13 procedure. However, an appropriate determination — which is precisely what is at issue — has not yet been presented.

151. Accordingly, it must be held that the Italian Government was entitled to adopt temporary measures under Article 12(1) of Regulation No 258/97 in that, as a result of new information or a reassessment of existing information — which certainly includes the moratorium — it had valid grounds for assuming that the use of the foods at issue might endanger human

health or the environment. The validity of the grounds is to be determined by a Commission or Council decision under Article 12(2) in conjunction with Article 13 of the Regulation. The temporary measures may be maintained until that decision is adopted.

C — *Classification of the action by the Commission under the simplified procedure (third question referred for a preliminary ruling)*

1. Arguments of the parties

152. The *Italian Government* considers that the determination of substantial equivalence is at present the sole responsibility of the firm which places the food at issue on the market. The Commission does not examine the notification of placing on the market and therefore does not adopt any decision of approval. It can, however, under the procedure laid down in Article 3(4) in conjunction with Article 13 of Regulation No 258/97, review the conditions of use for the simplified procedure and, in that context, come to a positive or negative decision as to substantial equivalence.

153. The Council, like the Italian Government, considers that the legal status of the Commission's actions under the simplified procedure is of no importance in the light of the powers of the Member States under Article 12. The Member States can take protective measures independently of the type of approval, if valid reasons exist for doing so.

154. The *Norwegian Government* also considers that the Commission's receipt of the notification pursuant to Article 5 of Regulation No 258/97 cannot be construed as tacit assent to the approval of a novel food. Even if the Commission were to neglect a call to review the existence of substantial equivalence under the Article 13 procedure, this does not constitute tacit confirmation of substantial equivalence. In any event, any tacit determination by the Commission would not comprise a reviewable act pursuant to Article 230 EC, because it does not produce legal effects which would prejudice the legal position of the Member State. On the contrary, the latter can itself act under Article 12.

2. Assessment

155. By its third question, the Tribunale Amministrativo Regionale basically asks

whether the Commission takes a (tacit) decision concerning the approval of novel foods under the simplified procedure. If that were the case, the national court then also asks what consequences that would have for the powers of the Member States under Article 12 were the approval decision to prove unlawful, for example because the determination of substantial equivalence was not correct.

156. The wording of Article 5 does not provide any basis for the Commission to review the notification of the placing on the market of a novel food or even to take a decision on approval. As the Italian Government correctly points out, it is at present up to the company which places the product on the market either to evaluate substantial equivalence itself on the basis of generally recognised scientific findings, or to have it established by the competent national food authority.

157. The Commission only receives the notification and the relevant information, forwards it to the Member States and publishes the notification in the *Official Journal*. It takes a decision only in the case of a review of the conditions of use for the simplified procedure under the second subparagraph of Article 3(4) in conjunction with Article 13.

158. Therefore, there is no need to consider the further parts of the question. However, it should be reiterated that the competence of the Member States to adopt protective measures under Article 12(1) depends solely on the existence of new indications that a novel food poses a risk to human health or the environment.

159. However, the admissibility of protective measures depends neither on whether the food in question was placed on the market under the simplified procedure nor under the authorisation procedure nor on whether the specific procedure was faulty or not. Even an unlawful decision issued under the authorisation procedure must be complied with by a Member State until it is repealed by the competent Community body. [62] However, errors in an approval can result in uncertainties concerning risk assessment, which would justify action by the Member State under Article 12 with regard to the precautionary principle.

160. The answer to the third question must therefore be that under the simplified procedure in Article 5 of Regulation No 258/97, the Commission does not take

62 — See the case-law cited in footnote 43.

a tacit decision concerning the approval of the food whose placing on the market is notified to it.

D — *Validity of Article 5 of Regulation No 258/97 (fourth question referred for a preliminary ruling)*

1. Arguments of the parties

161. *Monsanto and others*, the *Norwegian Government* and the *Council* point out that the Community legislature enjoys wide discretionary powers in elaborating the procedure for the placing on the market of novel foods and in defining the objectives to be pursued in that respect. [63] In taking a decision, it must consider complex technical and scientific circumstances. Review by the Court of Justice of the use of discretionary powers is restricted to examining whether a manifest error of assessment or misuse of powers occurred, or whether the body clearly exceeded its discretion.

63 — Joined Cases 197/80 to 200/80, 243/80, 245/80 and 247/80 *Ludwigshafener Walzmühle Erling and Others* v *Council and Commission* [1981] ECR 3211, paragraph 37.

162. *Monsanto and others* claim that Article 5 does not breach the principles put forward by the national court.

163. The foods for which the simplified procedure can be used do not endanger the environment, since they do not contain any genetically modified organisms and therefore cannot develop further or propagate.

164. Nor is human health endangered. In the absence of generally recognised scientific findings, only a national food assessment body can confirm substantial equivalence. For that purpose, the relevant institutions carry out — contrary to the misgivings of the national court — a comprehensive safety assessment. That was also done in the present case, as is clear from the opinion of the competent authorities.

165. In addition, the simplified procedure allows for adequate participation by the Member States. There is participation by the national authorities concerned prior to the placing on the market, inasmuch as they determine substantial equivalence. When a national body has made that

determination, the authorities of the other Member States are bound to follow it under the principle of mutual recognition. After a food has been placed on the market, the Member States retain only the powers granted them under Article 12.

166. According to the *Norwegian Government*, foods derived from genetically modified organisms are never substantially equivalent to the corresponding traditional foods, even if they no longer contain genetically modified organisms as such. The placing on the market of such foods under the simplified procedure infringes the provisions concerning health and consumer protection in Articles 95(3), 152(1), 153(1) and 174(2) EC. Article 3(4) of Regulation No 258/97 is accordingly invalid inasmuch as it refers to foods within the meaning of Article 1(2)(b).

167. The *European Parliament*, the *Council* and the *Commission* defend the validity of the Regulation.

168. The *European Parliament* states that the question is not in fact the validity of Article 5 itself, but rather the validity of Article 3(4).

169. Although Article 100a of the EC Treaty (now, after amendment, Article 95 EC) was used as the legal basis for the Regulation, the rules are also important for human health; therefore, Article 153(2) and Article 174(1) EC must be complied with. [64]

170. Article 3(1) of the Regulation lays down clear provisions for the protection of health. Moreover, every novel food requires an approval, whether under the simplified or the authorisation procedure. That is in accordance with the precautionary principle, which also finds expression in Article 12. In addition, novel foods must be specifically labelled in accordance with Article 8.

171. There is no doubt concerning the validity of the Regulation where the approval provisions are correctly applied. On the basis of the documentation which must be submitted under Article 5, the Commission is able to subject the conditions of use for the simplified procedure, in particular the existence of substantial equivalence, to

64 — Case C-376/98 *Germany* v *Parliament and Council* [2000] ECR I-8419, paragraph 78, the '*Tobacco*' judgment.

review, in accordance with the second subparagraph of Article 3(4). Since the Member States receive notification, they can request such a review. If it were to show that the simplified procedure was not applicable, an authorisation procedure would have to be conducted.

172. The *Council* states that a legal act is not invalid because it proves in retrospect to be inadequate. It is therefore of no importance that the Commission's proposal for a new regulation [65] no longer provides for a simplified procedure. There is also a simplified approval procedure for pharmaceuticals, which the Court of Justice has held to be lawful. [66]

173. The provisions concerning the simplified procedure take sufficient account of health protection. The procedure only applies to foods which pose no particular risk. It ensures, through the examination of substantial equivalence in each individual case, that dangers are excluded. Where there are doubts as regards substantial equivalence, the Regulation provides for an assessment procedure.

174. Finally, foods approved in accordance with the rules can at any time be withdrawn from the market under the safeguard clause in Article 12 if valid grounds for risks to health come to light.

175. The *Commission* points to substantially the same characteristics of the simplified procedure as does the Council, in order to demonstrate that sufficient attention was given to health protection, pursuant to Articles 153 and 174 EC. It points out, in particular, that the contested foods underwent a detailed evaluation of substantial equivalence by the United Kingdom food assessment body and that the Italian bodies had confirmed their harmlessness.

176. The Regulation also takes account of the precautionary principle and the principle of proportionality. It should be taken into account in that regard that the Regulation was the first legislation in this area and was guided by the scientific information available at the time of its adoption. The safeguard clause in Article 12, in

65 — Cited in footnote 13.

66 — Case C-368/96 *Generics (UK) and Others* [1998] ECR I-7967, paragraph 60 et seq., in which the Court of Justice reviewed the validity of a provision of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20), as amended by Council Directive 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36), as regards the simplified approval procedure for generic drugs.

particular, gives expression to the precautionary principle. However, that provision may not be invoked by the Member States for the purpose of enforcing their own policies. Rather, it should constitute the foundation for constructive cooperation between the Member States and the Commission.

177. The provisions concerning the simplified procedure are in principle guided by proportionality, inasmuch as they allow a specific group of low-risk foods to be placed on the market under less onerous provisions, without, however, neglecting health protection.

2. Appraisal

178. The national court essentially asks whether the rules in Regulation No 258/97 concerning the simplified procedure are sufficient to protect human health from risks posed by foods derived from genetically modified organisms. The relevant provisions are, first, Article 3(4), which establishes the conditions of use for the simplified procedure, and secondly, the specific procedural norm under Article 5. The two provisions constitute a single unit. Although the national court asks only about the validity of Article 5, that provision can only be understood in conjunction with Article 3(4), as some of the parties have pointed out.

179. In the opinion of the national court, those provisions could be invalid because they infringe the following norms of primary law:

— Article 153(1) and (2) EC, according to which the Community is to contribute to protecting the health of consumers, and consumer protection is to be taken into account in the framework of other Community policies,

— Article 174(1) and (2) EC, which defines the protection of human health as an objective of Community policy on the environment and lays down the precautionary principle as the guideline for Community action in the field of environment policy, and

— the principle of proportionality and reasonableness.

180. Those Treaty provisions and general legal principles cannot, however, be considered in isolation. The situation in which the Regulation was adopted was primarily characterised by the fact that companies, subject to the provisions of the deliberate release directive and to any national rules, could place on the market foods derived from genetically modified organisms without an approval or notification. Products lawfully placed on the market could be traded without restriction through the Community, in the framework of the free movement of goods. The point of departure is therefore freedom of action for companies and the free movement of goods.

181. On the other hand, it was always evident that novel foods could pose risks to human health — some of which are as yet unknown. The legislature was therefore called upon to subject the marketing of novel foods to restrictions, in order to preclude risks to human health. In order to prevent restrictions on trade arising from differently formulated national rules, the Community acted on the basis of former Article 100a of the EC Treaty and adopted Regulation No 258/97. [67] In the interests of protecting the health of consumers, that legislation restricted the freedom of companies to place novel foods on the market by introducing uniform approval procedures. [68]

182. Therefore, when drawing up Regulation No 258/97, the Community legislature had to reconcile the rights of companies which place novel foods on the market and the rights of consumers to adequate health protection, as well as protection of the environment. That required the assessment of complex scientific relationships, which was complicated by the fact that the development of foods derived from genetically modified organisms was still at an early stage in 1997 and that, in part, no completely certain scientific information was yet available.

183. In that case, in the light of the evaluation standard to be used by the Court of Justice, the following finding applies: [69]

'In a sphere in which the Community legislature is called on to undertake complex assessments based on technical and scientific information which is liable to change rapidly, judicial review of the exercise of its powers must be limited to examining whether it has been vitiated by a manifest error of assessment or a misuse of powers or whether the legislature has manifestly exceeded the limits of its discretion.'

184. The provisions concerning the simplified procedure would therefore be invalid

67 — See the first recital in the preamble to Regulation No 258/97.

68 — See the second recital in the preamble to Regulation No 258/97.

69 — Case C-127/95 *Norbrook Laboratories* [1998] ECR I-1531, paragraph 90. See also the judgments cited in footnotes 61 and 63.

only if the Community legislature had, when formulating them, misunderstood the scope of the norms mentioned in paragraph 179 in a manner that constituted a manifest error of assessment or exceeded its discretion.

185. The protection of human health was not yet expressly mentioned as an objective of consumer protection policy in Article 129a of the EC Treaty (now, after amendment, Article 153 EC) in the formulation of the Treaty of Maastricht, which was in force when Regulation No 258/97 was adopted.

186. However, health protection was already established at that time in other parts of the Treaty. Thus, Article 3(o) of the EC Treaty (now, after amendment, Article 3.1(p) EC) stated that it was an objective of the Community to contribute to the attainment of a high level of health protection. According to the third subparagraph of Article 129(1) of the EC Treaty (now, after amendment, Article 152 EC), health protection requirements were also to form a constituent part of the Community's other policies. Finally, under Article 130r(1) of the EC Treaty (now, after amendment, Article 174(1) EC), Community policy on the environment is to contribute to the pursuit of protecting human health.

187. The case-law at the time the Amsterdam Treaty came into force also recognised health protection as a constituent part of the Community's other policies. [70] In particular, the objective of the protection of human health can also be pursued by the adoption of harmonising measures. [71]

188. As has already been stated, [72] the protection of health is closely linked to the precautionary principle, which as a general principle of Community law has importance beyond the field of environment policy. [73]

189. It is necessary to examine whether the simplified procedure is so formulated that it guarantees a sufficient examination of novel foods, leading to the detection of potential risks and making possible a factual assessment as to whether the placing on the market of a food can be justified.

190. First, it must be pointed out that the procedure is only used for a specific group

70 — Judgment in Case 68/86 *United Kingdom* v *Council* [1988] ECR 855, paragraph 12, and Order in Case C-180/96 R *United Kingdom* v *Commission* [1996] ECR I-3903, paragraph 63.

71 — See *Tobacco*, paragraph 78 (cited in footnote 64).

72 — See paragraph 108.

73 — See paragraph 134.

of novel foods, in particular foods which are produced from genetically modified organisms but do not contain them. Even if it is the case that those foods are not free of risk *per se*, since they contain traces of transgenic material even though they no longer contain DNA, the risks nevertheless appear to be smaller than those as regards genetically modified organisms themselves.

191. A further condition of use is that the novel food be substantially equivalent to a comparable conventional product. In accordance with the interpretation developed above, substantial equivalence is established only if it has been ascertained that the differing characteristic which was introduced does not pose any appreciable dangers to human health.

192. For that reason, the argument by the national court, that under the simplified procedure foods could be placed on the market which have not been subject to adequate safety assessments, must be rejected, at least in a case such as the present case. Moreover, it is not correct that the determination of substantial equivalence — as it is here understood — gives no information on the effects on human health of the traces of transgenic material found in novel foods.

193. If, under the simplified procedure, only foods which meet the requirements in Article 3(4) may be placed on the market, the Commission cannot be accused of a manifest error of assessment in the form of the procedure. However, in order to ensure compliance with the conditions of use in practice, a control mechanism is required.

194. First, such a control is ensured by the procedure set out in the second subparagraph of Article 3(4) in conjunction with Article 13. The disadvantage of that procedure is, however, that the assessment takes place only after the food has already been placed on the market by the responsible party, since Article 5 does not require the responsible party to delay the placing on the market until the Commission has received the notification and notified the Member States. Accordingly, the food can already be on the market when the Commission takes action on its own initiative, or at the request of a Member State, under the second subparagraph of Article 3(4) in conjunction with Article 13.

195. Secondly, at least where the responsible party does not cite generally recognised scientific findings, a national food assessment body carries out an assessment of substantial equivalence. In that regard, Article 3(4) should be interpreted to mean that the responsible party must obtain the

opinion of that body before placing the product on the market. That also ensures that a prior verification will be made of the conditions governing the use of the simplified procedure.

196. However, the responsible party can, in its notification, rely on generally recognised scientific findings as proof of substantial equivalence rather than on an expert opinion by a national food assessment body. The concept of generally recognised scientific findings is extremely vague, however, and leaves room for a number of interpretations. Above all, in that case there is no assessment of substantial equivalence by a national body before the novel food is placed on the market. As a result, the formulation of the procedure does not adequately guarantee that possible risks to human health are considered before a product is placed on the market, as required under the precautionary principle.

197. The fourth question referred for a preliminary ruling does not refer to that case, however, since in the main proceedings no use is made of the possibility to demonstrate substantial equivalence by referring to generally recognised scientific findings. Therefore, it is not necessary, for a decision in the main proceedings, to rule conclusively on the validity of that part of Article 3(4) of the Regulation. Nevertheless, there is reason to deem the provision invalid in that respect.

198. The national court bases its doubts concerning validity on the fact that the simplified procedure does not make adequate provision for participation by the Member States. Those doubts must be rejected.

199. First, it is not evident why all the Member States should be involved in all the stages of the procedure in order to guarantee the protection of human health and observance of the precautionary principle. Rather, it should be considered sufficient that a prior evaluation of substantial equivalence be the sole responsibility of the food assessment body of a Member State and that the other Member States be required — subject to possible review under the procedure set out in the second subparagraph of Article 3(4) in conjunction with Article 13 — to recognise the opinion of that body.

200. The other Member States still have the opportunity to put forward their point of view at a later stage of the procedure, by requesting a review of the conditions of use for the simplified procedure. If the misgivings of a Member State are accepted and it is accordingly determined that the simplified procedure is not applicable, a notification procedure must be carried out, under which the Member States have further rights of participation.

201. Finally, it must also be taken into consideration that Article 12 grants the Member States the right to take protective measures at any time if there are valid grounds to suspect a risk to human health.

202. Accordingly, the provisions concerning the simplified procedure which are relevant to the main proceedings adequately take into account the protection of health and the precautionary principle.

203. In addition, the national court mentions the principle of proportionality. However, it is not apparent in what respect that principle can influence the validity of the provisions as regards the simplified procedure in connection with the present case.

204. According to the principle of proportionality, which is one of the general principles of Community law, actions by the Community institutions may not go beyond what is appropriate and necessary in order to achieve the objectives legitimately pursued by the legislation in question. When there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued. [74]

205. The national court, however, does not at all take the view that the measures adopted, namely the introduction of the simplified procedure for the placing on the market of certain novel foods, go beyond what is necessary in order to achieve the objective of protecting human health. On the contrary, that court considers them insufficient for the purpose of attaining that objective. It argues not for a less stringent instrument, as the undertakings concerned would perhaps do with reference to the principle of proportionality, but rather for a stricter instrument.

74 — According to the case-law; see Joined Cases C-27/00 and C-122/00 *Omega Air and Others* [2002] ECR I-2569, paragraph 62, Case C-331/88 *Fedesa and Others* [1990] ECR I-4023, paragraph 13, and *BSE*, paragraph 96 (cited in footnote 54).

206. The principle of proportionality is not applicable in this case. If the measure is insufficient for the purpose of ensuring the protection of human health, the infringement would lie in an insufficient consideration of the protection of health and not in a breach of the principle of proportionality.

207. It must therefore be held that, in the context of the examination of the fourth question referred for a preliminary ruling, there is no indication that the Community legislature committed a manifest error of assessment or exceeded its powers of discretion in formulating the simplified procedure.

V — Conclusion

208. On the basis of the preceding observations, I propose that the questions referred for a preliminary ruling be answered as follows:

(1) Article 3(4) of Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients should be interpreted to mean that foods and food ingredients within the meaning of Article 1(2)(b) of the Regulation are to be considered as substantially equivalent and may consequently be placed on the market under the simplified procedure, following a notification in accordance with Article 5 of the Regulation, when those foods and food ingredients still contain residues of transgenic protein but it has been demonstrated that those materials do not present a danger for the consumer.

(2) A Member State may adopt temporary measures in accordance with Article 12(1) of Regulation No 258/97 provided that, as a result of new information or a reassessment of existing information, it has valid grounds for considering that the use of that food at issue endangers human health or the environment. Whether those grounds are valid or not is to be established by a Commission or Council decision pursuant to Article 12(2) in conjunction with Article 13 of the Regulation. The temporary measures may be maintained until the adoption of that decision.

(3) The Commission does not, under the simplified procedure in Article 5 of Regulation No 258/97, tacitly adopt a decision to approve a food which has been notified to it for placing on the market.

(4) The examination of the fourth question referred for a preliminary ruling has not given rise to any consideration which could vitiate the validity of the provisions concerning the simplified procedure in Article 3(4) and Article 5 of Regulation No 258/97, in so far as they — as in the present case — require the production of an opinion of a national food assessment body in order to demonstrate substantial equivalence.